The Use of the Ankle Brachial Pressure Index (ABPI) in General Practice- A Mixed Methods Study

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Abstract

Background

Peripheral Arterial Disease (PAD) is an increasingly prevalent long-term illness globally. The Ankle Brachial Pressure Index (ABPI) is a well-established, simple, relatively quick, inexpensive and non-invasive assessment useful in diagnosing and quantifying PAD. International guidelines have supported its use in both secondary and primary care, stating that it has a critical role in assessment and management of patients with PAD. Though many theoretical benefits exist, ABPIs are underutilised in general practice. No extensive literature has investigated its longitudinal usefulness in this setting.

Aims

The aims were to describe why and how ABPIs are being used at Mosgiel Health Centre (MHC) and to assess whether ABPI use is associated with a change in clinical management. The study also aimed to explore perspectives of health professionals on the role of the ABPI.

Methods

This study used quantitative and qualitative methods. The quantitative arm used ten years of electronic practice data from MHC. The qualitative arm analysed one-to-one interviews with health care professionals, mainly General Practitioners (GPs), on their experience and view of the usefulness of the ABPI in general practice.

Results

The quantitative arm assessed patients who had ABPIs at MHC between 2006 and 2015. This is the longest international retrospective study of ABPI patients followed-up in general practice. Of all 379 ABPIs, over half were completed to investigate patient eligibility for compression therapy for venous disease and just under half were completed to investigate perceived arterial-related symptoms. Between 21.6-24.5% of all ABPI values indicated PAD leading to 23.2% of patients being reassured of having no PAD, 16.9% of patients managed as having PAD, and 17.7% requiring additional management or investigation. Approximately 73% of ABPI patients were not referred to secondary care.

The qualitative arm showed that most GPs are aware of the main benefits of performing ABPIs in primary care; including to rule in or out PAD to aid management choices, to aid referral and for triage purposes. Many practical barriers to use were discussed, including cost, time and...
low patient need. When considered together, barriers outweighed benefits for many GPs when determining whether ABPI was justified for use. However, both primary and secondary care health professionals agreed that there was a role for ABPI use in the community if barriers were overcome. Most interviewees agreed that having a ‘specialised’ professional to complete ABPIs would be most beneficial for patients in the community.

Conclusions

1. Common indications for ABPI use at MHC included to guide management of venous disease, and to investigate suspected arterial symptoms.

2. Of the 379 patients having ABPIs tests, 26.39% were referred to the secondary care vascular department. ABPI use prevented inappropriate referrals in over 70% of cases.

3. There was consensus among GPs that ABPI use is beneficial.

4. Many GPs named similar, practical barriers for why ABPIs are not more commonly done.

5. There is a role for ABPIs in primary care, although it may be more practical if it became a specialised tool for an individual clinician to complete for a community.
Presentations

What do health professionals think about the Use of the Ankle Brachial Pressure Index (ABPI) in Primary Care? T Ding, S Dovey, H Lloyd. Presented at the National Primary Care Research Weekend in Cromwell, New Zealand, on 13th September 2015.

The Use of the Ankle Brachial Pressure Index (ABPI) in General Practice. T Ding, S Dovey, H Lloyd. Presented at the Department of General Practice and Rural Health Conference Seminar Series in Dunedin, New Zealand, on 22nd November 2015.
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<th>Abbreviation</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>ABI</td>
<td>Ankle Brachial Index</td>
</tr>
<tr>
<td>ABPI</td>
<td>Ankle Brachial Pressure Index</td>
</tr>
<tr>
<td>ACC</td>
<td>American College of Cardiology</td>
</tr>
<tr>
<td>AHA</td>
<td>American Heart Association</td>
</tr>
<tr>
<td>BP</td>
<td>Blood Pressure</td>
</tr>
<tr>
<td>BPAC</td>
<td>Best Practice Advocacy Centre</td>
</tr>
<tr>
<td>CSV</td>
<td>Comma Separated Values [digital file format]</td>
</tr>
<tr>
<td>DALY</td>
<td>Disability-Adjusted Life Years</td>
</tr>
<tr>
<td>DP</td>
<td>Dorsalis Pedis [Artery]</td>
</tr>
<tr>
<td>DVT</td>
<td>Deep Vein Thrombosis</td>
</tr>
<tr>
<td>FDA</td>
<td>USA Food and Drug Administration</td>
</tr>
<tr>
<td>GP</td>
<td>General Practitioner</td>
</tr>
<tr>
<td>ICD-10</td>
<td>International Statistical Classification of Diseases and Related Health Problems 10th Revision</td>
</tr>
<tr>
<td>LEAD</td>
<td>Lower Extremity Arterial Disease</td>
</tr>
<tr>
<td>MHC</td>
<td>Mosgiel Health Centre</td>
</tr>
<tr>
<td>MoH</td>
<td>Ministry of Health</td>
</tr>
<tr>
<td>MRCGP</td>
<td>Membership of the Royal College of General Practitioners [Qualification]</td>
</tr>
<tr>
<td>NHC</td>
<td>National Health Committee [of New Zealand]</td>
</tr>
<tr>
<td>NICE</td>
<td>National Institute for Health and Care Excellence</td>
</tr>
<tr>
<td>NZ</td>
<td>New Zealand</td>
</tr>
<tr>
<td>NZGG</td>
<td>New Zealand Guidelines Group</td>
</tr>
<tr>
<td>NZSEI</td>
<td>New Zealand Socio-Economic Index</td>
</tr>
<tr>
<td>NZWCS</td>
<td>New Zealand Wound Care Society</td>
</tr>
<tr>
<td>PAD</td>
<td>Peripheral Arterial Disease</td>
</tr>
<tr>
<td>PAOD</td>
<td>Peripheral Arterial Occlusive Disease</td>
</tr>
<tr>
<td>PHO</td>
<td>Primary Health Organisation</td>
</tr>
<tr>
<td>PMS</td>
<td>Patient Management System</td>
</tr>
<tr>
<td>PVD</td>
<td>Peripheral Vascular Disease</td>
</tr>
<tr>
<td>PT</td>
<td>Posterior Tibial [Artery]</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
</tr>
<tr>
<td>--------------</td>
<td>-------------</td>
</tr>
<tr>
<td>PVR</td>
<td>Pulse Volume Recording</td>
</tr>
<tr>
<td>s.d.</td>
<td>Standard Deviation</td>
</tr>
<tr>
<td>SIGN</td>
<td>Scottish Intercollegiate Guidelines Network</td>
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<tr>
<td>TASC II</td>
<td>Trans-Atlantic Inter-Society Consensus for the Management of PAD II [guideline]</td>
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<td>United States of America</td>
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<td>WHO</td>
<td>World Health Organisation</td>
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Chapter 1: Introduction to Thesis

The increasing health burden of long-term conditions is a well-established challenge the world is working to deal with. Patients may live with long-term conditions for decades, resulting in ongoing impairments and insults to the physical, emotional and spiritual aspects of their lives. Not only is this a large burden on themselves but also on the wider community and national health systems as a whole.

Peripheral Arterial Disease (PAD) is an atherosclerotic long-term condition of public health importance, where in developed countries almost 20% of the population aged >75 years is afflicted. This number seems to be rising slowly over time with aging populations and improved treatment but PAD is often underdiagnosed and undertreated globally. The condition may manifest clinically as claudication, restricted mobility, or critical ischemia, and in some people results in limb amputation or death. Patients with PAD have an increased risk of fatal cardiovascular events, with myocardial infarction accounting for up to 60% of PAD-related mortality.

In the USA, PAD alone accounted for 2.3% of total health spending in 2001 ($4.37 billion). In New Zealand (NZ) it accounted for approximately 5.2% of total cardiovascular health spending in 2011-12 ($26 million) excluding associated complications. Despite the many statistics regarding PAD, perhaps the most difficult fact to comprehend is that PAD is preventable, so for every person who dies because of a PAD-related cardiovascular event, preventable moments have been lost.

The Ankle Brachial Pressure Index (ABPI) is a basic, relatively quick, reliable and safe investigative assessment that has been used extensively for decades in the diagnosis and monitoring of PAD in secondary care. It involves relatively little equipment and operators need little training to achieve competence. This makes the ABPI easy for health care professionals to use in many settings. Further, the ABPI allows clinicians to obtain an objectively measured numerical ratio, to measure severity of disease. The ABPI value obtained by the investigation may inform timely management changes which can lead to a limb or life saved.

Nevertheless this investigative tool is not widely used in primary care, in particular general practices. In the literature, there is a lack of longitudinal studies of patients having undergone ABPIs in primary care. Therefore there is no long term data showing the likely benefits in general practice and so a lack of evidence to support its use. Further, potential practical
difficulties such as time or lacking the relevant skills has been alluded to in many papers but not extensively described in the literature. Therefore, there are knowledge gaps about how the ABPI can be used in general practice.

This thesis reviews the body of literature which surrounds the ABPI since its inception in the 1950s-60s and discusses two complementary arms of a mixed methods study aiming to expand knowledge and evidence regarding ABPI use in New Zealand general practice. The quantitative arm of the study examines the use of ABPI in one large Dunedin general practice over ten years by analysing descriptive data on all 379 ABPI tests completed at the practice during this time. The second qualitative arm analyses one-to-one interviews with health care professionals, mainly general practitioners (GPs), regarding their experience with, and view on, the usefulness of the ABPI in their workplaces. Both arms contribute to an overall assessment of how the ABPI has been used in general practice already, and provide the opportunity for comment on the suitability of its use in this setting. Ultimately, the underlying question is whether testing patients’ ABPI in general practice can make a difference in preventing morbidity and mortality for the increasing number of patients living with PAD in New Zealand.

**Overarching Aims of this Research:**

1. To establish from the published literature if, why and how the ABPI has been and is being used already, in particular in general practice, and what the consequences of its uses have been.

2. To describe characteristics of patients undergoing ABPI at the Mosgiel Health Centre (MHC) over the last ten years, and consider the influence of this test on their clinical management.

3. To provide context by discussing the views, prior experience and opinions of local health professionals regarding the ABPI in general practice.
Chapter 2: Literature Review

2.1 Introduction to Literature Review

There is a substantial literature regarding both Peripheral Vascular Disease (PVD) and ABPIs dating back to the 1950s. Existing research has resulted in many published national guidelines and guidance documents pertaining to clinical assessment and management of the illness. However, no follow-up data on patients who have had an ABPI assessment could be identified in the literature. This chapter evaluates published research surrounding the ABPI in an attempt to understand its use and to determine what is known about its efficacy.

2.2 Search Strategy, Search Scope

The search strategy for the literature review comprised of two main tasks:

The first task was to create a specific research question and literature review aims. Following an initial broad review of the literature and discussion with two supervisors, the following research question was developed: What is the usefulness of ABPIs in primary care? The literature review therefore aimed to investigate, review and summarise:

(A) What is known about PVD, in specific PAD? (See Section 2.3 Peripheral Vascular Disease (PVD) and Peripheral Arterial Disease (PAD))

(B) What is already known about the ABPI, both in general and within primary care? (See Section 2.4 Ankle Brachial Pressure Index (ABPI))

The second task was to systematically search for relevant studies. The following databases were used: Medline (Ovid), PubMed (National Library of Medicine), Web of Science Core Collection (Thomson Reuters), Scopus and Google Scholar. All the databases cover a wide variety of medical disciplines. Furthermore, the grey literature was searched (including clinical guidelines, guidance articles, reports, reviews and other articles not published in peer-reviewed journals). Hand searching was included when recurring articles were referred to by the literature.

The search terms used key words relating to three domains: (1) the ankle brachial pressure index itself, and covered terms including ‘ABPI’, ‘ankle brachial pressure index’, ‘ABI’, ‘ankle brachial index’, ‘ankle arm index’, ‘ankle brachial’; (2) key words relating to peripheral vascular disease, including ‘peripheral vascular disease’, ‘peripheral arterial occlusive disease’,
‘peripheral arterial disease’, ‘lower extremity arterial disease’ and corresponding acronyms (such as ‘PVD’, ‘PAOD’, ‘PAD’, ‘LEAD’); and (3) key terms relating to primary care, such as ‘primary care’, ‘primary health care’, ‘general practice’, ‘family practice’ and ‘ambulatory care’. The three domains were combined using Boolean operators to find literature pertaining to all three subject areas together. Supplementary key terms were added where more specific information regarding ABPIs was required, including ‘history’, ‘technique’, ‘effectiveness’, ‘limitations’, ‘indications’, and ‘New Zealand’.

The body of literature was narrowed in scope to include papers that were recent (the last ten years), older than ten years but cited often by later research, or papers specifically relating to a subtopic (e.g. historical papers first explaining ABPI).

The boundaries of the literature search included content related to ABPI use and its applicability to PAD. Surrounding topics such as related cardiovascular and other conditions or events (e.g. diabetes, myocardial infarction) are discussed, but not in detail as they lie outside the scope of this literature review.

The literature search was not restricted by language or publication descriptors.

All searches were conducted between November 2014 and January 2015, and a final review of the more recent literature was conducted in September 2015.

### 2.3 Peripheral Vascular Disease (PVD) and Peripheral Arterial Disease (PAD)

#### 2.3.1 Introduction and Definitions

PVD is a broad term defined as any non-cardiac disease affecting the circulatory system. It encompasses multiple pathophysiological manifestations that affect many vessel types: arterial, venous and lymphatic. Aetiologies include: organic pathologies, structural pathologies, widespread systemic disease (e.g. systemic lupus erythematosus) as well as less-specific functional changes (e.g. vessel spasms, Raynaud’s). The resultant pathway is a narrowing of peripheral vessels compromising blood (or lymph) circulation to and from extremities, bowel and other viscera.

PVD can be specified further into PAD, which defines disease specific to non-coronary and non-carotid arterial vessels. The 2005 joint American College of Cardiology (ACC) and American Heart Association (AHA) guidelines define PAD as encompassing a “range of
noncoronary arterial syndromes which are caused by altered structure and function of the arteries that supply the brain, visceral organs and the limbs.\textsuperscript{16}

Causes of PAD tend to be organic in nature, most commonly due to atherosclerosis or fatty build-up in the inner walls of arteries, explaining the synonymous term Peripheral Arterial Occlusive Disease (PAOD). PAD commonly affects the arteries of the legs (lower extremities).\textsuperscript{4} Left untreated PAD can be limb-threatening, leading to gangrene and potentially the need for amputation. Lower extremity PAD is the third leading cause of atherosclerotic cardiovascular illness after stroke and coronary heart disease and greatly increases mortality risk from all major cardiovascular events.\textsuperscript{21}

Fortunately, as with other atherosclerotic diseases, progression of PAD is preventable.\textsuperscript{9} It can be diagnosed and monitored with thorough clinical history and examination and confirmed reliably using the ABPI (see Section 2.4 Ankle Brachial Pressure Index (ABPI)). PAD is still often underdiagnosed in clinical practice.\textsuperscript{22}

### 2.3.2 Epidemiology and Public Health Relevance

Quantifying global and local burdens of disease for long-term conditions such as PAD provides insight into the scope of the issue. It also emphasises the increasing need for more effective solutions to management as countries face increasing PAD prevalence. The following section describes existing global and New Zealand knowledge regarding PAD prevalence.

