Table of Contents

List of Tables

List of Figures

Lists of Appendices

Introduction

The human foot is a masterpiece of engineering and a work of art.

(Leonardo da Vinci, n.d.)

Every 20 seconds a lower limb is lost to diabetes according to the International Diabetes Working Group on the diabetic foot. It is estimated that 70% of all non-traumatic lower limb amputations are due to diabetes (Hinchliffe et al., 2012; Reekers & Lammer, 2012). Diabetic foot disease is the leading cause of lower limb amputation in New Zealand (Ministry of Health, 2008). Early diagnosis and intervention has been shown to reduce diabetic foot ulcerations and lower limb amputation, with up to 50% being preventable (Boulton, 2015). The number of people with diabetic foot disease is still not known within the New Zealand diabetes population.

In New Zealand the Ministry of Health recommends a diabetes annual review be carried out in primary care by general practice. The purpose of the annual review is to allow appropriate treatment plans to be put in place for ongoing monitoring (Editor, 2010). In spite of this, New Zealand has no data on who is or is not receiving a foot screen at the time of the diabetes annual review. The type of care for people with diabetes differs throughout the country depending on the individual district health boards. For some people they only see their general practitioner whereas for others they receive a specialist service included health professional's specialising in diabetes (e.g., Endocrinologists or Diabetologists). There is also no consistency in diabetes podiatry services within New Zealand.

Diabetes and its Complexities

Diabetes is a metabolic disorder, characterised by hyperglycaemia, (high blood glucose levels) (World Health Organisation, 2013). By 2030 diabetes will be the seventh leading cause of death worldwide (World Health Organisation, 2013). It is also predicted by 2035 that diabetes will affect 592 million of the global population, equating to one adult in ten, which means that three adults every ten seconds are being newly diagnosed with diabetes (International Diabetes Federation, 2014; Wild, Roglic, Green, Sicree, & King, 2004). This illustrates that diabetes is a serious global health concern.

Hyperglycaemia occurs when there is lack of insulin and or insulin resistance. The pancreas, which is a part of the endocrine system, is made up of a number of glands which secrete hormones into the blood stream. The pancreas produces several of these hormones, with one of them being insulin. Insulin is produced by the beta cells in the pancreatic islets of Langerhans (Holt, Cockram, Flyvbjerg, & Goldstein, 2010). Insulin enables the body to absorb glucose from the blood and use it for energy. It also regulates lipid and protein metabolism (International Working Group on the Diabetic Foot, 2005). Diabetes is a chronic condition and there are two main classifications of diabetes, type 1 and type 2 diabetes. Irrespective of the type of diabetes once a person has been diagnosed with the condition it is for life. Therefore diabetes has a significant impact on one's life.

Type 1 diabetes affects approximately 10% of the population and more commonly develops in young people (World Health Organisation, 2013). It is an autoimmune disorder and occurs when there is damage to the beta cells, which results in no insulin being produced by the pancreas. People with type 1 diabetes need insulin injections throughout the day to manage their blood glucose levels (Holt et al., 2010; International Working Group on the Diabetic Foot, 2005)

Type 2 diabetes comprises 90% of all people with diabetes (World Health Organisation, 2013). It normally occurs over the age of 30 years (McDowell, 2007). It is a gradual and progressive condition, where the insulin produced is ineffective or there is insulin resistance (Holt et al., 2010). Typically type 2 diabetes is caused by a poor diet, high in saturated fat and sugar and a sedentary lifestyle, which has led to a person being overweight. This contributes to insulin resistance. People with type 2 diabetes often have a strong family history of the condition. Those with type 2 diabetes can go unrecognised for several years before diagnosis, and therefore can present to a health professional with a complication associated with diabetes at the time of their diagnosis (World Health Organisation, 2013). It is initially managed by diet and exercise, however if this is not successful oral medication with or without insulin will be required (Watkins, 2003; World Health Organisation, 2013).

The diagnosis of diabetes here in New Zealand and internationally is made by performing a glycosylated haemoglobin level blood test or HbA1c, if the HbA1c result is ≥50 mmol/mol, then this indicates a person has diabetes, if the result is between 41–49 mmol/mol, the individual needs to be monitored closely (Ministry of Health, 2012). This blood test is also useful as a monitoring tool, showing health professionals and the person with diabetes, their long-term blood glucose level.

Common practice for people with type 1 diabetes is self-monitoring of blood glucose levels by using a personal blood glucose meter; this checks their blood glucose levels instantaneously. People with type 2 diabetes do not need to check their blood glucose levels if they are diet controlled or on a particular oral hypoglycaemic medication, however it is recommended that blood glucose levels be performed if they are on insulin and or on sulphonylureas, one type of oral hypoglycaemic medication (Ministry of Health, 2012). The target range is between 4mmol/L and 8mmol/L. Anything below 4mmol/L is considered hypoglycaemia and needs to be corrected with glucose to bring the levels back up to above 4mmol/L. Hypoglycaemia can result in unconsciousness if not treated urgently. If the self-monitored blood glucose level shows a prolonged period of hyperglycaemia and the HbA1c is elevated, for people with type 1 diabetes then a change in their insulin regime is required. It can be difficult for people with type 2 diabetes who are hyperglycaemic to know what needs to be adjusted, therefore it is recommended that all aspects of their treatment plan including diet, exercise and medication are reviewed (Ministry of Health, 2012; Watkins, 2003). Diabetes self-management is an important part of the condition and is very challenging for the individual.

Poorly managed diabetes resulting in prolonged hyperglycaemia, can cause macrovascular and microvascular disease (Holt et al., 2010). This contributes greatly to complications and the high morbidity and mortality rates for people with diabetes.

Macrovascular disease occurs when the large blood vessels become thickened, narrow or blocked. This is known as atherosclerosis. A person with diabetic macrovascular disease will often suffer complications due to the metabolic syndrome, a combination of hyperglycaemia, hypertension and hypercholesterolemia (McDowell, 2007). This causes damage to the major arteries resulting in coronary heart disease. The leading cause of death for people with diabetes is cardiovascular disease (World Health Organisation, 2013).

Sustained hyperglycaemia also affects the mechanism of the blood vessel and causes microvascular disease. Microvascular disease affects the small blood vessels of the eye, kidney and nerves. Unfortunately some people have a genetic predisposition to microvascular disease which puts them at greater risk of microvascular changes and associated complications (Fowler, 2011). Microvascular disease can result in blindness, renal failure and or lower limb amputation (Holt et al., 2010).

The Diabetic Foot

In the 19th century the diabetic foot was known as 'diabetic gangrene' (McKeown, 1992). This term encompassed any foot issue associated with diabetes regardless of the level of blood flow and infection. At this time there was not a clear understanding of the vascular processes, the role of infection or diabetes peripheral neuropathy, which are common symptoms of a diabetic foot complaint. Before 1980 limited progress was made in the assessment and treatment of the diabetic foot, however over the last 25 years there has been considerable advancement in the study of the diabetic foot (Connor, 2008; Holt et al., 2010). Any condition that affects the foot of people with diabetes falls under the rubric of the diabetic foot. This includes both minimal and extensive changes that can occur to the foot due to the effects of diabetes.

Causes of the Diabetic Foot. The primary causes of diabetic foot disease are peripheral neuropathy and peripheral arterial disease. Other contributing factors include hyperkeratosis/callus, foot deformity and other long-term complications related to diabetes such as renal failure (Boulton, 2015). An individual who shows no indication of these concerns is considered low risk. An 'at risk' individual may have one or two of these influences however they can remain problem free for many years (Holt et al., 2010). When trauma and infection occurs in an already insensate foot with compromised blood flow then this can lead very quickly from a foot ulcer to a lower limb amputation. Peripheral diabetes neuropathy and peripheral arterial disease will now be described in more detail.

Peripheral Diabetes Neuropathy. Peripheral diabetes neuropathy affects 50% of all people with diabetes, it is the most common contributing factor to diabetic foot ulcers, as it is normally asymptomatic (Edmonds & Foster, 2003). When trauma occurs to the foot in the presence of nerve damage, it can result in an ulcer developing. The individual is often unaware that they have lost the "gift of pain" (Boulton, 2012) and therefore less likely to notice trauma or infection.

Diabetes is the major cause for peripheral neuropathy and can affect the sensory, motor and autonomic nerves. There is a range of terminology for the various types of neuropathy (Tesfaye, Boulton, & Ebrary, 2009). For the purposes of this research the following terms will be used, peripheral sensory neuropathy, peripheral autonomic neuropathy and peripheral motor neuropathy. The loss of protective sensation is a common term used by American publications to describe peripheral sensory neuropathy. Peripheral sensory neuropathy occurs initially in the toes and feet before extending up the legs. When it is well established in the lower limbs it will usually then involve

the hands, the 'glove and stocking' effect (Tesfaye et al., 2009). It is symmetrical, progressive, and involves autonomic neuropathy before motor nerve changes occur. When the ability to feel pain is lost; trauma to the foot, such as standing on a nail or glass goes unnoticed. There is also no differentiation between hot or cold. This can result in burns occurring from either sitting too close to heaters or from the use of hot water bottles. Proprioception is decreased, this is an unawareness of the foot position and when this is altered it causes the formation of hyperkeratosis. All of this can result in a wound developing without a person detecting it (International Working Group on the Diabetic Foot, 2005)

Peripheral autonomic neuropathy in the foot affects the functioning of the capillaries, the small blood vessels, and venules which link into the veins. The shunts between the capillaries and venules remain dilated (open) and this affects the overall blood flow in and out of the foot. This results in a foot which is warm, swollen with distended veins, while oxygenated blood flow to the rest of tissues is reduced (Boulton, 2012). Peripheral autonomic neuropathy also contributes to the sweat glands not functioning properly in the foot, which results in the skin becoming very dry and causes fissures (cracks) in the skin(International Working Group on the Diabetic Foot, 2005).

Peripheral motor neuropathy causes wasting of the muscles and weakness in the foot. This contributes to retraction of the toes which then puts abnormal pressure on other areas of the foot. Symptomatic muscle weakness occurs later in the disease process, as peripheral motor neuropathy is not common in the initial stages of peripheral neuropathy (International Working Group on the Diabetic Foot, 2005; Tesfaye et al., 2009).

The symptoms of peripheral neuropathy can range from numbness, pins and needles, and sharp shooting pains. The subjective description of pain is important, to determine if the type of pain being experienced by the individual is related to neuropathic changes or due to peripheral arterial disease (Boulton, 2004; Tesfaye et al., 2009).

Screening tests for peripheral diabetes neuropathy. The common screening tests for peripheral diabetes neuropathy that indicate a loss of sensation in the foot are all non-invasive and can be used by all health professionals. These are well documented throughout the international literature (Boulton et al., 2008). The Semmes-Weinstein, 10g monofilament, (see Appendix A) is used on a number of different areas of both feet. It is an indicator for light touch; if one site is not detected then the individual is signalling peripheral diabetic neuropathy. A loss of vibration on the foot

is an early sign of peripheral diabetes neuropathy, however it also occurs with ageing and other disorders that involve peripheral nerves (Walker, Hall, & Hurst, 1990). Vibration testing can be performed using the 128Hz tuning fork, which is placed on the bony prominences either at the end of the hallux (big toe) or on the medial side where the metatarsal meets the hallux (Boulton et al., 2008; O'Brien & Karem, 2013). Electronic vibration devices such as the biothesiometer are used on the same sites as described for the tuning fork. Anything less than 25 volts indicates increased risk of ulceration. These investigations all aid in providing information on the sensation loss and the extent of peripheral diabetes neuropathy that is affecting an individual (Edmonds & Foster, 2003; International Working Group on the Diabetic Foot, 2005).

If autonomic neuropathy is present when examining the foot, there will be a lack of perspiration resulting in dry skin and fissures. Structural disturbances of the foot with the retraction of toes and muscle weakness are signs of motor neuropathy. When there is severe foot deformity due to bone and joint destruction from nerve damage this is known as a Charcot foot (Edmonds & Foster, 2003). Charcot foot was first described by Jean–Martin Charcot, a French neurologist in 1863 where he found it associated with nerve damage due to syphilis. Nerve damage does occur in other diseases such as leprosy, unrelated to diabetes (Rogers et al., 2011). Diabetic peripheral neuropathy plays a key role in the disruption of the diabetic foot and in the development of diabetic foot disease (International Working Group on the Diabetic Foot, 2005).

Peripheral Arterial Disease. The relationship between diabetes and peripheral arterial disease is thought to be due to metabolic changes that alters blood vessel structure and function (Shrikhande & McKinsey, 2012). Hyperlipidaemia, hypercholesterolemia and smoking are contributing factors to peripheral arterial disease. In the year 2012 to 2013, approximately 18% of the New Zealand population reported being current smokers (Ministry of Health, 2014i). This was a reduction from the 1996 to 1997 year, when 25% of the population were current smokers.

Signs of peripheral arterial disease include shiny skin, thinning due to atrophy of the subcutaneous tissue, and a loss of hair on the lower leg and foot. The toenails can be either brittle or thickened and the foot will be pale and cool to touch (Jaff & White, 2011). The symptoms of peripheral arterial disease are commonly rest pain and intermittent claudication (pain on walking). The person can usually only walk short distances and needs to rest often. This is due to the effect of

peripheral arterial disease has on the blood vessels below the knee - the tibial and peroneal arteries (Hinchliffe et al., 2012).

Table 1 shows the progression to critical limb ischaemia (severe peripheral arterial disease). The leg and foot will become a dusky red or cyanotic blue/purple colour (Jaff & White, 2011). The impaired blood flow causes poor tissue perfusion, which contributes to an increase in pain and muscle wasting of the calf muscles. If trauma occurs to the foot with critical ischemia, this can result in an ulcer developing. This tissue loss can rapidly lead to necrosis or gangrene. It is usually difficult to revascularise the lower limb at this point (Edmonds & Foster, 2003; Shrikhande & McKinsey, 2012).

Table 1

*Fontaine Classification for Critical Limb Ischaemia**

Stage	Clinical Classification
I	Asymptomatic
II	Claudication
III	Ischemic rest pain
IV	Ulceration or rest pain

**Source:* Vascular Disease – Diagnostic and Therapeutic approaches (Jaff & White, 2011)

Examinations for peripheral arterial disease. A simple examination of the limb for peripheral arterial disease, includes pedal pulses, palpation of three areas on the foot (dorsalis pedis, anterior tibialis and posterior tibialis), as shown in Appendix E. Commonly only dorsalis pedis and posterior tibialis are recorded, as dorsalis pedis and anterior tibialis are both on the dorsum (top) of the foot; however 10% of the general population do not have a palpable dorsalis pedis (Merriman & Tollafield, 1995). At the same time as palpating for pulses, this is a good opportunity to assess temperature (hot or cold) by touching both feet and taking the temperature gradient, and to look at the colour (red, purple, white or black) of each foot. It is important to look at both feet to compare the difference between them for any notable changes.

If pulses cannot be palpated, then a hand held doppler ultrasound device should be used to locate the pulse sites. Once the doppler signal has been found, listening to the wave forms of the foot and ankle arteries is beneficial to understanding potential problems with the artery. An important measurement using the hand held doppler is an ankle brachial pressure index (ABPI), which is derived by finding the systolic occlusion pressure in the arm and at the ankle (Jaff & White, 2011). In

the normal foot the ratio is 0.9-1.2, less than 0.8 can indicate the presence of peripheral arterial disease. Any value above 1.2 is likely to represent artefact, most likely as a result of incompressible calcified vessels (Edmonds & Foster, 2003). This is very common with diabetes and seriously hampers the value of ABPI's in these patients. Toe pressures can also be performed, less than 30mmHg suggests peripheral arterial disease.

