Costs and benefits of the Diabetic Foot Clinic in Samoa

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Preface

This thesis is made as a completion of the bachelor in Health Sciences at the University of Twente in Enschede, the Netherlands. The thesis contains an overview of costs and benefits of the Diabetic Foot Clinic and the Tupua Tamasese Hospital (TTM) in Samoa, with the aim to provide insight into the benefits and costs of maintaining the Diabetic Foot Clinic in Samoa. Quantitative data is collected through patient records and qualitative data is collected through client interviews and staff questionnaires.

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Samenvatting

In juni 2015 opende een Diabetische Voetenkliniek zijn deuren op het eiland Samoa in de Westelijke Stille Oceaan regio, met de hoogste diabetes mellitus prevalentie in de wereld. Diabetes is een wereldwijd groeiend probleem en brengt ernstige complicaties met zich mee zoals voet ulcera. De incidentiecijfers voor het ontwikkelen van een voet ulcer lopen op tot 25%, de behandeling is complex en duur en voet ulcera leiden in veel gevallen tot amputaties van het onderbeen.

Het doel van deze studie was het in kaart brengen van de kosten die gemaakt zijn in de Diabetische Voetenkliniek en de behaalde effecten zoals wondgenezing. Deze kosten en effecten werden vergeleken met die van het Tupua Tamasese Ziekenhuis (TTM) in Samoa. Er waren tot op heden geen inzichten beschikbaar over de kosten die de behandelingen van diabetische voet ulcera met zich mee brachten in beide situaties.

Om deze informatie te verkrijgen is een prospectieve follow-up studie uitgevoerd. Kwantitatieve informatie over behandelingen en kosten van zorg werden verzameld van één geselecteerde populatie bestaande uit 46 personen die behandeling kreeg in de Diabetische Voetenkliniek tussen de periode juni 2015 en mei 2016 en één geselecteerde populatie van 46 personen die behandeld werd in het TTM Ziekenhuis tussen juni 2013 en juni 2015. Data werd verzameld in de studieperiode tussen 2 mei en 23 mei, 2016.

Patiëntendossiers werden doorgenomen om informatie over wondgenezing te achterhalen en de duur van behandelingen. Informatie vanuit het ziekenhuis werd verzameld om de kosten van opnames, chirurgische ingrepen en werknemers te bepalen en in de Diabetische Voetenkliniek werd informatie over de kosten van werknemers en de kosten van materiaal voor verschillende offloading technieken verzameld.

Kwalitatieve data werd verzameld om mogelijke subjectieve effecten te onderzoeken. Deze informatie werd verzameld aan de hand van patiënten interviews en vragenlijsten voor de werknemers van de Diabetische Voetenkliniek.

De belangrijkste uitkomsten van deze studie waren het aantal genezen ulcera en de behandelkosten per patiënt. Geen van de ulcera genas in het ziekenhuis, voornamelijk door de ernst van de ulcera die hier behandeld werden. De focus in het ziekenhuis lag op acute zorg, het onder controle krijgen en bestrijden van de infecties. Rond de 70% van de patiënten onderging chirurgische ingrepen, de gemiddelde opnameduur was 11 dagen en de gemiddelde kosten per patiënt waren 7.329 Tala per opname. In 30% van de patiënten moest een amputatie worden uitgevoerd, waarvan in totaal 20% van de amputaties op major level, boven de voet.

In de Diabetische Voetenkliniek werd in 50% van de patiënten genezing bereikt in een gemiddelde behandelperiode van 105 dagen, met gemiddelde behandelkosten van 1.114 Tala per patiënt. Offloading werd toegepast in 70% van de patiënten en uiteindelijk moest één patiënt alsnog worden opgenomen in het ziekenhuis tijdens de studieperiode.

Een kostenanalyse liet zien dat de Diabetische Voetenkliniek met een genezingspercentage van minimaal 12,6% het financiële omkeerpunt bereikt, omdat vanaf dit percentage van genezen ulcera de Diabetische Voetenkliniek minder kosten zou maken vergeleken met de situatie waarbij alle patiënten in het TTM Ziekenhuis werden behandeld. Door de korte observatietijd van 11 maanden zijn de gezondheidseffecten niet volledig aan te tonen, maar er kan worden aangenomen dat een genezingspercentage van 12,6% behaald was.

Summary

In June 2015, a Diabetic Foot Clinic has opened in Samoa, Western Pacific. This region is known for the highest prevalence rates of diabetes mellitus in the world. Diabetes complications like diabetic foot ulcers are common in Samoa as they have a lifetime incidence up to 25%. Treatment of diabetic foot ulcers is complex and these ulcers often lead to lower extremity amputations.

The aim of this study was to compare the costs and benefits, like ulcer healing, of diabetic foot treatments, between the Tupua Tamasese Hospital (TTM) and the Diabetic Foot Clinic in Samoa. Insight in the costs and benefits of diabetic foot treatments were not available in both situations.

A retrospective follow-up study was done to provide this information. Quantitative data about treatments and the costs of treatments were collected from one population of 46 clients who were treated for a foot ulcer at the Diabetic Foot Clinic between June 2015 and May 2016 and the same data was collected from a population of 46 clients who were treated for a foot ulcer at the TTM Hospital between June 2013 and June 2015. The data was collected between the second of May and the 23thrd of May 2016.

Client files were included to collect information about ulcer healing and the duration of treatments. Information about admission costs, the costs of surgical interventions and the salary costs were collected from the TTM Hospital and information about salary costs and material costs for offloading techniques were collected from the Diabetic Foot Clinic.

Qualitative data was collected through structured client interviews and staff questionnaires at the Diabetic Foot Clinic.

Main parameters in this study were ulcer healing and treatment costs per client. No ulcers healed during hospital admission, due to the severity of the foot ulcers that were treated in the hospital. The hospital treatment was focused on acute care, mainly to get the infection of the ulcer in control. About 70% of the clients had to undergo surgical interventions, the clients were discharged after a mean of 11 admission days and the mean costs per treatment was 7,239 Tala. Amputations were performed in 30% of the clients, with a total of 20% at major level, above the foot.

In the Diabetic Foot Clinic, 50% of the clients achieved healing of their ulcer with a mean healing time of 105 days and mean costs per client were 1,114 Tala. Offloading was used in 70% of the clients and in the study period only one client needed to be admitted to the TTM Hospital after all.

A cost-analysis showed that the Diabetic Foot Clinic would break-even in costs, compared with the TTM Hospital in a situation without Diabetic Foot Clinic, when a healing rate of minimal 12.6% is achieved. Though the observation time of the study was short and health effects cannot be proven, it is likely to assume that the Diabetic Foot Clinic would attain a healing rate of 12.6%.

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Chapter 1 INTRODUCTION

Diabetes Mellitus is an increasing health problem. According to the International Diabetes Federation (IDF) there are 415 million people diagnosed with diabetes worldwide and about 75% of those people live in low- and middle-income countries [1].

Diabetes is a group of metabolic chronic diseases, characterized by hyperglycaemia resulting from defects in insulin secretion, insulin action, or both [2]. This insufficient insulin secretion or action leads to metabolic disturbance that causes damage to different organs or organ systems, especially in the eyes, kidneys, nerves, heart and blood vessels [2]. In the long-term, these damaged organs will lead to serious complications such as peripheral artery disease and peripheral neuropathy, which in turn increase the risk of diabetic foot ulcers. These foot ulcers are mainly caused by mechanical pressure acting on the foot during walking in the presence of lost protective foot sensation from peripheral neuropathy [2, 3, 4]. Diabetic foot ulcers are a major cause of morbidity and mortality in individuals with diabetes, with a life time incidence of 25% [5]. It is estimated that every 30 seconds a (part of a) lower limb is amputated somewhere in the world as a consequence of diabetes [2].

People living in developing countries have a higher risk of lower limb amputation compared to developed countries [6]. Low- and middle-income countries have less developed health care and less expenditure on diabetes care, because of the comparatively slow development of health systems. Diabetes is often poorly controlled which lead to organ damage, earlier than in people living in high income countries with better diabetes control. Also, diabetic foot clinics are scarce in low-income countries and the foot care education for individuals who have a diabetic foot ulcer is limited [7]. Diabetic foot prevention programs are highly cost-effective in high- and middle-income countries, but are not widely implemented in low-income countries despite evidence that they reduce hospitalizations for diabetic foot lesions and the length of hospital stays [8, 9, 10, 11].

Treatment of diabetic foot ulcers is complex. The International Working Group on the Diabetic Foot (IWGDF) provides international guidelines in which is reported that a multidisciplinary team approach to diabetic foot care has been shown to result in fewer amputations and better healing outcomes [12]. Nevertheless, treatment costs of foot ulcers are high compared to regular diabetes treatment, due to the multidisciplinary involvement and the chronic characteristics of ulcers. Foot ulcers are therefore an extra burden for low- and middle-income countries because their healthcare systems are poorly financed. However, little data is available about the expenditures and the burden of diabetic foot ulcers in these countries.

The expenditure on diabetes care is comparatively higher in high income countries. For example, in the Western Pacific region 88 billion US dollars was spent on diabetes care in 2013, whilst the total expenditure for Europe was 147 billion US Dollars and the expenditure for the United States of America (USA) was 263 billion US Dollars. However, the number of individuals with diabetes is almost four times as high in the Western Pacific as in the USA and Europe [1]. Some of the islands in the Western Pacific have a prevalence up to 37.5% and eight islands in this region are listed in the top ten of countries with the highest diabetes prevalence in the world [1]. Where Samoa had a diabetes prevalence of 5% in 1980, the diabetes prevalence in 2014 was 25% [13]. In 2013, 187 million deaths were attributable to diabetes in the Western Pacific region, 44% of them occurred in people under the age of 60 [14]. In contrast with high income countries, where the biggest diabetes population is aged between 60 and 80, the age-group with the highest prevalence of diabetes in low- to middle income countries is between 40 and 60 years [1].

Expenditure on diabetic foot care in the Western Pacific region, and especially Samoa, is not available in literature. There is some information from other developing countries like India and Tanzania which shows that the expenditure for an uncomplicated foot ulcer are around 3,400 US Dollars in India and 1,500 US Dollars in Tanzania [15]. However, the more common foot ulcer is complex and costs around 20,000 US Dollars in India and 3,000 US Dollars in Tanzania [15]. Most of the clients in low- and middle income countries are responsible for up to 100% of the costs of treatments, even though these costs can be as high as a 5.7 years of annual income, seen in India [15].

In June 2015 the Diabetic Foot Clinic in the Western Pacific region has opened its doors in Samoa, this is the first diabetic foot clinic in the Western Pacific. The diabetes prevalence was 25% in 2014 and it is estimated that less than 50% of adults over 50 years of age are aware of their diabetes in Samoa [13, 16]. The mean diabetes related expenditure per person in Samoa was only 312 US Dollars annually [17]. However, there is no data available about the costs of treating a diabetic foot ulcer in Samoa and no data is analysed yet about the benefits of the Diabetic Foot Clinic. Insight into the costs and benefits of the Diabetic Foot Clinic will improve the management of the Diabetic Foot Clinic and it may improve management of diabetic foot management of the National Health Service in Samoa. If the clinic is cost-saving and more effective than previous treatment, it may lead to more diabetic foot clinics in the Western Pacific region. Therefore it is desirable to start a cost-benefit study to provide more information about the benefits of diabetic foot care in this region.