#### 2.3.2.1 Global Data

PAD affects 12-14\% of the general population in many developed countries.\textsuperscript{4, 8, 23, 24} The prevalence of PAD increases significantly with increasing age. In people aged >60 years in the UK, prevalence is around 10\% of the general population.\textsuperscript{4} In people aged >75 years from the same population, prevalence reaches 20\%.\textsuperscript{4} Similarly, a section of the German Epidemiology Trial on Ankle Brachial Index (getABI) study examined 6,880 participants aged >65 years demonstrated a 21\% prevalence of PAD in this population.\textsuperscript{25}

A French study found that prevalence increased up to 38\% among people who are considered at risk of PAD (see Section 2.3.6 Risk Factors).\textsuperscript{26}

There was no significant variation in total PAD prevalence between men and women.\textsuperscript{27, 28}
Fowkes et al conducted a recent systematic review of 34 community-based studies to estimate global epidemiology of PAD.\textsuperscript{21} PAD was defined as an ABPI value <0.9 (the definition that most studies use).\textsuperscript{28} Approximately 202 million people globally were estimated to have PAD in 2010.\textsuperscript{30} It was determined that one in ten people aged >70 years and one in six people >80 years have PAD, globally.

The review covered populations in both high and low income countries. Of the 202 million, the majority (70%) were from low to middle income countries including 54.8 million in Southeast Asia and 45.9 million in the western Pacific Region.\textsuperscript{30} The Southeast Asia region had the largest number of people living with PAD of all World Health Organisation (WHO) regions in 2010.\textsuperscript{21} Fowkes et al also found that PAD was equally prevalent in men and women at all ages between 45 and 89 years in high income countries. However, there was some discordance in low to middle income countries where females were estimated to have higher PAD prevalence. This may be confounded by differing age and gender proportions in low to middle income countries. Tables 1 and 2 summarise prevalence of PAD for people in high and low to middle income countries respectively.

**Table 1: Prevalence of PAD by Age and Sex in High Income Countries**\textsuperscript{30}

<table>
<thead>
<tr>
<th>Prevalence</th>
<th>Male (%)</th>
<th>(confidence interval)</th>
<th>Female (%)</th>
<th>(confidence interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Young (45-49 years)</td>
<td>5.28%</td>
<td>(3.38-8.17)</td>
<td>5.41%</td>
<td>(3.41-8.49)</td>
</tr>
<tr>
<td>Middle (60-64 years)</td>
<td>8.82%</td>
<td>(6.85-11.28)</td>
<td>8.60%</td>
<td>(6.65-11.05)</td>
</tr>
<tr>
<td>Older (85-89 years)</td>
<td>18.83%</td>
<td>(12.03-28.25)</td>
<td>18.38%</td>
<td>(11.16-28.76)</td>
</tr>
</tbody>
</table>

**Table 2: Prevalence of PAD by Age and Sex in Low to Middle Income Countries**\textsuperscript{30}

<table>
<thead>
<tr>
<th>Prevalence</th>
<th>Male (%)</th>
<th>(confidence interval)</th>
<th>Female (%)</th>
<th>(confidence interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Young (45-49 years)</td>
<td>2.89%</td>
<td>(2.04-4.07)</td>
<td>6.31%</td>
<td>(4.86-8.15)</td>
</tr>
<tr>
<td>Middle (60-64 years)</td>
<td>5.47%</td>
<td>(4.40-6.48)</td>
<td>8.87%</td>
<td>(7.53-10.41)</td>
</tr>
<tr>
<td>Older (85-89 years)</td>
<td>14.94%</td>
<td>(9.58-22.56)</td>
<td>15.22%</td>
<td>(10.08-21.02)</td>
</tr>
</tbody>
</table>

Further, in high income countries, people aged >55 years made up the largest proportion of people with PAD. Conversely, in low to middle income countries, PAD was more prevalent in the population aged <55 years.\textsuperscript{30} This reflects differing age structures in different parts of the world.
When PAD prevalence in 2000 and 2010 were compared, a 23.5% increase was found. This has been described as a ‘global pandemic’. Of most striking difference was the increase in PAD in older age groups. In particular, an increase of over 35% occurred among people aged >80 years between 2000 and 2010. The increasing life expectancy of people in low and middle income countries in the last decade probably influenced this finding.

Despite the large prevalence changes, there is still likely to be an underestimation of the true prevalence of PAD because the majority of people living with PAD are asymptomatic and often are not diagnosed immediately, leading to underdiagnosis (see Section 2.3.5 Clinical Aspects). Additionally, many descriptive epidemiological studies have defined PAD based on ABPI values alone, without the use of other methods (such as toe pressures or duplex ultrasound). Relying on the ABPI assessment alone will mean that inherent limitations should be taken into consideration when interpreting prevalence findings (see Section 2.4.7 Limitations of the ABPI). Moreover, different methods of ABPI determination are possible, and this can profoundly influence prevalence patterns seen in different studies. More in depth surveillance strategies and research may be required to assess the disease prevalence more fully and accurately in the future.

2.3.2.2 New Zealand

The National Health Committee (NHC) provides routine analysis of health conditions in NZ. The NHC summarises data from several NZ surveillance data sets and studies to inform the government in making priorities to improve health outcomes and efficiency. The main sources of information used by the NHC include: the National Minimum Dataset of Hospital Separations, the New Zealand Burden of Disease Study, New Zealand population-based surveys and the New Zealand Health Tracker database (a New Zealand health census). The following summarises the most recent national epidemiological data about PVD from the NHC.

In the 10 years to 2008, the New Zealand Health Tracker database showed the prevalence of PVD as being 416 per 100,000. This equals 17,000 individual cases per year. Prevalence was higher in males than in females (491 vs 347 per 100,000 respectively). Similar to global studies, prevalence increased with advancing age. Ethnicity data showed that prevalence was higher in non-Māori than in Māori (438 vs 269 per 100,000 respectively).

Based on 2006 data, 1,300 Disability-Adjusted Life Years (DALYs) were attributed to PVD in NZ, making up 1% of overall DALYs in that year. There were more than 100 PVD-associated deaths in 2006, approximately 1% of the total all-cause mortality rate in NZ that year. The age
group ‘over 85 years’ contributed 22% of total DALYs attributed to PVD and over 50% of PVD related deaths.

Health utilisation and cost analyses estimated that $26 million was spent on PVD in 2011-12. This was comprised of costs for 2,409 hospitalisations for 1,859 patients (1.3 hospitalisations per patient) lasting an average of 1.7 days. To put this in perspective, pulmonary embolism and venous thromboembolism accounted for $14 million of NZ expenditure together. A single hospitalised individual with PVD is estimated to cost the health system an average of $14,100.

The NHC and the Ministry of Health (MoH) recognise the public health importance of cardiovascular diseases in general, acknowledging PAD as one of the contributors. One way the NHC and MoH have addressed cardiovascular disease management includes creating national health targets for heart checks (cardiovascular risk investigations). For example, a past national target included 90% of the eligible population having received a heart check by 2014. Still, it seems that there is no national intervention targeted solely at PVD, and nothing currently being done to contain increasing prevalence trends. Investigation into the use of the ABPI in primary care could help to inform one possible method of ameliorating the problem.

### 2.3.3 Pathophysiology

Vascular disease is responsible for the highest proportion of all human diseases. The term ‘vascular disease’ includes both central (cardiac) and peripheral vascular disease. PVD has a number of biological causes. To understand the pathological mechanisms behind the development of PVD, it is first necessary to understand the physiology of normal vessels, and their response to injury or damage.

#### 2.3.3.1 Arterial Vessel Anatomy and Pathophysiology

A normal arterial vessel is made up of three layers: an ‘intima’ with an endothelial cell lining, a ‘media’ primarily made of smooth muscle, and a connective tissue rich ‘adventitia’. Not all vessels in the body are the same however. They have different compositions to accommodate different functions. This means that different pathologies can occur in different vessels of the body.

Arterial disease includes all pathologies that impede blood flow through mechanical obstruction or by causing abnormal vascular reactivity. These mechanisms cause ischemia due
to the reduced ability for tissue metabolism. An exclusive list of causes includes arteriosclerosis, atherosclerosis obliterans, atherothrombosis, functional vasoreactive arterial disorders, arteritic disorders, vasculitides and aneurysms. Degenerative disorders such as in Marfan syndrome can also cause arterial disease and PAD. Claudicating pain is caused by PAD due to a build-up of lactic acid in active muscles when there is a switch from aerobic to anaerobic metabolism as a consequence of lack of oxygen.

Arteriosclerosis is the commonest arterial pathology (namely atherosclerosis). Arteriosclerosis means a “hardening of the arteries” reflecting abnormal wall hypertrophy and loss of elastic property. There are three patterns of arteriosclerosis:

- **Arteriolosclerosis**- which affects small-sized arteries and arterioles, often caused by hypertensive damage and/or diabetes mellitus.

- **Mönckeberg medial calcific sclerosis**- where muscular arteries are calcified (radiologically visible) but do not encroach into the lumen and so are not generally clinically significant.

- **Atherosclerosis**- Greek for “gruel/hardening”, characterised by atheromatous lipid-cholesterol plaques in the intima covered by fibrous caps protruding into the lumen. Atherosclerosis commonly affects large and medium sized arteries and is the most common type of arteriosclerosis (see Figure 1).

PAD also increases thrombogenicity secondary to platelet activation, increasing the risk of ischaemic cardiovascular events, commonly seen sequelae in PAD patients (see Section 2.3.9 Complications).
PAD is often a polyvascular disease, meaning atherosclerotic disease is present in more than one vascular area. This means that diagnosing PAD is not only useful so that intervention can be implemented to treat the site affected, but intervention can be introduced to avoid other atherothrombotic cardiovascular events from occurring.

The Reduction of Atherothrombosis for Continued Health (REACH) registry is the largest international PAD registry study conducted to date. The registry collected data from over 67,800 patients from 44 countries to establish concordance of atherosclerotic risk factors and polyvascular disease.34 The study showed that atherothrombotic patients from around the world had similar risk factor profiles.34 Of those with symptomatic atherothrombosis, 15.9% had symptomatic polyvascular disease.34 Vidakovic et al studied 431 patients with known PAD using ultrasound measurements and revealed that only 29% had a single affected arterial territory as compared to 45%, 23% and 3% having two, three and four affected arterial territories respectively.35 In the subset of those with symptomatic PAD, 39% were found to have had at least one other territory affected other than that already known initially to the recruiters. These studies show that atherosclerotic PAD commonly affects multiple sites and so should be best treated as a systemic disease.
2.3.3.2 Venous Vessel Anatomy and Pathophysiology

Venous vessels are larger in luminal size, larger in diameter and have less well organised walls than arterial vessels.\(^{36}\) They also have lower flow velocities within them. These properties allow the venous system to have larger capacitance, constituting over two thirds of all systemic blood. Consequently they are not prone to the atherosclerotic diseases that occur in arterial channels. Conversely, these properties mean they are more prone to dilation, compression, and the effects of gravity in causing venous pooling.

Venous disease includes all pathology which involves changes in venous vessel anatomy and function. Varicose veins and thrombophlebitis (usually of deep veins) account for 90% of total venous disease.\(^{32}\) Other venous diseases include venous thromboembolism, valvular incompetence, venous ulcers, deep venous thrombosis, pulmonary embolism, and post thrombotic syndrome.

Venous incompetence and consequential venous ulceration are common lower limb vascular conditions with treatment costs accounting for 1% of the healthcare budget in Western countries.\(^{37,38}\) Lifestyle modification and compression therapy are mainstays of treatment for venous pathologies to improve venous return, often implemented in general practice.\(^{38,39}\)

While ABPIs are not used at all to detect venous pathologies, they are used to detect mixed vessel disease (arterial and venous disease together) when patients present with venous-related symptoms (see Section 2.4.3.3 Determination of Ulcer Management). Verma et al emphasises the importance of determining the presence of mixed disease before embarking on venous intervention.\(^{40}\) ABPI use before compression is also recommended by the New Zealand Wound Care Society.\(^{39}\)

2.3.3.3 Lymphatic Vessel Anatomy and Pathophysiology

For completeness, lymphatic anatomy and disease is mentioned, but there is little research regarding lymphatic PVD. Lymphatic vessels are thin-walled and their endothelium lining helps to drain excess interstitial fluid (lymph).\(^{41}\) Besides this, the vessels also carry mononucleoeytes and proteins. This lymph mixture becomes filtered into lymph nodes promoting an inflammatory or infection fighting response.

Lymphatic diseases are rare (least common PVD) and tend to be caused by secondary processes rather than primary ones.\(^{41}\) Lymphangitis is caused by a secondary process of inflammation arising when infectious agents spread through the channels. Primary familial
and secondary lymphoedema can cause ulcers and change the connective tissue structure around skin resulting in altered function and a brawny induration (peau d’orange) appearance.

ABPIs have no role in detecting or managing lymphatic diseases so discussing lymphatic disease in any more depth is beyond the scope of this thesis. Lymphatic disease is excluded from this study as the focus is on the ABPI and PAD.

2.3.4 Classification

2.3.4.1 Classification by Clinical Categorisation Systems

Clinically, PAD can broadly be split via symptomology into:\n
- Asymptomatic PAD- patients are diagnosed via ABPI but no symptoms are reported (patients may have atherosclerotic narrowing which does not greatly impede blood flow to the extremities).
- PAD with intermittent claudication- patients have discomfort in the calf muscles with exertion that resolves with a few minutes of rest. This is due to failure of meeting oxygen demands on exertion.
- Chronic limb ischaemia- patients have long-term ongoing pain at rest due to restricted blood flow causing damage to the tissues.
- Acute limb ischaemia- a surgical emergency where patients have great pain in their limbs due to a significant restriction of blood flow which is causing damage to the tissues.

Fontaine was the first to classify PAD into clinical stages, developing the Fontaine classification staging system in 1954.\n
Stages range from I (asymptomatic) to IV (ulceration or gangrene). The Rutherford-Baker classification 1997 is a more recent and updated classification system which uses six categories as opposed to four. Table 3 compares and contrasts both systems. Table 4 shows the Rutherford Classification system for acute limb ischemia.

The ABPI can also be used clinically classify ABPI into mild, moderate and severe PAD. The ABPI classification system is discussed in more depth in Section 2.4.5.4 Interpretation.
**Table 3: Comparison of Fontaine and Rutherford-Baker Classification Systems for Chronic Limb Ischaemia**

<table>
<thead>
<tr>
<th>Fontaine Classification</th>
<th>Rutherford-Baker Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade</td>
<td>Clinical description</td>
</tr>
<tr>
<td>I</td>
<td>Asymptomatic</td>
</tr>
</tbody>
</table>
| Ila | Mild (intermittent) claudication | I | 1 | Mild (intermittent) claudication | -Completes treadmill exercise test  
- Ankle BP following test >50mmHg but at least 20mmHg lower than resting value |
| Iib | Moderate to Severe (intermittent) claudication | I | 2 | Moderate (intermittent) claudication | -Between categories 1 and 3 |
|   |   | II | 3 | Severe (intermittent) claudication | -Cannot complete treadmill test and;  
- Ankle BP after exercise <50mmHg |
| III | Ischemic rest pain | II | 4 | Ischaemic rest pain | -Resting Ankle BP <40mmHg  
- Ankle or metatarsal PVR is flat or barely pulsatile  
- Toe BP <30mmHg |
| IV  | Ulceration or gangrene | III | 5 | Minor tissue loss - non-healing ulcer, focal gangrene with diffuse pedal ischaemia | -Resting Ankle BP <60mmHg  
- Ankle or metatarsal PVR is flat or barely pulsatile  
- Toe BP <40mmHg |
|   |   | III | 6 | Major tissue loss - extending above transmetatarsal level, functional foot no longer salvageable | (as above) |

BP= Blood Pressure  
PVR= Pulse Volume Recording  
*Treadmill test= 5 minutes at 2mph on a 12% incline  

NB: Under the Rutherford-Baker classification Grades II and III, and Categories 4, 5, 6 are all termed “chronic critical ischaemia”
<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
<th>Findings</th>
</tr>
</thead>
</table>
| I        | Viable- not immediately threatened       | - Clinically: Nil sensory loss or muscle weakness  
|          |                                          | - Doppler signals audible for arterial and venous vessels                 |
| IIa      | Marginally threatened- salvageable with  | - Clinically: Minimal sensory loss at toes only  
|          | prompt treatment                        | - Doppler signal may be inaudible in arterial vessels                    |
| IIb      | Immediately threatened- salvageable with  | - Clinically: Sensory loss detected, may have rest  
|          | immediate treatment                     |     pain, and/or mild to moderate muscle weakness  
|          |                                          |     - Doppler signal may be inaudible in arterial vessels                 |
| III      | Irreversible- major tissue or nerve      | - Clinically: Profound sensory and motor loss  
|          | damage                                   | - Doppler signal inaudible in both arterial and venous vessels           |

### 2.3.4.2 Classification by International Statistical Classification Codes

The International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10) is a free medical reference coding system created by the WHO to systematically code all known health conditions, abnormal findings, complaints or circumstances. Having a standardised coding system aids in comparability during analysis of research data.