If these tests show poor blood flow, then investigation of the arterial anatomy to try and identify any narrowed or blocked arteries may be required. Existing imaging modalities include arterial duplex, CT angiography, MR angiography and the gold standard conventional catheter angiography (Jaff & White, 2011). Each test has its own advantages and draw backs. The choice is often at the discretion of the individual clinician. Imaging aims to identify a lesion that is limiting blood flow, and could be treated either by endovascular techniques or bypass surgery. If nothing can be revascularised to promote wound healing the risk of a major amputation is increased.

Foot Ulceration and Amputation. The lifetime incident risk for a person with diabetes developing a foot ulcer is reported to be between 12-25% (Singh, Armstrong, & Lipsky, 2005), and up to 85% of diabetic foot ulcers will lead to lower limb amputation (Boulton, 2004; Reekers & Lammer, 2012).

Ninety percent of diabetic foot ulcerations are due to neuropathy, with pure ischaemic ulcers representing 10% (Boulton, 2015). Approximately 5% of people with type 2 diabetes will develop a diabetic foot ulcer due to peripheral arterial disease (Reekers & Lammer, 2012). There has been an increase of neuro-ischaemic ulcerations where there is the presence of both peripheral diabetes neuropathy and peripheral arterial disease (Campbell, 2011; Hinchliffe et al., 2012).

The first stage of a diabetic foot ulcer is a pre-ulcerative lesion, which could potentially breakdown due to the formation of hyperkeratosis over pressure areas such as the metatarsal heads and toes (Clayton & Elasy, 2009). Once skin loss occurs a management plan is essential to stop the ulcer site from deteriorating to involve deeper tissues such as tendons and bone. If the bone does become involved this is when osteomyelitis is likely to develop. If there is no improvement with conservative treatment, surgery is required (Boulton, 2015). The purpose of surgery is to either remove the infected bone, or undertake a minor amputation of digit. If there is severe infection with necrosis and or peripheral arterial disease involvement, this can result in a major amputation.

Lower limb amputation contributes to a poorer quality of life and also a high mortality rate. Following a non-traumatic lower extremity amputation a person is more likely to die within 18 months amputation. There is also a 50-60% chance of developing a problem with the remaining limb within a year of a major amputation (Davis, Kuznicki, Praveen, & Sferra, 2004).

It is well documented that men are more likely to develop a diabetic foot ulcer than women, so it follows that men will have a higher amputation rate when compared with women (Boulton, 2015; Peek, 2011). The prevalence of a foot ulcer increases with the duration of diabetes and it is associated with poor diabetes control and co-morbidities such as heart failure and renal failure (Schaper, 2012).

Cost of the Diabetic Foot. The diabetic foot is the most common reason for hospital admissions for people with diabetes (Boulton, 2015). Diabetic foot disease results in a large financial burden to the health sector. The estimated cost to the United States healthcare system for diabetic foot complications, ulcerations and amputation in 2001 was US$10.9 billion (Boulton et al., 2005). In a more recent publication from the United Kingdom, it was estimated that the cost of diabetic foot care for the year 2010/11 was £280 million, equating to almost 0.6% of National Health Service expenditure in England (Kerr, Rayman, & Jeffcoate, 2014).

Diabetic Foot Screening

The risk of developing a diabetic foot ulcer in people with diabetes has been recognised for decades (Boulton, 2004). As mentioned earlier, it has only been in the last 20 years that there has been a focus on understanding the pathogenesis and management of the diabetic foot. This is evident in the increase of journal publications and the development of diabetic foot focus groups, such as the International Working Group on the Diabetic Foot (Boulton, 2004). This dedicated group works under the International Diabetes Federation. Since the development of this group a consensus document was released in 2005, which clearly outlines the importance of screening for risk factors for diabetic foot ulceration(International Working Group on the Diabetic Foot, 2005). The International Diabetes Federation suggests if a foot screen is performed early and is followed by appropriate interventions, this will reduce the complications of diabetic foot disease such as chronic ulceration and amputation (International Working Group on the Diabetic Foot, 2005).

Globally there are a number of guidelines which highlight the importance of foot screening including: from the United Kingdom, the National Institute for Health and Care Excellence (NICE) Type 2 Diabetes foot problems: prevention and management of foot problems in people with diabetes (National Institute for Health and Care Excellence, 2004). The Scottish Intercollegiate Guidelines Network (SIGN) Management of diabetes (2010) and the American Diabetes Association Standards of Medical care in diabetes (2013). It is well documented that feet are often forgotten about as they are hidden in shoes and in the presence of neuropathy, with the loss of sensation the person is unlikely to complain of pain or be aware that they have a foot problem (Boulton, Vileikyte, Ragnarson-Tennvall, & Apelqvist, 2005).

United Kingdom screening programmes. In the United Kingdom foot screening has been implemented as a result of the 1990 St Vincent declaration which called for a 50% reduction in lower limb amputation (McCabe et al., 1998). To achieve this goal the National Health Service developed a foot screening programme for people with diabetes. It identified those people at high risk of lower limb amputation and allowed for preventative procedures for people at a primary care level (McCabe et al., 1998).

In the United Kingdom using data from national foot screening and subsequent research, it is now possible to predict the number of people with diabetes who will develop a foot ulcer and which groups need to be monitored closely (Boulton, 2015). Boulton et al. (2005) suggested that through the use of simple and inexpensive equipment (e.g.10g monofilament and tuning fork) the at-risk diabetic foot can be identified.

The Scottish Diabetes Foot Action Group used clinical criteria endorsed by the International Working Group on the diabetic foot, to develop a comprehensive diabetic foot risk, stratification and triage tool, as shown in Appendix B (Leese et al., 2007). Validated following its use in the 2006 Scottish study (Leese et al., 2006), it was endorsed by the Scottish Intercollegiate Network Guideline and included in the clinical guidelines, 'Management of diabetes' (Scottish Intercollegiate Guidelines Network, 2010). This triage document is being used throughout Scotland and has been shown to improve foot care for patients with diabetes (Leese et al., 2011). The diabetes risk stratification tool from the Scottish foot action group classified diabetic foot disease into low risk, moderate risk, high risk and active foot disease (Leese, Stang, Pearson, & Scottish Diabetes Foot Action Group, 2011). This tool will be utilised in the methodology of this research.

Low risk is a normal foot with no sensation loss or impaired blood flow. Moderate risk is the presence of one risk factor of reduced sensation (10g monofilament and vibration), impaired blood flow. High risk is when there are two or more risk factors including neuropathy, impaired blood flow, history of amputation or ulceration, callous and deformity. Active foot is when there is an ulcer, ischemia, spreading infection and a Charcot foot (Leese et al., 2011).

The intervention differs for each risk category. Low risk person should receive education, have an agreed self-management plan and follow-up with a diabetes annual review, which includes a foot screen. The moderate risk foot requires an annual review by a general podiatrist, education, and an agreed individual management plan for the patient. The high risk foot requires an annual assessment by a specialist diabetes podiatrist, and an agreed tailored management plan for the patient. The active risk category requires a referral to a member of a multi-disciplinary foot team, an agreed tailored management plan and specialist intervention when required (Leese et al., 2011). All of the categories state education to be written and given verbally, with emergency contact numbers to be provided.

United States of America foot screening programmes. The American Diabetes Association (ADA) Standards of Medical care in Diabetes document has been in place since 1988, and was last revised in October 2013 (American Diabetes Association, 2014). This illustrates that diabetes has been a concern in America for over three decades. It has recommended annual foot screening, and the main clinical tests are for neuropathy - loss of protective sensation and peripheral arterial disease (American Diabetes Association, 1998). In 2008 the ADA published screening recommendations. It describes that following a comprehensive foot assessment timely referrals to the appropriate foot care provider should be made (American Diabetes Association, 2014). This is either for ongoing preventative care and monitoring or to a multi-disciplinary foot clinic if a foot ulcer is identified. These have both been shown to reduce lower limb amputation rates (Boulton et al., 2008).

Diabetes in New Zealand/Aotearoa

In New Zealand there are approximately 242 000 people who have a diagnosis of diabetes (European and other 166 000, Māori 34 000, Pacific people 28 000, Indian 13 000). Approximately 100 000 people are undiagnosed with diabetes and a further 500 000 people with pre-diabetes (HbA1c 41–49 mmol/mol) (Health Quality & Safety Commission, 2014; Ministry of Health, 2014c).

The New Zealand Health Survey 2013/14 described that the rate of diabetes increases with age, which equates to one in ten New Zealand adults aged 65 years and over having been diagnosed with diabetes. The rates of diabetes are higher among Māori (7%), Pacific (9%) and Asian (6%) adults (Ministry of Health, 2014a). This survey also outlined that those adults living in deprived areas with diabetes was higher (7.9%) compared to adults living in least deprived areas (4.9%). Simmons has published a number of New Zealand based diabetes related studies, which have highlighted that Māori and Pacific people have a high number of diabetes risk factors. These studies have also emphasised the impact that diabetes has had on health services in New Zealand (Joshy & Simmons, 2006; Simmons, 1996).

Diabetic foot disease is the leading cause of lower limb amputation in New Zealand (Ministry of Health, 2008). A major concern is that Māori and Pacific populations have disproportionately high amputation rates compared with New Zealand Europeans. It is unknown why amputation occurs more often in these populations but it could be surmised that diabetes control in Māori and Pacific peoples is less than optimal (Gu, Warren, Kennelly, Neuwelt, & Harwood, 2014).

In June 2000 the New Zealand Ministry of Health launched the Get Checked programme, which was a free annual review performed in primary care for all people with diabetes. "Get Checked", included a review of HbA1c, blood pressure, and cholesterol, as well as an eye screen and foot check. The New Zealand Guidelines Group (Management of type 2 diabetes guideline, 2003) recommended that every person with diabetes should have a diabetes annual review including a foot examination (Editor, 2010; New Zealand Guidelines Group, 2003). The New Zealand Primary Care Handbook, (2012), contains a range of relevant guidelines and guidance documents, including the updated management of Type 2 diabetes (2003) document and the cardiovascular disease risk assessment. This handbook was developed for health professionals working within general practice.

In 2012 "Get Checked" was terminated due to inadequate uptake and no identified benefits to people with diabetes. The data from the "Get Checked" has not been able to provide an accurate estimate of the number of people with high risk feet within the New Zealand diabetes population, it is still an unknown population (Editor, 2012; Joshy, Lawrenson, & Simmons, 2008). The "Get Checked" programme has been replaced by the Diabetes Care Improvement Plan. The diabetes annual review is a requirement of general practice. However there is no current programme evaluation to show if the foot screening aspect of the diabetes annual review is being carried out.

The Ministry of Health recommended through the Diabetes and Cardiovascular Disease Quality Improvement Plan (2008) that the national diabetic foot guidelines need to be improved. They suggested screening and triage of high risk feet needs to be implemented. The plan also highlighted the need for increased specialised podiatry and foot care services, which is still not distributed equally throughout the country (Ministry of Health, 2008). The Pricewaterhouse document (2001), 'Review of Type 2 Diabetes, Managing for Better Health Outcomes', which was carried out on behalf of Diabetes New Zealand, highlighted the lack of data on the diabetic foot and the services available for people with diabetes with high risk feet (Diabetes New Zealand, 2001). The unknown number of people with diabetic foot disease and the state of foot care services has been an ongoing concern for many years within New Zealand.

The Ministry of Health, recently updated the Quality Standards for Diabetes Care Toolkit (2014). This toolkit recommends the utilisation of the diabetic foot risk and stratification triage tool from the Scottish Intercollegiate Guidelines Network, (2010) to assess the risk status of the diabetic foot (see Appendix B) (Ministry of Health, 2014g; Scottish Intercollegiate Guidelines Network, 2010). These guidelines have also been endorsed by New Zealand Society for the Study of Diabetes (New Zealand Society for the Study of Diabetes, 2014). These guidelines will help to standardise diabetic foot care in New Zealand. The numbers of people within each risk category are currently unknown, which makes it difficult to know whether there are sufficient clinical services and resources available for diabetic foot care. The Ministry of Health service specification document, 'Allied Health Services - Podiatry for People with At-Risk / High-Risk Feet Tier Level Three Service Specification' suggests that an individual with either an 'at risk' or 'high risk' diabetic foot should receive specialist podiatry services. However, it is uncertain if this is being achieved in all District Health Boards across primary and secondary care foot care services (Ministry of Health, 2011).

Diabetic Foot Care in the Waikato Region. The Waikato District Health Board cares for almost eight percent of the New Zealand population. The boundary encompasses the Coromandel Peninsula, south to Taumarunui, from Raglan on the West Coast and east to Waihi and Tokoroa. There are 10 territorial local authorities within the Waikato District Health Board boundaries – Hamilton City, Hauraki, Matamata-Piako, Otorohanga, (part of) Ruapehu, South Waikato, Thames Coromandel, Waikato, Waipa, and Waitomo (see Appendix C).

The Waikato Regional Diabetes Service is a centre for education, management and research of diabetes within the Internal Medicine service cluster of Waikato District Health Board. The Waikato Regional Diabetes Service is for all people aged over 15 years. It is based in Hamilton with a range of outreach clinics being conducted on a regular basis. Health professionals under the auspices of the Waikato Regional Diabetes Service include clinical nurse specialists, dietitians, endocrinologists, and podiatrists.

In 2013 the Ministry of Health estimated that the number of people with diabetes for the Waikato region was 20 000. This estimation of people with diabetes in the Waikato region, identified with the following ethnic groups: Māori 4 400, Pacific people 700, Indian 700 and European 14 000 (Diabetes New Zealand, 2014; Health Quality & Safety Commission, 2014). The Waikato Regional Diabetes Service has a database, which showed a similar number of people with diabetes registered. However this registry could not identify the number of people with diabetic foot disease.

The amputation rate for people with diabetes as reported by the Health Quality and Safety Commission New Zealand (2013) was 0.3% in the Waikato region, just higher than the national percentage of 0.21%.

The Waikato region is representative of New Zealand's diabetes population and therefore this project should allow a national understanding of diabetic foot risk, which is currently unknown. Identifying the prevalence of people with diabetes and their foot risk status will help in the long-term planning of diabetic foot services across primary and secondary care which in turn can be applied to the entire country.

Prevalence studies have been carried out internationally. The following literature review of previous studies in diabetic foot disease will detail international rates of diabetic foot disease.

Literature Review

Introduction

There are limited New Zealand publications on diabetic foot disease and the prevalence of diabetic foot disease in New Zealand is unknown. Diabetic foot disease is a serious complication of diabetes, costly with long length of hospital stays and detrimental to an individual's well-being (Bolton, 2014). Additionally, diabetic foot disease is known to be the leading cause of amputations in New Zealand (Ministry of Health, 2008).

A study carried out in South Auckland, reviewed foot care among 750 people with diabetes (Simmons, Scott, Kenealy, & Scragg, 1995). It identified close to half (48.5%) of people presented with a foot problem including: amputation, foot ulcer, blister, callus or fungal infection. This study was performed over 20 years ago and as discussed earlier a lot has changed in this time within diabetes care. A risk categorisation tool was not used and the study was performed in what appears to be a high risk population.

Ihaka, Bayley, and Rome (2012) researched diabetic foot problems in Māori from two primary health organisations in 2007-2008. This study identified 17% of participants had a history of ulceration and/or amputation, and 53% had pre-ulcerative lesions. Two Podiatrists performed an assessment on 53 participants using a number of comprehensive podiatry assessments for peripheral neuropathy, peripheral arterial disease, and musculoskeletal issues including measures such as the ankle brachial pressure index and a thorough joint mobility assessment. The foot risk classification system that was used in this study was complex and required assessment by a podiatrist. It is unfortunate this study had a small sample size and was not reflective of the general diabetes population.

Diabetic foot examinations performed by a total of 1091 primary care nurses were investigated by Daly et al. (2014). Foot examinations were only performed in 46% of their consultations for people with diabetes. This highlights that feet are still unfortunately neglected in general practice, even when a person is known to have diabetes. If the person was older, was reviewed by a district nurse, and if time was not barrier they were more likely to have a foot examination. Many of the nursing teams who participated in this study did not use a risk category.