1.1 Research goals and research question

The Diabetic Foot Clinic can be said to be a more cost effective strategy for the National Health Service than previous treatment approaches, when the costs of sustaining the Diabetic Foot Clinic are the same or less than the previous treatment costs. Ulcer healing will be the primary parameter to indicate benefits for the clients who visit the Diabetic Foot Clinic, because data about quality of life may not be present. A literature review will be performed to identify and collect data about diabetic foot clinics and its costs and benefits in case not all data will be available in Samoa.

Because of the limited availability of research that is conducted about the diabetic foot treatments in Samoa, a study about costs and benefits will be done with the following research question: Has diabetes care in Samoa improved on expenditure and benefits since the introduction of the Diabetic Foot Clinic compared to the two years before the Diabetic Foot Clinic opened?

Chapter 2 LITERATURE REVIEW

This chapter describes the problem and reasons to perform the research. A literature study is done to show existing information about the problem the used parameters for this literature study are also shortly explained in a theoretical framework. At the end of this chapter some background information about Samoa and its health care system is given.

2.1 Description of the problem

There is no insight into the costs and benefits of the Diabetic Foot Clinic in Samoa. Research on the costs and benefits of the Diabetic Foot Clinic is desirable as it can assist to improve the management of the Diabetic Foot Clinic and it may also improve the care within the national health care system of Samoa. The Government of Samoa is responsible for most costs in the health care system, improving the health care system will therefore have a major impact for the Government as the Diabetic Foot Clinic might be a cost-saving health care service.

2.2 Literature review

2.2.1 Introduction

In June 2015 a diabetic foot clinic in the Western Pacific region has opened in the island Samoa. The diabetes prevalence was 25% in 2014 [13] and there are still many people undiagnosed [18, 19]. It is estimated that less than 50% of adults over 50 years of age are aware of their diabetes in Samoa [16]. Only little research is available about the diabetes population and the size and effect of diabetes on the health care system is unknown. The mean diabetes related expenditure per person in Samoa without diabetic complications was 312 US Dollars annually [17]. However, complications such as diabetic foot ulcers can increase health expenditure dramatically [15].

To structure the literature study, a key question was formed: Is health expenditure in diabetic foot clinics cost saving and do clients have more health benefits compared to diabetic foot healthcare in non-diabetes-specialised settings?

To answer this question, literature about the costs of treating a diabetic foot ulcer needed to be studied, not only in the situation of a diabetic foot clinic but also in a situation with a treatment through a different service. To estimate benefits, literature about healing time and healing rates was compared to amputation rates.

2.2.2 Method

To perform the literature study, search strings were used including: “Diabetic foot clinic” in combination with “developing countries”, “low- to middle-income countries”, “costs”, “ulcer healing”, “amputation”, “complications” and “economic evaluation” in the online library from the University of Twente [20] (54 hits) that includes articles from Science Direct, and a wide range of journals. In PubMed the strings “Diabetic foot clinic” and “Pacific” had 2 hits and “Diabetic foot clinic” and “Developing countries” had 12 hits. In Scopus the strings “Diabetic foot clinic” AND “Pacific” had 3 hits between 2005 and 2016. “Diabetic foot clinic” AND “developing country” gave 12 hits and “Diabetic foot clinic” only had 637 hits between 2005 and 2016. The cut-off point of 2005 was chosen to make sure collected information was still accurate.
The literature study was performed between the second of March and June 16th.

2.2.3 Treatment and outcomes of diabetic foot ulcers in Developed countries

The International Working Group of the Diabetic Foot (IWGDF) provide guidelines for the treatment of diabetic foot ulcers [11]. They recommend the inclusion of a multidisciplinary team in the treatment of diabetic foot ulcers and key factors are debridement, removal from dead tissue, and offloading,

which is a technique used to relieve mechanical pressure in the ulcer area [11,21,22,23]. A prospective study from the United Kingdom in 2008, showed a decrease in total amputation rates of 40% after implementing a multidisciplinary team in the diabetic foot care [24]. The treatment of diabetic foot ulcers is complex, partly due to the chronic characteristics of foot ulcers. A prospective evaluation to determine the healing duration in diabetic foot ulcers undertaken in Germany [25], showed an average healing time of 78 days in patients with neuropathic foot ulceration, an average healing time of 123 days in a group of clients with neuroischemia and an average healing time of 133 days in clients with peripheral artery disease. A prospective cohort study from Sweden that focused on foot ulcers with deep infections, shows that the rate of healing without surgery can be as low as 40% of all clients [26]. The deep infected foot ulcers from this study had a median healing time of 24 weeks (168 days) [26], see table 1 for healing duration outcomes in different studies.

Surgical costs, like amputation costs, are high and therefore some studies [27, 28] compare diabetic foot ulcers and amputation costs as costs of illness versus costs of treatment. The risk of amputation is high in poorer countries and complications after amputations are more common, which increases the treatment costs [28]. However, there is evidence that amputation of limited tissue may prevent from more extensive amputation and therefore effectiveness of treating diabetic foot ulcers should not only be seen in the context of amputation prevention [29, 30]. Eventually, between 12 and 27% of all ulcers result in surgical removal of bone [30, 31, 32], though these rates vary between different countries.

Prevention of diabetic foot ulcers should begin by identifying people who are at high-risk for developing diabetic foot ulcers and therefore increased risk of amputation [21]. Someone is at high-risk when peripheral neuropathy, peripheral artery disease, foot deformities, or callus is present in one or both feet [21, 33].

Overall, literature in high income countries shows that treatment with a multidisciplinary team approach is more effective than previous treatments with less caregivers involved, more ulcers heal after surgical interventions and it shows that ulcers have chronic characteristics with long healing rates.

Table 1: Literature review of mean healing time, healing rates and amputation rates in diabetic foot ulcers.

Article	Country	Study type	Study population	Mean healing time
Developed countries				
Elgzyri, T. et al. (2013). [34]	Sweden	Prospective follow-up	Ischemic foot ulcers	Without major amputation, median healing time of 27 weeks
Zimny, S. et al. (2002). [26]	Germany	Prospective evaluation	N=31 clients	Neuropathic group (N=13) 78 days (11weeks) Neuroischemic group (N=10) 123 days (18weeks) Ischemic group (N=8) 133 days (19 weeks)
Oyibo, S. O. et al. (2001). [32]	UK	Prospective follow-up		Median ulcer healing (N=149) of 10 weeks
Tennval, G.R. et al. (2000). [27]	Sweden	Prospective follow-up	N=184 clients	Low-cost clients (N=92) 19 weeks High-cost clients (N=92) 61 weeks

				Healing rates
Monteiro-Soares, M. et al (2014). [35]	Portugal	Retrospective follow-up	N=813 clients	76% ulcers healed in three-year period.
Elgzyri, T. et al. (2013). [34]	Sweden	Prospective follow-up	N=602 Ischemic population	67% of ulcers healed (N=400) without vascular intervention in 22 years follow-up until healing or deceased.
Prompers, L. et al. (2008). [36]	14 centres in Europe	Prospective follow-up	N=821 clients	After 1 year follow up: 77% (N=647) of the ulcers healed.
				Amputation rates
Krishnan, S. et al. (2008). [24]	UK	Prospective follow-up	N= 345,890 clients Followed between 1995-2005	Incidence dropped from 53.2 to 16.0 out of 10,000 diabetic patients with foot problems in the study period.
Developing countries				
				Healing Rates
Rezende, K. F. et al. (2009). [37]	Brazil	Prospective follow-up	N=109 clients	39% (N=43) had primary healing 48% (N=52) healed after surgery 13 % (N=14) died during hospitalization
Viswanathan, V. et al. (2005). [38]	India	Prospective follow-up	N=1259 clients	68% ulcers healed in a 27-month period (N=854).
				Amputation rates
Win Tin, S. T. et al. (2014). [39]	Pacific Region	cross-sectional study	Populations from three different Islands	Nauru 11% diabetes-related amputations (N=11, study population N=100) Solomon Islands 11% diabetes-related amputations (N=17), study population (N=160) Vanuatu 11% diabetes-related amputations (N=21), study population (N=199)
Rezende, K. F. et al. (2009). [37]	Brazil	Prospective follow-up study	N=109 clients	85% (N=93) had surgical treatment • 62% (N=58) had an amputation (n=26 minor, n=32 major) • 38% (N=35) had surgical debridement
Dangelser, G. et al. (2003). [40]	Reunion Islands	Prospective follow-up	3,600 diabetic clients Age 30-69	N=289 amputations have been performed in 1 year.

2.2.4 Treatment and outcomes of diabetic foot ulcers in Developing countries

Developing countries have certain cultural and social habits that may put people with diabetes at higher risk for developing foot ulcers and amputation [41]. Lack of facilities in nearby hospitals and unsatisfactory metabolic control are major contributory factors for foot problems in these countries [41]. Certain factors such as barefoot walking, late presentation by patients, ignorance about diabetic foot care among primary care physicians and beliefs in alternative systems of medicine, contribute to a high prevalence of amputations in India [33], and probably in other developing countries as well. A study done in the Reunion Islands [40] showed that 77% of the people who had an ulcer cleaned the wound themselves and 88% of these people only visited a doctor if they did not see any improvement in the wound.

In a root cause analysis [42] performed to detect events leading up to amputation in the Pacific Region, it was shown that the main events in 55% of the amputations were trauma and an infected wound. Only 6% of people sought treatment immediately after the event occurred, 5% the next day and 38% within one week. According to a qualitative observational study [43], the main patient factors acting as barriers and facilitators to care in the management of diabetes in primary care in a low/middle income country, were individual-financial constraints, compliance with medication and compliance with diet. The same study outlined that the most common organisational barriers were availability of medication, the use of chronic disease clinics and clinician workload [43].

A prospective cohort study done in Brazil showed health outcomes of 109 patients that were seen at a hospital where staff were not specially educated for diabetic foot care and where patients had no access to multidisciplinary teams or rehabilitation facilities [37]. The patients who were seen had chronic infected deep ulcers due to late presentation and 85% of them needed surgical treatment of which 62% had to undergo an amputation.

A prospective cohort study from 2005 performed in South India [38] showed that intensive treatment and education for clients with type 2 diabetes at high-risk for diabetic foot wounds, resulted in significant higher healing rates in clients who were adherent to the treatment. Of the 718 people with diabetic foot ulcers that were adherent to treatment, 82% achieved ulcer healing. In contrast, the healing rates of the total population, including clients who were not adherent, was 68% (n=854), see table 1 for an overview of healing rates in different studies.

Summarized, diabetic foot care seems to be more effective than regular care in developing countries too. Though developing countries have other cultural habits than in developing countries, which influence the healing outcomes as people in developing countries have late presentations with their foot ulcers.

2.2.5 Costs of diabetic foot ulcers

Health economic studies have shown that costs due to foot ulcers and amputations are high in both the short and long term [44, 45]. Treating diabetic foot ulcers is complex and most diabetic foot ulcers heal slowly. Treatment of diabetic foot ulcers is a time consuming process, which is one of the reasons why diabetic foot ulcers are expensive for health services [45]. However, a study that focused on the costs of the treatment of diabetic foot ulcers concludes that management of the diabetic foot according to guideline-based care improves survival, reduces diabetic foot complications, is cost-effective, and even cost-saving compared with usual care [31]. Another study that focused on the same guideline-based diabetic foot concludes that multidisciplinary diabetic foot care improves survival, reduces diabetic foot complications, is cost-effective, and even cost-saving compared with usual care [45]. Increasing evidence suggests that the costs for implementing diabetic foot teams can be offset over the long-term by improved access to care and reductions in foot complications and in amputation rates [22, 46, 47].