ICD-10 codes have been applied to the New Zealand Health Tracker, a national health census which links data in the NHC and MoH collections. A recent NHC report on cardiovascular diseases published on December 2013 included the following ICD-10 codes under PAD:

- I70.2 Atherosclerosis of arteries of extremities
- I72.0 Other aneurysm and dissection [of arteries of the upper or lower extremities]
- I73.9 PVD, unspecified
- I74.0 Arterial embolism and thrombosis

The above codes fall under category IX: “Diseases of the circulatory system”, and more specifically under the subcategory I70-I79: “Diseases of arteries, arterioles and capillaries”. These codes cover the most common forms of PAD, but are highly selected and fail to incorporate rarer related conditions sometimes considered PAD too.

ICD-10 codes are also used in the New Zealand secondary care system. PAD and all other conditions are coded on every discharge summary completed in New Zealand hospitals.
2.3.5 Clinical Aspects

The aim of management for PAD is to reduce symptoms, improve functioning and where possible reverse or diminish progression. Preventive strategies are important for primary prevention (lowering blood pressure, the use of statins, smoking cessation) and secondary prevention of unwanted cardiovascular events and complications (through treatment intensification). As with every patient consultation, a thorough history and examination is pivotal in the analysis of patients’ problems to formulate appropriate treatment plans.

2.3.5.1 Clinical History

PAD has a broad spectrum of disease progression from asymptomatic through to painful limb-threatening ischemia. A comprehensive and detailed history is required for clinicians to determine current PAD severity and impairment, along with patients’ overall longitudinal illness experience.

The history should include a targeted vascular review of symptoms; assessing any claudication, walking or exertional impairment, ischemic rest pain, site of pain, description of pain and any non-healing wounds. A review of systems should include wider cardiovascular symptoms and risk factors such as smoking status. If the presenting complaint was not of vascular origin, but such that other cardiovascular risk factors are identified, the 2005 ACC/AHA guidelines strongly encourage a vascular history and assessment in these circumstances as well.

Patients with symptomatic PAD classically present with intermittent claudication. Intermittent claudication is defined as continuous exercise-induced discomfort and may be described by patients as pain when walking a certain distance, with a greater pace, or up a slope. It is generally relieved with rest as blood flow returns to match demand. Claudicating pain may lead to lifestyle limiting consequences resulting in a more sedentary lifestyle than preferred. The distance walked should be documented so that changes in severity can be tracked over time. Symptoms that come on with less effort and distance may mark advances in disease.

However, classical intermittent claudication is described by only 10-35% of PAD patients. Most patients who have claudicating or resting leg pain actually exhibit atypical symptoms. This could in part be due to comorbidities, sedentary lifestyles, and alteration in pain pathways. Descriptions may include discomfort, tightness, a burning sensation or fatigue in the legs.
Pain at rest (or rest pain) is an indication of severe vessel narrowing, and commonly requires immediate specialist review and intervention to reperfuse the limb. If metabolic demands of the muscles of the lower extremity at rest are exceeding oxygen supply received, this results in anaerobic metabolism and ultimately tissue ischaemia causing pain. Patients experiencing rest pain often relieve symptoms by placing the legs in a dependent position such as over the bedside when occurring at night, or by standing to allow gravity to aid perfusion.

Patients may also present with lower extremity ulcers, which may be arterial in origin. Arterial ulcers often seem to be ‘non-healing’ due to inherent poor circulation. Ischemic ulcers may start as minor (often traumatic) wounds, but that then fail to heal. Non-healing wounds may lead to pain on light pressure (such as with clothing) or infection if not kept adequately clean. Arterial ulcers are often punched out and deeper in size than more common venous ulcers which are superficial and large.\textsuperscript{47, 48} It is important to define the aetiology of the ulcer to inform management \textit{(see Section 2.3.8 Management)}. Distinguishing the aetiology may be elicited on history taking, but a thorough examination should always be used to document the ulcer further to track ulcer progression.\textsuperscript{39}

Nonetheless, up to half of all PAD patients are asymptomatic.\textsuperscript{45} These patients are identified only when a screening ABPI or other vascular investigations are performed to uncover a PAD diagnosis. Detection of PAD in asymptomatic individuals may be of value because PAD is a risk factor for atherosclerotic disease elsewhere in the body \textit{(see Section 2.3.9 Complications)}, and patients may benefit from early intervention. In the \textit{PAD Awareness, Risk, and Treatment: New Resources for Survival (PARTNERS) programme}, only 1865 (29\%) of 6979 patients with risk factors for PAD had been diagnosed prior to study investigations. Based on this study, physician awareness of PAD in their patient populations is claimed to be very low.\textsuperscript{45}

The 2005 ACC/AHA guidelines suggest that the distribution of PAD presentations in patients over 50 years is as follows:\textsuperscript{16, 21, 49}

- 10-35\% exhibit classic claudication symptoms
- 40-50\% experience atypical leg pain
- 20-50\% are asymptomatic
- 1-2\% present with a threatened limb- such as with rest pain, gangrene (i.e. Rutherford categories IIa and IIb for acute PAD)
Based on the global estimate of 202 million people living with PAD by Fowkes et al, this would mean up to 100 million people have atypical leg symptoms.\textsuperscript{21}

Although a thorough history should document all of these important features, many guideline documents state that an ABPI assessment should be made to confirm or deny clinical suspicion of PAD elicited in the history.

2.3.5.2 Clinical Examination

The assessment of patients with vascular history should include a full vascular examination. A systematic approach should be used.

The examination should include recording of resting brachial blood pressures and assessing all relevant pulses, including femoral, popliteal, dorsalis pedis and posterior tibial pulses. Any dampening, delay or diminishing of a pulse could be a sign of disease and should be documented. Similarly, inter-arm pressures or pulse asymmetry should also be documented.

Palpation and auscultation of carotid and abdominal aortic pulsations may be included to investigate further vascular disease. Auscultation may reveal bruits indicating disease.

Foot inspection for wounds, colour, temperature, distal hair loss and skin integrity should be assessed for perfusion status.\textsuperscript{16}

The Buerger’s test is a commonly used assessment of arterial insufficiency. With the patient supine, clinicians lift the examining leg straight into the air superiorly. The angle between the patient and the leg when it becomes pale due to poor circulation is called the Buerger’s angle (or vascular angle).

Patients who show signs of abnormally cool peripheries, presence of bruits or pulse abnormalities have an increased risk of PAD. In asymptomatic patients, the presence of femoral bruit or any pulse abnormality are highly suggestive of PAD, with likelihood ratios being above three, described by Khan.\textsuperscript{50}

An evaluation of pain, pallor, pulselessness, paraesthesia and paralysis is often discussed in textbooks and is used to indicate PAD severity.\textsuperscript{36} It is possible to find pulses in some cases of peripheral limb ischaemia owing to a microvascular thrombosis as a cause of PVD, but this is rare.\textsuperscript{51}

Although clinical history and examination are necessary in every consultation with patients to give clinicians an impression of PAD, clinical examination findings alone are of only limited
value for diagnostic accuracy. Skin colour and temperature are influenced by individual characteristics (of both clinicians and patients) as well as the ambient environmental temperature. Pulse calculations may be incorrect due to inconsistency of technique and where clinicians feel a pulse from their own fingertips. Pulse examination alone misses up to half of all PAD cases. Therefore, there is a need for a more reliable assessment such as the ABPI investigation (see Section 2.4 Ankle Brachial Pressure Index (ABPI)). This can be used in conjunction with examination.

The National Institute for Health and Care Excellence (NICE) has developed a succinct and practical resource for clinicians to follow in the assessment and diagnosis of lower limb PAD. The pathway advises examination in individuals who have symptoms suggestive of PAD, who have diabetes, non-healing wounds, unexplained leg pain, or who are being considered for interventions to the leg or foot, including compression hosiery. Although a short guide, the pathway provides primary care clinicians with a brief explanation of the necessary aspects of vascular assessment. It also recommends use of the ABPI following examination.

2.3.6 Risk Factors

As PAD is generally attributed to atherosclerosis, risk factors for the condition are appropriately similar to that of other cardiovascular diseases. Internationally recognised risk factors for PAD include all of: \footnote{21, 52}

- Older age (>50 years)
- Diabetes mellitus
- Hyperlipidaemia
- Hypertension
- Cigarette smoking (previous and present)
- Previous or co-existing atherosclerotic disease

PAD patients have a high rate of co-existing atherothrombotic or cardiovascular disease. The getABI study showed an odds ratio of 1.8 for having any cerebrovascular event ever in PAD patients compared with non-PAD patients. \footnote{53} Similarly the odds ratio for having any cardiovascular event ever in PAD patients was 1.5. \footnote{53}
The 2005 AHA/ACA guidelines state that individuals at risk of lower extremity PAD, and whom the ABPI is recommended for, are patients:  

- Aged 50 years or below with diabetes and one other atherosclerosis risk factor (smoking, dyslipidaemia, hypertension)
- Aged 50-69 years and a history of smoking or diabetes
- Aged 70 years or older
- Having leg symptoms suggestive of claudication
- Having an abnormal lower extremity pulse examination, or
- Having known atherosclerotic coronary, carotid or renal artery disease

The 2011 ACCF/ACHA Guidelines recommend modifying the age for ABPI consideration to ≥65 years (rather than ≥70 years) in light of the getABI trial. This trial determined that 21% of the patients aged >65 years have diagnosed PAD (see Section 2.3.2 Epidemiology and Public Health Relevance).

2.3.7 Differential Diagnoses

When attempting to diagnose lower extremity pain, and in many cases of atypical claudication, clinicians must think widely about possible causes. Although common, atherosclerotic PAD may not be the correct diagnosis despite a perceived ‘clear’ history of claudicating limb pain.

Pain caused by spinal stenosis, arthritis, fibromyalgia, neuropathy, statin-induced myalgia and non-specific muscular pain should all be considered.

Often clinical clues may lead into deciphering aetiology. Typical claudication often affects older individuals, is predictable, is unlikely to vary between days, and affects muscle groups rather than joints. In younger patients who present with claudication with associated sores and Raynaud’s phenomenon, a low ABPI value may suggest thromboangiitis obliterans (Buerger’s disease) rather than lower extremity atherosclerotic PAD.

Difficulty may ensue when patients present with ‘pseudo-claudication’, that may be difficult to distinguish from true claudication. For example, pseudo-claudication is a cardinal feature of
pain in spinal stenosis. However subtle features, such as the discomfort relieved by sitting rather than by standing (as in PAD) may help to distinguish true claudication.\textsuperscript{54}

Furthermore, concurrent PAD with co-morbidity (such as diabetes or other chronic illnesses) could obscure a classic clinical picture. A full history and examination alongside a broad differential diagnosis are pivotal in determining whether features are most suspicious for PAD or for other conditions to determine best management. ABPIs may also aid this process.

### 2.3.8 Management

Managing patients with PAD combines skills in using recommended diagnostic and therapeutic interventions based on evidence-based guidelines as well as reasoned clinical judgment. It often depends on when the PAD is detected (early versus late), on symptomology in respect to co-morbidity, and on patient preference. The ultimate goal in management of PAD is to improve both functionality and quality of living.\textsuperscript{16}

Several guideline standards have been published regarding management pathways. The most widely cited and used include:

1. American College of Cardiology and American Heart Association (ACC/AHA) 2005 Guidelines\textsuperscript{16} with an ACC/AHA 2011 update\textsuperscript{18}
2. Trans-Atlantic Inter-Society Consensus for the Management of PAD II (TASC II) Guidelines 2007\textsuperscript{9}

Mohler compared the ACC/AHA and TASC II guidelines above and concluded that there was consensus in most areas, although there were differences regarding weighting of evidence to supplement recommendations.\textsuperscript{55}

In addition, several other guidelines have discussed management of PAD:

3. The very recent 2015 (American) Society for Vascular Surgery practice guidelines for atherosclerotic occlusive disease of the lower extremities\textsuperscript{56}
4. New Zealand Best Practice Advocacy Centre (BPAC) Guideline Article on ABPI use\textsuperscript{52}
5. National Institute for Health and Care Excellence (NICE) Lower limb PAD guidelines\textsuperscript{17}
All the above recommend the use of the ABPI in assessment of PAD, and that the interpretation of the ABPI value can determine the next best step in management.

Algorithms pertaining to ABPI values have been created to guide management. An ABPI value of <0.9 is considered diagnostic of PAD. Patients with severe PAD (<0.5) should generally be referred to secondary care where surgery may be considered to eliminate the blockage. An ABPI value of 0.9-1.2 is considered normal, and no further PAD management is deemed necessary. An ABPI of >1.2 may require further vascular tests such as Doppler waveforms or toe pressures to better evaluate these patients (see Section 2.4.5.4 Interpretation).

Despite these algorithms, individual tailoring is advised by several guidelines. Individualised treatment should be guided by patient comorbidities, severity of disease, functional impairment, anatomic variances and predictions on the success of any chosen management. To be considered an effective treatment, “a minimum threshold of over 50% likelihood of sustained efficacy for at least 2 years” is one suggested benchmark. For instance, there should be at least a 50% chance that a surgery being considered will decrease symptoms or reverse disease progression for at least the following 2 years without major complications.

The management of PAD should address the claudication symptoms and prevent disease progression. Medical interventions such as using the phosphodiesterase inhibitor cilostazol or xanthine derivative pentoxifylline have proven to be effective in improving ABPI. In other cases, surgical means such as angiographic techniques (with potential intervention such as angioplasty, atherectomy, stenting), other endovascular treatments or surgical revascularisation (such as bypass grafting) can effectively treat PAD.

All the guidelines emphasise the importance of cardiovascular risk factor modification and medical intervention to improve general cardiovascular outcome measures. ABPI values of <0.9 are associated with a three to six times increased risk of cardiovascular mortality. Conservative measures to modify risk factors include appropriate exercise therapy prescription, diet and nutritional guidance, smoking cessation, motivational interviewing, improved glycaemic control and general health education. Medical intervention measures include antidiabetic, antiplatelet, and antihypertensive treatment, and statins where appropriate. Cardiovascular risk management therapies and regimes are well-established in the literature as effective in reducing the risk of ischaemic and thrombotic events occurring.