This study recommended that foot risk should be classified, as this would help with treatment plans for those individuals with high risk feet (Daly et al., 2014).

As encouraging as it is to see research being performed here in New Zealand, it has been scarce. All of this research was undertaken prior to the national adoption of the Diabetic Foot Risk Stratification and Triage Tool from Scottish Foot Action Group (see Appendix B). It remains difficult to ascertain the number of people with diabetic foot disease from this research due to the limited sample sizes and participant selection approach. It is important to have data to ensure foot care services are available and are being delivered to those who need it. Prevalence studies are therefore necessary to find where there are inequalities within populations.

Cross-sectional studies are helpful in assessing the needs of populations and evaluating the prevalence of the disease and risk factors within a representative sample of their population (Bonita, 2006). Prevalence measures the number of existing cases of disease at a given point in time, in comparison to incidence which is the number of new cases of the disease over a given period (e.g., a year) (Bonita, 2006). The aim of this review is to analyse the prevalence of diabetic foot disease in a representative sample of people with diabetes.

Method

A literature search was carried out using the following search terms: diabetes, prevalence, cross-sectional studies and foot disease. Medline was the only database utilised in this systematic review, because it has over 5000 journal titles with a high quality of biomedical material on offer for all health professionals. No secondary sources or grey literature have been used. The inclusion criteria for this systematic review were that all the studies were cross-sectional in nature showing the prevalence of diabetic foot disease in a primary care setting. The participants were adults with either type 1 or type 2 diabetes, from the general population. The search was from the years 2000 to 2013. This was to ensure that the studies reviewed had the latest advances that have occurred in diabetic foot disease over the past decade. Secondary articles that used data from the primary studies were excluded, as the data reported was similar to original articles. Research articles not available in English were excluded. A total of 106 articles were found with five prevalence studies meeting the inclusion criteria.

Results

The studies were from Sweden (Kärvestedt et al., 2011), France (Malgrange, Richard, & Leymarie, 2003), the Caribbean (Gulliford & Mahabir, 2002), and two from the United Kingdom (Abbott et al., 2002; Sampson et al., 2002). This review will highlight the similarities and differences in the prevalence of diabetic foot disease in different populations. The analysis will review the tools used, who performed the foot screen, and what information was collected on the participants. The outcomes from the studies will also be evaluated, in particular how they have benefited people with diabetic foot disease. A summary of the aims and objectives of the five studies are now provided.

Study 1. Kärvestedt et al. (2011) aimed to investigate peripheral neuropathy including autonomic neuropathy in a population-based study in people with type 2 diabetes from Stockholm, Sweden. The inclusion of autonomic neuropathy was emphasized as an important factor for this research as it is often not assessed.

Study 2. The purpose of the study by the French Working Group on the Diabetic Foot (Malgrange et al., 2003) was to determine the prevalence of people with diabetes at risk of foot ulceration in France. The objectives of this research were to review the distribution of patients in the risk categories, from the International Working Group of the Diabetic Foot. This group also evaluated the effect of peripheral arterial disease as an independent risk factor. This study included 16 hospitals, which within New Zealand would classify as secondary or tertiary care, however as it included a significant primary care component it has been included (Malgrange et al., 2003).

Study 3. The aim of the North-West Diabetes Foot Care Study by Abbott et al. (2002) in the United Kingdom was primarily to review the incidence of foot ulceration. It also evaluated the simple clinical foot screening methods and tools used in clinical practice. This study also assessed the risk factors for ulceration in people with diabetes in primary care.

Study 4. In this prevalence study from Trinidad, Gulliford and Mahabir (2002) sought to find information related to the occurrence of diabetic foot related problems and the risk factors that cause diabetic foot ulcers to develop in a primary care population. A key objective was to help plan strategies for the prevention of diabetic foot disease, as there was no information available on this for people in Trinidad and Tobago.

Study 5. Sampson et al. (2002) in the Norfolk and Norwich, United Kingdom, utilised an already established retinal eye screening programme, to perform a diabetic foot screen. The aim of

this project was to perform a vascular and neurological foot assessment on all people with type 2 diabetes who are managed in primary care. This would allow those people identified with high risk feet to have a suitable treatment plan put in place.

Demographic Data. The demographic data gathered from the studies is shown in Table 2. The lack of information on the foot status of people with diabetes was an underlying motivator for all of these studies (Malgrange et al., 2003). Prevalence studies are important to help with identifying the proportion of populations. Having a large cohort of participants allows this to be shown accurately and clearly. Kärvestedt et al. (2011) had 156 people participate in their study. The French Working Group study (Malgrange et al., 2003) had 556 participants. Abbott et al. (2002) had 9710 participants and screened 41 percent of all people with diabetes from six health care districts of Northwest England. Gulliford and Mahabir (2002) had a sample population of 2106 people, across 35 public primary care practices. This study was undertaken in response to findings from 1990 that identified 78 lower limb amputations in people with diabetes over a 26 week period (Gulliford & Mahabir, 2002). Sampson and colleagues (2002) had a screened sample population of 4022.

All of the studies indicate that men are more likely to develop a foot complaint. Even though Gulliford and Mahabir (2002) had 70% of women in its study, it still identified that amputation occurred more often in men than women.

Gulliford and Mahabir (2002) discussed that their sample represented the low socioeconomic population who were more likely to be admitted to hospital for diabetic foot ulceration. Abbott and colleagues (2002) and Malgrange et al. (2003) reviewed the participants living arrangement. Abbott et al. (2002) found that 22.8% of people lived alone. The French Working Group (Malgrange et al., 2003) reviewed the participants psychosocial status (~12%), which included living alone, their mental health, excess alcohol intake and body hygiene. Ethnicity was collected by the Kärvestedt et al. (2011) and Abbott et al. (2002), where both showed the participants were predominately Caucasian.

Diabetes Data. Malgrange et al. (2003) and Abbott and colleagues (2002) collected data on both type 1 and type 2 diabetes which explains why they both had a higher number of people who were on insulin, compared to Kärvestedt et al. (2011), Gulliford and Mahabir (2002), and Sampson et al. (2002). These three studies only had people with type 2 diabetes who are more likely to be treated with either oral hypoglycaemic agents and or diet control.

Table 2

A Comparison of the Demographic and Diabetes Data for the Five Studies

	Sample Size (n)	Age (year ± SE)	Gender (male) (%)	Ethnicity (Caucasian) (%)	Smoking Status (%)	Type of Diabetes	Duration of Diabetes (year ± SE)	Treatment			
								Diet (%)	OHA (%)	OHA + Insulin (%)	Insulin (%)
Kärvestedt et al., 2011	156	61 ± 7	61	95	31	Type 2	7 ± 6	28	44	8	19
Malgrange et al., 2003	555	56 ± 15	52			Type 1 & 2	13 ± 10	46.4**			53.6
Abbott et al., 2002	9710*	61 ± 14	54	88	22	Type 1 & 2	9 ± 11	NR	NR	NR	NR
Gulliford & Mahabir 2002	2106	59 ± 7	32			Type 2	8 ± 8	17	71		12
Sampson et al., 2002	4022	69 ± 11	57			Type 2	6.5	33	62		3

*6613 rescreened; OHA = Oral Hypoglycaemic Agent. NR=Not recorded. **Did not differentiate between diet and OHA. SE=Standard error.

Table 3

A Comparison of the Diabetes Foot Screening Data for the Five Studies

	Neuropathy (%)	PAD (%)	10g monofilament	Tuning fork	VPT	ABPI	Pedal Pulses	History of Foot Ulcer (%)
Kärvestedt et al., 2011	33	26	Y	Y	Y	N	Y	7
Malgrange et al., 2003	27.1	17	Y	N	N	Y	Y	7.2
Abbott et al., 2002	22	21.1	Y	Y	N	N	Y	3.1
Gulliford & Mahabir, 2002	50	NA	N	N	N	N	N	12
Sampson et al., 2002	29	19	Y	N	Y	Y	Y	1.0

NA = Not assessed. Y=Yes. N=No. VPT=Vibration Perception Threshold

Foot Screening. Sampson et al's. (2002) research was carried out by a single podiatrist over a two year period in the Norfolk and Norwich district, United Kingdom. The foot screening service was attached to an established retinal screening programme, managed in primary care.

Gulliford and Mahabir (2002) data was gathered by the Nutrition and Metabolism Division of the Ministry of Health, through an interview and a self-reported questionnaire. No physical examination or clinical data were collected. This study highlighted how podiatry is not accessible in the Caribbean population. Gulliford and Mahabir (2002) reported on 9 people who saw a nurse and 4 people who saw a Podiatrist. The majority of participants treated themselves, in regards to toenail care and if a wound occurred on their foot. Most people liked to go barefoot, predisposing them to injury (Gulliford & Mahabir, 2002).

The screening data from Abbott et al. (2002) was performed over a two year period from April 1994. This time frame allowed the participants to be rescreened for foot disease. The purpose of rescreening was to review if the initial group of participants had developed a new foot ulcer or not. Rescreening was done through a postal questionnaire. Sixty-eight percent of the participants responded. This was a large cohort of people with type 1 and type 2 diabetes. A fulltime research nurse or podiatrist was assigned to screen GP practices, diabetes centres, and hospital out-patient clinics in each of the chosen six health districts. The majority were screened at their annual review appointments, 67.2% were screened in primary care (GP practices), 32.4% in secondary care (hospital and podiatry clinics), and 0.4% were screened at home over the 2 year period.

Malgrange et al's. (2003) study was performed on a single day in May 2001, across 16 different hospitals. They used a standardised form, developed in conjunction with a representative from each centre. They were also responsible for showing the form to all the investigators involved in the study from their hospital. This study did not state the number of investigators or which discipline/s the investigators were from. It used the International Working Group on the Diabetic Foot (IWGDF) foot screening consensus document.

Kärvestedt and colleagues (2011) study was performed in three primary health care centres within Stockholm. There were no details on the timeframe. The data were gathered by trained nurses. The foot screening was based on the IWGDF consensus document, guidelines on neuropathy and Swedish protocols which had been in place since 1993 across the three primary heath care centres (Kärvestedt et al., 2011).

Peripheral Diabetes Neuropathy. Three out of the five studies used two or more tools when testing for neuropathy. The 10g monofilament has been used throughout four of the prevalence studies (see Table 3). The 128Hz tuning fork is another standard tool for testing neuropathy and was used in the Kärvestedt et al. (2011) study alongside the neurothesiometer and 10g monofilament. In the Abbott et al. (2002) study the 128Hz tuning fork was also used to screen for neuropathy, in conjunction with the 10g monofilament. The biothesiometer as well as the 10g monofilament was used by the Sampson research group (2002). Gulliford and Mahabir (2002) included the neuropathic status of the participant based on the self-reported data of the participants.

The rate of neuropathy varied across the studies, as shown in Table 3. Prevalence ranged from 21% in the Abbott et al. (2002) study to 50% in the Gulliford and Mahabir (2002) study. Kärvestedt et al. (2011) divided neuropathy into peripheral autonomic neuropathy at 43%, peripheral sensory neuropathy 33% and peripheral motor neuropathy 15% (Kärvestedt et al., 2011).

Malgrange et al. (2003) reviewed people for hyperkeratosis (45%) and foot deformity (21.1%). Abbott et al. (2002) calculated a foot deformity score, from six different variables. Thirty percent of people had ≥3 abnormalities. Kärvestedt et al. (2011) examined the skin for fissures and found 13% of men and 4% of women, had this issue. Dry skin was the same between genders. Hair not present on the foot was reported at 41% in men and 65% in women.

Peripheral Arterial Disease. Four of the five studies screened for peripheral arterial disease by locating the posterior tibialis and dorsalis pedis pulses. Sampson et al. (2002) also palpated the popliteal pulse, which is located behind the knee.

Another assessment tool used by French Working Group (Malgrange et al., 2003) and Sampson et al. (2002) was the ankle brachial pressure index (ABPI). The ABPI in the Malgrange et al. (2003) was not performed on the day of the study. Instead the data were gathered retrospectively. Sampson et al. (2002) performed the ABPI on the day of the foot screen. The range for the peripheral arterial disease was found to be between 17%-26%, across all four studies from their screened data.

A common factor investigated through all of the studies was the history of foot ulceration and or amputation. Gulliford and Mahabir (2002) found that 88% had no history of foot ulcer and 12% self-reported a history of foot ulceration. Of those who reported an ulcer nearly half had also reported being admitted into hospital.

Abbott et al. (2002) found a prevalence rate of active foot ulceration at 1.7%. There were 291 people confirmed to have developed a new ulcer within a two year period, giving an overall annual incidence of 2.2% (Abbott et al., 2002). Sampson et al. (2002) showed similar results with one percent of participants either having an active foot ulceration or previous foot ulceration.

Malgrange et al. (2003) and Kärvestedt et al. (2011), reported just over seven percent of the participants had a history of an ulceration and or amputation.

Diabetes Foot Risk Categories. Malgrange et al. (2003) and Kärvestedt et al. (2011), both used the IWGDF, diabetic foot risk classification. The IWGDF grading of diabetic foot risk used by Malgrange et al. (2003) was an earlier version (1999) compared to the one used by Kärvestedt and colleagues (2011). Malgrange et al. (2003) identified 72.8% were low risk (grade 0), 9.7% (grade 1), 9.8% (grade 2) and 7.7% (grade 3). Therefore 7.7% were in the highest-risk category according to the IWGDF diabetic foot risk category. Kärvestedt et al. (2011), found low risk 48%, moderate risk 40% and high risk 12%. This study also used the risk classification for the diagnosis and outpatient management of diabetic peripheral neuropathy. Abbott et al. (2002) and Gulliford and Mahabir (2002) did not use a risk category.

Sampson et al. (2002) used a risk classification of high, moderate and low risk, yet it did not state which risk classification system it used. People with both neuropathy and peripheral arterial disease were referred to a diabetic foot clinic or diabetes centre. People with either neuropathy or peripheral vascular disease were considered to be moderate risk and referred to local podiatry services. A person in the low risk category with no neuropathy or peripheral vascular disease was advised to register with local podiatry services.

Health Status Data. Kärvestedt and colleagues (2011) collected a range of biomedical data including lipids and their non-diabetes medication. Participants who were on vitamin B treatment and had increased alcohol consumption were both excluded because of the effect these substances have on the nervous system. This decreased the prevalence of the different neuropathies by two percent.

Kärvestedt et al. (2011) and Abbott et al. (2002) both reviewed smoking, which indicated that 31% and just over 20% of their participants smoke, respectively.

Discussion

These studies highlight the high frequency of foot disease in the diabetic population, supporting the necessity for clinical guidelines noted in the introduction of this study. These studies have provided both strengths and weaknesses that can assist in the development of methods for measuring prevalence in future studies.

The prevalence of foot disease across the five studies was identified by varying factors either looking at the prevalence of foot ulceration or using a specific risk factor such as neuropathy, as detailed in the Kärvestedt et al. (2011) study. Malgrange et al. (2003), Abbott et al. (2002) and Sampson et al. (2002) reviewed both neuropathy and peripheral arterial disease. The strength of the Abbott et al. (2002) study was rescreening of participants at the two year mark. It was the only study out of the five which performed a rescreen. It showed the initial prevalence of foot ulceration a little under one percent and the data from the rescreen showed the annual incidence of foot ulceration at just over two percent. Gulliford and Mahabir (2002) was the only research carried out in a developing country. It was unique in that the entire study was based on subjective data. This study would have been strengthened if objective measures had been used to confirm the neuropathy status of the participants, and if peripheral arterial disease of those who participated had been reviewed.