Diabetic foot ulcers are, besides the high direct costs of treatment, also a burden on indirect costs. These indirect costs of the diabetic foot and its consequences such as ulcers and amputations involve loss of productivity, individual patients' and family costs and loss of quality of life [48]. These indirect costs are hard to measure. An economic evaluation of diabetes costs in the USA [49] included indirect costs as increased absenteeism and reduced productivity while at work for the employed population, reduced productivity for those not in the labour force, unemployment due to disease-related disability and lost productive capacity due to early mortality. The amputation of the lower limb is one of the most feared diabetic complications, associated with loss of mobility, poor quality of life and significant financial burden on family finances [50]. The financial cost can be high for patients and their families, particularly in countries that lack a comprehensive health service and/or have a low income.

Overall, treating diabetic foot ulcers is costly due to long treatments and high rates of amputations. Evidence shows that treating diabetic foot ulcers in a diabetic foot clinic with guideline-based care and a multidisciplinary team approach is cost-effective compared with usual care [31, 45]. Though diabetic foot clinics are more effective, amputations cannot be completely prevented. Social and cultural factors are proven to have influence on treatment outcomes as well. Therefore it is important to include these factors into economic evaluations as well as direct and indirect costs in long and short term.

2.3 Theoretical Framework

2.3.1 Cost-benefit analysis

A cost-benefit analysis is a variation of an economic evaluation and it can address whether it is worthwhile expanding the budget for services [51]. This approach allows the use of more than one consequence or benefit, such as life-years gained, disability days avoided, medical complications avoided or quality of life gained [51]. This analysis fits the projects aim, as there will be different consequences for the diabetes clients, the health care providers and the National Health Service (NHS) in Samoa.

2.3.2 Costs

Direct costs

Health economic studies have shown that costs due to foot ulcers and amputations are high in the short and in the long run [44, 45]. Treating diabetic foot ulcers is complex and most diabetic foot ulcers heal slowly. Treatment of diabetic foot ulcers is a time consuming process, which is one of the reasons why diabetic foot ulcers are expensive for health services [45]. Increasing evidence suggests that the costs for implementing diabetic foot teams can be offset over the long-term by improved access to care and reductions in foot complications and in amputation rates [24, 45, 46, 47].

In this study, direct costs will considered to be the operation costs, the costs of a hospital stay, medication costs, costs of dressings, surgical intervention costs, diagnosis costs, the costs of offloading devices and salary costs of the nurses, doctors, podiatrist and orthotist.

Indirect costs

Indirect costs related to the diabetic foot and its consequences involve loss of productivity, individual patients' and family costs and loss of quality of life [49]. Though indirect costs will be hard to identify, literature shows that diabetes in general reduces productivity. For example, if a person has to undergo an amputation of (a part of) the foot, the ability to do physical work decreases. As there is no

orthotic service available in Samoa, most people who had undergo amputation cannot work anymore. It may be acceptable to conclude that there will be indirect costs due to loss of productivity, individual patients' and family costs and loss of quality of life in Samoa as well.

2.3.3 Diabetic foot clinic

A diabetic foot clinic is a health service where clients with diabetic foot ulcers get treated by a multidisciplinary team that is specialised in diabetic wound-care, diabetes education, and education about diabetic foot ulcers and offloading. There are studies available about the effectiveness of a multidisciplinary team [24, 46, 47], even the International Working Group on the Diabetic Foot recommend in their guidelines to involve a multidisciplinary team in the diabetic foot care [11].

2.4 Background Samoa

Samoa has a current population of 194,693 people (51.6% men) [52] and in 2014, 25% of the adult population on this island was diagnosed with diabetes [13] and there are still many people undiagnosed [18, 19]. It is estimated that less than 50% of adults over 50 years of age are aware of their diabetes in Samoa [16].

Samoan people, with limited health literacy and limitations in speaking the English language have significantly lower knowledge of their diabetes and its complications [53].

Diabetes is a growing problem in Samoa and the trend can be partially explained by the migration from rural to urban areas. The rural population has declined over the last 10 years, mainly due to migration to the urban area and overseas. The rural-urban migration is impacting upon the health of urban communities in Samoa. The ready access to unhealthy foods combined with smoking, alcohol and physical inactivity is contributing to the increasing prevalence of Non Communicable Diseases (NCDs). The National Health Service reported the urban drift to be resulting in sub-standard living conditions in some areas and increasing impact on urban infrastructure including services such as education and health services like the Tupua Tamasese Meaole Hospital (TTM) [54].

In both the US territory of American Samoa and the independent nation of Samoa, the traditional subsistence culture of fishing and farming is being replaced by a more sedentary way of life as well as a dietary shift toward increased caloric, sodium, and animal-origin saturated fat intakes [55]. The neo-traditional dietary pattern was characterised by high intake of local foods, including crab/lobster, coconut products, and taro, and low intake of processed foods, including potato chips and soda. The modern pattern was characterized by high intake of processed foods such as rice, potato chips, cake, pancakes and low intake of local foods [53]. As a result, mortality and morbidity in these island nations is being increasingly accounted for by NCDs such as cardiovascular disease, obesity, and type 2 diabetes mellitus, with a diminishing role for infectious disease and maternal and perinatal mortality [55].

Almost 30% of men and over 50% of women in Samoa are obese [16]. It were males who were most likely to have high cholesterol, high blood pressure, and high fasting blood glucose, whereas females had significantly higher BMI and central obesity as well as a greater number of risk indicators for NCD's overall [55].

Health Care system

There are two entities in the Samoan health care structure: the Ministry of Health and the National Health Service (NHS).

The Ministry of Health concentrates on legislative and regulatory directions for the health sector. This includes policy development, monitoring and evaluation of all public health services. The Ministry of Health is also responsible for the new public health movement through health promotion and preventive programs. The NHS is responsible for the delivery of clinical services from Government owned health facilities [54]. There is one main hospital in the capital Apia, there are seven district hospitals in Samoa and there are four medical centres [56].

The Diabetic Foot Clinic is situated in the TTM Hospital in Apia. The clinic was established by Motivation Australia, an Australian non-government organisation in partnership with the NHS, and has been running since June 15th 2015. Motivation Australia initiates the facilities for the National Health Service so they can eventually take over the mobility device service and the Diabetic Foot Clinic. Motivation Australia provides technical, clinical and service systems support to the clinic, which is managed by the NHS.

The clinic has a capacity of 76 clients per year and is open on two mornings per week for four hours. The service is free for clients and the health care providers accomplish a safe and caring environment where clients report feeling accepted and listened to, according to outcomes from interviews with Diabetic Foot Clinic clients, see appendix 5.

The staff at the Diabetic Foot Clinic consists of a podiatrist, a (non-specialised) nurse and an orthothist who work together as a multidisciplinary team who provide wound-care, education and offloading. There is no specialist involved in the treatment of diabetic foot ulcers in the clinic, whereas the treatment at the TTM Hospital involves nurses, doctors and surgeons.

Chapter 3 METHOD

This chapter familiarises the reader with the most important study parameters and the method used for the inclusion of clients during the study.

3.1 Study Design

A cost analysis where the costs of treatment in the TTM Hospital per client were compared to the costs of treatment in the Diabetic Foot Clinic per client was performed. To do so, two populations were included in the study, a population of clients who were treated for diabetic foot ulcers in the TTM Hospital between June 2013 and June 2015 and a population of clients who were treated at the Diabetic Foot Clinic between June 2015 and May 2016.

3.2 Study parameters/endpoints

The primary parameter in this study is ulcer healing rates and the treatment costs for the TTM Hospital and the Diabetic Foot Clinic in Samoa. Only when an ulcer was reported as healed in a client file, ulcers were considered as healed in this study. Treatment costs included the salary costs, costs for offloading, costs for surgical interventions like amputations and debridement, costs for diagnosis, antibiotic costs and costs for hospital stay.

Secondary parameters are the amount of visits per client, the time to healing, the amount of surgical interventions needed, the mean costs per visit, the mean costs per surgical intervention, the mean admission costs and the mean offloading costs.
Amount of visits per client in the Diabetic Foot Clinic were counted by the follow-up forms in the client files, even as the time to healing. The staff of the Diabetic Foot Clinic reported the wound size in the follow-up forms, as soon as the wound size was zero a wound was considered to be closed.

Mean costs per visit were estimated by the mean costs of offloading materials per client who received offloading and the mean salary costs per visit. For the hospital, the mean costs per treatment, like mean surgical costs, had to be calculated differently as there was no information available about the surgery costs, antibiotic costs and diagnostic costs. Therefore, the Eurodiale study [36] was used as an example to calculate treatment costs, as this study researched the costs in clients with diabetic foot ulcers. The costs in clients treated for infected diabetic foot ulcers, but without vascularisation (group B), were used from the Eurodiale study as guideline. The clients seen at the TTM Hospital all had infected ulcers but there are no vascular surgeons available for vascularisation.

The costs for amputations, other surgical interventions, antibiotics and diagnosis were estimated in percentages, by calculating the percentage of these costs from the mean hospital stay costs in the Eurodiale study.

To describe client characteristics, different variables were included like age, gender, smoking, drinking behaviour, diabetes management and compliance to the treatment. Compliance was measured by counting the ‘did not show up’s’ in the individual files. If a client did not show up on a follow up appointment two times or more, it was noted as non-compliant.

3.3 Study procedures

Data about the two different populations was collected between the second of May 2016 and the 23thrd of May 2016. Data was collected from: client records in the TTM Hospital at the Medical Record service, client records from the Diabetic Foot Clinic at the Mobility Device Service and surgical lists at the operation theatres in the TTM Hospital. Qualitative data was collected through

structured interviews with clients from the Diabetic Foot Clinic. To prevent language barriers, a Samoan translator was involved during all interviews.

TTM Hospital population

To include clients in from the TTM Hospital, the clients found in the database about circulatory complications from diabetes were divided into three age groups. This was done to get insight in the client characteristics and it helped to make sure that the age of clients included is comparable with the overall TTM Hospital population, see figure 1. Three lists with 50% male/female were handed to employees from the Client File department in the TTM Hospital. Only the client numbers were noted on these lists, all other details weren't shown. The employees made a random selection in the three different groups.

A total of 114 files were handed over by the staff, though there was not adequate time to go through all 114 client records. A total of 73 client files were included and information from these records was collected, see table 2 for the inclusion and exclusion criteria. In 27 files the reason of admission did not match the inclusion criteria and these clients were excluded. The other 46 clients were included as they were admitted for existing foot complications as the main reason for admission, see figure 1.

Diabetic Foot Clinic

The Diabetic Foot Clinic had a total of 72 clients who were seen in eleven months. Of these 72 clients, 46 clients (64%) were included as they met the inclusion criteria described in table 2 below.