It is also important to note the management of ulcers and wounds.
It is recommended that patients with ulcers and wounds should have an ABPI assessment to distinguish between arterial and venous or mixed pathology (see Section 2.4.3.3 Determination of Ulcer Management). Further, the ABPI value can indicate the best type of management for patients.

The most recent Accident Compensation Corporation review document endorsed by the New Zealand Venous Leg Ulcer Advisory Panel stated that the recommended treatment for venous ulcers is high compression bandaging. High compression elastic or inelastic multi-layer systems are more effective than low compression or single layer compression bandaging. Bandaging should be adequately graded, and should have protective padding at the tibial crest and malleoli. The document concludes that compression hastens the healing process for venous ulcers.

For ulcers with arterial pathology (based on ABPI results), referral to a vascular specialist is advised. Compression therapy is contraindicated in mixed or arterial ulcers where ABPI <0.7/0.8 because compression could occlude and compromise blood flow to the muscles and capillary beds. Therefore it has been argued that these patients (where ABPI values are <0.7/0.8) should be considered for percutaneous revascularisation for timelier wound closure.

Pain management may be required. Regular analgesia (such as paracetamol), management of oedema, elevation of wound, and using non-adherent wound dressings are advised.

Education on the condition (venous or arterial) is pivotal in encouraging patient compliance. Further, conservative advice such as walking (activating calf pumps, and increasing venous return) can reduce symptoms and complications.

Ideally, multidisciplinary teams involving primary care providers, medical and/or surgical specialists, podiatrists, diabetes specialists and other health care providers should be appointed in accordance with a patient-centred approach.

2.3.9 Complications

PAD can lead to loss of limb and loss of life, and progresses if not diagnosed and treated early. Complications include worsening claudication, functional impairment, critical limb ischaemia and non-fatal and fatal cardiovascular events. Figure 2 displays a schema for 5-year outcomes for PAD patients and the natural history of PAD syndromes.
2.3.9.1 Critical Limb Ischaemia

Around 1-2% of patients with PAD diagnoses may progress to develop critical limb ischaemia.\textsuperscript{16} This is characterised by severe resting ischaemic leg pain, non-healing wounds or gangrene which could necessitate limb amputation. It is predicted that 50% of patients with critical ischaemia will require revascularisation, 25% require aggressive medical intervention and 25% primary amputation.\textsuperscript{9} Further, patients with critical limb ischaemia have an annual mortality rate of 25\%.\textsuperscript{9}

2.3.9.2 Cardiovascular Disease and Mortality

Another key complication of PAD is the associated increased risk of ischaemic events. PAD patients are six times as likely to experience all-cause mortality within 10 years as non-PAD patients, whether symptomatic or not.\textsuperscript{54, 61} Specifically, the largest cause of mortality for PAD patients is coronary artery disease (40-60\%) followed by cerebrovascular disease (10-20\%).\textsuperscript{54} This means that PAD confers equal risk for a major vascular event as a past myocardial
infarction. Equally importantly, the severity of the PAD is correlated with poorer survival rates.

A 5-year prospective cohort study of 6880 participants in primary care demonstrated that patients with PAD were 1.7 times more likely than others to experience ischemic stroke. Further, it showed that people with PAD were 1.4 times more likely to experience nonfatal stroke and 2.5 times more likely to experience fatal stroke. Lower ABPI values were associated with increased risk for stroke. Another recent study identified a 2.8 times greater risk of cardiovascular mortality with a decline in ABPI value of 0.15 within a 10 year period. As a result, PAD should not be taken lightly, even if asymptomatic.

2.3.9.3 PAD & Diabetes

PAD and its complications can present additional challenges in patients with diabetes. PAD patients with concomitant diabetes:

- Have higher risk of cardiovascular mortality and morbidity
- Tend to be younger
- Tend to have PAD progress more rapidly
- Tend to have poorer outcomes following surgery

In addition, PAD patients with diabetes tend to be asymptomatic for a longer duration than PAD patients without diabetes. This may mean that PAD is detected at a later or more advanced stage. Consequently these patients may also be subject to a larger number of and riskier procedures than otherwise they should have had.

Early detection of PAD and risk factor management is pivotal to preventing complications for diabetic PAD patients.

2.4 Ankle Brachial Pressure Index (ABPI)

2.4.1 Introduction and Definition

The Ankle Brachial Pressure Index (ABPI, or ABI) is an objective measure of arterial blood flow and pressures in the lower extremities. It is considered the simplest, most effective tool to detect and diagnose PAD in a large population. The ABPI is crudely the ratio of the systolic
blood pressure in the ankle versus the brachial (arm) arteries. Pressures are obtained using standard blood pressure cuffs, a handheld Doppler ultrasound and probe.

In normal healthy patients, this ratio should usually be 1, meaning the blood pressure is equal in both the upper and lower extremities. If the ABPI is <1, there is suggestion of lower extremity PAD, caused most likely by atherosclerosis and a narrowing of arterial lumen. An ABPI value of <0.9 is diagnostic of PAD.17, 19

2.4.2 History of the ABPI

Doctors were investigating lower limb arterial pressures as early as 1930.69 However, theory behind the use of the ABPI was first documented by Californian doctor, Travis Winsor, in the 1950s.12 He described difference in pressure gradients in the extremities between normal and diseased legs and found a gradient of as much as 50-60mmHg distal to the site of an obstructed artery. Since Winsor’s description, ABPIs can now also be measured using a Doppler ultrasound (gold standard) and peripheral angiography techniques.16

The concept of the ABPI was popularized by Yao et al in 1969 who showed a marked difference in the pressure index between normal patients versus patients with proven occlusion, stenosis and atheroma (see Figure 3).70 The ABPI is now used internationally.5

Figure 3: The Ankle Systolic Pressure Index in Four Groups of Patients in 1969. Source: Yao et al, 1969. Reproduced with permission.70
2.4.3 Uses and Indications

The ABPI is a widely used assessment for several related but distinct purposes. The uses of the ABPI include aiding in diagnosis or exclusion of PAD, ongoing assessment in measuring PAD severity for management purposes, to guide management of ulcers to reduce the risks of compression in arterially compromised patients, informing cardiovascular risk status and also it can be used to screen for asymptomatic individuals.

2.4.3.1 Diagnosis or Exclusion of PAD

One of the primary uses of the ABPI is to diagnose or exclude PAD in patients who present with symptoms indicative of vascular pain (see Section 2.3.5 Clinical aspects). ABPI assessments follow standard vascular physical examinations in the evaluation of patients, and can confirm suspicions of PAD or atherosclerotic claudication found in the history.

The ABPI can also quantify severity of PAD. Lower values or ratios correspond to more severe disease (see Section 2.4.5.4 Interpretation). Measure of severity can convey level of urgency for revascularisation in secondary care.

The TASC II guidelines strongly recommend ABPIs are conducted in patients experiencing difficulty walking, patients aged 50-69 years (inclusive) with known cardiovascular disease risk factors, patients aged >70 years regardless of risk factors, and patients with an existing Framingham risk score of 10-20%. Similar recommendations were given by the updated ACC/AHA guidelines. Therefore the ABPI can be used to diagnose PAD in not only symptomatic patients, but should be used with a high index of suspicion where any risk factors are present.

2.4.3.2 Ongoing Assessment of PAD

The ABPI is a reliable tool for ongoing assessment of PAD severity or reoccurrence.

If used in the community, the ABPI can quantify changing disease severity in patients with established but not significantly impairing PAD. This could reinforce ongoing conservative management if ABPI values remain constant over time, or alert clinicians to changes and the need for further investigation or referral. For example, a patient who has an ABPI value of
0.85 (mild PAD) may only require GP follow-up in the community. Where GPs believe there is no current need for a referral to vascular surgeons, GP monitoring may be appropriate.

In addition, the ABPI could monitor the short and long term efficacy of medical and surgical management in the in-patient or hospital setting. This would help secondary care clinicians to monitor the status and success of treatment, such as before and after revascularisation surgery, and inform whether and when discharge is possible.

### 2.4.3.3 Determination of Ulcer Management

Common vascular issues seen in both primary and secondary care settings are leg ulcers. The NZ Wound Care Society (NZWCS) recommends using the ABPI to evaluate whether an ulcer may be arterial or mixed in pathology (see Section 2.3.3.2 Venous Vessel Anatomy and Pathophysiology). Diagnoses of aetiology help to inform ulcer management.

In addition, the ABPI can be used to determine appropriateness of compression therapy in treating venous ulcers and wounds, by excluding any arterial insufficiency. If compression is used in the presence of arterial disease inappropriately, this could result in worsening of ulceration, progression to gangrene and potentially limb amputation.

The ABPI value can also indicate what type of compression hosiery is safe to use. BPAC guidelines state that in patients with an ABPI >0.8, compression therapy is safe, while in patients with ABPI <0.8, high compression hosiery is not recommended, and if ABPIs are <0.5, compression hosiery should not be used.

The ABPI is a practical assessment to help inform clinicians in general practice (such as GPs and nursing staff) on whether to implement compression therapy and types of compression to use.

### 2.4.3.4 Determination of Cardiovascular Morbidity and Mortality risk

A low ABPI value (<0.9) is an independent risk factor for cardiovascular morbidity and mortality. Patients with low ABPI values have a 5.5 times increased risk of mortality by any cardiovascular cause, and a 2.5 fold increased risk of any coronary artery disease or stroke (see Section 2.3.9 Complications). The ABPI can provide information on risk stratification, and prompt risk modification in at-risk patients.
One systematic review revealed the specificity of a low ABPI to detect future cardiovascular events as being high (88%), making it fairly accurate in predicting future morbidity.72

A 2008 meta-analysis examining at the specific use of the ABPI in predicting cardiovascular mortality found a J-shaped relationship between ABPI value and cardiovascular risk. Risk increased greatly at every 0.1 ABPI increment below 0.9. Risk also increased above ABPI values of 1.4, creating the J-shape.73 The same study found that when compared to the well-known Framingham Risk Stratification tool, a low ABPI (<0.9) approximately doubled the risk of ten year total mortality, total cardiovascular mortality and of major coronary events for all Framingham risk categories. This would mean a significant reclassification of risk (with treatment implications) for 36% of females and 19% of males previously classified by the Framingham risk score.73

The ABPI can be useful as another aid in detecting and communicating cardiovascular risk to patients, and initiating primary prevention measures to minimise the chance of future cardioischaemic events.

2.4.3.5  Screening for PAD in Asymptomatic Individuals

Asymptomatic individuals with PAD have similar morbidity and mortality risk to patients who are symptomatic so it may be just as important to identify these individuals in order to prevent previously unforeseen consequences.8, 25, 74 Some studies suggest that ABPI screening in generally healthy individuals may confer advantage to lower overall prevalence rates via early intervention.75

However, the literature has polarising views on whether screening for asymptomatic PAD is cost-effective and worthwhile at the population level.

Marshall considered the ABPI against each of Wilson’s Criteria for Screening, criteria that should be met to consider a health screening campaign worthwhile. Marshall found that the ABPI tool only met six the ten criteria.66, 76 It was unclear or unknown if three of the remaining four criteria could be met. No evidence though could be identified demonstrating that the benefits outweigh the economic cost of screening.

The USA Preventive Services Task Force agrees that the benefits do not outweigh economic cost of screening. The task force recommends against routine screening for PAD based on the rational that the ABPI would not provide additional practical information beyond the standard cardiovascular risk assessment.20
A recent Cochrane review found no randomised controlled trial evidence for PAD screening, and suggested that high quality research is required to inform whether this would be advantageous for populations.\textsuperscript{77}

Currently, screening is a theoretical use of the ABPI in the literature with much debate.

### 2.4.3.6 Other Specialised Uses

Additional research into the role of ABPIs has identified alternative and specialised situations where the ABPI could be helpful. Although many of these specialised uses are beyond the scope of this thesis, they show the wider usefulness and utility that the ABPI may have as a clinical tool.

Recent studies have found that a low ABPI value (<0.9) is associated with worse cognitive performance in older patients.\textsuperscript{78, 79} Cognitive performance relates to a range of cognitive changes from mild cognitive impairment to dementia, and can be grouped collected together under the umbrella term ‘cognitive disorders’. A recent systematic review examined 12 publications, of which all but one reported a significant association between low ABPI values and cognitive disturbances.\textsuperscript{79} Confounding variables including age, sex, childhood mental ability and history of cardiovascular or cerebrovascular disease were controlled for in this review. The significant association remained even when participants with a past history of stroke were excluded.\textsuperscript{80} Further, it was determined that patients with low ABPIs were also at increased risk for cognitive decline and Alzheimer’s dementias and not only poorer cognitive performance. Research suggests that the ABPI could have further relevance to neurological and geriatric fields.

There is an association between a low ABPI and an increased risk of rapid decline in renal function, and accordingly an increased risk of renal failure.\textsuperscript{81} This association was present even when adjusted for age, sex, baseline estimated Glomerular Filtration Rate and standard risk factors for chronic kidney disease. This indicates that ABPI is a useful marker of generalised atherosclerotic processes that are commonly co-present in the kidney. PAD patients commonly have atherosclerotic changes in the renal vasculature.\textsuperscript{81}

### 2.4.4 Equipment

ABPIs require relatively little equipment, making primary care adoption feasible. Some essential and non-essential apparatus is discussed below:
2.4.4.1 Standard Equipment

A mercury sphygmomanometer attached to an appropriately sized blood pressure cuff is a standard piece of equipment in any practice, and is used to measure individual blood pressures of arteries in the limbs. An appropriately sized blood pressure cuff is one that has a bladder 20% larger than the diameter of the measured limb, or 40% of the limb circumference.\(^6^8\)

A Doppler ultrasound is required for easy auscultation of arterial flow, and for the calculation of the ABPI value. The Doppler ultrasound consists of a probe transducer, connected to a small ultrasound device which can be hand-held. There are many different varieties and brands, some having different capabilities, but all serving the same purpose of evaluating vascular flow. The machine operates by transmitting high-frequency sound waves that are reflected off of internal structures back to itself.\(^8^2\) It communicates information in the form of audible sound to the sonographer. When assessing arteries, it produces a ‘whooshing’ noise denoting blood flow at changing velocities. The movement of blood flow causes a change in reflected sound pitch; known as the Doppler Effect. Where there is no flow, the pitch will not change. Therefore, the Doppler ultrasound is essentially an electronic stethoscope, and listening to its messages helps users to easily determine patency of the vascular channels and possibility of disease.

Doppler ultrasounds can be manipulated in several different ways to gain selected information. Some common types of Doppler ultrasound include:\(^8^3\)

- The **continuous wave or bedside/pocket Doppler** solely uses the sound function as explained above. It is an easy and relatively cheap tool with basic diagnostic abilities (see Section 2.4.4.2 Cost and Availability of the Doppler Device). This is usually the type required to calculate ABPIs discussed in guidelines and research.

- The **Duplex Doppler ultrasound** uses computer methods to produce visual pictures of blood vessels and surrounding organs (much like the traditional obstetric ultrasound) for enhanced interpretation.

- The **Colour Doppler ultrasound** is like a Duplex Doppler ultrasound, but has the added value of having overlaid colours on ultrasound images of vessels, representing different speeds and directions of flow.
Aside from manually operated (pocket) Doppler ultrasounds, automated devices are also available to calculate ABPIs, though are more commonly used in vascular laboratories (see Section 2.4.8 Alternative of Adjunctive Non-invasive Techniques to the ABPI). Pocket Dopplers may be more useful in primary care due to its lower capital cost and availability.