The inter-rater reliability is a strength of the Sampson et al. (2002) study, with a single Podiatrist performing the foot screen, enabling consistency in the measurements being carried out. The disadvantage in this study was the inability to account for measurement bias. Malgrange et al. (2003) and Gulliford and Mahabir (2002) did not clearly state who the assessors were or how many health care professionals were involved. Kärvestedt and colleagues, (2011) used trained nurses, however did not state the number of nurses in the study. Abbott et al. (2002) used podiatrists and nurses, however once again it did not indicate how many from each profession or from each clinic. This raises the issue about the reliability of the foot assessment being performed. Abbott et al. (2002) Kärvestedt et al, (2011), and Malgrange et al. (2003) had multiple assessors but made no reference to inter-rater reliability testing in their method. Implementing inter-rater reliability would have helped to ensure consistency of all the foot assessments. The method for use of tools to test for neuropathy were detailed and techniques such as finding pedal pulses were explained and shown to those performing the foot screen. Abbott et al. (2002) suggested that finding a pedal pulse does have its

difficulties, however acknowledged that with standardised training it is a valuable test for assessing vascular risk.

The 10g monofilament is a reliable tool, simple to use and low cost (Malgrange et al., 2003). The four studies that used the 10g monofilament demonstrated that it can successfully be used by any health professional in determining sensation loss in people with diabetes. Abbott et al. (2002), Malgrange et al. (2003), and Sampson et al. (2002) all used the 10g monofilament plus one other tool to test for vibration, either the tuning fork or biothesiometer. This helped to clarify the diagnosis of neuropathy. Kärvestedt et al. (2011) study focused on the various types of neuropathy - peripheral sensory neuropathy, peripheral autonomic neuropathy and motor neuropathy, and utilised the three different tools to determine the degree of neuropathy. This study collected data not specific to either diabetes or neuropathy, nor were the data useful in determining the prevalence of diabetic foot disease. However it was used in an earlier unrelated publication in 2009 (Kärvestedt et al., 2009).

The skin integrity and foot deformity were reviewed in three of the studies. The French Working Group (Malgrange et al., 2003) looked at both hyperkeratosis and foot deformity and they discussed the association between these two variables and peripheral neuropathy. Kärvestedt and colleagues (2011) also reviewed the skin integrity, finding a connection between skin changes and peripheral neuropathy, in particular to autonomic and motor changes. Abbott et al. (2002) reported a foot deformity score, and if there were three or more variables present with neuropathy, participants were considered to be high risk. This study recommended using devices like orthotic footwear and custom made insoles to minimise the impact of deformity and neuropathy on the foot. These three studies have highlighted that hyperkeratosis and foot deformity, in the presence of neuropathy are important factors when examining the foot.

Malgrange et al. (2003) noted that peripheral arterial disease has not always been recognised as a significant risk factor in diabetic foot ulcers. At the time of their study there had been no international consensus in the diagnostic criteria for peripheral arterial disease. This group was forward thinking in identifying that work needed to done to clearly define peripheral arterial disease in the diabetic foot. The International Working Group on the Diabetic Foot have since defined peripheral arterial disease, in 2011 where it released a guidelines document titled, “Specific guidelines for the diagnosis and treatment of peripheral arterial disease in a patient with diabetes and ulceration of the foot” (Schaper et al., 2012).

There was a range of 1%-12% for the history of diabetic foot ulceration throughout the studies. Sampson et al. (2002) and Abbott et al. (2002) documented between 1%-3%, Malgrange et al. (2003) and Kärvestedt et al. (2011) were both at 7% and Gulliford and Mahabir (2002) 12%. The self-reported method of data collection from Gulliford and Mahabir (2002) may have contributed to the higher prevalence rate, and this population did not wear shoes. The United Kingdom studies of Abbott et al. (2002) and Sampson et al. (2002) were performed in primary care clinics hence the low reporting of ulceration. This would indicate that those who have a history of ulceration would more likely be under the care of a secondary diabetic foot care service. The Malgrange et al. (2003) and Kärvestedt et al. (2011), studies did not detail the diabetic foot care systems in their countries. Therefore it was not explained who predominantly manages diabetic foot complications. The lack of clarity may explain why the foot assessment of the participants for these two studies was on the higher side at seven percent for history of foot ulceration.

Smoking is a known contributing factor to peripheral arterial disease, which is one of the causes of diabetic foot disease. Therefore it was unfortunate that only two studies, Kärvestedt et al. (2011) and Abbott et al. (2002) specified the smoking status of those people that participated in their research.

The diabetic foot risk category from the studies was not clearly defined with the two studies Kärvestedt et al. (2011) and Malgrange et al. (2003), using the consensus document from International Working Group on the Diabetic Foot. Sampson et al. (2002) discussed a risk category however it did not detail which one it was using. Unfortunately it also did not the state the percentage of each category from the findings except to state that it had a high prevalence of at risk feet, which was comparable to findings from other studies carried out in the United Kingdom (Sampson et al., 2002). This shows that internationally there are different risk categories which can be used; it would be helpful if there was one standardised diabetic foot risk category that was used internationally.

Overall the findings from the five studies show that those with high risk of foot ulcerations had a longer history of diabetes. The age range of the participant's for all of the studies was between 41-75 years of age, which was expected when the population is predominately people with type 2 diabetes, who have a higher risk of diabetic foot disease. The studies suggest it is important to screen for peripheral arterial disease and neuropathy, as they are both indicators of diabetic foot disease. Particularly neuropathy as it is asymptomatic and the longer people have diabetes they are more

likely to develop neuropathy. The studies undertaken by Abbott et al. (2002) and Malgrange et al. (2003) highlighted that those living alone and with poor psychosocial support are more likely to have high risk foot problems. Gulliford and Mahabir (2002) reported that a majority of the participants came from low-socioeconomic areas within Trinidad and had higher rates of hospital admission.

The recommendations were consistent across all of the studies. Malgrange et al. (2003) stated that screening and classifying people with diabetes into a risk category is simple, rapid and inexpensive. This would help to offer effective management of the risk factors before an ulcer or amputation occurred (Malgrange et al., 2003). These recommendations were reiterated by Abbott et al. (2002) who also identified that simple screening procedures should allow for appropriate foot care management via education and referral to appropriate services to protect the foot. If consistent tools are available other health professionals outside of podiatry could perform the foot screen. Abbott et al. (2002) showed that annually two percent of participants included in this community based study will develop a new diabetic foot ulcer. Although this foot ulcer may not be as severe as those seen in high risk clinics, the aim should still be to reduce their occurrence and progression (Abbott et al., 2002).

Gulliford and Mahabir (2002) stated that an immediate increase of health care staff skilled in the prevention and treatment of diabetic foot disease is required to improve diabetic foot care within its communities. It reported a very low number of people in their population currently seek health professional help when they have a foot problem. It also acknowledged that internationally there should be more shared models of good practice and resources within foot care, which would help in effective management of diabetic foot disease.

Sampson et al. (2002) recommended including a foot screen using an existing, established mobile eye screening programme. This set up had been simple and helpful in improving access for foot care across primary and secondary care diabetes services (Sampson et al., 2002).

Current Study

This project is a prevalence study and will identify the proportion of people with diabetic foot disease from a large cohort of people attending the Waikato Regional Diabetes Service retinal photo screening programme. Currently in New Zealand the prevalence of diabetic foot disease is unknown. One can only expect it is similar to other Organisation for Economic Co-operation and Development (OECD) countries as shown in the international research outlined previously.

This study plans to use the tools outlined in previous prevalence studies, 10g monofilament, tuning fork 128Hz and palpation of pedal pulses. It will also gather similar demographic data on the participants as shown in Table 2.

Obtaining data on the prevalence of diabetic foot disease in New Zealand will assist in future planning of podiatry and foot care service for people with diabetes in both primary and secondary care. Diabetes is unfortunately increasing. This study also has the opportunity to look at the prevalence and relationships in different subgroups, for example age, gender, ethnicity, and smoking. This study will further contribute to assisting people who may develop a diabetic foot complaint.

Method

Participant Inclusion Criteria

Eligible participants were people aged 15 years and over, registered with the Waikato Regional Diabetes Service mobile retinal photo screening service. This includes all known people with either type 1 or type 2 diabetes in the Waikato region. It does exclude those with established retinopathy, who attend a specialist eye clinic. A retinal eye screen is recommended every two years for all people with diabetes. In 2014, 5873 people had their eyes screened. This study was carried out over a 6 month period where 3850 people were sent an appointment letter to have their eyes screened.

This study was an audit rather than an investigation for those who did not participate. It was important that characteristics such as age, gender, and type of diabetes were included to be able to interpret the results.

Research Team

An enrolled nurse (identified as research assistant) performed the foot screen. The primary researcher has been a New Zealand Registered Podiatrist for 14 years and for the last 10 years has worked with people with diabetes who have active foot complications both in New Zealand and the United Kingdom.

Four weeks was spent training the research assistant. Training was conducted under the supervision of the primary researcher. It included how to perform all the foot screening measures. The research assistant had to have an understanding of the project and the intentions of the project and therefore practiced on explaining this to staff members and patients of the Waikato Regional Diabetes Service during the training period.

Measures

Demographic and medical information was obtained from each participant in an interview format (see Appendix D). This included general demographic and diabetes health related information. The participant was asked whether they had a history of an ulcer or wound that had taken longer than four weeks to heal and if they regularly see a Podiatrist.

Semmes Weinstein 10g Monofilament. The protocol on the use of this device was described in the New Zealand Guidelines Group (2003), which is based on international standards (see Appendix A). The device used in this study was the Owen Mumford neuropen, 10g monofilament, and is shown in Appendix A. The monofilament is pressed against the skin until it bends then it is lifted from the skin. This assessment was performed on six areas of each foot. If the monofilament was detected then there was no sensation loss. If any of the areas were not detected by the participant after retesting then this was classified as a loss of sensation.

Tuning fork 128Hz. Vibration is viewed as one of the first sensations to be affected by sensory neuropathy (Merriman & Tollafield, 1995). The tuning fork was placed on the end of the hallux (big toe) and first metatarsophalangeal joint. Participants were asked if they could detect the buzzing sensation. This was timed, greater than 30 seconds was considered normal, less than 30 seconds was considered as some changes occurring, and not detected indicated neuropathy.

Pedal pulses. The dorsalis pedis and posterior tibial pulses were examined, as shown in Appendix E. These two sites are commonly palpated as they are indicators of the blood supply to the dorsal and plantar of the foot (Boulton et al., 2008). The pulses were recorded as either being present or absent. If pulses were absent or only one site was present out of the possible four sites then this would indicate vascular compromise.

Pictorial records. An iPad3 (Apple Inc.) flat screen tablet was used to record two standard digital images of the feet including a dorsal and plantar view, examples of digital images taken are profiled in Figure 1. If the research assistant was concerned of anything outside of these two views, extra images were taken, (e.g., a blister or cut). The data were entered directly onto a spreadsheet. At the end of each session the spreadsheet and images were uploaded into the database that is held on the Waikato District Health Board server.

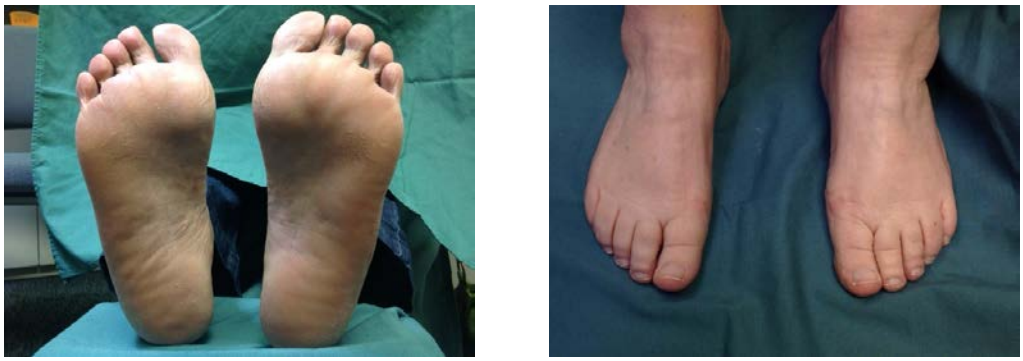

Figure1. Two examples of the digital photos taken during the study.

Diabetic Foot Risk Stratification and Triage Tool. This was endorsed by the New Zealand Society for the Study of Diabetes (NZSSD) in October 2013. It was initially developed by the Scottish foot action group to categorise the foot status and has been included in the Scottish Intercollegiate Guidelines Network for the Management of diabetes (SIGN, 2010; see Appendix B). The categories include low, moderate, high and active risk.

Procedure

Ethical approval was obtained from University of Auckland Ethics Committee (Ref. 010483), which included consultation with Te Puna Oranga (Māori Health Unit, Waikato District Health Board). Support was also obtained from the Clinical Director of the Waikato Regional Diabetes Service, Waikato District Health Board to conduct this project.

Participants were notified about the project through a mail out (see Appendix F), which included a copy of the patient information sheet (see Appendix G). This was sent with their eye screening appointment letter informing them that they would have the opportunity to have their feet screened at the same appointment as the retinal eye screening appointment.

On the day of the participants eye screen, they were asked by a member of the retinal eye screening team if they would like to participate in the study. If they agreed to participate in the project, its methods and aims were then explained by the research assistant and any questions or concerns addressed. If the participant was agreeable then written consent was obtained (see Appendix H).

The initial phase of an eye screen is to have eye drops placed in the eyes. The foot screen occurred immediately after the eye drops were placed in eye, as it takes approximately 15-20 minutes for the eye to dilate before a retinal photo can be taken. The foot screen was performed within this time so it would not cause any disruption to the eye screening clinic. The research assistant initially asked the participant the predetermined questions (see Appendix D). Then the physical screen of the feet was performed, in the following order: from left foot to right foot were pedal pulses, 10g monofilament and vibration. The final step in the screen was taking digital images of the feet.

At the end of each screening session the data set and the digital images were evaluated by the primary researcher. The feet were reviewed for hyperkeratosis, deformity, lower extremity

amputation, ulceration, ischemic changes, including whether hair was present and skin integrity. Using the Scottish Intercollegiate Guidelines Network Diabetic Foot Risk and Stratification and Triage Tool the foot was categorised into a low, moderate, high or active risk status (see Appendix B).

The participant's primary health care provider (general practitioner) was notified of the results of the foot screen (see Appendix I), so a treatment plan could be put in place. This was to ensure patient safety and a patient care pathway could be put in place particularly for the purposes of identification of an active foot complication.

Statistical Analysis

Descriptive and multivariate statistics were performed using statistical packages STATA version 11 and SPSS version 22 for Windows. Results with $p < .01$ were considered statistically significant. Demographic data were compared between those who participated in the foot screen and those who did not participate. Descriptive statistical testing was used to analyse the prevalence of foot disease in the screened population. Univariate statistics (chi-square) have been used to review the risk factors associated with foot disease in particular to the high risk population.

Inter-Rater Reliability

To determine the inter-rater reliability, a random five percent of the screened population were independently rescreened by the primary researcher, a New Zealand registered Podiatrist. This assessed the consistency of the screening assessment by the research assistant.

The kappa-statistic measure of agreement was calculated. There was no significant difference found for any of the measures pedal pulses, 10g monofilament and 128Hz tuning fork (see Appendix J). Therefore this analysis shows that the foot screening data gathered by a non-podiatrist is clinically valid.

Results

Characteristics of the Study Population

The study population included 2192 (57%) participants with type 1 and type 2 diabetes. They were recruited from a possible 3850 participants who were sent an appointment for a retinal eye screen (see Figure 2). One thousand six hundred and forty-four (43%) people did not have their feet screened. The majority of this group 939 (57%) did not attend (DNA), 646 (39%) did not consent (DNC) to the study and 59 (4%) people did not wait (DNW) to have their feet screened. Fourteen people were excluded. Ten people had an impaired glucose tolerance test, three people had gestational diabetes, and one person had drug induced diabetes.