Table 2: Inclusion and exclusion criteria for the Diabetic Foot Clinic population

TTM Hospital	Inclusion criteria	Exclusion criteria
	• Diabetes related admissions, reported as 'circulatory complications' • Admissions reported as 'Diabetic foot sepsis'	• Ulcers on hands, arms, backs or legs • No diabetic foot problems reported
Diabetic Foot Clinic	• Clients who were treated at DFC • Clients who had a foot ulcer	• Clients who denied treatment DFC • Clients who presented without open foot ulcer(s) • Clients who were referred after first assessment to another health care provider

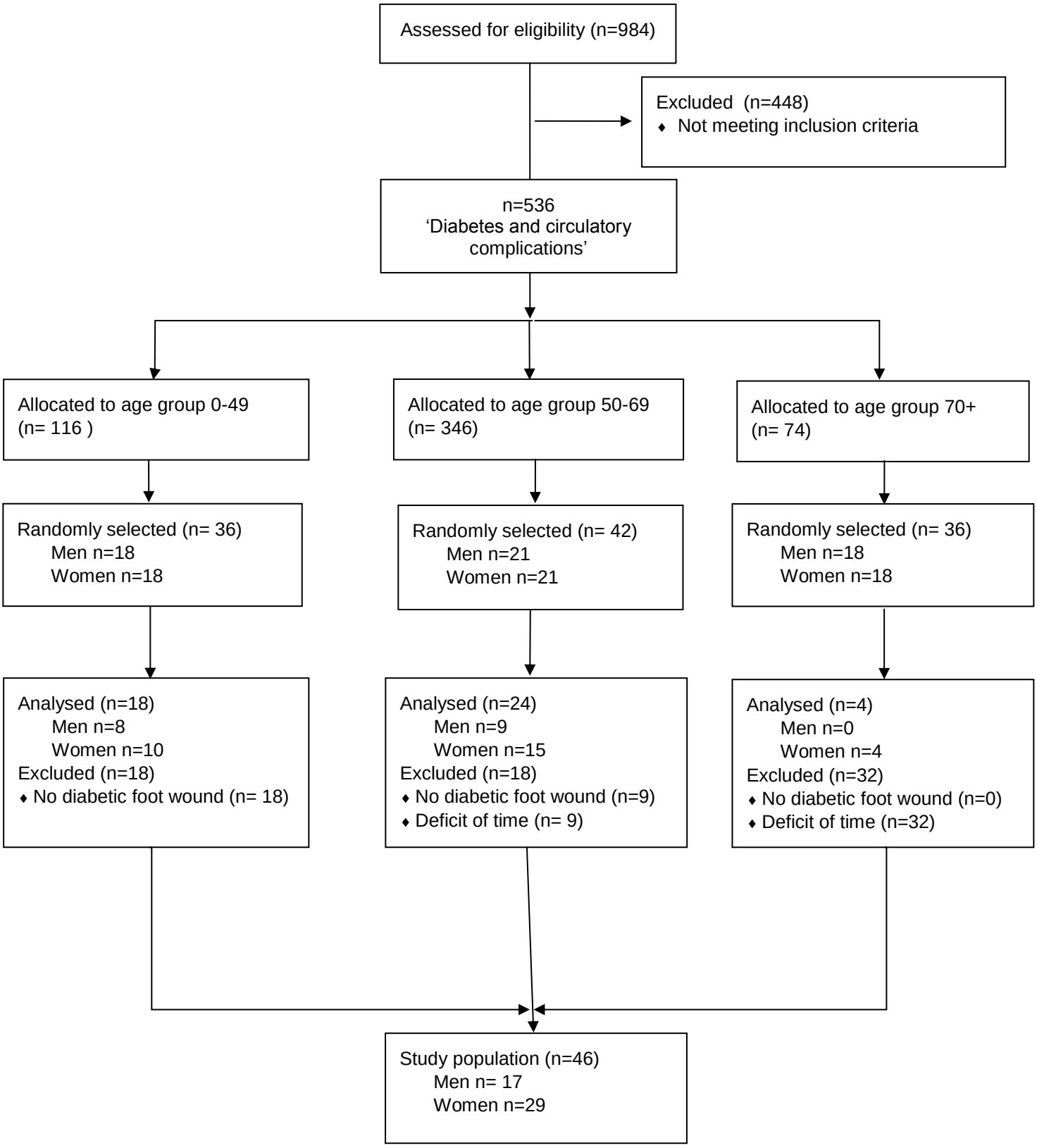
Costs

The costs that were made for clients treated at the TTM Hospital were surgical costs, admission costs and medication costs. Surgical information from the TTM Hospital was collected throughout surgical lists from January 2015 until April 2016. The costs that were available from the hospital were salary costs for nurses and the costs per bed per day. Other costs like materials used during operations, medication costs and the costs of running the operation theatre were not available. The operating costs

of the hospital were not included as both populations are treated in the same building and it was not possible to calculate the operating costs for the Diabetic Foot Clinic.

The costs that are involved in the treatment at the Diabetic Foot Clinic are the salaries of the nurses, podiatrist and orthotists and the costs of the offloading devices made for the treatment.
All costs were mainly reported in Tala, the Samoan currency. Australian Dollars were used to show the total costs of each calculation as the research was performed for Motivation Australia. The currency of 1 Samoan Tala was 0.53 Australian Dollar on the 19th of July 2016 on the website xe.com [57].
Data from client records was collected and analysed with IBM SPSS Statistics 23. After using the descriptive statistics and frequencies of different variables, one-sample t-test, paired t-tests, one-way ANOVA and Chi^2-tests were performed to determine if differences were significant; statistical significance was defined as a p-value of <0.05.

Figure 1: the inclusion of clients who were admitted at the TTM Hospital for diabetic foot sepsis.



Chapter 4 RESULTS

This chapter shows an overview of the results from the data collection in the Diabetic Foot Clinic and the TTM Hospital.

4.1 Results

The results in this section are divided in two sections. The first section outlines the results of the data collection from medical records, surgical lists and salary information from the TTM Hospital in Samoa. The second section will be about the data collected from client records, offloading resources and client interviews in the Diabetic Foot Clinic in Samoa.

4.1.1 TTM Hospital, Samoa

The TTM Hospital in Samoa had 1151 hospital admissions registered for diabetes related complications in 984 clients, between June 2013 and June 2015. The diabetes related complications that included diabetic foot ulcers were circulatory complications, as the hospital uses the circulatory complications as the main category to register clients with diabetic foot wounds. In the two year period, 667 hospital admissions related to diabetes and circulatory complications were registered in 536 clients. Data was collected from medical records in a total of 46 selected clients, see table 3 for information about the different populations and see the method section for an overview of the inclusion procedure.

Table 3: Socio-demographic characteristics of the TTM Hospital population.

TTM Hospital June 2013 – June 2015	Total clients with diabetes related admissions N=984	Admitted clients with circulatory complications* N=536	Research population with diabetic foot sepsis N=46
Mean age	59 (12)	58 (11)	55 (10)
Male (%)	47% (N=541)	50% (N=267)	37% (N=17)
Mean admission days	10 (9)	11 (9)	11 (9)
Admitted second time (%)	14% (N=134)	15% (N=80)	26% (N=12)
Admitted more than two times (%)	5% (N=52)	4% (N=22)	4% (N=2)
In hospital mortality	12% (N=121)	11% (N=58)	0%
Diabetes Type 2 (N=45)	-	-	100% (N=45)
Diabetes managed (N=25)	-	-	20% (N=5)
Smokes cigarettes (N=35)	-	-	9% (N=3)

*All clients appear in the list once, when admitted more than once the last admission was taken into account. Note: values are mean (Standard Deviation) or percentage.

Compared to all clients admitted to TTM Hospital with diabetic complications and circulatory complications in the two years between June 2013 and June 2015, the study population was younger and had proportionally less males.

Most client characteristics were poorly reported in the medical records of the 46 included clients, information about the duration of diabetes in clients was only reported for two clients (4 years, (SD 0)), information about pulses in the feet was only reported in three clients (67%, N=2) and information about neuropathy was not reported at all.

4.1.2 Treatment

All 46 clients in the study population were admitted to hospital with a foot sepsis. In twenty-three clients, a second complication was registered and three clients had third complications, see appendix 1 for the different complications.

The mean length of admission in all clients was eleven days and each client received on average nine different types of medication, including antibiotics that every client received. In 40 cases blood glucose was measured when they were admitted, resulting in a mean blood glucose level of 15.9. Of these 40 clients, the mean blood glucose on their last day of admission was 9.6. More information about the treatments is shown in table 4.

Table 4: Treatment characteristics TTM Hospital population (N=46).

TTM Hospital	First admission N=46	Second admission N=12
Mean admission days	11 (9)	10 (5)
Mean blood glucose at admission date	15.9 (7.6)*	12.2 (6.2)
Mean blood glucose at discharge date	9.6 (4.0)*	9.3 (2.9)
Mean amount of medicines	9 (3)	8 (3)
Surgical interventions	70% (N=32)	67% (N=8)
X-Rays	15% (N=7)	8% (N=1)
Electrocardiography	78% (N=36)	58% (N=7)

*Data analysed in N=40 clients.

Note: All values are mean (Standard Deviation) or in percentage.

During the first admission, 32 clients had to undergo a surgical intervention. A total of 44 surgeries were performed in these clients, see appendix 3. Nine clients (20%) had undergone a major amputation due to the diabetic foot ulcer and surgical debridement was done in 22 clients (48%). The mean duration before the clients received this surgical intervention was 4 days. Two clients refused any surgical interventions and four clients refused amputations but agreed to get debridement of the wound. Debridement is the process of removing necrotic tissue or foreign material from and around a wound to expose healthy tissue.

After being discharged from the TTM Hospital, sixteen of the 46 clients were referred to different health care providers. In 21 clients no referrals were registered in the medical records and six clients did not have a follow up planned. Of the sixteen referred clients, ten were referred to medical or surgical follow up within the hospital itself, five clients were referred to community care and one client was referred to a district hospital. Three clients left the hospital because they refused any treatment and did not want to be followed up.

The clients who refused surgical intervention had a mean age of 53 years and a mean admission time of 8 days (SD 5). Two clients were advised to stay in the hospital but self-discharged. Four of the clients who refused a surgical intervention or amputation were admitted a second time in the hospital. Two clients received a major amputation (above the ankle) during the second admission, one client still refused any surgical intervention and the other client did not need surgical intervention during the second admission.

A total of twelve clients from the study population (n=46) were admitted a second time in the two year period, six of them were admitted within eleven days after their first admission. The mean time between admissions for the twelve clients was 63 days (SD 81).

The reason for all re-admissions was foot sepsis, ten clients were suffering from a foot sepsis in the same foot as during their first admission. The mean duration of the second admission was ten days and all twelve clients were given antibiotics. They received an average of eight different medicines per client, including their antibiotics.

Seven clients received surgical intervention for the second time and one client received surgical intervention for the first time during this second admission. One client refused for the second time to undergo any surgical intervention during the treatment.

Information about surgeries performed in clients who were admitted with a diabetic foot sepsis was collected from surgical lists provided by the TTM Hospital for the period of January 2015 until April 2016. In this population (n=253) that had undergone surgical interventions due to diabetic foot ulcers, 30% of the clients (N=76) had to undergo a major amputation and in 64% of the clients (N=162) surgical debridement's were performed.