The correct probe transducer should also be used in relation to what information users want from their Doppler ultrasound. Probe transducers pick up different frequencies, and users should have an understanding of each probe’s capabilities. Common types include the 5MHz or 8MHz transducers. The 5MHz transducer is used for deep vascular studies or assessing larger oedematous limbs. This is due to having an optimum transduction range of 1-8cm. The 8MHz probe is used for standard or ‘average sized’ limbs. This is because the 8MHz probe transducer has an optimum transduction range of 2mm-4cm. An 8MHz probe transducer is generally sufficient for ABPI assessment, except if patients have significant adiposity or oedema.

Diagnostic ultrasound is a safe tool as it uses no ionising radiation and no adverse biological effects are reported with in the literature its use. The USA Food and Drug Administration (FDA) states that ultrasound imaging tools “have been used for over 20 years and have an excellent safety record”. However, ultrasound theoretically confers heat transfer which theoretically could confer damage to tissues if overused. The American Institute of Ultrasound Medicine recommends that a prudent amount of ultrasound use should be considered because of this. The risk of thermal effects is discussed more in depth in relation to its use in an obstetric setting with its potential impact on foetuses. However, there have been no thermal risks described regarding the ultrasound in any of the literature surrounding ABPIs.

Ultrasound transmission gel or ultrasonic gel is required to promote the passage of sound waves from the ultrasound through to skin. The gel is typically viscous and water-soluble. It is applied to patients’ skin and sits between the area being assessed and the probe transducer as arterial pressures are being measured. It is safe to use.

A standard sized examination table (“bed”) is used to lie patients supine. This is part of a normal general practice so would not confer any added expenditure.

No anaesthesia is required as the Doppler ultrasound is generally non-invasive and non-painful. Despite this, pressure upon inflating the cuff has potential to cause mild discomfort which the patient should be warned about.
Cling film or light bandaging may be appropriate to cover any ulceration present, and to confer as much sterility as possible.

2.4.4.2 Cost and Availability of the Doppler Device

As the Doppler device is the only piece of equipment which is not part of standard general practices, an understanding of the cost and availability of these machines is needed if they are to be used in this setting. Haigh et al suggests that one of the reasons ABPIs are not performed more often in general practice is due to the reported lack of available equipment.87

Hand-held portable Doppler devices (8-10MHz) can generally be purchased for under NZ$700.52

There is a large range of Doppler types found easily among New Zealand medical supplier websites, with cheaper devices costing over $369 and more expensive devices costing up to $1,745.88-92 Differences in price owe to manufacturing location and how complicated each device is. More expensive types may come with printing options and liquid crystal display screens to show waveforms. This information is correct as of 30/01/2015 when the candidate made phone enquiries to NZ suppliers.

Ultrasonic gel is relatively cheap, but will incur an ongoing cost to practices as it is used up. A 250ml container costs around $10 from most NZ suppliers.88, 89, 91 However, this can be purchased in bulk (such as 5L containers) at cheaper rates.

2.4.4.3 Calibration of Device

Calibration is the act of adjusting the accuracy of the measurement device, often using another standardised piece of equipment to do so. It important to standardise diagnostic or therapeutic tools for accuracy, as well as for commercial quality assurance before devices are sold commercially.

There are several older studies prior to 1991 which discuss possible Doppler ultrasound calibrating devices.93-95 One study of calibrated therapeutic ultrasound units showed that more than 33% of machines tested were outside the calibration standard for at least one variable setting.96 The study suggested that further improvements in calibration may be required in health workplaces. It would be inappropriate to extrapolate these data to
diagnostic ultrasound machines due to the differences in physical equipment and paucity of information.

No literature could be identified regarding recommendations in or the need for calibrating the diagnostic Doppler ultrasound.

Several NZ suppliers of Doppler ultrasound stated that calibration was not required for their machines when the candidate inquired by phone, including two companies Amtech and Hallmark Surgical. Again, this was correct as of 30/01/2015.

2.4.5  Performing and Evaluating the ABPI

2.4.5.1  Anatomy

The ABPI tests three main arteries; the brachial artery in the arm, the Posterior Tibial (PT) artery and Dorsalis Pedis (DP) artery in the foot.

In the upper limb, the brachial arteries arise from the axillary arteries around the lower margin of the teres major muscle. The brachial artery continues in the upper arm down to the cubital fossa or elbow crease where it then divides into the radial and ulnar arteries of the forearm.

In the lower limb, the popliteal artery behind the knee divides to become an anterior and posterior tibial artery in the lower leg (see Figure 4 Arteries of the Lower Limb). The PT artery runs down the posterolateral region, and around the medial malleolus to become the plantar arteries on the plantar aspect of the foot. The anterior tibial artery becomes the DP artery when it travels antero-inferiorly and reaches the ankle. The DP then runs between the tendons of the extensor hallucis longus and the most medial tendon of the extensor digitorum longus (i.e. the tendons of the first and second toes). The DP and PT arteries branch into smaller arteries and join creating a collateral supply.

Both PT and DP arteries are considered the most peripheral major arteries of the body. Where one artery develops significant atherosclerosis or becomes occluded, the collateral arteries from the other can help to supply the area that has occluded blood supply. It is pivotal to test both arteries when performing the ABPI because of the human body’s ability to produce collateral supply.

Although these arteries are specifically targeted during ABPI assessment, the ABPI result may have wider implications on the rest of the cardiovascular system, and may indicate further
potential atheromatous pathology elsewhere (see Section 2.3.3.1 Arterial Vessel Anatomy and Pathophysiology).

Figure 4: Arteries of the Lower Limb. Source: Pozniak MA, Clinical Doppler Ultrasound Expert Consult: Online, 2013.

2.4.5.2 ABPI Measurement

The standard method is described in Table 5 below:
Table 5: Measurement Method of the ABPI (Adapted from Parkin et al.98)

<table>
<thead>
<tr>
<th>Step no.</th>
<th>Procedure</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Have all necessary equipment prepared in advance (see Section 2.4.4 Equipment)</td>
<td>Preparation to ensure a smooth procedure</td>
</tr>
<tr>
<td>2</td>
<td>Explain the procedure to the patient</td>
<td>Information sharing</td>
</tr>
<tr>
<td></td>
<td>Gain informed consent (considering language barriers and cognitive or learning difficulties)</td>
<td>Allows the patient to be confident and trust in the clinician</td>
</tr>
<tr>
<td>3</td>
<td>Remove tight clothing form all limbs including stockings</td>
<td>Allows for comfort and accuracy of the test</td>
</tr>
<tr>
<td></td>
<td>(considering cultural and sex differences)</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Remove dressings and apply clear cling film over any ulceration</td>
<td>Prevents trauma to the ulcer via pressure and contamination of the Doppler equipment</td>
</tr>
<tr>
<td></td>
<td>(not of significant discomfort to the patient)</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Allow for a pre-test resting time of 10 minutes in a supine or seated position (see further in this Section below)</td>
<td>Reduction in inaccuracies</td>
</tr>
<tr>
<td>6</td>
<td>Wrap an appropriately-sized sphygmomanometer cuff around the limb of which the blood pressure is being measured (e.g. begin with the right arm/brachial artery)</td>
<td>An inappropriately sized cuff will not be able to occlude the artery or will distort the pressure reading</td>
</tr>
<tr>
<td>7</td>
<td>Locate the pulse by palpitation and apply a generous amount of ultrasound gel to the area located (enough to cover the entire skin surface the probe will be touching) (see further in this Section below)</td>
<td>Finds the site at which the Doppler probe will be placed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The ultrasound gel allows the Doppler to work effectively</td>
</tr>
<tr>
<td>8</td>
<td>Place an appropriately sized Doppler probe angled at 45 degrees into the direction of the blood flow; the signal (sound of blood flow) should be heard</td>
<td>Maintain and acquire the pulsation without occlusion</td>
</tr>
<tr>
<td>9</td>
<td>Inflate the sphygmomanometer cuff until the signal disappears. Then deflate the sphygmomanometer cuff until the signal reappears- recording the value at this moment</td>
<td>To obtain limb pressure</td>
</tr>
<tr>
<td>10</td>
<td>Repeat the procedure with the other limbs (5 other arteries). There should be values or attempts at values for all of: Right brachial artery Right posterior tibial artery Right dorsalis pedis artery Left brachial artery Left posterior tibial artery Left dorsalis pedis artery</td>
<td>To obtain all ABPI values required for calculation</td>
</tr>
<tr>
<td>11</td>
<td>Calculate and Interpret the ABPI (see Section 2.4.5.3 Calculation and 2.4.5.4 Interpretation)</td>
<td>For calculation and interpretation</td>
</tr>
</tbody>
</table>
Pre-test rest time

Pre-test rest time involves resting the patient supine on the examination table (or alternatively, seated) in order to attain the patient’s physiologic or resting blood pressure as close to normal. This eliminates falsely elevated readings (such as in the case of stress or post-exercise). The pre-test rest duration in the literature ranges from 5 to 30 minutes\(^9\) reflecting some inconsistency between guidelines. A systematic review of 1658 titles revealed that no study has directly evaluated the efficacy of differing pre-test rest durations on ABPI measurements.\(^9\) However, in studies examining the effect of pre-test rest time on ABPI, the hydrostatic effects of gravity on blood were reduced after approximately 10 minutes following supine or seated rest.\(^9\) No further reduction was gained following 10 minutes. Despite a lack of direct evidence, research suggests that 10 minutes is probably sufficient.

Locating PT and DP Pressures

To find the PT pressure, the area between the Achilles tendon and the medial malleolus is a reliable area for palpation.\(^36\)

To find the DP pressure, it is helpful to palpate within 1-1.5cm of the prominence of the navicular bone in the foot as a reliable bony landmark.\(^97\) The DP pulse is impalpable in 3.1-13.8% of the healthy population but with Doppler ultrasound, only 1.9% if patients have an absent signal.\(^97\)

Pressures may be unobtainable or non-occludable in some instances. For example, anatomical variants such as an absent dorsalis pedis pulse would mean a DP pulse would be unobtainable. A calcified artery holding a vessel open despite external compression (as in diabetes mellitus) could mean that a DP pulse is non-occludable.

Variation in measurement

Klein & Hage reviewed 100 randomly selected publications commenting on technique and variations in ABPI method. The authors found that there were “no fewer than 39 different ways to calculate [ABPI]... reported in 77 of 100 studies” showing the diversity in using the ABPI.\(^100\) The other 23 of 100 studies did not report their technique and so findings are likely to be an underestimation of calculation variation. The method represented in Table 5 is the most common validated protocol as identified in many of the guidelines in the literature.\(^29\)
2.4.5.3 Calculation

To calculate the ABPI, the following formula is most commonly used, utilising appropriate pressures collected:

\[
ABPI \ (\text{leg}) = \frac{BP \ (\text{leg})}{BP \ (\text{brachial})}
\]

Where:

- \(ABPI \ (\text{leg})\) = the Ankle Brachial Pressure Index for a specific right or left leg
- \(BP \ (\text{leg})\) = the higher blood pressure obtained from the ankle vessels for that leg (either the DP or PT pressure)
- \(BP \ (\text{arm})\) = the higher brachial blood pressure of the two arms (i.e. brachial artery pressure)

2.4.5.4 Interpretation

The 2005 and 2011 ACC/AHA Guidelines for ABPI Interpretation are summarised as follows:

Table 6: 2005 and 2011 ACC/AHA guidelines for ABPI Interpretation

<table>
<thead>
<tr>
<th>ABI limits based on 2005 ACC/AHA Guidelines</th>
<th>Interpretation</th>
<th>ABI limits based on 2011 ACC/AHA Guideline update</th>
</tr>
</thead>
<tbody>
<tr>
<td>Greater than 1.30</td>
<td>Non-compressible</td>
<td>Greater than 1.40</td>
</tr>
<tr>
<td>1.00-1.29</td>
<td>NORMAL</td>
<td>1.00-1.40</td>
</tr>
<tr>
<td>0.91-0.99</td>
<td>Equivocal or borderline</td>
<td>0.91-0.99</td>
</tr>
<tr>
<td>0.41-0.9</td>
<td>Mild to moderate PAD</td>
<td>0.41-0.9</td>
</tr>
<tr>
<td>&lt;0.4</td>
<td>Severe PAD</td>
<td>&lt;0.4</td>
</tr>
</tbody>
</table>

The ABPI interpretation differed between 2005 and 2011 based on publication results by the Ankle Brachial Index Collaboration reviewed by the ACC/AHA Guideline Working Group.18, 73

Using <0.5 as a marker of severe PAD

Research has suggested that <0.5 is a sufficient marker of severe PAD from a clinical point of view.4 Patients who have ABPI values <0.5 are at higher risk of having lower extremity pain while resting.29, 54 Further, cardiovascular disease risk in ABPI values <0.5 is estimated to be
37%, compared to 27% in patients with ABPI 0.5-0.7. Therefore, previous research has commonly used 0.5 as a marker of severe disease as well as <0.4 which 2005 ACC/AHA guidelines have used.

**Normal Variance**

Similar to other biological measures (such as blood test results, tidal breathing volumes, height and weight), there is inter- and intra-variability in ABPI values in individuals. The ABPI may differ between days, as blood pressure does. Baker et al defines a significant change in ABPI value as being a difference of at least 0.15. This means that clinicians should be aware that changes of ≤0.15 may not be clinically significant in the absence of symptomatic change.

Normal ABPI values are also subject to ethnic and sex variability. The Multi-Ethnic Study of Atherosclerosis found ABPI values were approximately 0.02 lower in blacks than in non-Hispanic whites. Similarly, the study showed women having a lower ‘normal’ distributive curve than men (0.02 ABPI units lower). Although small, this study shows normal variation.

**2.4.6 Additional Merits of the ABPI**

Many of the merits of the ABPI have been highlighted in Section 2.4.3 Uses and Indications. However, there are other aspects of this assessment which make the ABPI highly useful in clinical practice, as discussed below:

**2.4.6.1 Well-Established and Used Globally**

There have been many internationally published research articles and evidence-based guidelines which have reinforced the benefits that the ABPI has to offer. The ABPI is widely used in many countries in secondary care and some primary care facilities and its use has been reviewed extensively by medical and research communities. The tool objectively measures PAD severity and values correlate well to self-reported quality of life.

**2.4.6.2 Relatively Low Financial Cost**

The ABPI is described repeatedly as a relatively inexpensive investigation in the literature, which can result in diagnosis and measurement of a modifiable disease. Most of the required equipment is already available in a standard general practice office or hospital.
setting. A Doppler ultrasound is the only incurred capital cost and inexpensive ultrasonic gel is the only continued expenditure (see Section 2.4.4 Equipment).

2.4.6.3 Specificity and Sensitivity

Overall the ABPI has high specificity and sensitivity.

The specificity of a low ABPI to detect leg stenosis of >50% is 98% (Ranging from 83-99% in different studies). Higher specificity will result in a lower false-positive rate.

ABPI sensitivity ranges broadly between 15-79% based on a meta-analysis completed by Xu et al. In contrast, many other papers have evaluated ABPIs and have stated higher sensitivities reaching 90-95%. A relatively lower sensitivity may be due to several things: (A) that mild PAD may not be detected as significant narrowing is required to reduce ankle blood pressure; (B) the ABPI does not pick up lesions along the internal iliac or profunda femoral arteries; and (C) if calcifications are present, an ABPI value may not be obtained. These inherent limitations are discussed in Section 2.4.7 Limitations of the ABPI.

Despite varying sensitivities reported, it was concluded that pooled sensitivity, specificity and accuracy measures allowed the ABPI to fall within acceptable diagnostic ranges to detect PAD with significant stenosis.