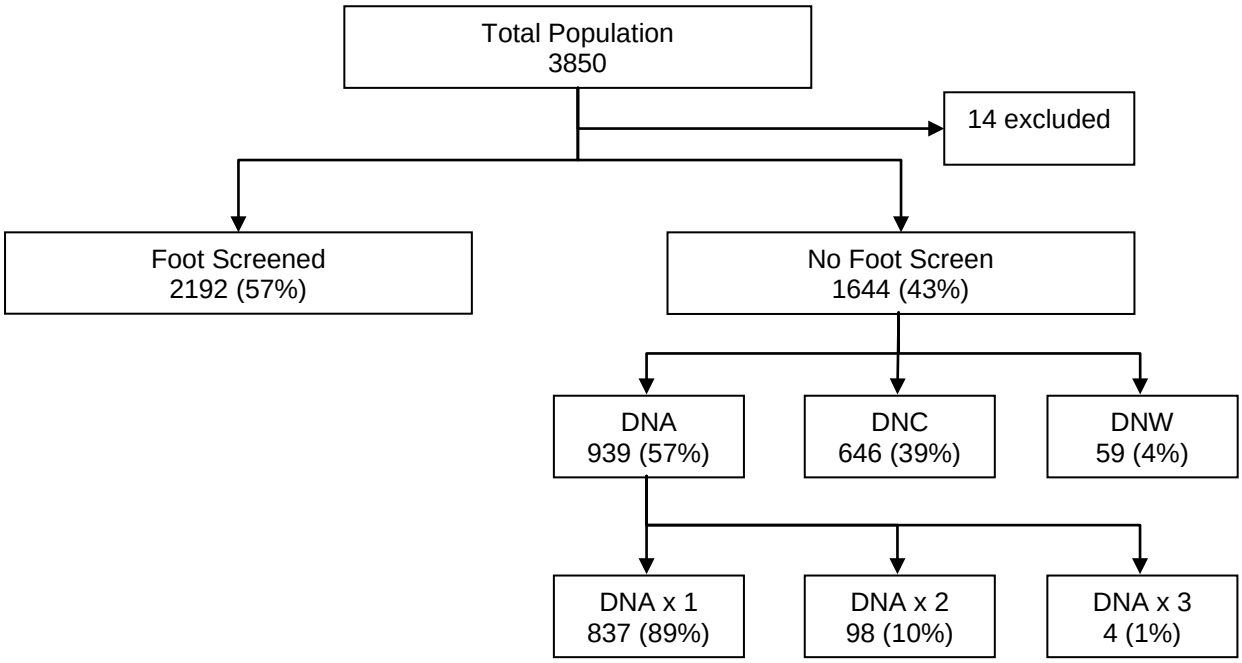

Figure 2.An overview of the foot screening population.

Characteristics of the screened and non-screened participants are listed in Table 4. The mean age of the screened participants was 63 years. The non-screened group were significantly younger, χ^2 (5, N = 3836) = 163.71, p < .001) with the mean age 57 years. The majority of the screened participants and the non-screened individuals were in the 45-64 years age group. There were 1145 (52%) male and 1047 (48%) female participants and this was the same for unscreened participants. Screened participants included 20.8% Māori and 79.2% non-Māori. The non-Māori identified with the following ethnic origin, New Zealand European (59.9%), Pacific People (3.6%), Indian (5.0%), Asian (3.6%), Other European (5.6%), other (1.6%). Seventy percent of the non-

screened participants were Non-Māori and 30% were Māori. Therefore Māori were less likely to have a foot screen χ^2 (1, N = 3836) = 53.16, p < .001).

Table 4

The Participant Characteristics Comparing the Screened and Non-screened Populations

	Screened participants (n=2192)	**Non screened participants (n=1644)**	***p*-value***
Age			< . 001
≤30 years	41 (2%)	122 (7%)	
31-44 years	171 (8%)	251 (15%)	
45-64 years	923 (42%)	717 (44%)	
65-74 years	647 (30%)	338 (21%)	
75-84 years	338 (15%)	174 (11%)	
85+ years	72 (3%)	42 (2%)	
Average age in years	63	57	
Gender			.93
Male	52%	52%	
Female	48%	48%	
Ethnicity			< .001
NZ European	1312 (60%)	813 (50%)	
Māori	455 (21%)	511 (31%)	
Pacific Peoples	79 (4%)	83 (5%)	
Asian	79 (4%)	75 (5%)	
Indian	110 (5%)	74 (4%)	
Other European	123 (5%)	66 (4%)	
Other	34 (1%)	22 (1%)	
Non Māori v Māori	79% v 21%	69% v 31%	
Clinic Location			.18
Urban	47%	49%	
Rural	53%	51%	
Diabetes Data			
Diabetes Duration (average)	9.1 years	8.4 years	.03
Diabetes Type			.00
Type 1	147 (7%)	154 (9%)	
Type 2	2045 (93%)	1330 (81%)	

Screening was performed in 19 different locations within the 10 territorial local authorities of the Waikato District Health Board catchment area. The majority of participants were screened in Hamilton City (47.1%), followed by South Waikato (12.2%), Thames-Coromandel (9.9%), Matamata-Piako (6.8%), Waikato (6.6%), Otorohanga & Waitomo (5.9%), Waipa (4.7%), Hauraki (4.2%), and (part of) Ruapehu (2.6%). Forty-seven percent lived in an urban area while 53% lived in a rural area. Statistics New Zealand has profiled the classifications for urban and rural sector in detail, for the purposes of this study the simple definition for an urban area is a minimum population of 30 000 people. Anything else has been deemed rural (Statistics New Zealand, 2014).

The majority of people who attended the eye screening service in this 6 month time period had type 2 diabetes (87%). Figure three indicates the duration of diabetes for the screened and unscreened participants was also similar.

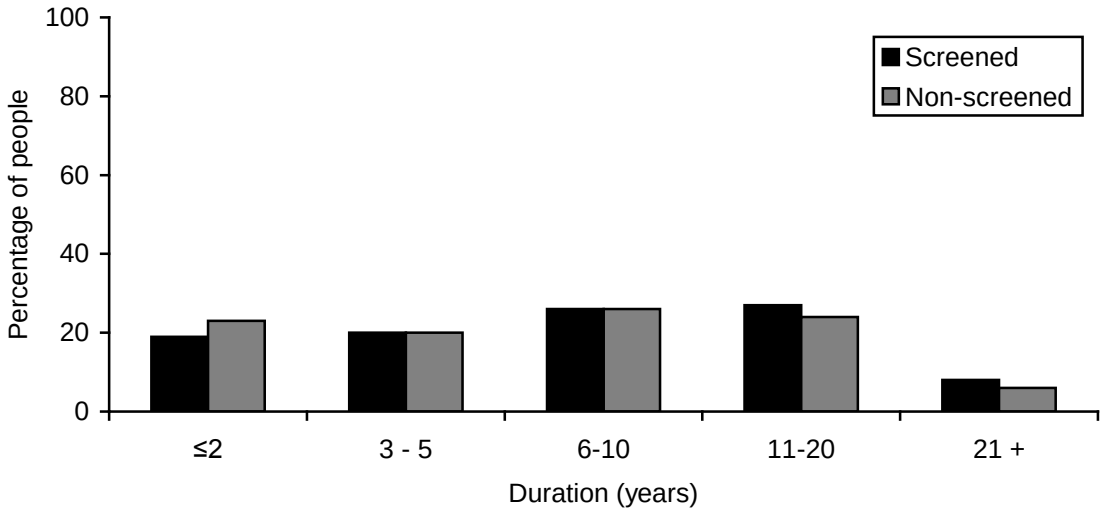

Figure 3. Diabetes duration between the screened and non-screened population.

Diabetes Foot Risk Data - Low, Moderate and High Risk Categories

The Scottish diabetic foot group risk stratification was used to categorise people into the following risk groups, low, moderate and high which included those with active ulceration. Thirteen percent of participants were in the high risk category and approximately 1% of the participants within this high risk category had an active ulceration. Sixty-five percent of people were in the low risk group and 22% in the moderate group (see Figure 4). Appendix K presents all of the demographic, health and foot data for the three risk categories.

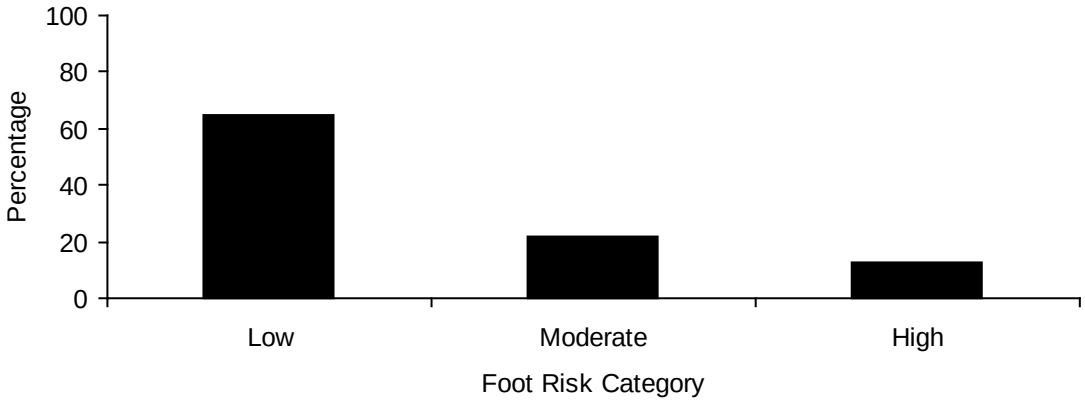

Figure 4. Percentage of people in low, moderate, and high risk foot categories.

Diabetes Foot Risk Data Comparing Low Risk Group to the Moderate-High Group

The moderate and high foot risk groups have been combined for the purposes of analyses and will be referred to as moderate-high risk group. The rationale behind this grouping is that it is unlikely that once a person's foot is classified at moderate risk, will it return to being low risk. These people are also reviewed more often with regards to their diabetes health care. This will help to identify the proportion of people who are more likely to require podiatry services. Table 5 and Table 6 compare the low risk group to the moderate–high group.

Comparisons between the use of the 10g monofilament, 128 Hz tuning fork, pedal pulses, callus and deformity, history of ulceration and amputation are shown in Table 5.

Monofilament. The 10g monofilament was captured as detected or not detected. Ten percent of people did not detect the 10g monofilament and all were in the moderate-high risk foot group.

Tuning Fork. Using the 128 Hz tuning fork vibration was also captured as detected or not detected. Similarly 10% of participants did not detect vibration and were all in the moderate-high risk category.

Pedal Pulses. Five percent of the population sample had either only one pulse site palpable or nothing palpated. These people were all in the moderate-high risk group.

Hyperkeratosis and Deformity. Chi-square analyses demonstrated a significant relationship between deformity and risk category χ^2 (1, N = 2192) = 761.37, p < .001) and callus and risk category χ^2 (1, N = 2192) = 494.50, p < .001). These significant relationships can partially be explained by the risk stratification tool, where presence of both of these complications combined automatically places you in the moderate risk group.

Ulceration. One hundred and ten people (5%) stated they had a history of ulceration, this also included two people who had an active ulceration. Chi-square analyses demonstrated a significant relationship between ulceration and risk category χ^2 (1, N = 2192) = 219.981, p < .001). This however is explained by the risk stratification tool, which places them automatically into this category. There were more males (58%) who had a history of ulceration, however, this was not shown to be statistically significant χ^2 (1, N = 2192) = 1.64 p < .20).

Amputation. Twenty-two (2.9%) people had an amputation of a digit, partial foot or lower limb. Two people had a major amputation of the left limb and six people had a major amputation of the right limb. Although males were over-represented in the amputation group (59%), this was not statistically significant χ^2 (1, N = 2192) = 0.42, p < .52.

Table 5

Foot Screening Data for the Low Risk Foot Group and the Combined Moderate and High Risk Foot Group

	Low (n=1436)	Moderate-High Risk (n=756)	*p*-value*
10g Monofilament			< .001
Detected	1436	530 (70.1%)	
Not detected	0	226 (29.9%)	
Tuning Fork			< .001
Detected	1436	540 (71.4%)	
Not detected	0	216 (28.6%)	
Pedal Pulses			< .001
≤1 site detected	0	109 (14.4%)	
> 2 sites detected	1436	647 (85.6%)	
History of Ulceration			< .001
Yes	0	110 (14.6%)	
No	1436	646 (85.4%)	
History of Amputation			< .001
Yes	0	22 (2.9%)	
No	1436	734 (97.1%)	
Hyperkeratosis			< .001
Yes	140 (9.7%)	399 (52.8%)	
No	1296 (90.3%)	357 (47.2%)	
Deformity			< .001
Yes	78 (5.4%)	439 (58.1%)	
No	1358 (94.6%)	317 (41.9%)	
Annual Review			.07
Yes	1229 (85.6%)	625 (82.7%)	
No	207 (14.4%)	131 (17.3%)	
GP/PN Foot Check			.05
Yes	809 (56.3%)	392 (51.9%)	
No	627 (43.7%)	364 (48.1%)	
Podiatry Input			< .001
Yes	115 (8%)	151 (20%)	
No	1321 (92%)	605 (80%)	

Note: *See Table 7 for Chi-square results

There was a significant relationship between type of diabetes and foot risk χ^2 (1, N = 2192) = 13.83, p < .001. Thirty-five percent of people with type 2 diabetes were in the moderate to high risk groups compared to twenty percent with type 1 diabetes.

A participant's age χ^2 (5, N = 2192) = 192.77, p < .001 and the length of time a person has had diabetes χ^2 (4, N = 2192) = 12.93, p = .01 were related to foot risk. As can be seen in Table 6, the older you were and the longer you had diabetes the more likely you were to have a moderate-high risk foot problem. In particular, results showed people over the age of the 65 years are more likely to be in the moderate-high risk group. The majority of people in the moderate-high risk group, had diabetes for three years or more.

The ethnicity group for each of the risk categories shows there were similar proportions of males and females and Māori and non-Māori. No significant relationship was found between gender and foot risk or ethnicity and foot risk (see Table 6). There was a significant difference however between urban and rural χ^2 (1, N = 2192) = 12.50, p < .001 with more rural participants being in the moderate-high risk foot category (37.9%). Furthermore, there was a relationship between residence and ethnicity, with more Māori living in rural regions χ^2 (1, N = 2192) = 21.97, p < .001.

The smoking status was obtained due to it being a recognised as a risk factor for peripheral arterial disease and foot disease. The results showed that 12% of the sample population are current smokers. Forty four percent of participants had a past history of smoking which was the same number as those that had never smoked. Smoking was therefore significantly related to foot risk χ^2 (2, N = 2192) = 14.32, p = .001. This can be seen in Table 6, 60.4% who were either past smokers or current smokers were in the moderate-high risk foot category.