4.1.3 TTM Hospital Costs

The treatment costs in the TTM Hospital were not available, therefore, the costs were based on costs calculations in the Eurodiale study [36]. A percentage of amputation costs, intervention costs, diagnostic intervention costs and the costs of antibiotics was calculated from the total hospital costs in this study. These costs were calculated using the group with infected ulcers but without vascularisation in the Eurodiale study, as the TTM Hospital has no vascular surgeons but all wounds are infected.

The percentages of the admission costs were: amputation costs (13%), other intervention/surgical costs (27%), diagnostic intervention costs (3%) and the costs of antibiotics (31%).

The costs per bed per day were available in the TTM Hospital in Samoa and were used for the cost calculation. The hospital stay per day per bed at the TTM Hospital was 446 Tala; including administrative expenses and personnel costs. These costs were used to estimate the total direct costs per client, see Table 5.

During the inclusion of the study population (n=73), a total of 37% (n=27) were excluded as they were not admitted due to a diabetic foot ulcer or sepsis. Assuming that the total hospital admissions of 667 has the same percentage of clients admitted for a different circulatory complication than diabetic foot sepsis, in two years a total of 420 admissions related to diabetic foot ulcers were assumed.

Information about amputations or other (surgical) interventions in these clients was not available, therefore the amount of clients who needed to undergo amputations, other surgical interventions or the amount of clients who did not need any surgical interventions were estimated with the included population of 46 clients. In the study population, the 46 clients had 60 admissions in total. In these admissions, 30% had to undergo an amputation, 40% had a surgical intervention other than amputation and 30% did not need any surgery. These percentage were used to estimate the total direct costs in the overall hospital population of 420 admissions, see table 5.

Table 5: Direct hospital costs for clients treated for diabetic foot sepsis in the TTM Hospital between June 2013 and June 2015.

TTM Hospital admissions (n=420)	Clients undergone amputation (n=128)	Clients without amputation but with other surgical interventions (n=164)	Clients without surgery (n=128)
Mean admission days	13(10)	13(10)	6(3)
Hospital costs per bed per episode	5,798	5,798	2,676
Diagnostic costs	169	169	78
Antibiotics costs	1,794	1,794	828
Amputation costs (n=14)	754	-	-
Other (surgical) intervention[1] costs (n=18)	-	1,560	-
Direct costs per client per treatment	8,515	9,321	3,582
Total direct costs (Tala)	(128*8,515)= 1,089,920	(164*9,321)= 1,528,644	(128*3,582)= 458,496
Total direct costs (AUD)*	577,658	810,181	243,003

[1]: Other interventions and surgery: surgical debridement, plastic surgery, orthopaedic surgery, other surgery.
*Currency used was 1 Tala = 0.53 AUD [62].

The total direct costs of the 420 foot sepsis admissions at the TTM Hospital is estimated at 3,077,060 Tala in two years. The direct costs for diabetic foot ulcers ranged between 9,321 and 3,582 Tala per treatment, with a weighted average of 7,329 Tala per client per episode. However, not all costs are included as some costs were not available. Figure 2 shows a comparison of costs per client between the Diabetic Foot Clinic and the TTM Hospital.

4.1.4 Diabetic Foot Clinic Samoa

In June 2015, the Diabetic Foot Clinic opened within the TTM Hospital. The Diabetic Foot Clinic is open two mornings a week for four hours and has seen a total of 72 clients in one year. Of these 72 clients, 46 clients (64%) were included as they met the inclusion criteria as described in table 2. The other 36 clients were excluded as some of them had no open wounds, some were only registered and treated at the Mobility Device Service and some denied treatment.

In 35 clients the ulcer duration before they visited the clinic was reported, with a mean duration of 32 weeks (SD 55). During the first visit, wounds were graded with the Wagner scale, see table 7. One wound was graded with a Wagner scale 0 which means that there was no wound. However, this client received wound treatment and wound sizes were recorded, therefore this client was included.

Clients had a mean amount of 10 visits and in 50% of the clients (N=23) the ulcer healed after a mean healing time of 15 weeks (105 days), see table 7 for the client characteristics.

Table 7: Diabetic Foot Clinic client characteristics.

Diabetic Foot Clinic clients	Total population N=46	Female N=25	Male N=21	P-value
Mean age	58 (9)	57 (8)	58 (11)	0.58
Diabetes type (n=46)				0.42
Diabetes type 2	83% (n=38)	78% (n=20)	89% (n=19)	
Diabetes type 1	0%	0%	0%	
Unknown	12% (n=6)	13% (n=3)	11% (n=2)	
Gestational	5% (n=2)	9% (n=2)	0%	
Diabetes duration in years (n=26)	11 (6)	10 (6)	11 (6)	0.951
Diabetes controlled (n=32)	31% (n=10)	32% (n=6)	31% (n=4)	0.961
Smoking cigarettes (n=31)	19% (n=6)	6% (n=1)	33% (n=5)	0.146
Pulses in the feet (n=35)	69% (n=24)	71% (n=15)	64% (n=9)	0.941
Neuropathy (n=34)	82% (n=28)	79% (n=15)	87% (n=13)	0.894
Number of visits (n=46)	10 (10)	11 (11)	8 (8)	0.363
Ulcer healed (n=46)	50% (n=23)	52% (n=13)	48% (n=10)	0.887
Healing time in weeks (n=23)	15 (11)	19 (13)	10 (7)	0.043
Wagner Grade (n=23)				0.094
Grade 0	4% (n=1)	0%	12.5% (n=1)	
Grade 1	48% (n=11)	60% (n=9)	25% (n=2)	
Grade 2	26% (n=6)	13% (n=2)	50% (n=4)	
Grade 3	22% (n=5)	27% (n=4)	12.5% (n=1)	

Note: values are mean (Standard Deviation) or in percentage.

4.1.5 Treatment

Clients seen at the Diabetic Foot Clinic mostly had wounds recorded as Wagner grade 1. Deep infected wounds were not admitted to the Diabetic Foot Clinic, those were referred to the TTM hospital. Debridement was done in 85% of the clients (N=39), five clients (11%) did not need debridement and in two clients (4%) it was not reported in their files.

Offloading was provided in 32 clients (70%) with a mean of two devices per person (SD 2). See table 8 for the different offloading modalities.

Table 8: The different offloading techniques used in the Diabetic Foot Clinic

Offloading	N	Number used per client
Felt padding	32	7.1
Post op shoe	21	1.1
Cam boots	8	1
Total contact cast	11	5.6
Removable total contact cast	16	3.8
Foot orthosis EVA	12	1.3
Forefoot offloading shoe	10	1
Canvas rocker cast shoe	12	1.3
Rear foot offloading shoe	3	1.3

Clients had an average of ten visits during their treatment. A total of 28 clients (61%) were compliant to the treatment and showed up frequently. Twelve clients (26%) did not show up in at least two visits and for six clients (13%) it was not possible to decide whether the client did not show up, because the date of follow up was not registered.

Blood glucose was measured during the first and last visit in 21 clients and there was a significant difference between the mean blood glucose level at admission and the mean blood glucose at their last admission (13.8 ±5.5 - 12.2 ±4.6, <0.01). The mean duration between the first and last measurement was eleven weeks (SD 8).

The combination of wound care, offloading and education resulted in a healing rate of 50% (N=23). Eleven clients developed a second ulcer during treatment; in nine of these eleven clients the second ulcers closed with a mean healing time of 6 weeks (SD 4).

4.1.6 Diabetic Foot Clinic costs

Involved in treatment at the Diabetic Foot Clinic are a podiatrist, one nurse and an orthotist. During some mornings there was a second orthotist, however, this orthotist is working as a volunteer-mentor and did not receive a salary from the National Health Service. See table 9 for the annual salary costs for the Diabetic Foot Clinic.

Table 9: Working hours and salaries of the diabetic foot team.

Diabetic Foot Clinic Salaries	Hour rate	Per week (8hours)
Orthotist	20.0	160
Nurse	14.2*	114
Podiatrist	39.3	314
Total (Tala)	73.5	588
Total (AUD)**	-	312

*Mean of different salary scales was taken, see table 13 in appendix 2 for the range of salaries. **Currency used was 1 Tala = 0.53 AUD [62].

In one week, twelve clients can be treated at the Diabetic Foot Clinic. Per client, the average salary costs are 49 Tala per appointment. For the total 11 month period, or 47 weeks, the estimated total salary costs of the Diabetic Foot Clinic were 27,636 Tala or 14,647 AUD.

Clients had an average of 10 visits, the average salary cost for treating one client is therefore 490 Tala. However, not only salary costs were made in the Diabetic Foot Clinic. Offloading techniques were used in 32 clients, the costs per offloading technique used in the clinic were estimated by Motivation Australia in 2015, see table 10.

Table 10: costs per offloading technique.

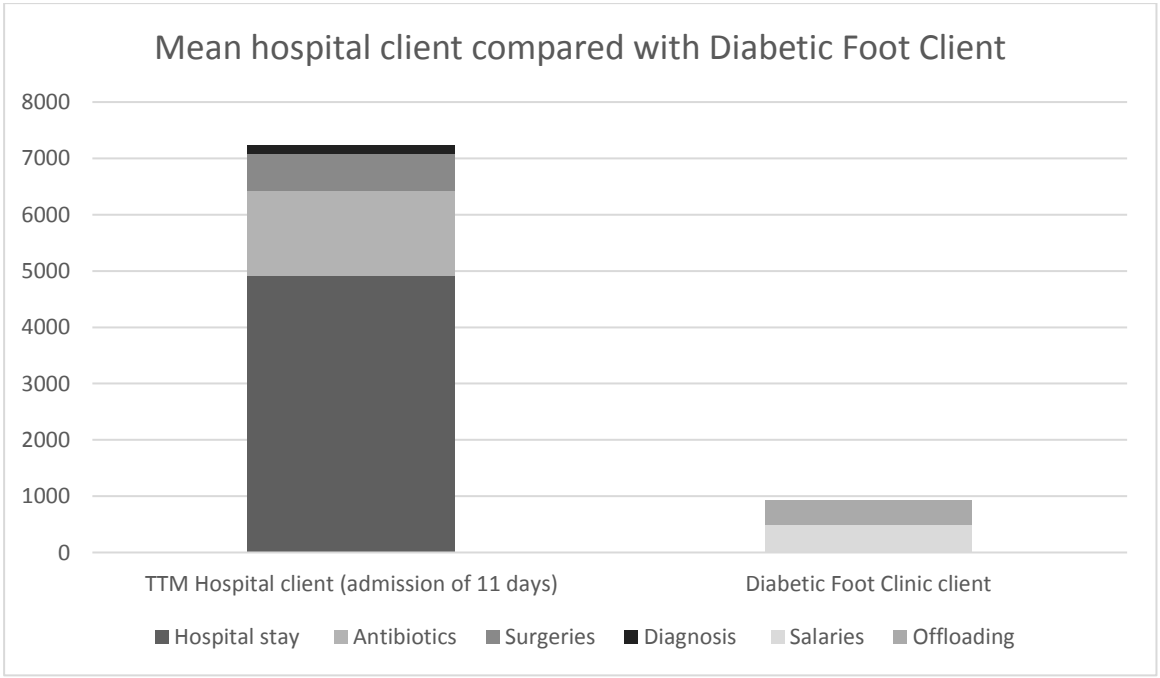
Offloading technique (Tala)	Costs per technique (Tala)	Amount used in n=32 clients	Total costs
Total contact cast	136	62	8,432
Total contact cast shoe	128	60	7,680
Offloading shoe	42	14	588
Post-op shoe	25	32	800
Canvas Rocker cast shoe	28	15	420
Felt padding	9	228	2,052
Total in 11 months (Tala)	-	323	19,972
Total in 11 months (AUD)*	-	323	$10,585

*Currency used was 1 Tala = 0.53 AUD [62].