2.4.6.4 Ease of Use

Little training is involved with being able to perform the ABPI, and results are reliable when performed by different users. The ABPI has been shown to be reproducible between vascular surgeons, vascular physicians, general practitioners, and nurses with Doppler sonography training, with intra-observer variability differing only by 8% and inter-observer variability being 9% according to one study. Therefore it could be said that the ABPI is as practical as the simple blood pressure measurement used universally in the medicine. Klein and Hage found that estimates of intraobserver variability ranged from 12% for less experienced assessors to 7.3% for experienced assessors. Undergraduate and postgraduate training in ABPI measurement may be helpful in increasing accuracy and decreasing variability.
2.4.7 Limitations of the ABPI

Despite being a valuable diagnostic investigation, the ABPI does have limitations, as do all investigations:

2.4.7.1 Inherent limitations

Although the ABPI is a simple, widely available and a relatively inexpensive assessment, it is unable to detail length, type, or extent of disease.

Further, the ABPI is limited in sensitivity with regards to patients with certain pathologies such as diabetes mellitus and renal failure, as well as elderly patients.\(^{111}\) For instance, calcified arteries may result in non-occludable pressure. If pressures cannot be found or arteries are ‘incompressible’ the ABPI cannot be accurately interpreted.\(^{16}\) Potier states that efficiency of the ABPI is limited in diabetics with “concomitant clinical peripheral neuropathy or high risk of arterial calcification”.\(^{112}\)

In contrast, a New Zealand study of podiatric ABPI assessments for Māori patients with diabetes had a mean ABPI value in the normal range despite claims that ABPIs are distorted (generally high) in diabetics.\(^{113}\) However, the sample may not be representative of all diabetic patients as many participants were reported to have good foot-care knowledge (over 95% knew about general diabetic foot care and when to contact a podiatrist).

ABPIs can also miss arterial occlusions, depending on site affected. In patients with high grade aorto-iliac arterial occlusion, the Doppler ultrasound may not detect this due to the presence of a rich collateral arterial supply allowing for normal blood flows.\(^{63}\)

In cases where PAD is strongly suspected but not indicated by ABPI, referral for additional vascular review or further investigation is still warranted. Pulse volume recordings and toe brachial pressure indices are often used for patients with abnormally high or difficult to obtain ABPIs (see Section 2.4.7 Alternative or Adjunctive Non-invasive Techniques to the ABPI).

2.4.7.2 Assessment Variation

Finding patients’ true ABPI values can be difficult due to normal variation in patients as explained in Section 2.4.5.4 Interpretation. Just as expected for obtaining normal blood pressure, the patient-observer interaction, cuff sizing and placement, inflation and deflation rates and length of the pre-test rest period may all contribute to changing the clinically
measured ABPI value. Also, patients’ blood pressures vary physiologically, again complicating the measurement.\textsuperscript{108} Inflating the cuff continually or leaving the cuff inflated for a lengthier period of time can cause a hyperaemic response, and a reduction in distal blood pressure.\textsuperscript{98}

The variability of ABPI assessment attributable to the assessor and technique is considerably less than the variability attributable to biological factors.

Standardisation is recommended to overcome avoidable variability, and awareness of normal biological variation will aid in interpreting values found.

2.4.7.3 Contraindications

There are several contraindications to performing the ABPI which inhibit its use. These include patients being unable to lie supine (e.g. heart failure), and the presence of cellulitis, Deep Vein Thrombosis (DVT) or painful ulcers. In these circumstances, performing the ABPI could exacerbate symptoms or cause unnecessary pain. Aside from the obvious discomfort and stress, symptom exacerbation could also disturb the blood pressure readings and the ability to interpret the test accurately. If contraindications are present, further investigation into managing the contraindication is first recommended, and an additional appointment for an ABPI should be scheduled when resolved (either at the practice or vascular laboratory).

2.4.7.4 Lack of Knowledge

Lack of knowledge of either the ABPI itself, or of how to perform it correctly are limitations of its use in settings outside of vascular surgery or clinics.\textsuperscript{114} Wyatt et al found that common errors internal medicine residents made when performing the ABPI in 2010 included: \textsuperscript{115}

- Failure to use a Doppler to assess brachial pressures (residents used stethoscopes instead)
- Failure to assess both pedal vessels (DP and PT)
- Failure to assess both brachial systolic pressures
- Failure to accurately record a Doppler signal from a brachial or pedal artery

In the same study, only 35% of participants reported previous experience with using the ABPI. Once educational intervention and feedback were provided, post-intervention ABPI tests showed a significantly reduced number of errors compared with baseline results. Both paucity
in previous experience and the common errors identified at baseline display a gap in the knowledge of the ABPI. Post-educational interventional studies showed a reduction in common errors.\textsuperscript{115}

\subsection{2.4.8 Alternative or Adjunctive Non-invasive Techniques to the ABPI}

The literature strongly supports the use of the resting ABPI as first line in assessing suspected PAD or arterial occlusion. However, there are numerous alternative or supporting techniques to using the standard ABPI, discussed below:

Automated devices are often used by vascular technicians to obtain segmental pressures in the lower limb. They can provide more information in defining more precise anatomical data regarding arterial blockages or narrowing.\textsuperscript{116} Some studies state that ABPIs calculated via automated devices and the standard ABPI yield comparable results and can be interpreted similarly.\textsuperscript{84}

However, there has been suggestion of variability between standard ABPI and automated device readings in other studies. Jeelani et al found that the DINAMAP™ device produced significantly higher median ABPI values than the Doppler method, although this study had only 14 patients.\textsuperscript{117} Aboyans also demonstrated that ABPIs by automatic devices did not compare reliably to Doppler ultrasound ABPIs.\textsuperscript{14} More research is needed to fully evaluate the precision of automated devices.

The term ABPI has been used to denote single level or single limb ABPIs within this thesis so far. Multilevel or segmental ABPIs are used to describe the simultaneous ABPI measurement of all limbs at different sites (calf, above knees, thighs, arms), where multiple cuffs are used at the same time. This is done using an automated device. Segmental ABPIs may be able to determine the location of occlusion by comparing values with one another. This is often completed at a vascular laboratory where site determination is important for secondary care intervention.

Stress ABPIs or post-exercise ABPIs are assessments carried out following a short period of exertion such as on treadmill. It is indicated when resting ABPI is found to be normal but a high degree of clinical suspicion exists.\textsuperscript{16} The stress test is thought to induce a reduced ABPI value (via reduced ankle pressure to stress demands) indicating PAD. Diehm et al found that post-exercise ABPI did not have any significant influence on ascertaining the prognosis of mortality or selected cardiovascular events beyond the resting ABPI.\textsuperscript{118}
Migliacci et al compared the traditional ABPI via Doppler ultrasound with ABPI via palpation only.119 There was sufficient sensitivity of the palpation method (88%) to exclude PAD but it had a poor positive predictive value (18%).119 Similarly, Aboyans et al found that ABPI via the palpatory method underestimated the true ABPI when done by Doppler.14 Therefore, it would be possible to consider the palpatory method only as a method to exclude PAD but it is not specific or reliable enough to detect true positive results. Therefore it performs poorly as a conclusive diagnostic test.

Carmo et al studied the accuracy of obtaining the ABPI via a stethoscope (Korotkoff method), compared to using the gold standard Doppler probe. Using a stethoscope yielded a sensitivity of only 71.4% and a specificity of 91%, showing that it may be a suitable screening tool to measure the ABPI in the absence of a Doppler ultrasound.120 However, this method is still suboptimal compared to the standard ABPI (see Section 2.4.6.3 Specificity and Sensitivity).

Specific questionnaires have been developed to subjectively assess PAD and impairment.121, 122 However, questionnaires may be inadequate to identify PAD in many patients, including patients with atypical features and asymptomatic patients.54 For instance, the Edinburgh Claudication Questionnaire has a sensitivity of 56.2% in finding PAD, which is low with a positive predictive value of 59.4%.122 In comparison, the ABPI has higher sensitivities (see Section 2.4.6 Additional Merits of the ABPI). Questionnaires may be useful as an aid to assessment, but should not replace the ABPI.

Pulse Volume Recordings (PVR) can be used in conjunction with the ABPI to show waveforms, useful in identifying PAD where arteries are incompressible.123 PVRs visually display volume changes in an artery. Multiple pressure cuffs are applied to different parts of the leg, and inflated to a nominal pressure to obtain all PVRs at once. Volume changes will translate to changes in pressure in the cuff bladder, being detected and graphed via a transducer.123

The Toe Brachial Pressure Index (TBPI) is the toe equivalent to the ABPI, and requires a smaller toe cuff replacing the ankle cuff. This assessment is performed when there are abnormally high amounts of plaque and calcification, resulting in a high or non-compressible ABPI value. It is recommended for assessment in patients with diabetes.112 The TBPI is generally more accurate than the ABPI in identifying perfusion in the feet and extremities in these patients as it finds end arterial pressures.124 This has been recommended for use by the 2005 ACC/AHA guidelines.49 The cut-off points for normal and abnormal TBPIs are different to the ABPI with >0.7 indicating no arterial disease and <0.64 indicating arterial disease.125
Measuring the difference between brachial blood pressures is another proposed way of assessing risk of cardiovascular disease in people without using the ABPI. A difference of less than 10mmHg is said to be normal, while a difference of over 20mmHg is said to be abnormal, indicative of underlying vascular pathology.\textsuperscript{126} NICE guidelines recommend this as an easy way for general practitioners to evaluate risk, and this measure could be used in conjunction with the ABPI.\textsuperscript{17}

The duplex ultrasound is another ultrasonic imaging tool commonly used in secondary care to identify the site of atherosclerotic lesions (see Section 2.4.4 Equipment). This device is costlier than the simple Doppler ultrasound, and requires more specialised training for use.

Other, more invasive secondary care techniques are beyond the scope of this thesis.

### 2.5 Primary Care & Use of ABPI

There is limited previous research examining any use of ABPIs in NZ primary care. The literature surrounding potential or existing use of the ABPI in general practice or primary care internationally is presented in this section.

#### 2.5.1 Benefits of ABPI Use in Primary Care

Several papers have concluded that the Doppler ultrasound ABPI method is a reliable tool in general practice and primary care.\textsuperscript{53, 63, 105} Aside from its inherent uses, ABPI is suitable for use in primary care as it allows confident appropriate referrals to secondary care services, provides a patient-centred service for people with vascular issues and is a relatively simple tool for use in the community.

##### 2.5.1.1 Aids with Appropriate Referrals to Secondary Care

A 2014 study examining the impact that service provision has on referral rates showed a positive association between Doppler ultrasound use in general practice and referrals to specialist services.\textsuperscript{127} Approximately 22% of the patients evaluated by the Doppler were referred to hospital internal medicine, dermatology, neurology, surgery or orthopaedics services. Use of the Doppler may have revealed morbidity which was not treatable by GPs, allowing for necessary referral.
Further, there is evidence to suggest that ABPI use in general practices could reduce inappropriate referrals to secondary care settings. Poots et al states that in 41% of diagnosed intermittent claudication cases, diagnosis by history alone led to inappropriate referrals to vascular surgery departments. Poots’ study concluded that ABPI could result in a more efficient use of clinical resources. This would mean that waiting lists could be reduced, and secondary care clinicians’ time would be used to see ‘appropriate’ cases only (for patients with objectively measured PAD or questionable ABPI values).

2.5.1.2 Patient-Centred Service

ABPIs in primary care contribute to more patient-centred services. Discussion of ABPI results along with PAD between clinicians and patients increases awareness of the disease and its implications, which may encourage healthier behaviours. Adherence and cardiovascular risk factor management is pivotal in reversing, preventing and treating PAD (see Section 2.3.8 Management).

The Society of Vascular Surgery practice guidelines for PAD state that the “management of PAD is multidisciplinary, involving primary care physicians and vascular specialists with varying expertise in diagnostic and treatment modalities”. This conveys the importance of primary care physicians working in collaboration with secondary care physicians to manage this common chronic disease.

2.5.1.3 Ease of Use in General Practice

Much research has stated that the ABPI is a simple test which can be introduced to new users relatively easily. When discussed in the context of primary care, ease of use is contentious in the literature. Nexoe et al concluded that ABPIs are not simple procedures but are easily introduced into general practice. More education may help to reduce variability and increase precision of technique. Another study measured and found that there was great variability between individuals’ ABPI measurements carried out in primary care and the vascular laboratory. Despite this, the study concluded that there was overall comparability and relevance for the ABPI to be done at a population level. While there may be some question of accuracy when completed in a general practice setting, the ABPI is said to be very achievable in attaining its goal of diagnostics in the primary care setting (comparatively to other useful diagnostic procedures).
2.5.2 Barriers and Limitations for ABPI Use in Primary Care

Several barriers to the use of the ABPI in primary care were identified in the literature. These included the ABPI taking too much time in general practice, primary care practitioners being unaware of the value of the ABPI, potential inaccuracies in measurement, and lacking staff availability to be able to carry out the ABPI.

2.5.2.1 Time as a Barrier

Time is a recurring limitation of ABPI use in primary care in publications. The average time to complete an ABPI is 5 minutes, ranging from 3-11 minutes. This may be seen as a trivial amount of time in secondary care or to the patient, but can be viewed differently by primary care clinicians. When coupled with the time it takes to explain the test, set up the test equipment, and obtain and explain the test results, the full ABPI assessment could take up over 20 minutes. In general practice the time allocated to each patient is usually 10-20 minutes (or 30 if a double booking is made) - meaning consultations of extended length are difficult to accommodate. The time an ABPI test takes is balanced against the need to see other patients, and if GPs do not think ABPI results will add anything to their management they may decide that it is of less value than seeing another patient. Further, if GPs are not compensated financially for that time, then conducting the test is not cost-effective for them.

Chen et al found that time restrictions were an underlying reason for infrequent ABPI use in a cross sectional study of Western Australian Podiatrists. This supports the concept of time poverty being a barrier to ABPI use in a heterogeneous group of professionals, not only GPs.

If clinicians were given clear and consistent guidelines on how to perform the entire vascular assessment and ABPI, this could reduce the total time it would take to perform the test. Bjork et al published guidance titled “Bedside ankle-brachial index testing: Time Saving Tips” in Wound Care Advisor, designed to help practitioners mitigate the barrier of time. Tips include using initial Doppler sounds to avoid unnecessary ABPIs and advice on how to integrate ABPIs into initial assessments to be more efficient in the clinic.

2.5.2.2 Lack of Knowledge Regarding Benefits or Recommendations

A French survey of 165 general practitioners showed that only 42% knew that the ABPI was recommended by health authorities. Further, 1 in 5 respondents considered ABPI to be irrelevant, possibly because they did not know of guidelines. The main barrier to ABPI use was
lack of knowledge of the benefits of the ABPI, and the recommendations of health authorities to use it. Wyatt et al found similarly that only 35% of a group of internal medicine residents reported previous practical experience with ABPIs (see Section 2.4.7.4 Lack of Knowledge).

2.5.2.3 Inaccuracies in ABPI Measurement

Nicolai et al found that ABPIs are often not correctly carried out in general practice due to inaccurate methods of measurement and calculation. Another study found that a high number of false-positive tests occurred when the ABPI was used by nurses and GPs following a course. Unlike in the community, tighter quality control can generally be applied in regional vascular laboratories allowing more consistency in technique and interpretation. Despite the inter-user variability, some studies conclude that there is overall comparability and relevance for the ABPI to be performed in primary care (see Section 2.5.1 Benefits of ABPI Use in Primary Care).

2.5.2.4 Staff Availability and Reimbursement

Having the personnel available to undertake the investigation is a concern for some general practices.