Table 6

Demographic and Health Data for the Low Risk Foot Group and the Combined Moderate and High Risk Foot Group

	Low (n=1436)	Moderate-High Risk (n=756)	*p*-value*
Age			< .001
≤30 years	39 (95.1%)	2 (4.9%)	
31-44 years	138 (80.7%)	33 (19.3%)	
45-64 years	703 (76.2%)	220 (23.8%)	
65-74 years	380 (58.7%)	267 (41.3%)	
75-84 years	155 (45.9%)	183 (54.1%)	
85+ years	21 (29.2%)	51 (70.8%)	
Ethnicity			.18
Non-Māori	1150 (66.2%)	587 (33.8%)	
Māori	286 (62.9%)	169 (37.1%)	
Gender			0.33
Male	761 (66.5%)	384 (33.5%)	
Female	675 (64.5%)	372 (35.5%)	
Clinic Location			< .001
Urban	716(69.3%)	317 (30.7%)	
Rural	720 (62.1%)	439 (37.9%)	
Type of Diabetes			< .001
Type 1	117 (79.6%)	30 (20.4%)	
Type 2	1319 (64.5%)	726 (35.5%)	
Duration of Diabetes			.012
≤ 2 years	296 (69.6%)	129 (30.4%)	
3-5 years	282 (64.5%)	155 (35.5%)	
6-10 years	397 (68.7%)	181 (31.3%)	
11-20 years	363 (62.3%)	220 (37.7%)	
21+ years	98 (58.0%)	71(42.0%)	
Medication (Current)			.170
Diet	403 (64.8%)	219 (35.2%)	
Oral	712 (64.4%)	394 (35.6%)	
Insulin	321 (69.2%)	143 (30.8%)	
Smoking			< .001
Never	677(69.4%)	299 (30.6%)	
Past	588 (61.2%)	372 (38.8%)	
Current	171 (66.8%)	85 (33.2%)	

Note: *See Table 7 for Chi-square results

Table 7

Chi-Square Statistics for the Low and Combined Moderate and High Risk Foot Group

	Pearson Chi-square	***df***	***p*-value**
Type diabetes	13.83	1	<.001
Age group	192.77	5	<.001
Duration of diabetes	12.93	4	.012
Gender	.961	1	.327
Ethnicity	1.79	1	.184
Residence	12.50	1	<.001
Smoking	14.32	2	<.001
Foot screening data			
10g monofilament	478.63	1	<.001
Tuning Fork	455.14	1	<.001
Pedal Pulses	217.88	1	<.001
History of ulceration	219.98	1	<.001
History of amputation	42.21	1	<.001
Hyperkeratosis	494.50	1	<.001
Deformity	761.37	1	<.001
Annual review (GP/PN)	3.22	1	.07
Foot check (GP/PN)	4.02	1	.05
Podiatry input	66.50	1	<.001

Health Data

Ninety-three percent of the screened population had type 2 diabetes. Table 8 is a comparison of treatment for diabetes control between the initial therapy at diagnosis and current therapy. The treatment options consisted of diet control, oral medication, and insulin. Those participants on both insulin and oral medication were grouped together into the insulin group. At diagnosis of diabetes 52% of people were diet control only, compared to their current treatment plan where now 50% of people are on oral medication.

Table 8

Diabetes Treatment Data for the Total Screened Population (n = 2192)

	Initial Therapy	Current Therapy
Diet	1152 (53%)	622 (28%)
Oral medication	845 (38%)	1106 (51%)
Insulin	195 (9%)	464 (21%)

According to the participants self-report, 85% had had a diabetes annual review within the last year by their GP or Practice Nurse. Close to half (55%) reported having a foot screen during that annual review. A small number (n=5) could not remember having either a diabetes annual review or a foot screen. Twelve percent of the participants reported they had seen a podiatrist in the last year.

Discussion

The purpose of this research project was to determine the prevalence of diabetic foot disease in the Waikato region. Thirteen percent of the people screened had a high risk diabetic foot. The moderate risk group made up 22% of the sample, therefore a third of people with diabetes are at risk of developing a moderate to high risk diabetic foot problem in New Zealand. Thirty percent of the moderate-high risk group showed signs of neuropathy and 14% indicated signs of peripheral arterial disease. Fifteen percent of people had a history of ulceration and twenty-two people had an amputation. People in the moderate-high risk group were more likely to require foot care either in primary or secondary care services.

Prevalence of Diabetic Foot Disease in the Waikato

This is the first prevalence study carried out in New Zealand on early diabetic foot disease. Up until now there has been no expansive data on diabetic foot disease to help in the future planning of primary or secondary care diabetes foot care services. This research project represents the diabetes population within the Waikato Region and we believe is reflective of the New Zealand diabetes population in age, ethnicity and type of diabetes.

The results from this prevalence study of diabetic foot disease has shown that 65% of people are categorised as low risk, 22% as moderate risk, 13% as high risk and 1% of this high risk group are in the active risk category. In 2011 the Scottish foot action group published the Scottish data, which screened 61% of its diabetes population. They identified low risk 69%, moderate risk 20%, high risk 11% and active 4% of the high risk population (Leese et al., 2011), which is similar to the data gathered from this research project.

Internationally there has been a number of different foot risk classifications developed. Malgrange et al. (2003) used the clinical recommendations from the International Working Group on the Diabetic Foot, and identified 72.8% in the (grade 0) low foot risk group, (grade 1) 9.7%, (grade 2) 9.8% and (grade 3) 7.7% of people had a high risk foot. Kärvestedt et al. (2011) reported low risk 48%, moderate risk 40%, and high risk 12%. The Scottish foot action group diabetes foot screening and risk stratification tool was developed after the Malgrange et al. (2003) study, hence the use of the word ‘grade’ through their study. Kärvestedt et al. (2011) used the low, moderate and high risk

terminology which would suggest that they have adopted the more commonly used terms. The Scottish Diabetes Foot Action Group diabetes foot screening and risk stratification tool has shown to be successful in assisting the evaluation of the risk status of diabetic feet for this study. The categories within the tool are clearly defined and easy to use, as shown in Appendix B. Ideally to have a universal screening and risk classification tool would help in standardising diabetic foot care for the health professional and for people with diabetes.

A possible reason for the active risk category being slightly lower in the Waikato sample is because some people with active foot disease may be under the care of the specialist eye clinic at Waikato hospital. These people would be more likely to have established eye disease that has gone beyond only requiring a biannual retinal eye screen, and therefore not screened in this study. Commonly when complications do start to occur in people with diabetes they are not isolated events, for example if there is eye disease due to the microvascular problems it is highly likely there will be changes in kidney and nerve function. These complications are irreversible, hence that once a person has identifiable eye disease, or nerve dysfunction then the health care service required changes from only needing monitoring or regular screening to ongoing medical care (Holt et al., 2010).

The variables of type of diabetes, duration of diabetes, age, residency and smoking, have all been found to have a relationship with diabetic foot disease. The older the person, the longer they have diabetes, people with type 2 diabetes and those who live in a rural area have an increased chance of having a diabetic foot related problem. The prevalence studies reviewed earlier in this document have also recognised these factors as contributing to diabetic foot disease (Abbott et al., 2002; Sampson et al., 2002)

Abbott et al. (2002) and Malgrange et al. (2003) both reviewed type 1 and type 2 diabetes and showed similar results for the demographic data gathered in the current study. In both of these studies, there were slightly more men 54% and 52% respectively. This study also had 52% men in the sample population while in the high risk group there was a similar proportion between women (35%) and men (33%). International publications have indicated that men are more likely to experience a lower limb amputation (Peek, 2011). In this study more men had experienced an amputation; however this was not statistically significant, possibly due to the small sample size of those who had an amputation.

The proportion of Māori who participated in this study is comparable to the general diabetes population in the Waikato region. The estimated percentage of Māori in the Waikato is 22% and Māori made up 21% of the screened participants. Māori and non-Māori had similar foot risk outcomes. This study encompassed the urban and rural sectors of the region. This is where there was significance, where people living in a rural area were more likely to be in the moderate-high risk foot group. This was also shown in the New Zealand Health Survey 2013/14 that those living in more deprived areas had higher rates of diabetes. When residency and ethnicity were reviewed this also identified a relationship. If the participant was Māori and lived in a rural area they were more likely to be in the moderate-high risk group. This was a unique finding compared to the other prevalence studies where residence was not reported.

Abbott et al. (2002) reviewed if a person lived alone (22.8%). The Malgrange et al. (2003) study reviewed the participant's psychosocial status (12%), which included if a person lived alone, their mental health, excess alcohol intake and body hygiene. Gulliford and Mahabir (2002) had a low socioeconomic population, and were commonly admitted into hospital for diabetic foot related concerns. These studies have highlighted that those living alone, with poor psychosocial functioning and from a low socioeconomic background are more likely to have high risk foot problems. Therefore this study has identified a need to review health services within the rural community. Additionally reviewing if a person lives alone, their psychosocial needs and their socioeconomic status should all be included for those people with moderate-high risk foot disease. This would allow adequate support services to be put in place such as access to relevant health professionals.

Smoking was shown to be a significant factor in the moderate-high risk foot group (12%). This was a lower rate than the 18% of the general population that the Ministry of Health reported for the year 2012/13. Kärvestedt et al. (2011) and Abbott et al. (2002) who also reviewed smoking, identified a higher number of people were current smokers at 21% and 31% respectively and past smoker results were 36% and 33%. This study had 44% of people who were past smokers. Possibly the numbers are higher for current smokers in these studies as the data was gathered over ten years ago and since then a lot of legal changes and sustained public health campaigns have occurred nationally and internationally in regards to smoking. These findings highlight the direct relationship between those people who are either past or current smokers, and have diabetes are at risk of developing a foot problem.

In this study the impact of having seen a podiatrist in the past year was a significant factor for the 12% that saw a podiatrist. Those that had been reviewed by a podiatrist were not asked why they had attended a podiatrist or if they had been referred by another health professional. If an individual is seen by a podiatrist one would expect them to have a foot complaint of some description, therefore this could be deemed bias. Abbott et al. (2002) also reviewed podiatry input and stated that podiatrists were more likely to review those at risk of ulceration or have a current ulceration, therefore this could be recognised as a confounding variable. However in this study there were still 31% of people with moderate-high risk foot complaint who had not seen a podiatrist and it is recommended by the Scottish diabetic risk stratification tool that those with high risk foot disease are reviewed by podiatrist and do benefit from podiatric input (Leese et al., 2011). This finding of 31% may be a reflection of the inability of health professionals who are performing the foot screen in primary care not knowing how to access or what podiatry services are available within primary care. Guilford and Mahabir (2002) described how podiatry was not accessible for their population, and indicated that it would be necessary to improve the knowledge and skills in the prevention and treatment for health care professionals working with people with diabetic foot disease.

Clinical Presentation of Diabetic Foot Disease

Peripheral Diabetes Neuropathy. The 10g monofilament and the tuning fork 128Hz were both used to identify peripheral neuropathy. There was no difference in the results between the research assistant and lead researcher when using the monofilament or tuning fork. Ten percent of the total screened population could not detect the 10g monofilament, however within the moderate-high risk group, 30% of the group were unable to detect the 10g monofilament.

The 10g monofilament is a tool commonly used to identify peripheral neuropathy, however the results of non-detection varied across different prevalence studies Abbott et al. (2002) 19.7%, Malgrange et al. (2003) 27.1% and Kärvestedt et al. (2011) 15%. The possible reasons for the discrepancies across all the studies are the populations from the earlier studies are over ten years old. Diabetes care and education has improved in this time. The Malgrange et al. (2003) study which had the highest result for the 10g monofilament, did not discuss any training for the multiple health professionals using this tool nor did it discuss inter-rater reliability.

In this study 10% of the total screened population could not detect the tuning fork 128Hz, however in the moderate-high risk group it was not detected in 29% of the category. The tuning fork was also used in the Abbott et al. (2002) where 34% did not detect and Kärvestedt et al. (2011) where 24% did not detect.

In this study 80% of those that could not detect the tuning fork were over the age of 65 and 65% of those that could not detect the tuning fork had been diagnosed with diabetes for longer than 5 years. The detection of the tuning fork not only reduces when there are early signs of nerve changes related to diabetes, but also with age and other underlying medical conditions (Walker et al., 1990). The Kärvestedt et al. (2011), and Sampson et al. (2002) did use a biothesiometer and these two studies did identify a higher number of people with peripheral neuropathy. For reliability, a biothesiometer would offer a consistent voltage to the foot. Another research project could be to review the use of vibration as a screening tool comparing the tuning fork 128Hz with a biothesiometer.

It is important to remember that these tools are only identifying the early signs of diabetes peripheral neuropathy. Unfortunately neuropathic changes are often not recognised by the individual because of the varying degrees of diabetes peripheral neuropathy.

Peripheral Arterial Disease. The absence of a pedal pulse was the key indicator in detecting peripheral arterial disease which was identified in 5% in the total population. In the moderate-high risk group 14% showed signs of peripheral arterial disease. Sampson et al. (2002) identified 19% of people with peripheral arterial disease and Malgrange et al. (2003) identified 17%. Both of these studies had trained health professional present to perform an ankle branchial pressure index, which does help in identifying peripheral arterial disease, however if there is calcification present it does provide a false reading. Abbott et al. (2002) signified that the palpation of pulses with adequate training is favourable when screening for vascular concerns.

In the Abbott et al. (2002) and Sampson et al. (2002) studies the prevalence of active foot ulceration was around one percent and this project also indicated similar results for those who had an active ulceration. In regards to those who had a history of ulceration five percent reported to having a wound/ulcer longer than four weeks, while studies by Malgrange et al. (2003) and Kärvestedt et al. (2011), illustrated approximately seven percent of the participants had a history of ulceration and or amputation. In this project twenty-two people (2.9%) had a history of amputation, which included digital, forefoot, below knee and above knee amputation. Therefore the results for history of

amputation, history of ulceration or active ulceration is similar to what has been found in previous international prevalence studies.

An ankle brachial pressure index is recognised as being clinically useful for measuring peripheral arterial disease. It was used in the studies from Sampson and colleagues (2002), Malgrange et al. (2003), and Ihaka et al. (2012). It was not used as part of this foot screen, due to a number of factors. It should only be performed when there is an indication of peripheral arterial disease, therefore it was appropriate to only use the pedal pulses, as a screen for peripheral arterial disease. Anything more sinister was referred to the general practitioner for further investigation. Ideally a hand-held doppler should be performed by a trained and experienced health professional, because it is a specialist test this would have added costs to the project for the purchase of a doppler and the salary for a more experienced health professional.

Time would also be a factor for using a doppler in an eye screening clinic, as the eye screen process is approximately 20 minutes from the eye drops to the eye photograph. This would not allow an ankle brachial pressure index to be properly undertaken, as a person needs to rest for 15 minutes before an ankle branchial pressure index is performed. Clinic space would also need to include a bed for a person to lie flat, which was another important factor when performing the ankle brachial pressure index.

Hyperkeratosis and Deformity. The hyperkeratosis variable was identified both in the low risk category where it was present in six percent of the screened population, and in the moderate-high risk group where 74% of people were identified as having hyperkeratosis present. If the hyperkeratosis was bilateral and there were no other concerns indicated then this variable was interpreted normal for the person. The Malgrange et al. (2003) prevalence study reviewed the foot for both hyperkeratosis and deformity and showed there was a link between the presence of these variables and peripheral neuropathy.

In this study when classifying deformity four percent of the total screened population were in the low risk category and 85% of all those who presented with a deformity were in the moderate-high risk foot category. Once again when the foot was reviewed for deformity if the participant had bilateral pes planus feet or both feet had bunions with no other changes detected this was deemed normal for that individual. It can be difficult to classify these two variables, as they can contribute to foot

ulceration developing in the person with diabetes, however usually only in the presence of peripheral arterial disease and or peripheral diabetes neuropathy (Abbott et al., 2002; Malgrange et al., 2003).

Service Implications for Diabetic Foot Disease

The uptake of screening was an identified issue. Some eligible participants chose not to participate because they had their feet screened in general practice, as part of their diabetes annual review. Although eighty-five percent of people reported having had a diabetes annual review in general practice, 45% of them did not receive a foot screen at the same time. This is similar to Daly et al. (2014) who identified that nurses in primary care were not routinely carrying out a foot screen for people with diabetes. This finding raises the question of how do you make the foot screen a compulsory component of the diabetes annual review? It is important to engage the person with diabetes to empower them firstly to ask about their feet being checked and secondly to help them understand why they need to have it done. A diabetes annual review is an important factor in ensuring people stay in the low foot risk category. Another imperative factor is that their diabetes management is reviewed not only at the annual review, but whenever a visit is made to their general practice. This would be a good opportunity for general practice to provide health promotion focused education to the individual.