A total of 19,972 Tala was spend on offloading techniques in eleven months. The average costs of offloading techniques per client was 624 Tala.

The direct costs for treating 46 clients at the Diabetic Foot Clinic in the eleven months was 42,508 Tala or 22,529 AUD [57]. With mean treatment costs of 490 Tala per client who did not need offloading and 1,114 Tala for clients who did need offloading. The weighted average expenditure per client was 924 Tala, see figure 2. The total costs in eleven months were 48,420 Tala, this is including the clients who were excluded from the study, such as clients without active ulcers.

Figure 2: The costs of a client admitted at the TTM Hospital compared with the costs of a client treated at the Diabetic Foot clinic



4.1.7 Cost-effectiveness

The required information about the treatment costs and the effects in the TTM Hospital and Diabetic Foot Clinic was not completely available. Yet, to provide an insight in the health care costs and perceived effects in the situation with the Diabetic Foot Clinic running in Samoa, different scenarios were described to estimate these costs and the effects.

Assumed was that clients who were treated at the Diabetic Foot Clinic would have ended up with an infected ulcer or foot sepsis at the TTM Hospital if they had no access to treatment in the Diabetic Foot Clinic, as most ulcers do not heal without treatment [46].

The different scenarios were described to outline the possible healing outcomes and number of hospital admissions in clients seen at the Diabetic Foot Clinic. The observed chance of getting admitted in the TTM Hospital after a treatment at the Diabetic Foot Clinic in this study, is based on a short observation time. Therefore, healing rates in two other studies were used as well to provide a more robust overview of the costs and health outcomes of treatments in diabetic foot clinics.

Costs

The costs that were taken into account in the treatment of clients in the Diabetic Foot Clinic were the salary costs and the costs for offloading devices. The mean amount of visits was 10 times in the observed situation in Samoa and a total of 70% of the clients received offloading during their treatment. See table 11 for the mean costs per client per treatment. In the described scenarios to predict costs of the health care system with the Diabetic Foot Clinic, a total of n=1000 clients was used to describe the different treatment outcomes and their costs.

In all three different scenarios, the Diabetic Foot Clinic used offloading in 700 clients with total treatment costs of 779,800 Tala. The other 300 clients who were treated without offloading had a total treatment costs of 147,000 Tala. Together, the Diabetic Foot Clinic made a total of 926,800 Tala as direct costs.

The costs that were made in the TTM Hospital for treating diabetic foot sepsis were based on three different situations. In 40% of the clients who were observed in the study, surgical interventions were performed. In 30% of the admitted clients, amputations were done and another 30% of the clients did not need any surgery. Clients who had surgery had a mean admission duration of thirteen days and the clients without surgery had a mean admission of six days. See table 11 for the mean costs per client per treatment for the three different situations.

These treatment outcomes were used to design three possible scenarios of costs from the Diabetic Foot Clinic as described below. In all scenarios, a population of n=1000 clients was used to describe the different treatment outcomes and their costs.

Scenario 1: The first situation was the observed situation in the Diabetic Foot Clinic, where a total of 23 clients healed their ulcer, 1 client needed to be admitted in hospital and 22 clients were still in treatment. Predicted was that one more client would eventually be admitted in the TTM Hospital of the 22 clients who still followed treatment. A healing rate of 21/23= 91% was taken into account for this scenario.

The calculated direct costs in n=1000 clients was 926,800 Tala in the Diabetic Foot Clinic, however, the healing rate in this scenario was 91% which means that 90 clients (9%) still had to be admitted in the TTM Hospital.

The costs for those clients are divided in the three different categories. Surgical interventions was performed in 36 clients (40%) with total costs of 335,556 Tala. The 27 clients (30%) who had to undergo an amputation made total costs of 229,905 Tala and the 27 clients (30%) without any surgery had total treatment costs of 96,714 Tala. The overall direct hospital costs were 662,175 Tala in this scenario and the total direct costs of treating 1000 clients with the Diabetic Foot Clinic and a healing rate of 91% was 1,588,975 Tala or 842,157 AUD [57], see table 11.

Situation 2: In the second situation, the 77% healing rate from the Eurodiale study [36] was taken as a guideline to predict healing outcomes at the Diabetic Foot Clinic.

Again with n=1000 clients treated at the Diabetic Foot Clinic had total direct costs of 926,800 Tala. In this scenario the amount of clients who still needed to be admitted in hospital is 230 (23%).

Treatments including surgical interventions were performed in 92 clients (40%) and had total costs of 857,532 Tala, treatments with amputations were done in 69 clients (30%) and had total costs of 587,535 Tala and the total costs of treating the other 69 clients (30%) without any surgery was 247,158 Tala. The overall TTM Hospital costs in this scenario was 1,692,225 Tala. Together with the treatment costs in Diabetic Foot Clinic, the total direct costs for treating 1000 clients with a healing rate of 77% was 2,619,025 Tala or 1,388,083 AUD [57], see table 11. However, these healing rates are from different clinics in Europe. Therefore it is likely that these healing rates will differ from the situation in Samoa.

Situation 3: In the last situation, a healing rate of 68% was taken into account, which was a healing rate found in a prospective cohort study in India [3]. As India is a developing country as well, this healing rate was considered as more realistic than the healing rates from the scenarios above.

This scenario predicts that a total of 320 clients who were treated at the Diabetic Foot Clinic, still had to be admitted in the TTM Hospital. The three treatment situations are again the same, treatments with surgical interventions was performed in 128 clients (40%) with total costs of 1,193,088 Tala. In 96 clients (30%) amputations had to be done, these treatments had a total costs of 817,440 Tala and the total treatment costs of the 96 clients (30%) who did not need any surgery during their treatments had a total costs of 343,872 Tala. The overall TTM Hospital costs in this scenario were 2,354,400 Tala. Together with the total treatment costs of 926,800 Tala from the Diabetic Foot Clinic, this scenario with a healing rate of 68% in the Diabetic Foot Clinic had total costs of 3,281,200 Tala or 1,739,036 AUD [57], see table 11.

These situations were compared to a fourth situation in which the Diabetic Foot Clinic was not there. All 1000 clients had to be treated at the TTM Hospital, which means 400 (40%) had an admission and surgical intervention with total direct costs of 3,728,400 Tala. The treatment costs for the 300 clients (30%) who had to undergo amputation was 2,554,500 Tala and the treatment costs of the 300 clients (30%) without any surgery was 1,074,600 Tala. The total costs of treating all these 1000 clients at the TTM Hospital was 7,357,500 Tala or 3,899,475 AUD [57], see table 11.

Table 11: An overview of the direct costs for the Diabetic Foot Clinic, four assumptions.

	Direct costs per client (Tala)	Situation 1 Healing rate 91% N=1000	Situation 2 Healing rate 77% N=1000	Situation 3 Healing rate 68% N=1000	Situation 4 Only Hospital N=1000
TTM Hospital					
Client with amputation (30%)	8,515	229,905	587,535	817,440	2,554,500
Client with other surgical Intervention (40%)	9,321	335,556	857,532	1,193,088	3,728,400
Client without surgery (30%)	3,582	96,714	247,158	343,872	1,074,600
Diabetic Foot Clinic					
Client with offloading (70%)	1,114	779,800	779,800	779,800	-
Client without offloading (30%)	490	147,000	147,000	147,000	-
Total direct costs (Tala)	-	1,588,975	2,619,025	3,281,200	7,357,500
Total direct costs (AUD)*		842,157	1,388,083	1,739,036	3,899,475

*Currency used was 1 Tala = 0.53 AUD [57].

Effects

The health effects of the treatment at the Diabetic Foot Clinic are unknown due to the short observation time of the study. Yet it is likely that the health effects are positive, as there was no other service in Samoa that provided specialised wound care for clients with diabetic foot ulcers.
The treatment of the Diabetic Foot Clinic is an extra service, to prevent unnecessary amputations in clients who have foot ulcers that can heal with a treatment from the Diabetic Foot Clinic. Most health effects will be expected in this group, as these clients will heal their wounds and will continue to participate in social and economic networks. Treating these clients at the Diabetic Foot Clinic is not only better for their health outcomes, it is also less expensive than hospital treatments and therefore these treated clients are cost-saving for the National Health Service.

Not all ulcers can be healed though, some clients will have chronic ulcers that won't close with treatment at the Diabetic Foot Clinic. These chronic ulcers that show little or no healing at all are mostly seen in clients with ischemic foot ulcers [58]. The Diabetic Foot Clinic will make more costs in these clients compared to the old situation, as amputations may be necessary in these clients.

To estimate the lowest healing rate necessary for the Diabetic Foot Clinic to break even with the TTM Hospital costs in these situations with n=1000, the linear formula of y=7,358n + 926,800 was formulated. The variable costs are 7,358 as these are the average treatment costs for the hospital, the 'n' is the amount of clients admitted to hospital and 926,800 are the fixed costs of the Diabetic Foot Clinic for treating 1000 clients. This formula was used to calculate the highest number of clients that could be referred from the Diabetic Foot Clinic to the TTM Hospital without making more costs than the TTM Hospital costs in situation 4, using: 7,357,500 = 7,358n + 926,800. The highest number of referred clients was n=874, which equals a minimum healing rate of 12.6% (n=126) for the Diabetic Foot Clinic to break even with the hospital costs.

Chapter 5 DISCUSSION, CONCLUSION AND RECCOMENDATION

5.1 Discussion

The results from the study show several health benefits for clients at the Diabetic Foot Clinic, with the most important outcome the ulcer healing. The Diabetic Foot Clinic showed also economic benefits, compared to the costs of a treatment at the TTM Hospital. Treatment costs per client at the Diabetic Foot Clinic are low compared to hospital costs, though the population seen at the TTM Hospital had diabetic foot sepsis while the clients treated at the Diabetic Foot Clinic had more superficial wounds and no infections. Deep infected wounds are known for higher costs and longer healing times compared to the more superficial wounds [38]. Other factors in the two populations that influenced the study are discussed below.

5.1.1 TTM Hospital

The included TTM Hospital population of 46 clients differed from the overall hospital population. The rate of males included was less and the mean age of the population was slightly younger than the overall population. Age was controlled as a potential confounder, yet no significant difference were found in treatment variables such as admission days, amount of medication, days to surgical intervention, amount of X-rays taken and the amount of ECG's, see appendix 4.

In 2015, a total of 60% of all admitted clients had to undergo surgical interventions. Surgical interventions are a high burden on the hospital costs, see table 5. The main barrier Samoan health care needs to deal with is the supply of resources and the development of care. However, the costs calculation in this study was based on the Eurodiale study with results from diabetic foot clinics in Europe. It is high likely that those costs in Europe differ from the costs made in Samoa.
The costs for surgical interventions in the group of clients who did not had an amputation but needed surgical interventions were higher than amputation costs. This can partly be explained by the difference in surgeries performed, there were less amputations performed than surgeries with other interventions in the study population.