Less than a third of health professional respondents to the large ultrasound PAD Awareness, Risk, and Treatment: New Resources for Survival (PARTNERS) ABPI utilisation study in the USA stated that a family physician was the sole staff member who performed the test. Around 38% of respondents indicated that a nurse or nurse practitioner was responsible for performing it in addition to the doctor. As the results of the ABPI are not usually indicative of imminent death, the test may be placed lower on priority lists. General practitioners commonly have access to a vascular laboratory in urban centres so referring to the laboratory could save the practice time, financial and staff resources needed in doing the ABPI themselves.

2.6 Chapter 2 Summary

The literature review indicates that the ABPI is generally described as a simple, relatively quick, inexpensive and non-invasive assessment useful in detecting PAD in patients presenting with varying symptomatology. There is a well-established literature supporting its use and it has been the focus of many guidelines groups around the world. ABPIs are critical for initial and
ongoing assessment of patients with vascular disease, and determination of the best next step in management. ABPIs have a logical scientific base and have been shown to be reliable and effective as a diagnostic and measurement tool by many authorities and research agencies. Yet ABPIs are still underutilised in general practice.7

PAD has also been described extensively in the literature, with focus on its clinical consequences such as critical limb ischaemia, cardiovascular events and increased risk of mortality and morbidity from these. Due to the global increase in ageing and chronic disease such as diabetes, PAD is predicted to increase in prevalence and will be a condition needing to be addressed in more and more people.54 Fortunately, PAD can be prevented or delayed by cardiovascular risk factor management and lifestyle modification. The ABPI can detect and quantify levels of atherosclerosis in patients easily in the community.

There is some literature regarding use of the ABPI in general practice. Some studies have discussed its value, while others have identified practical barriers to use, and variability among results and methods. Completing the ABPI assessment in general practice helps to identify PAD as a definite diagnosis in patients, and allows for appropriate referrals to be made to secondary care where needed. It aids clinicians in guiding management of patients who present with ulcerations and prevents the compression of ulcers with mixed aetiology. Practical barriers such as time and staff availability tend to prevent its utility in general practice. With these barriers addressed, it would be useful to implement ABPI use in general practice.54 Nevertheless, no literature pertaining to ABPI use in New Zealand general practice could be identified.
Chapter 3: The Use of the ABPI in a General Practice Over Ten Years- The Quantitative Arm of the Study

3.1 Introduction

Dr Hywel Lloyd is a GP of 23 years’ experience, and has been performing ABPIs on patients for nearly 10 years (2006 – 2015) at the Mosgiel Health Centre (MHC).

Dr Lloyd first became aware of ABPI tests when he was a GP in Wales, but became more interested when he came to New Zealand in 2003. This was because he noticed that there were very few ABPIs being done in primary care compared to Wales and the only alternative was referral to a secondary care vascular service.

In 2006, Dr Lloyd began performing ABPIs so he could diagnose and manage patients with lower leg vascular disease. Subsequently, he began accepting referrals for ABPIs from other GPs at MHC and from GPs outside MHC. Dr Lloyd sees the ABPI as a valuable tool GPs can use to more effectively and efficiently manage patients in the community. Ultimately, he believes it improves healthcare for patients in the community.

Chapter 3 describes the first of this study’s two arms. This arm is a quantitative analysis which examines descriptive data collected by MHC and Dr Lloyd to present demographic characteristics of patients for whom ABPIs are being conducted at the practice. The analysis also examines how and why it is being used, and whether ABPI measures are associated with changes in management subsequently. These findings will contribute to conclusions about the usefulness of the ABPI in this community setting.

3.1.1 Aims

- To describe MHC patients 2006 – 2015 when the ABPI data were collected.
- To describe the sample of patients receiving ABPI investigations conducted at MHC between 2006 and 2015.
- To describe why and how the ABPI is used in the MHC.
- To analyse whether ABPI use is associated with a change in clinical management (compared to what would have been done without ABPI).
• To interpret the significance and effectiveness of conducting the ABPI.

3.1.2 Hypothesis

The study hypothesis of this quantitative arm is that the use of ABPIs in this general practice (MHC) is associated with changed clinical decisions regarding vascular management.

3.2 Study Design

The design of the entire study is split into a quantitative analysis arm (Chapter 3) and a qualitative analysis arm (Chapter 4).

The study design involved in this arm is a quantitative analysis of ABPI data collected between 2006 and 2015 by MHC and Dr Hywel Lloyd.

3.2.1 Study Participants and Setting

3.2.1.1 Participants

Participants were patients seen at MHC 2006 – 2015 including both patients of Dr Lloyd’s, and patients referred to Dr Lloyd who have had an ABPI completed at MHC.

3.2.1.2 Population Setting

All participants were seen physically as patients at MHC, 21 Ingles St, Mosgiel (see Figures 5 and 6).

Mosgiel is part of Dunedin city. The area has a total population of 3,975 in Mosgiel East (3.3% of Dunedin City’s population) and 2,733 in Mosgiel South (2.3% of Dunedin City’s population) according to the New Zealand census 2013.\textsuperscript{135,136} MHC also serves patients from nearby areas such as Bush Road (2,502 people) and East Taieri (1,527 people)\textsuperscript{137,138}.

MHC had 9,890 enrolled patients at 25/04/2015. The practice has 7 full-time GPs, 7 part-time GPs (totalling 2.5-3 full time equivalents), 7 nurses, 1 nurse manager, 1 clinical administrator, 7 receptionists, 1 administrator and 1 practice manager.
Figure 5:  Google Maps Image of the location of Mosgiel Health Centre (MHC) in relation to Mosgiel and Dunedin, New Zealand. Accessed 20/07/2015. Released to the public domain, reproduced with permission under fair use, Google Incorporated.

Figure 6:  Sign outside Mosgiel Health Centre, 21 Ingles St, Mosgiel. Photo taken with permission from MHC.
Figure 7: MHC Practice Boundary Map (Patients served in the region). Reproduced with permission from MHC.
3.3 Methods

3.3.1 Quantitative Methods Used

This quantitative arm of the study uses routine electronic practice data from MHC for analysis and evaluation. This was from the practice’s Patient Management System (PMS).

3.3.2 Data Collection

In this arm of the study, data were collected in a variety of ways.

3.3.2.1 Collection of Demographic and Other Descriptive Data

Demographic and other descriptive data for all MHC patients were collected between 2006 and 2015. Data were stored on Medtech32 and extracted for analysis on 25/04/2015 (see Section 3.3.2.5 Data Extraction and Cleaning).

Further chapters describe what is meant by demographic and other descriptive data (see Section 3.3.4.2 Demographic Definitions, and Section 3.3.4.4 Definitions of Medical Conditions and Risk Factors).

Demographic and other descriptive data were originally recorded by administrative or health professional staff at MHC on the practice’s Medtech32 PMS throughout the 10 years. Data were gained either by speaking with patients (e.g. ethnicity, deprivation indexes from address information), or through clinical encounters (e.g. consecutive high systolic blood pressure measurements and a clinician coded diagnosis of hypertension). Further information could have come from previous medical records sent to MHC by former healthcare providers.

To maintain accuracy of demographic data, administrative staff often checked information provided earlier with returning patients. Similarly, the nursing team do a standard check of demographic information and other descriptive data whenever a new patient arrives at the clinic. These procedures maintain quality and accuracy of information stored on the practice’s electronic records system, and therefore enhance the quality of the data used for this arm of the study.
3.3.2.2 Collection of ABPI Data

ABPI data were collected between 2006 and 2015 using an electronic ‘ABPI Data Capture tool’ on the Medtech32 database following ABPI measurements by clinical staff (see Section 3.3.2.3 ABPI Data Collectors and Section 3.3.3 ABPI Test Method).

ABPI data include the date of the ABPI procedure linked with the patient identification number, left and right brachial pressures, left and right PT and DP pressures, left and right ABPI values and whether any pressures were non-occludable or unobtainable.

The clinician performing the ABPI simply recorded values for each of the arteries seen, and an automatic calculation by the form then produced the left and right ABPI values or ratios.

Figure 8 shows the ‘ABPI Data Capture Tool’, built by Dr Lloyd using Advanced Form technology within the Medtech32 system. Visual basic scripting was used to ensure data quality for input and the correct calculation of the ABPI ratios. The data collected from the Advanced Form was written back to Medtech32 and stored in a ‘[MEASUREMENT]’ table visible to all clinicians under the ‘screening’ tab of the patient manager window. The data were then able to be extracted from the ‘[MEASUREMENT]’ table (see Section 3.3.2.5 Data Extraction and Cleaning).

Figure 8: Display of the ABPI Data Capture Tool based on an Advanced Form Built by Dr Lloyd for Input of ABPI Values on the MHC PMS. Reproduced with permission from MHC.

3.3.2.3 ABPI Data Collectors

ABPI data were collected and recorded primarily by Dr Lloyd.
A minority of ABPI investigations were conducted by nursing staff from MHC. Two registered nurses (under the pseudonyms “MH” and “NC” within the data) were trained by Dr Lloyd to conduct the ABPI. Dr Lloyd often validated values obtained by the nurses by completing the ABPI again himself. In all instances where Dr Lloyd redid the ABPIs, values did not differ significantly. ABPI data was recorded only once in these cases to prevent duplication in reporting.

Dr Lloyd graduated from the University of Liverpool medical school in 1989 and in 1992 became a successful candidate of the UK’s vocational training scheme for GPs (MRCGP programme). He worked as a GP in the UK for 9 years, between 1994 and 2003. In this setting, he conducted ABPIs. He moved to New Zealand in 2003 and has been working at MHC since, for a total of 12 years till 2015. Dr Lloyd currently works part time at the practice.

Dr Lloyd based his ABPI method and clinical management on an older version of the Scottish Intercollegiate Guidelines Network (SIGN) PAD guidelines while in the UK, and on a former New Zealand Guidelines Group (NZGG) guideline document while in NZ. Full texts of both guidelines could not be found in the literature as they are outdated. A newer SIGN PAD guidelines document which has similar protocol guidelines to earlier versions was found. NZGG was closed under voluntary liquidation in 2012, and previous web links to old guidelines had been removed. As a result, no current NZGG documents could be found.

3.3.2.4 Collection of Indications and Outcomes Data

Data regarding indications and outcomes for the ABPI were collected by the candidate. This was done by searching through relevant patient records, and inputting findings into an Excel spreadsheet. This was completed during July 2015.

Permission for this study was granted by both the Human Ethics Committee and MHC (see Appendices A, D and F and Section 3.3.6 Ethical Considerations).

Clinical record entries by staff and scanned referral letters were read and used to collect data. Binomial results “YES” and “NO” were used to identify presence or absence of indications and outcomes (see Table 7). Binomial results on an Excel spreadsheet were used as this is easily understood by statistical software packages, and allows for proportions and percentages to be calculated in a logical method.
Table 7: Dummy Table showing how Indication and Outcome Data were collected

<table>
<thead>
<tr>
<th>ABPI Number</th>
<th>Indication 1</th>
<th>Indication 2</th>
<th>Outcome 1</th>
<th>Outcome 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>2</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>3</td>
<td>YES</td>
<td>NO</td>
<td>NO</td>
<td>YES</td>
</tr>
</tbody>
</table>

The following describes how indications and outcomes data were organised:

**Indications for having the ABPI**

There were three overarching ‘indication category groups’ for the use of ABPI: (1) To investigate suspected PAD, (2) To guide management of venous disease, and (3) other. There were nine indication categories in total under these three groups, some of which were split into further subcategories, seen in Figure 9.

The candidate based the presence of indication categories on key words in the clinical notes or letters (e.g. where “intermittent leg pain” was stated, a “YES” was entered into under the category “intermittent leg pain”) or where descriptions clearly matched indication categories (e.g. “having pain in legs following walking 100m, of which he needs to stop, rest, and can walk a further 100m before needing to stop again” was interpreted as intermittent leg pain).
Outcomes following the ABPI

All outcomes were categorised into ‘outcome category groups’ via their ABPI outcome and clinical features (see Figure 10).

Patients who had an ABPI value of under 0.9 and related clinical symptoms were managed as having PVD/arterial disease (a single outcome category group), whereas patients who had clinically diagnosed venous disease without an ulcer were managed as such (another outcome
category group) and data were entered into the outcome categories beneath these groups accordingly.

For patients who had ABPI results >0.9, any management arranged was classified under ‘other management arranged’ as the management did not relate to any of the other outcome category groups. Where nothing more was found to have been done or where no management changed following the ABPI, this was recorded under the ‘nil further peripheral vascular management’ outcome category group.

‘Nil further management’ within each of the outcome category groups refers to no change to the normal management of the patient, however recognising the problem as PVD/arterial disease, venous disease with ulceration or venous disease without ulceration via the ABPI result or clinical findings.

In the case of managing venous disease, mixed disease identified using the ABPI would usually be referred to the secondary care vascular service, and would be recorded under ‘Management of venous disease with or without ulcer’ rather than under ‘management of PAD’.
**Figure 10: Outcome Category Groups and Outcome Categories**

<table>
<thead>
<tr>
<th>Management of PAD</th>
<th>Management of venous disease with ulcer</th>
<th>Management of venous disease without ulcer</th>
<th>Other management arranged</th>
<th>Nil further peripheral vascular management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nil further management</td>
<td>Nil further management</td>
<td>Nil further management</td>
<td>Conservative management</td>
<td>Nil further management</td>
</tr>
<tr>
<td>Other conservative management</td>
<td>Compression treatment</td>
<td>Compression treatment</td>
<td>Investigations for other diagnoses</td>
<td></td>
</tr>
<tr>
<td>Referral to Secondary care Vascular Dept.</td>
<td>Other conservative management</td>
<td>Other conservative management</td>
<td>Dermatological Investigation</td>
<td></td>
</tr>
<tr>
<td>District Nursing Services</td>
<td>District Nursing Services</td>
<td>District Nursing Services</td>
<td>Referral to Secondary care Vascular Dept.</td>
<td></td>
</tr>
<tr>
<td>Referral to Secondary care other department</td>
<td></td>
<td>Compression treatment</td>
<td>Referral to Secondary care other department</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>District Nursing Services</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Podiatry Services</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Compression treatment</td>
<td></td>
</tr>
</tbody>
</table>
**Vascular Secondary Care Services Categories**

Where referrals were made to vascular secondary care services, any investigation or management implemented was also recorded in the data tally. These outcomes were recorded as it was seen as important to follow through patients requiring more invasive treatment, and to examine the appropriateness of referral (if added opinion or further intervention was necessary).

Following referral to secondary care vascular services, information regarding certain data categories was collected, as shown in Table 8:

*Table 8: Vascular Secondary Care Services Categories*

- Investigations
  - Formal vascular lab ABPI
  - PVR
  - Exercise ABPI
  - Arterial duplex scanning
  - Angiography
  - Venous duplex scanning
- Compression stockings or bandaging
- Referral to the wound care nurse specialist or ulcer care clinic
- Angioplasty
- Lower limb endarterectomy
- Ulcer or wound debridement
- (Arterial) bypass operation
- Amputations
  - Toe amputation
  - Below-knee amputation
  - Above-knee amputation
- Sclerotherapy
- Other management
- Nil- this includes referral back to the GP with no change in management, or recommending conservative “watch-and-wait” management
- Waiting- patients who had been referred who had not been seen yet at a vascular clinic/lab as at 25/04/2015
3.3.2.5 Data Extraction and Cleaning

At the end of the study period on the 25/04/2015, all descriptive and ABPI data were extracted from Medtech32 by the creation of an activity report of the ‘[MEASUREMENTS]’ table (see Section 3.3.2.1 Collection of Demographic and Other Descriptive Data and Section 3.3.2.2 Collection of ABPI Data). This was exported into Comma Separated Values (CSV) file formats for analysis purposes; one CSV file for demographics of the patients at MHC between 2006 and 2015 and another for ABPI data.