Cost is an unlikely barrier to primary care health professionals performing the foot screen at the diabetes annual review. Abbott's research group (2002) identified that a majority of the participants were screened at their diabetes annual review in primary care. The simple screening tools of the 10g monofilament and tuning fork 128Hz tools are effective and relatively cheap, compared to the more elaborate screening tests for peripheral neuropathy and peripheral arterial disease the biothesiometer (vibration) and the doppler (ankle branchial pressure index). These devices are expensive, require more time to be performed and the results do need to be interpreted, therefore should only be used by appropriately trained health professionals. In a majority of cases they are only used after the simple screening tests have been carried out. The inter-rater reliability used in this project supports the idea that a foot screen be carried out in general practice as a trained non-podiatrist health professional was effective and a strength to this study. The earlier prevalence studies failed to discuss the importance of inter-rater reliability; however the study from Sampson et al. (2002) was different as they had a single Podiatrist perform the foot screen in their study.

The research assistant, an enrolled nurse, found no concerns using the 10g monofilament or tuning fork. Additionally, no significant differences were found between a non-podiatrist and podiatrist completing the foot screen. The main challenge for the research assistant was initially finding the pulse sites due to individual variants such as oedema (swelling) or if the environment was cold, which on occasion can make it difficult to palpate the pulse. The four week training process was imperative to the research assistant in use of the tools and detection of problems and recognising severity of problems.

There were 19 different clinic locations where the foot screening occurred, which allowed people to be seen closer to home. Twenty-four percent of the total population did not attend, this may have been lower if this project had been performed over a 12 month period, as the number of those who had a did not attend two or three times reduced remarkably after missing the initial appointment. It would be beneficial to engage with primary health organisations, to review where transport is already provided or where it is required for those in rural areas. This would help people get to their appointments from rural areas.

Sampson et al. (2002) study was similar to the current study in that the foot screen was performed when a person attended their retinal eye screen. A difference was that their retinal screening programme was managed in primary care. If the foot screen became a part of the overall eye screening process, the clinic locations would have to have adequate waiting space for people to feel comfortable. Then again if the primary care practice was to perform the foot screen as part of the diabetes annual review this would allow a person to be seen close to home and within a service that they already know and feel comfortable with.

Developing a Health TV educational package for the use in health service waiting areas could empower patients to ask about a foot screen. This would also help those with low health literacy skills and provide further information on the process and the importance of a foot screen. The high response rate of those who chose to participate in this project provides support that people with diabetes are interested in a foot screen.

A semi-virtual clinic was created with the use of the iPad to take digital images of the dorsal and plantar views of the foot. This allowed the images to be emailed directly to the lead researcher where it was filed and reviewed. This process worked well and was efficient. If there was any concern this was highlighted on the report back to the GP in conjunction with the other findings, as

indicated by the screener. To improve the process for the future a copy could also be provided to the patient to allow them to be aware of their foot status.

The lead researcher reviewed the digital images and data to determine the risk category for each person, which offered consistency for the screened population. Having another podiatrist to review the images and supporting information to compare the results would improve reliability; however the podiatry resource is low. Podiatry services typically only have one podiatrist, as there are just over 300 Podiatrists in New Zealand. This number reduces again when considering the proportion of Podiatrists with the necessary experience and skills working within diabetes. eHealth is the way of the future and it would work well for podiatry in diabetes because of the small workforce. eHealth would also benefit primary care practitioners working in isolation or in rural centres (Ministry of Health, 2013). With the introduction of smart phones and email capabilities this would allow a more effective triage process with a digital image of the foot complaint. This would benefit both the podiatrist and speed of the process for the person with the foot concern. Additionally, it may help encourage those who may be reluctant to have their feet screened who are potentially at greatest risk of poor foot care. In the future eHealth will also help people to track and monitor their own health data.

Recommendations for Future Research in Diabetic Foot Disease

This study highlights many opportunities for future research in the area of diabetic foot disease. The current thesis is the first of its kind in New Zealand looking at prevalence of diabetic foot disease. Therefore, it would be worth attempting to replicate the findings of this study within other regions of New Zealand to see if similar results are found.

An extension of this study would be to replicate this prevalence study in a diabetes population with eye disease (e.g. those who attend the specialist eye clinic). It is hypothesised that a majority would have a high risk foot with an active foot ulceration. It would be of interest to compare the results of age, type of diabetes, duration, gender and ethnicity to the current study. This would identify if there are any significant differences between the general diabetes population in primary care and those with diabetic eye disease that are more likely to be reviewed in secondary care.

For each participant a letter outlining the foot status was sent to the general practice. It would be of interest to determine what happened to the report if treatment was indicated, was this initiated or was it simply filed into the participants notes with no action.

The rate of those that did not have a foot screen was relatively high and there were some difference between the screened and non-screened groups. A further research question could be why are primary care practices not performing a foot screen at the diabetes annual review and what are the barriers preventing this from happening. A similar framework as Daly et al. (2014) could be used, where different professional groups could be compared.

Abbott et al. (2002) did a follow up and identified change over time to their participants. A more advanced analysis would be through the use of longitudinal data, so that changes over time within the risk categories in the current data could be analysed.

A positive yet surprising finding of this study was that there were no identified disparities between Māori and non-Māori with diabetic foot disease in the screened population. Yet amputation rates have shown to be high in Māori (Ministry of Health, 2008) and other studies have also identified foot risk factors for Māori with diabetes (Ihaka et al., 2012; Simmons et al., 1995). Ethnicity was also a factor when participating in the study with less Māori in the non-screened group. This suggests that more in depth studies are required within New Zealand to look at why Māori have similar rates of diabetic foot disease but higher rates of amputation.

Another useful study would be to develop and review if a virtual (eHealth) diabetic foot clinic would benefit health professionals as well as people with diabetes. This could be done by reviewing the use of digital images between health professionals and whether this improves the referral process (Jayaraman, Kennedy, Dutu, & Lawrenson, 2008). This possibility of an enhanced referral process may help those living in a rural location acquire treatment earlier and into the correct service, whether that be primary or secondary care. A further opportunity in eHealth would be to review those people who have access to their health details and examine if access helps to improve their foot awareness. Ultimately does this empowerment have the potential to reduce diabetic foot disease?

Conclusion

In conclusion this is the first prevalence study on diabetic foot disease in New Zealand. It identified over one-third of New Zealanders within the Waikato region with diabetes have moderate-

high risk diabetic foot disease. This has provided substantial data on diabetic foot disease, where previously this was unknown in the New Zealand population. We believe this sample is representative of the New Zealand diabetes population and highlights the need for foot care for all New Zealanders with diabetes. Significant factors that place people more at risk of diabetic foot disease included age, type of diabetes, and duration of diabetes, and smoking. Podiatry care for people in the rural community is also important as they are more likely to have moderate-high risk feet.

This research project has demonstrated that screening for foot complications is important. With the increasing number of people with diabetes, the presence of foot complications is likely to continue. There needs to be more podiatry services made available, as what currently exists is likely insufficient for the now identified need. More resources also need to be put in place to empower the person with diabetes to understand the concern of diabetic foot disease. Future planning needs to include effective foot screening which has been shown through this project to be easy to perform.

"In the past, the foot was the Cinderella in diabetes care and diabetes research,
but this relative neglect, by both doctor and patient, has clearly changed in the last decades",
(Schaper, 2012).

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Appendix A

Monofilament Use

1. Show the monofilament to the patient. Place the end of the monofilament on his/her hand or arm to show that the testing procedure will not hurt.
2. Ask the patient to turn his/her head and close his/her eyes to look at the ceiling.
3. Ask the patient to say 'yes' when he/she feels you touching his/her foot with the monofilament. DO NOT ASK THE PATIENT 'did you feel that?'
4. Hold the monofilament perpendicular to the skin and use a smooth motion when testing. Try 3 second sequence that includes:

- Placing the end of the monofilament on the sole of the foot
- Pushing the monofilament until it bends, then
- Lifting the monofilament from the skin.
- Repeat the sequence at another testing site on the foot (see Figure A1). DO NOT use a rapid or tapping movement.
- If the monofilament accidentally slides the skin, retest that area later in the testing sequence.

5. Use the monofilament in a random sequence, NOT moving from right to left.
6. If the patient does not say 'yes' when you touch a given testing site, continue on to another site. When you have completed the sequence RETEST the area(s) where the patient did not feel the monofilament.
7. Apply the filament along the perimeter of, and not on an, ulcer site, necrotic tissue, callus or scar.

Loss of protective sensation = absent sensation at one or more sites

The 5.07 monofilament will last indefinitely if you ALWAYS place it back in the case after use. This will keep you from accidentally bending or breaking the monofilament. To clean the monofilament, sodium hypochlorite (household bleach) 1:10 solution recommended.

Figure A1: *Guidelines for use of the 10 gram monofilament (Source: New Zealand Guidelines Group, 2003, p. 108)*

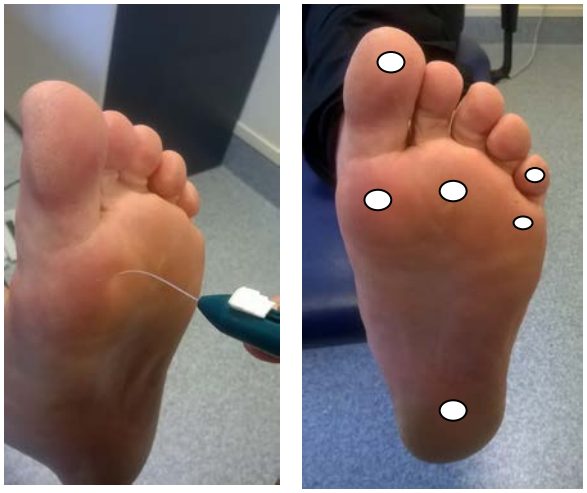

Figure A2: *How to use the monofilament and common test sites*

Appendix B

Diabetic Foot Risk Stratification and Triage Tool

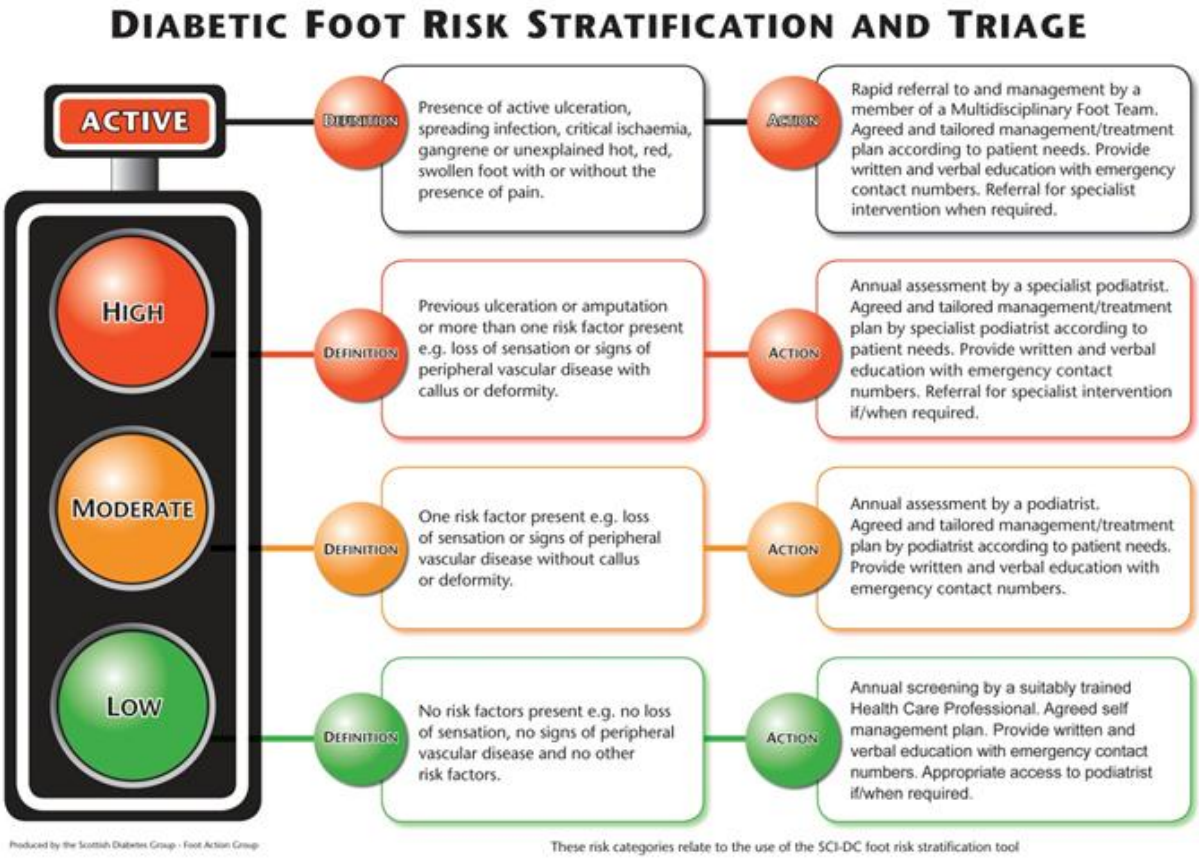

Figure B1: Diabetic Foot Risk and Stratification and Triage (Source: Scottish Intercollegiate Guidelines Network, 2010, p. 105)

Appendix C

The Waikato District Health Board Area

Figure C1: Map of Waikato District Health Board Area. (Source: Ministry of Health, 2014e)

Appendix D

Demographic Questionnaire

Attended	**Did Not Attend**	**Did Not Consent**	**Did Not Wait**

PATIENT DEMOGRAPHICS			
Name			
NHI			
DOB			
Gender	Male	Female	
Ethnicity	European	Māori	Other (please state)
Residence			
Smoking	Never	Past	Current

DIABETES INFORMATION					
What type diabetes do you have?	Diabetes Type 1	Two	Other		
What was the year you were diagnosed with diabetes?					
What was your initial therapy?	Initial Therapy	Diet	Tablets	Tab/insulin	Insulin
What is your current therapy?	Tablets	Tabs/Insulin	Insulin		
Have you had a diabetes annual review by your GP or PN in last 12 months?	Yes= Y	No=N	Don't know= DK		
Did you have your feet checked at your annual review in last 12 months?	Yes=Y	No=N	Don't know= DK		

FOOT INFORMATION		**Left**	**Right**
Have you had a foot ulcer/wound?	(Never; past; present)		
Have you had a lower limb amputation?	Amputation history (Toe, metatarsal, forefoot, BKA, TKA, AKA)		
	Pedal pulses (absent, DP, PT, both)		
	10g monofilament (0=absent, 1=<6, 2=>6)		
	Vibration 128Hz (0=absent, 1=<30sec, 2=>30sec)		
Do you see a Podiatrist?	Podiatry review (How many times a year?)	Yes	No
PODIATRIST ONLY	**Callous/deformity**		