It may be acceptable to conclude that there are also indirect costs involved in the economic situation in Samoa due to loss of productivity, individual patients' and family costs and loss of quality of life. Having a diabetic foot ulcer leads often to more than one hospital admission and there is a high risk on needing an amputation. The number of re-admissions in this study might differ from the real re-admission though. The mean time between admissions was 63 days, which makes it high likely that some of the included clients had admissions outside the observation time. Admittedly, interval censoring is not performed during the study and results will deviate from reality as the rates for clients who have been admitted more than once likely differ from the results shown in this study.

5.1.2 Diabetic Foot Clinic

The treatment in the Diabetic Foot Clinic is structured as chronic care and each appointment exists of wound care, education and offloading. Non-surgical debridement and dressings were performed by the podiatrist or nurse under supervision from the podiatrist. Every visit, education about wound care and diabetes was provided by all staff and the orthotist provided in 32 clients (70%) offloading devices. Approximately one-half of all diabetic foot ulcers occurred on the plantar foot surface and were mainly caused by mechanical pressure acting on the foot during walking in the presence of lost protective foot sensation from peripheral neuropathy [3, 4]. Offloading is a technique used to relieve mechanical pressure in the ulcer area throughout custom-made therapeutic footwear [23]. Some offloading techniques in the Diabetic Foot Clinic in Samoa were used in combination and since the

resources for offloading devices are scarce in Samoa, non-removable contact casts were often re-used as removable contact casts. These new removable contact casts made out of the previous non-removable casts were not taken into account for the cost analysis.

The healing rate of diabetic foot ulcers in the Diabetic Foot Clinic was 50% in an 11 month period. Literature shows different healing rates, a study from Brazil where clients were treated in non-diabetes-specialised hospitals showed 39% primary healing rates and 48% healed ulcers after surgical interventions. This prospective cohort study followed the included clients until they were discharged or deceased [32]. Another study done in South India showed healing rates of 68% in a diabetic foot clinic [3]. However, this study had a follow-up period of 27 months. The mean treatment duration for an ulcer to heal at the Diabetic Foot Clinic in Samoa was 15 weeks, therefore it is likely that ulcer healing rates could be higher if the observed time was longer.

Compliance in the total Diabetic Foot Clinic population was 61% and in the clients who achieved healing the compliance was 87%, though this was not significant in this study. Some literature shows that compliance does have a significant effect on the healing outcomes [3].

There was only very little information available for the cost-analysis. Only salary costs and the costs for offloading devices were taken into account to calculate the treatment costs at the Diabetic Foot Clinic. The costs for dressings and other wound care materials, operating costs and depreciation costs were not included as these were not available in the Diabetic Foot Clinic. Therefore these costs were also not included in the hospital costs.

5.1.3 TTM Hospital versus Diabetic Foot Clinic

The two populations who were seen at the TTM Hospital and Diabetic Foot Clinic in Samoa are not comparable due to big difference in wound complications. Clients seen at the Diabetic Foot Clinic have less complicated wounds than those who are admitted in the TTM Hospital. Nevertheless, treating clients at the Diabetic Foot Clinic looks like an effective way of preventing clients from getting admitted at the TTM Hospital as only one client was referred from the Diabetic Foot Clinic to the TTM Hospital in eleven months. The most important change that needs to be made is getting clients to present in an early stage after developing a foot wound so they can get treated at the Diabetic Foot Clinic. A lot of people in Samoa were waiting too long which resulted in an infection and admission in the hospital. Earlier presentation would make the amount of clients seen at the hospital decrease, even as the hospital costs.

However, this study shows that treatment at the Diabetic Foot Clinic achieves ulcer healing whereas there is no other health service in Samoa that focusses on the healing of foot ulcers. Only five clients who were discharged after their treatment at the TTM Hospital would be referred to community care, most clients would be referred to other hospital services and some would not be referred at all.

The overview of costs provides insight in the benefits that can be derived by the Diabetic Foot Clinic, though it is an expanding of the health care budget in the short-term as the Diabetic Foot Clinic is an extra service. It is high likely that expansion of the Diabetic Foot Clinic will show a decrease in hospital admissions in the long-term as more people will be prevented from getting a foot sepsis, which will in its turn decrease the total health expenditures on diabetic foot ulcers. The break-even point for the Diabetic Foot Clinic will be achieved with a healing rate of minimal 12.6%, which is high likely to be achieved.

5.1.4 Limitations

The study could not be performed as planned due to different kind of limitations. The biggest limitation was the difference between the two study populations, which was not expected when the research protocol was written. Since the TTM Hospital treated clients with worse foot ulcers than the clients at the Diabetic Foot Clinic. This resulted in different treatment goals; the TTM Hospital treated foot sepsis and was focused on reducing the infection of the wound whereas the Diabetic Foot Clinic focused on superficial ulcers and healing in a long-term setting. The study could be improved with more information about the follow up of the TTM Hospital clients as the wound treatment would be continued in community care. The effectiveness of health care in the two years prior to the Diabetic Foot Clinic can only be determinate by including the most important health care paths. Another common used treatment are the traditional healers in Samoa. The treatment from traditional healers can hardly be included though, as the traditional healers do not register any information about their clients.

Even in the TTM Hospital and Diabetic Foot Clinic, registered information was often incomplete and the structure in files was often not followed. Not all information that was needed for a proper cost-benefit analysis was available at the TTM Hospital; fixed costs relating to the Operation Theatre were not available, even as variable costs of materials used during operations and the costs of medication. Data collection in medical records was mostly subjective and not specified for research purposes. Follow-up information was poorly reported in client records, which made it difficult to determine the overall treatment for clients with a diabetic foot ulcer. Some data, like the operation times, were only available through estimations, therefore not all data is completely valid.

A second limitation was the population size, as both populations were small. The period of three weeks to collect data in Samoa was too short, getting access to the different files took a while and therefore the time to go through the files was very short. To improve the study, more clients should be included in the TTM Hospital population and it would be better to also have the patient characteristics of the clients who were excluded from the Diabetic Foot Clinic population. In this study, the included TTM Hospital population differed from the overall hospital population. A bigger study population would represent the overall population more realistic.

Overall it could be said that the research planning was not completely realistic as the data collection was more difficult than expected. This could be partly expected as the health care in Samoa is still developing and cultural habits slowed the process down. In other words, the circumstances were different than the circumstances that were anticipated on. Therefore, a longer time period to collect the data has to be taken into account for any research in the future.

5.2 Conclusion

The treatment costs of the Diabetic Foot Clinic in Samoa are low compared to the costs of admitting a client with a diabetic foot sepsis in the TTM Hospital. The two health services differ in treatment goals and the client populations were not comparable due to the difference in health status. However, a break-even point will be achieved if the Diabetic Foot Clinic achieves a healing rate of 12.6%. It is high likely that this healing rate will be achieved as the rate of clients who healed their ulcers during the study period was 50%.

5.3 Recommendation

Research gaps were also discovered while searching for the benefits of diabetic foot clinics in the Pacific region. Not many cost-benefit studies are performed in developing countries and no research was available about diabetic foot clinics in the Western Pacific Region as the Diabetic Foot Clinic in Samoa is the first in this region. However, this region has the highest diabetes prevalence in the world and health care is still basal. More insight in the treatment and prevention of diabetes and its complications should be collected and analysed to determine whether the approach used for the treatment and prevention of diabetes and its complications in this region is effective.

Treatment at the Diabetic Foot Clinic in Samoa has resulted in some good health outcomes for its clients, yet the management of the diabetic foot can be more optimized. There are short-term and long-term goals that the Diabetic Foot Clinic can take into account. The first recommendations will be about short-term goals.

One of the hardest, aspects in the management of diabetic foot ulcers is the client's compliance, yet this is also one of the most important aspects for good healing outcomes [3, 58]. The compliance in the Diabetic Foot Clinic was 61% (n=26), a number of clients did not show up regularly and there were no possibilities available to contact the clients for a new follow-up appointment. Therefore the first recommendation would be to improve the follow-up in clients of the Diabetic Foot Clinic. Clients need to understand the urge of getting consistent treatment for their ulcers and there should be a phone available to call clients after they did not attempt for an appointment.

The most important recommendation that clients gave during the interviews, was to expand the service of the Diabetic Foot Clinic. The outcomes of this study show that expanding the service would be an improvement in the management of diabetic foot ulcers in Samoa as there are many diabetic foot ulcers seen at the hospital yearly and treatment costs would be less if the Diabetic Foot Clinic expands.

More clients could be treated, which would high likely prevent clients from having to undergo an amputation. To get a better idea of the economic burden as a result of amputations, follow-up research would be recommended. The Samoan infrastructure is not adapted to people with little mobility, amputations are therefore a big burden on individuals. They lose the ability to do physical work and most of them are not able to work at all, which has consequences for the family. This effects the economics of Samoa as this is productivity loss. Losing a part of a limb has also an impact on someone's quality of life, though there is no scientific research about this subject in Samoa, it is high likely that losing a limb without having the possibility for a prosthesis lowers quality of life as the participation in daily life decreases and their dependency on others increases.

The TTM Hospital should work together with the Diabetic Foot Clinic and refer more of their clients who were treated for diabetic foot sepsis for the follow-up treatment at the Diabetic Foot Clinic. This is only possible if the Diabetic Foot Clinic has more hours available to treat clients. On short-term the National Health Service might have to invest more money, as the service will expand, but in long-term it should save the costs of re-admissions and costs for surgical interventions as shown in this study. To establish the expanding, it would be necessary to train new wound-nurses and to train a new podiatrist.

To improve the Diabetic Foot Clinic in the long-term, decisions about expanding the multidisciplinary team with a doctor should be considered. This would make it possible for the Diabetic Foot Clinic to treat infected wounds, as the doctor could describe the antibiotics and decide what the treatment should look like in clients with infected wounds. The Diabetic Foot Clinic would become the first health service where clients with diabetic foot ulcers would go to. A doctor makes it possible to screen

the clients and make decisions about who needs to be admitted in hospital and who could receive treatment from the Diabetic Foot Clinic. Things that need to be screened for at the baseline include neuropathy, ischemia and osteomyelitis if the clients has an infected wound.

It would be even better to involve a vascular surgeon at the hospital, as a lot of ischemic diabetic foot ulcers will not heal without vascularisation [58]. This is an expensive intervention, therefore it should be considered as a long-term goal.

Summarized, the first goal at the moment is to treat as many diabetic foot ulcers as possible as there are a lot of clients with foot ulcers in Samoa who can be treated effectively without vascular interventions. Though for future treatments, expanding the Diabetic Foot Clinic with more podiatrists, orthotists, nurses, doctors and even a vascular surgeon should definitely be considered.

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Appendix 1

Table 12: Second and third complications in clients at the TTM Hospital.

Second complications	N	Third complication	N
Fever	10	Hypertension	1
Hypertension	6	Diffusional	1
Osteomyelitis	4	Renal	1
Chest pain	2		
Pneumonia	1		

Appendix 2

Designation	Personnel	Salary per Person
Head of Unit	1	$116,289.00
Consultant Specialist General Surgery	1	$116,289.00
Senior Registrar 1	1	$51,510.00
House Surgeon 3	1	$41,437.00
Medical Officer 1	1	$37,967.00
House Surgeon 1	2	$34,026.00
Nurse Manager	1	$49,154.00
Senior Nurse Specialist	1	$49,154.00
Registered Nurse	1	$30,291.00
Registered Nurse	1	$27,295.00
Registered Nurse	2	$27,037.00
Registered Nurse	2	$26,393.00
Registered Nurse	2	$26,342.00
Registered Nurse	5	$25,750.00
Diabetic Foot Clinic	1	$14,752.00
Volunteer DFC	1	

Take 48 weeks for salary;

The Diabetic Foot Clinic is open for 51 weeks a year, running 8 hours a week. In the 11 months of the study, the clinic had opened for 47 weeks with a total of 376 hours.

Table 13: Annual salaries and the mean salaries.

Annual Salaries	Highest	Lowest	Mean	Weekly Salary[1]	Hour rate[2]
Nurse	30,291	25,750	27,185	631 – 536 – 566	15.8 – 13.4 – 14.2
Surgeon	41,437	34,026	37,732	863 – 709 - 786	21.6 – 17.7 – 19.7
Head of operation unit	-	-	116,289		
Podiatrist DFC	-	-	14,752	314[3]	39.3[4]
Orthotist				415	20.0

[1] : A year of 48 weeks. [2] : Based on 40 hours a week. [3] : Based on 47 weeks. [4] :Based on 8 hours a week.

Appendix 3

Table 14: The amount of surgical interventions per category.

TTM Hospital	Doctor 1 Estimated minutes for operations	Doctor 2 Estimated minutes	2015 Clients with surgery N=252	Jan –Jun 2015 Clients with surgery N=87	Included population N=46
Mean admission length in days			-	-	11 (9)
Mean days to surgical intervention			-	-	4 (3)
Surgical intervention					
Debridement	30	30	162	-	22
Debridement + amputation toe(s)	20-25	20	17	12	6
Amputation toe(s)	15	15	41	31	3
Forefoot amputation	45-60	45	-	-	1
Below knee amputation	60-90	60	45	39	4
Above knee amputation	60-90	60	31	24	5
Incision and drainage			12	-	1
Incision and drainage + debridement			11	-	-
Transtarsal amputation			16	11	-
Change of dressing			12	-	1
Change of dressing + debridement			10	-	-
Wound closure			3	-	1
Split skin graft			2	-	-
Unknown			1	1	
No surgical intervention			-	-	14
Total			362	118	44

Appendix 4

Table 15: Treatment variables divided in two age group to see if age is a confounder on treatment outcomes.

TTM Hospital AGE	55 (n=46)	>55 (n=23)	<55 (n=22)	P-value
Admission days	11 (9)	12 (10)	10 (8)	0.062
Amount of medication	9 (3)	9 (3)	8 (3)	0.721
Days before surgical intervention	4 (3)[2]	5 (4)*	3 (2)*	0.901
Amount of X-rays	0 (1)[1]	1 (1)[4]	0 (1) [6]	0.522
Amount of ECG´s	1 (1)[3]	1 (1)[5]	1 (1)[7]	0.098

[1]n=16, [2]n=32, [3]n=40, [4]n=10, [5]n=21, [6] n=6, [7] n=18

Note: all values are mean (SD). SD=Standard Deviation.

Appendix 5

Analysis client interviews

Socio-demographic characteristics

During the project in Samoa, 11 clients were interviewed after their visit to the Diabetic Foot Clinic. Before the interviews, all clients were informed of the aims of the study and clients had to read through a written informed consent, see appendix 5, and give their approval by signing the document.

The client characteristics are shown in table 13.

Table 13: Client characteristics of the interviewed Diabetic Foot Clinic clients.

	N=11
Mean age	51 (7)
Male (%)	55% (n=6)
Diabetes Type 2 – Type 1 – Don't know	18 % - 18% - 64%
Smoking	0%
Consuming alcohol	9% (n=1)
Numbness in feet	100% (n=11)
Burning feeling in feet	55% (n=6)

It is noteworthy that most clients (n=7) did not know what type of diabetes they have, it might show how little informed they were at the time of diagnosis. Furthermore, all clients have numbness feelings in the feet, which is an indicator for neuropathy. People with neuropathy are at high-risk for developing diabetic foot ulcers [20, 23], therefore the Diabetic Foot Clinic provides education about the personal foot care that clients have to perform. There are seven essential self-care behaviours in people with diabetes which predict good outcomes for preventing diabetic foot ulcers; healthy eating, being physically active, monitoring of blood sugar, compliant with medications, good problem-solving skills, healthy coping skills and risk-reduction behaviours [59]. All clients from the Diabetic Foot Clinic in Samoa reported that they take their diabetes medication every day and most clients seemed aware of the risks and did not walk barefoot inside or outside, see table 14. The table also shows that most of the clients check their feet for blisters or changes every day or every 1-2 days, which is important for the early detection of foot ulcers.

Table 14: Risk behaviour (barefoot walking) and foot care of the interviewed clients.

	Barefoot inside	Barefoot Outside	Checking for blisters or changes
Not at all	73% (n=8)	91% (n=10)	0%
Every day	9% (n=1)	0%	46% (n=5)
1-2 days a week	9% (n=1)	9% (n=1)	46% (n=5)
3-4 days a week	9% (n=1)	0%	9% (n=1)

Previous situation, TTM Hospital

Ten out of eleven had had at least one ulcer in the past before the Diabetic Foot Clinic had opened. One person did nothing after discovering an ulcer, two of them treated the ulcers themselves and seven went to the TTM Hospital.

The time between discovering the ulcer and visiting the hospital varied, the seven clients could choose four different answer options; there was one client that went to the hospital within three days, four clients went within one week, one client went within a month and two clients visited after a month.

Two of the clients seen at the hospital reported that their ulcers healed, one with a healing time of three months and the other client, who had two ulcers, healed one in nine months and the other one in eight months. The other five clients mentioned that they were still suffering from the same ulcer.

Eight clients had a removal in the past, see table 15.

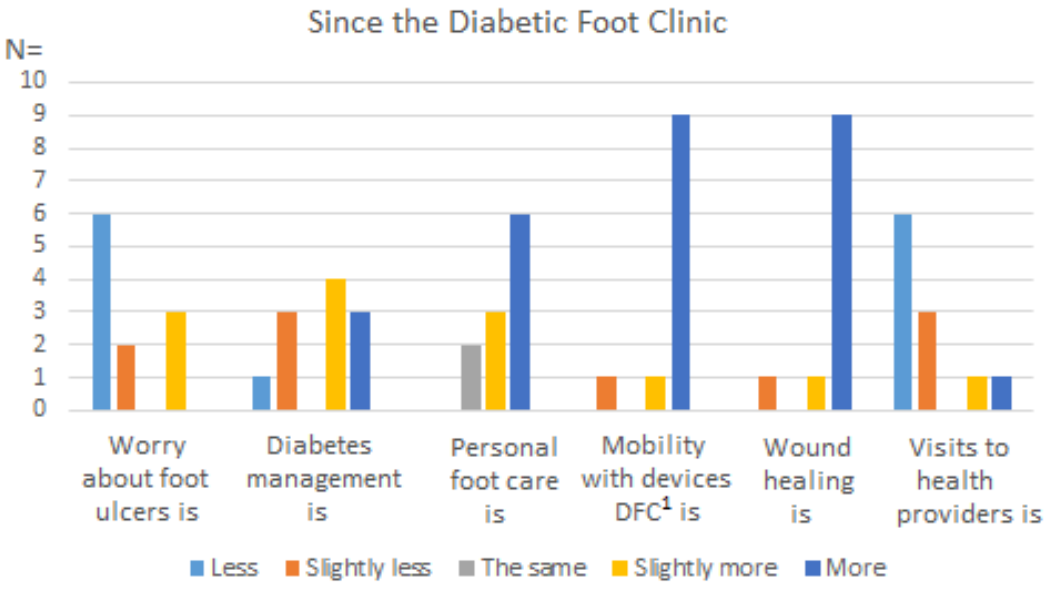
Table 15: Surgical removals in the interviewed population (n=11).

Amputation	First Removal N=8	Second Removal N=2	Third Removal N=2
One toe	62.5%	50%	50%
Two toes	12.5%	50%	0%
Three toes	12.5%	0%	0%
Forefoot	12.5%	0%	1

Diabetic Foot Clinic

Nine clients reported that they were still under treatment in the TTM Hospital when they were referred to the Diabetic Foot Clinic, one person visited the clinic within a month after the ulcer happened and one person visited the clinic after a month.

Ten of them visit the Diabetic Foot Clinic once a week since they started their treatment at the Diabetic Foot Clinic and one client visits twice a week. They filled in questions to



[1]DFC= Diabetic Foot Clinic.

Figure 2: Outcomes of changes experienced by clients since the Diabetic Foot Clinic

All clients reported that their health expenditure has become less since the Diabetic Foot Clinic opened, as the service is a free service at this moment.

Qualitative data

The eleven clients reported a total of 36 benefits, 1 problem was reported and 15 possible improvements were given for the Diabetic Foot Clinic. All interview results were divided in seven categories, see table 16.

Table 16: Perceived benefits, problems and personal improvement ideas of the clients (n=11).

	Amount of perceived benefits	Amount of problems	Amount of improvements
Quality of wound care	10	-	-
Quality of staff and education	12	-	3
Quality of diabetes management	4	-	-
Health care expenditure	3	-	1
Materials used	6	-	-
Waiting time	1	1	2
Building / expenditure service	-	-	9

Appendix 6

Costs and benefits of the Diabetic Foot Clinic in Samoa – Participant Information

For people with diabetes, foot wounds often causes amputations. The Diabetic Foot Clinic (DFC) has been established to increase the quality of care for people with diabetes, who have a foot wound.
We want to find out if the DFC has helped people with diabetic foot wounds. To do this, we would like to interview people who have used the service.

Participation

Every DFC client who wants to participate can talk to us.
You do not have to agree to talk to us about your experience.
You can change your mind at any time.
There will be no difference to how you are treated, or the care you receive if you say no.

Risks

We do not know of any risks of being involved in this study. If you choose to talk to us about your experience, it will help us to understand more about the DFC. This will help us to make good decisions in the future about the care of other Samoan's with diabetes.
It will also help other Pacific Islanders as we will share anonymous information with other services, in other Pacific countries.

Privacy

All information received during the interviews will be treated confidentially.
This means that we will not use your name, your address or any information that identifies you.

Conflict of interest

The research is being done as a partnership with the National Health Service, Motivation Australia and the University of Twente in the Netherlands.
We will not benefit financially from this research.
A report (including a plain English summary) will be available for anyone who is interested, including those clients who choose to participate.

Costs and benefits of the Diabetic Foot Clinic in Samoa – Participant Consent

For people with diabetes, foot wounds often causes amputations. The Diabetic Foot Clinic has been established to increase the quality of care for people with diabetes, who have a foot wound.

We want to find out if the Diabetic Foot Clinic has helped people with diabetic foot wounds. To do this, we would like to interview people who have used the service.

I _____ (insert name) agree to participate in the interview process for the cost benefit analysis of the Diabetic Foot Research.

- I agree to participate of my own free will
- I understand that all information collected will remain anonymous
- I understand that I can withdraw my participation at any time and that this will not affect the medical treatment I receive at the Diabetic Foot Clinic or other NHS service.

Signed: _____ Date: _____

Witness:_____ Date: _____

Appendix 7


DOCAFÉ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MAI SUKA
TAUSI IA
MALOLOINA OU
VAE
Ministry of Health


Digicel
NHS
DOCTORS'
PARKING