SIGN Risk Classification	**Low**	**Moderate**	**High**	**Active**

Appendix E

Pedal Pulse Sites

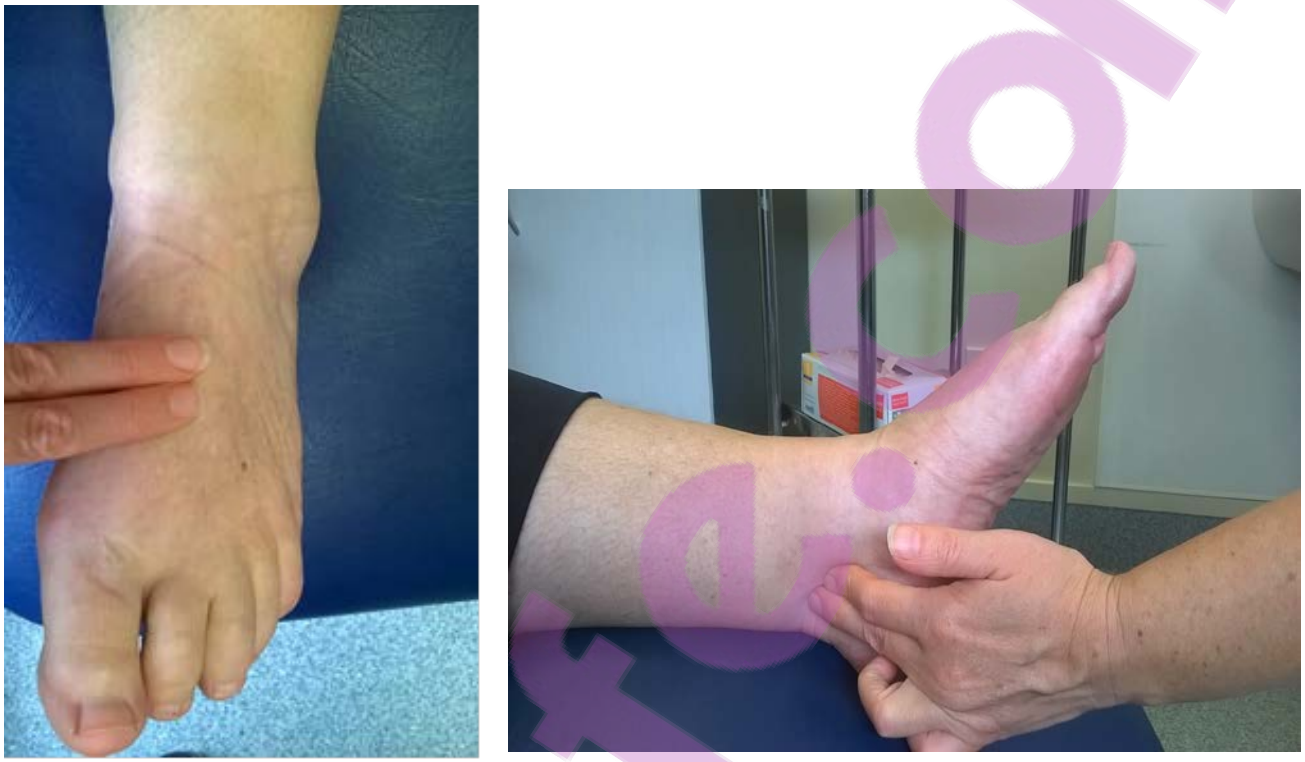

Figure E1. *Pedal Pulse Sites: Dorsalis Pedis and Posterior Tibialis*

Appendix F

Participant Invitation Letter

School of Population Health
Faculty of Medical and Health Sciences
Tamaki Campus
Department phone:
09 373 7599 ext 86335

Date

The University of Auckland
Private Bag 92019
Auckland, New Zealand

Dear

I would like to invite you to participate in my research project:

The prevalence of diabetic foot disease in the Waikato region

This research will involve you having your feet examined at the same appointment you have your eyes photographed.

The examination by the nurse will include:

1. **Explaining the tests and asking your permission.**
2. **Removing your shoes and socks**
3. **Feeling your feet for pulses, this tests for circulation**
4. **Touching your feet with a special instrument that will test for sensation (feeling)**
5. **Taking a photo of your feet.**

An information sheet has been enclosed and at the appointment you will have the opportunity to ask any further questions before you consent to participating, otherwise please do not hesitate to contact the researcher if you have any questions before your retinal eye screening appointment.

We look forward to you participating in this project.
Many thanks for your time
Kind regards

Claire O'Shea
Podiatrist – Waikato Regional Diabetes Service
FootScreening@waikatodhb.health.nz
Work telephone: 07 859 9180 or 021 846 326

APPROVED BY THE UNIVERSITY OF AUCKLAND HUMAN PARTICIPANTS ETHICS COMMITTEE ON 26/11/2013 FOR (3) YEARS REFERENCE NUMBER 010483.

Appendix G

Participant Information Sheet

School of Population Health
Faculty of Medical and Health Sciences
Tamaki Campus
Department phone:
09 373 7599 ext 86335
The University of Auckland
Private Bag 92019
Auckland, New Zealand

Project Title: The Prevalence of diabetic foot disease in the Waikato Region
Name of Researcher:
Claire O'Shea, BHSc Podiatry, PGDipHSc
Podiatrist - Diabetes service, Waikato DHB.
Masters in Health Science Student – Faculty of Medical and Health Sciences, School of Population Health, University of Auckland.

I would like to invite you to participate in this project, looking at the presence of foot disease in people with diabetes who live in the Waikato region. This project will be supervised by Professor Ross Lawrenson from the Waikato Clinical School.

Your feet, like your eyes, can also be affected by diabetes due to damage to the blood vessels and nerves. This can lead to a wound or ulcer which does not heal and in some cases can lead to a loss of a toe, foot or even a leg. If you chose to participate in this research your feet will be screened at the same appointment you have your eyes screened.

The aim of this research project is to find out the number of people with diabetic foot disease in the Waikato region.
The objectives of this research project are:

- To determine the prevalence of early diabetic foot disease.
- To review the use of an examination of my feet and interview with a non-podiatrist health professional as a screening method for foot disease.
- To obtain data that could help in planning for podiatry and foot care services in both primary and secondary care by reviewing the number of people identified with foot disease.

Project Procedure
This project will involve you taking off your shoes and socks and a health professional will feel your feet for blood vessel pulses and test your sensation with a 10g monofilament (piece of nylon). A photo will be taken of both your feet. You will be asked questions about your diabetes status and general foot health. The entire process will take
15 minutes.

The information will be stored confidentially and attached to your NHI number on a database. This database will be held on the Waikato District Health Board computer system. It will be accessed by a password by the researcher and health professional collecting the data. The data will be held indefinitely and may be used in future research.

The lead researcher will review the findings from this foot screen and if further action is required you will be referred to your GP for further assessment and an ongoing management plan.

You have the right to withdraw from participating in the research until one month after you have had your foot screened and all your data will be removed and deleted from the research. The Clinical Director has assured that your decision to participate or not will have no effect to your medical care.

This project has received funding from Eli Lilly 2013 Diabetes Specialist research award.

Please do not hesitate to contact the researcher for further information.

Contact Details
Lead Researcher
Claire O'Shea
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Hamilton
Telephone: 07 859 9180 or 021 846 326
Email: FootScreening@waikatodhb.health.nz

Supervisor
Professor Ross Lawrenson
Waikato Clinical School
Peter Rothwell Academic Centre
Private Bag 3200
Hamilton 3240
Telephone: 07 8398726

Associate Professor Peter Adams
Head of Department
School of Population Health
Faculty of Medical and Health Sciences
University of Auckland
Private Bag 92019
Auckland, New Zealand

For any concerns regarding ethical issues you may contact
The Chair, The University of Auckland Human Participants Ethics Committee.
The University of Auckland, Research Office
Private Bag 92019
Auckland 1142.
Telephone: 09 373-7599 ext. 87830/83761.
Email: humanethics@auckland.ac.nz

APPROVED BY THE UNIVERSITY OF AUCKLAND HUMAN PARTICIPANTS ETHICS COMMITTEE ON 26/11/2013 for (3) years, Reference Number 010483.

Appendix H

Participant Consent Form

School of Population Health
Faculty of Medical and Health Sciences
Tamaki Campus
Department phone:
09 373 7599 ext 86335
The University of Auckland
Private Bag 92019
Auckland, New Zealand

To the Participant

THIS FORM WILL BE HELD INDEFINTELY AND MAY BE USED IN FUTURE RESEARCH.

Project Title: The Prevalence of diabetic foot disease in the Waikato Region

Name of Researcher: Claire O'Shea, BHSc Podiatry, PGDipHSc

Masters in Health Science Student – Faculty of Medical and Health Sciences.

School of Population Health, University of Auckland.

I have read the Participant Information Sheet; have understood the nature of the research and why I have been selected. I have had the opportunity to ask questions and have them answered to my satisfaction.

☐ I agree to take part in this research where a non-podiatrist health professional will examine my feet and conduct an interview.

☐ I understand that I am free to withdraw participation at any time, and to withdraw any data traceable to me up to a month after I have had my foot screened.

☐ I agree / do not agree to have my feet photographed.

☐ I understand my General Practitioner will be contacted of my findings if a problem is detected, for a management plan to be put in place to attend to the foot complaint which has been identified.

☐ I understand that my data from this research will be stored confidentially on a password protected computer.

☐ I understand that my data will be kept indefinitely and the data can be used in future research, including this consent form.

☐ I understand that the Clinical Director has assured that my decision to participate or not will have no effect to my medical care.

For your information at completion of this project the findings will be displayed on the Waikato DHB website and at the Waikato Regional Diabetes Service.

Name _____

Signature _____ Date _____

APPROVED BY THE UNIVERSITY OF AUCKLAND HUMAN PARTICIPANTS ETHICS COMMITTEE ON 26/11/2013 FOR (3) YEARS REFERENCE NUMBER 010483

Appendix I

Report to GP

School of Population Health
Faculty of Medical and Health Sciences
Tamaki Campus
Department phone:
09 373 7599 ext 86335
The University of Auckland
Private Bag 92019
Auckland, New Zealand

Date

Dr
Address

Dear General Practice team

RE: DOB: NHI:
Recently the above patient had their feet screened alongside their retinal eye screen.

The foot screen information has been used in conjunction with the Diabetes foot risk stratification and Triage Tool, (SIGN, 2010).

From the foot screen the patient's foot risk is: LOW MODERATE HIGH ACTIVE

The following concerns have been identified:

- ☐ Neuropathy (could not detect the 10g monofilament)
- ☐ Absent or diminished pedal pulses
- ☐ Callous
- ☐ Deformity
- ☐ History of ulceration
- ☐ History of amputation
- ☐ Current ulceration
- ☐ None

Please manage the patient with an appropriate treatment plan, as you deem necessary from these findings.

This is part of a research project; a copy of the Patient information sheet is enclosed. It provides details of the research, which your patient consented to participating in; if you have any further questions please do not hesitate to contact the lead researcher.

Kind Regards,

Claire O'Shea
Podiatrist
Waikato Regional Diabetes Service
FootScreening@waikatodhb.health.nz
Work telephone: 07 859 9180 or 021 846 326

APPROVED BY THE UNIVERSITY OF AUCKLAND HUMAN PARTICIPANTS ETHICS COMMITTEE ON 26/11/2013 FOR (3) YEARS REFERENCE NUMBER 010483.

Appendix J

Inter-Rater Reliability

Table J1

Inter-Rater Reliability Kappa Statistic

	Agreement	Expected agreement	Kappa	Std. Err	Z	Prob>Z
Left foot						
Pulses	80.67%	43.68%	0.6568	0.0634	10.36	0.0000
Monofilament	100.00	80.23%	1.000	0.0814	12.29	0.0000
Tuning fork	100.00	45.23%	1.000	0.0679	14.72	0.0000
Right foot						
Pulses	80.67	45.07	0.6481	0.0632	10.25	0.0000
Monofilament	100.00	84.31	1.000	0.0750	13.34	0.0000
Tuning fork	100.00	47.71	1.000	0.0714	14.01	0.0000

Appendix K

Data for the Three Risk Categories

Table K1

Demographic and Health Data for the Low, Moderate, and High Risk Groups

	Low (n=1436)	Moderate (n=477)	High (n=279)
Age			
<30 years	39 (95.1%)	1(2.4%)	1 (2.4%)
31-44 years	138 (80.7%)	15 (8.8%)	18 (10.5%)
45-64 years	703 (76.2%)	135 (14.6%)	85 (9.2%)
65-74 years	380 (58.7%)	189 (29.2%)	78 (12.1%)
75-84 years	155 (45.9%)	114 (33.7%)	69 (20.4%)
85 plus	21 (29.2%)	23 (31.9%)	28 (38.9)
Ethnicity			
Non-Māori	1150 (66.2%)	375 (21.6%)	212 (12.2%)
Māori	286 (62.9%)	102 (22.4%)	67 (14.7%)
Gender			
Male	761 (66.5%)	243 21.2%)	141 (12.3%)
Female	675 (64.5%)	234 (22.3%)	138 (13.2%)
Residence			
Urban	716 (32.7%)	199 (19.3%)	118 (11.4%)
Rural	720 (62.1%)	278 (24.0%)	161 (13.9%)
Diabetes type			
Type 1	117 (79.6%)	20 (13.6%)	10 (6.8%)
Type 2	1319 (64.5%)	457 (22.3%)	269 (13.2%)
Duration of diabetes			
≤ 2 years	296 (69.6%)	88 (20.7%)	41 (9.6%)
3-5 years	282 (64.5%)	88 (20.1%)	67 (15.3%)
6-10 years	397 (68.7%)	126 (21.8%)	55 (9.5%)
11-20 years	363 (62.3%)	137 (23.5%)	83 (14.2%)
21+ years	98 (58.0%)	38 (22.5%)	33 (19.5%)
Medication (Current)			
Diet	403 (64.8%)	146 (23.5%)	73 (11.7%)
Oral	712 (64.4%)	244 (22.1%)	150 (13.6%)
Insulin	321 (69.2%)	87 (18.8%)	56 (12.1%)
Smoking			
Never	677 (69.4%)	195 (20.0%)	104 (10.7%)
Past	588 (61.3%)	226 (23.5%)	146 (15.2%)
Current	171 (66.8%)	56 (21.9%)	29 (11.3%)

Table K2

Foot Screening Data for the Low, Moderate, and High Risk Groups

	Low (n=1436)	Moderate (n=477)	High (n=279)
10g Monofilament			
Detected	1436 (73.0%)	383(19.5%)	147 (7.5%)
Not detected	0	94 (41.6%)	132 (58.4%)
Tuning Fork			
Detected	1436 (72.7%)	333 (16.9%)	207 (10.5%)
Not detected	0	144 (66.7%)	72 (33.3%)
Pedal Pulses			
<1 site detected	0	45 (41.3%)	64 (58.7%)
>2 sites detected	1436 (68.9%)	432 (20.7%)	215 (10.3%)
History of ulceration			
No	1436 (69.0%)	477 (22.9%)	169 (8.1%)
Yes	0	0	110
History of amputation			
No	1436 (66.2%)	477 (22.0%)	257 (11.8%)
Yes	0	0	22
Hyperkeratosis			
No	1296 (78.4%)	243 (14.7%)	114 (6.9%)
Yes	140 (26.0%)	234 (43.4%)	165 (30.6%)
Deformity			
No	1358 (81.1%)	245 (14.5%)	72 (4.3%)
Yes	78 (15.1%)	232 (44.9%)	207 (40.0%)
Annual Review			
Yes	1229 (66.3%)	408 (22.0%)	217 (11.7%)
No	207 (61.2%)	69 (20.4%)	62 (18.3%)
GP/PN Foot check			
Yes	809 (67.4%)	270 (22.5%)	122 (10.2%)
No	627 (63.3%)	207 (20.9%)	157 (15.8%)
Podiatry input			
Yes	115 (43.2%)	75 (28.2%)	76 (28.6%)
No	1321 (68.6%)	402 (20.9%)	203 (10.5%)

Appendix L

Chi-Square Data for the Three Risk Categories

Table L1

Chi-Square Statistics for the Low, Moderate, and High Risk Foot Groups

	Pearson Chi-square	***df***	***p*-value**
Type diabetes	13.93	2	<.001
Age group	218.22	10	< .001
Duration of diabetes	23.42	8	.003
Gender	.973	2	.615
Ethnicity	2.53	2	.282
Residence	12.52	2	.002
Smoking	16.09	2	.003
10g Monofilament	623.70	2	< .001
Tuning Fork	458.94	2	< .001
Pedal Pulses	285.82	2	< .001
History of ulceration	794.08	2	< .001
History of amputation	152.38	2	< .001
Hyperkeratosis	504.15	2	< .001
Deformity	825.16	2	< .001
Annual review (GP/PN)	11.34	2	.003
Foot check (GP/PN)	15.81	2	< .001
Podiatry input	83.40	2	< .001