These tabulated data were then cleaned manually by the candidate. A majority of the cleaning involved shifting misplaced information back into correct original columns. This was because data was divided inappropriately into separate rows during the extraction process (into CSV files). This affected data such as clinician coded diagnoses, as clinicians may have added commas to their written notes. The data were checked for any other errors upon cleaning. The information was not altered.

Missing data was also recorded in the process of cleaning the data (see Section 3.3.5 Missing Data).

Indications and Outcomes data were not extracted, as this was manually collected by the candidate (see Section 3.3.2.4 Collection of Indications and Outcomes Data).

3.3.2.6 Time Period Chosen for Data Collection

The time period captured for this data is between 01/01/2006 and 25/04/2015. This corresponded to the time ABPIs were conducted at MHC.

3.3.3 ABPI Test Method

The method of ABPI testing was discussed with Dr Lloyd, detailed below. This method is comparable to what is stated in published guidelines discussed Chapter 2 (see Section 2.4.5.2 ABPI Measurement).

3.3.3.1 Equipment and Apparatus

The equipment used to complete ABPIs at MHC included:
• One Seward Vascutrack 120 Doppler ultrasound owned by the practice
  o Made by Seward Medical Systems Ltd, Newport, United Kingdom
  o It was unknown by staff at MHC when this was purchased and how old it was
  o Tested and calibrated by Dental and Medical Equipment Ltd yearly

• A standard blood pressure sphygmomanometer and cuffs (varying sizes)

• A standard examination table

The ABPIs were all conducted in the treatment room at MHC, with the same equipment used for each patient (aside from different sized blood pressure cuffs based on individual patients).

**Figure 11:** Three Photographs of the Seward Vascutrack 120 Doppler Ultrasound Used by MHC in Completing ABPIs. Photos taken with permission from MHC.

### 3.3.3.2 Protocol

The protocol used for conducting the ABPI was as follows:

• The patient was taken to the treatment room by a practice nurse and was asked to lie down supine for 15-20 minutes.

• An explanation of what the investigation entailed was given to the patient by the clinician.

• The ABPI was conducted as follows, using appropriate blood pressure cuff sizes to measure segmental pressures:
The left arm (left brachial pressure) was measured first, followed by the right arm (right brachial pressure), followed by the left leg (PT then DP) and then the right leg (PT then DP). This order was followed for each patient.

In each case, the Doppler ultrasound probe was angled onto the patient’s skin over the relevant artery. The cuff was inflated until no sound was heard by the ultrasound, and the cuff was slowly deflated until a waveform or sound was heard by the clinician.

- These values were recorded onto the Medtech32 system (see Section 3.3.2.2 Collection of ABPI Data).
- If the pulse was unobtainable, or not found, then it was recorded as ‘unobtainable’.
- If the pulse was non-occludable by the sphygmomanometer, then it was recorded as ‘non-occludable’.

The left and right ABPI values (or ratios) were then calculated automatically by Medtech32 using these segmental pressures.

If referred by another clinician, the patient’s clinical records were read by Dr Lloyd only after the ABPI had been performed.

3.3.3.3 Cost to the patient

The ABPI investigation costs the patient the same amount as one 15 minute consultation at MHC. This amounted to NZ$36. This cost was independent of the amount of time spent doing the ABPI, and so would not cost the patient more than $36 in the unlikely event that the ABPI procedure took longer than 15 minutes.

3.3.4 Definitions for Data Analysis

Extracted or created tables of collected data in CSV format were imported into the open source R statistical software. This software package was used to calculate prevalence, proportions and details using R code.
3.3.4.1 Population Definitions

Populations to be examined within the total sample were defined prior to analysis. These populations include (1) the total enrolled MHC population, (2) the patients who have had an ABPI (“ABPI group”) and (3) the MHC Population who have never had an ABPI before. These are discussed sequentially:

(1) The total enrolled MHC population consists of all patients enrolled at MHC and alive at 25/04/2015. Enrolled MHC patients were defined in the data as patients who had been associated with the funding code “F” (denoting enrolment).

Any patient data where the patient status was recorded as being “dead” were excluded. Cases with neither a “live” nor “dead” status were assumed to be living, and were included.

(2) Patients who have had an ABPI (the “ABPI group”) are defined as including any patient who has been classified with a designated Read code of “585a”, denoting ABPI. Read codes are widely-used health codes that statisticians and government agencies use to classify investigations and diagnoses. MHC utilises these codes.

The ABPI group includes all patients who have had ABPI assessments. These patients are described in two ways:

1. Patients who have had ABPI assessments. As all patient information pertaining to all ABPI assessments is included, patient demographics may be doubled if patients have had more than one ABPI assessment.

2. Individual patients who have had (one or more) ABPIs before- a separate analyses of individual patients to describe the unique population who have had ABPIs ever, without doubling up information.

Unlike the total enrolled MHC population, ABPI group includes ‘ABPI patients’ who may have become deceased before 25/04/2015. This is so that all data from patients who have had ABPIs can be analysed. Therefore in order to compare the total enrolled MHC population alive at 25/04/2015, it is necessary to find the enrolled ABPI population who were also alive at 25/04/2015 as a subset of the ABPI group.

Patients who were referred to MHC for ABPI assessments were described as non-enrolled ‘casual’ patients.

(3) The MHC population who have never had an ABPI before includes all patients who have never been classified with the designated Read code of “585a”.
This was taken as the difference between the total enrolled MHC population and the total enrolled ABPI population.

3.3.4.2 Demographic Definitions

Descriptive statistics were calculated for several demographic variables for the three populations mentioned in Section 3.3.4.1 Population Definitions. Measures of normal distribution such as means and standard deviation (s.d.) were calculated for variables of continuous data. Raw numbers and proportions were calculated for all non-parametric demographic data. Graphs and histograms were used as appropriate to explain the data.

The demographics which were analysed for these population groups included:

Sex

Sex categories included male, female or unknown.

Age Distribution

The mean and range of all ages as of 25/04/2015 were determined for each population, except for ABPI groups; which took age at the time of ABPI. The age at ABPI was determined by deducting the date at which the ABPI was performed from the date of birth.

10-year Age Bands

Patients’ 10-year age bands were recorded, e.g. 80-89 years, 90-99 years. The only exception were all patients over 100 who are grouped together as the “100+” age band due to presumed small number of patients over 100 years.

Ethnicity

Patient ethnicity was based on Level 2 ethnicity codes as defined by the MoH. This quantitative analysis further grouped ethnicity as follows:

- NZ European/Pakeha- combined the categories “European Pakeha”, “European not defined”, “Other European”
- NZ Māori –classified as “NZ Māori”
- Pacific- combined the categories “Cook Island Māori”, “Tongan”, “Samoan”, “Fijian”, “Niuean”, “Tokelauan”, “Other Pacific”, “Pacific not defined”
- Chinese- classified as “Chinese”
- Indian- classified as “Indian”
- Other Asian- combined the categories “South Eastern Asian”, “Asian not defined”
- Other Ethnicity- combined the categories “African”, “Latin American”, “Middle Eastern”, “Other”
- Not specified/defined- if there was no recorded ethnicity

**Socio-Economic Status by Quintile**

The New Zealand Socio-Economic Index (NZSEI) was used to quantify patients’ socio-economic status and level deprivation based on home address.\(^\text{144-147}\) The NZSEI scale uses a reliable 1-5 sorting system where a quintile of 1 denotes most affluent mesh blocks and quintile 5 denotes least affluent mesh blocks.

**High Needs category**

Patients were recorded as being in a High Needs category if they were living in an area of quintile 5 or were of Māori or Pacific ethnicity. This was based on having a higher-risk of developing common conditions and clinical consequences.\(^\text{144}\) Individuals who did not meet the definition above were not in the High Needs category.

3.3.4.3  **ABPI Group Definitions**

The ABPI group (or population) was further organised into a number of subgroups. The subgroups are defined below:

**Enrolled and non-enrolled ABPI subgroups**

As discussed in Section 3.3.4.1 Population Definitions, the “ABPI group” includes all patients who have had an ABPI in the past, and includes both enrolled and non-enrolled “casual” patients.

There was no possible method of finding funding status or enrolment on any retrospective date before 25/04/2015. Patients who have had an ABPI and who were enrolled at MHC at 25/04/2015 were assumed to have been enrolled at the time of the ABPI, making up a majority of the “enrolled ABPI group”.

Non-enrolled or casual patients in the data were defined as not having an enrolment code of ‘F’ (funded) at 25/04/2015, and did not have a registration code of ‘R’ under their registration
code on Medtech32 (and who were not reported as being dead). All other patients were assumed to have been funded at the time of their ABPI.

**ABPI Value Subgroups**

The ABPI group can be further subdivided into clinically-relevant subgroups based on ABPI values.

These included:

- Individuals who had an ABPI result of 0.9-1.2 - corresponding to clinically ‘normal’ healthy patients
- Individuals who had an ABPI result of <0.9 - corresponding to patients who have PAD
- Individuals who had an ABPI result of <0.5 - corresponding to severe PVD
- Individuals who had an ABPI results of >1.2 - corresponding to potential abnormality in patients who have diabetes due to calcification of arteries, raising the ABPI

<table>
<thead>
<tr>
<th>ABPI Value</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;1.2</td>
<td>Potential calcification of arteries</td>
</tr>
<tr>
<td>0.9-1.2</td>
<td>Normal</td>
</tr>
<tr>
<td>&lt;0.9</td>
<td>PAD- based on clinical guidelines</td>
</tr>
<tr>
<td>&lt;0.5</td>
<td>Severe PAD</td>
</tr>
</tbody>
</table>

These parameters have been determined by multiple vascular surgical and cardiovascular societies and previous research as determined in the literature review (see Section 2.4.5.4 Interpretation).

### 3.3.4.4 Definitions of Medical Conditions and Risk Factors

Prevalence of different medical conditions and risk factors within populations was calculated using the extracted data and R statistical software (see Section 3.3.2.1 Collection of Demographic and Other Descriptive Data and Section 3.3.2.5 Data Extraction and Cleaning).

Medical conditions were defined as grouped Read codes established by the Primary Health Organisation (PHO) Performance Programme. The PHO Performance Programme outlines and recommends standardised codes for different medical conditions and classifications to be
used in data across the health sector in New Zealand. MHC used these codes in Medtech32 system, and so Read codes can be utilised appropriately in this quantitative analysis.

The definitions of each medical condition and risk factor are outlined in Tables 10 and 11 respectively:

**Table 10: Read code Definitions for Medical Conditions**

<table>
<thead>
<tr>
<th>Medical conditions and subtypes</th>
<th>Definition based on Read code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arterial Disease Arteriosclerotic Disease</td>
<td>G70-G73z G73-G73z</td>
</tr>
<tr>
<td>PAD subset</td>
<td>G73-G73z</td>
</tr>
<tr>
<td>Ischaemic heart disease</td>
<td>G3-G3z</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>G6-G6z</td>
</tr>
<tr>
<td>Venous Disease</td>
<td>G83-G83z 7A66-7A6Hz 14A9 2482</td>
</tr>
<tr>
<td>Peripheral Oedema</td>
<td>R023 R0234</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>C10-C10zz C11y0-C11y0z</td>
</tr>
<tr>
<td>Chronic leg or skin ulcers</td>
<td>M27 G830</td>
</tr>
<tr>
<td>Congestive Heart Failure</td>
<td>G58-G58z</td>
</tr>
<tr>
<td>Gout</td>
<td>C34-C34z 669-669z 1443</td>
</tr>
</tbody>
</table>

**Table 11: Definitions for Medical Risk Factors via Read codes**

<table>
<thead>
<tr>
<th>Medical risk factors</th>
<th>Subtype</th>
<th>Definition based on Read Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyperlipidaemia</td>
<td>n/a</td>
<td>C320-C325z</td>
</tr>
<tr>
<td>Hypertension</td>
<td>n/a</td>
<td>G2-G2z</td>
</tr>
<tr>
<td>Smoking status</td>
<td>Heavy smoker (20-39 cigs/day)</td>
<td>1375</td>
</tr>
<tr>
<td></td>
<td>Very heavy smoker</td>
<td>1376</td>
</tr>
</tbody>
</table>
3.3.5 Missing Data

There was no missing data for demographics and characteristics of the total enrolled MHC population, and therefore the total enrolled MHC population who have never had an ABPI before. However, alive/dead status was missing for 58 (0.59%) of the total enrolled MHC population, 2 (0.48%) of whom were enrolled patients who have had an ABPI at MHC.

In regards to ABPI data, there were missing data for both all ABPI assessments and individual ABPI patients. This was generally in very minute quantities for sex, age and ethnicity. There was more missing data on socio-economic quintile and High Needs categories for just under a quarter of all patients who had an ABPI (see Tables 12 and 13). Caution should be taken to interpret these results.

Table 12: Missing Data for Demographic Characteristics of Enrolled and Non-Enrolled Patients who have had ABPIs at MHC for Total ABPI Assessments

<table>
<thead>
<tr>
<th>Data reported as NA or missing</th>
<th>ABPIs completed on enrolled patients</th>
<th>ABPIs completed on non-enrolled “casual” patients</th>
<th>Total number of ABPIs completed on patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>% of total</td>
<td>n</td>
</tr>
<tr>
<td>Sex</td>
<td>0</td>
<td>0%</td>
<td>1</td>
</tr>
<tr>
<td>Age Band</td>
<td>0</td>
<td>0%</td>
<td>1</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>0</td>
<td>0%</td>
<td>6</td>
</tr>
<tr>
<td>Socio-Economic Quintile</td>
<td>87</td>
<td>23.8%</td>
<td>9</td>
</tr>
<tr>
<td>High Needs</td>
<td>87</td>
<td>23.8%</td>
<td>4</td>
</tr>
</tbody>
</table>

Table 13: Missing Data for Demographic Characteristics of Enrolled and Non-Enrolled Individual Patients who have had (one or more) ABPIs at MHC

<table>
<thead>
<tr>
<th>Data reported as NA or missing</th>
<th>Enrolled patients who have had an ABPI</th>
<th>Non-enrolled “casual” patients who have had an ABPI</th>
<th>Total patients who have had an ABPI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>% of total</td>
<td>n</td>
</tr>
<tr>
<td>Sex</td>
<td>0</td>
<td>0%</td>
<td>1</td>
</tr>
<tr>
<td>Age Band</td>
<td>0</td>
<td>0%</td>
<td>1</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>0</td>
<td>0%</td>
<td>6</td>
</tr>
<tr>
<td>Socio-Economic Quintile</td>
<td>76</td>
<td>23.5%</td>
<td>9</td>
</tr>
<tr>
<td>High Needs</td>
<td>76</td>
<td>23.5%</td>
<td>4</td>
</tr>
</tbody>
</table>
Table 14: Missing Data for ABPI results 0.9-1.2, <0.9, and <0.5

<table>
<thead>
<tr>
<th>Data reported as NA or missing</th>
<th>ABPI results 0.9-1.2 (Normal)</th>
<th>ABPI results &lt;0.9 (Abnormal)</th>
<th>ABPI results &lt;0.5 (Severely Abnormal)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>% of total obtainable values for either L or R leg</td>
<td>n</td>
<td>% of total obtainable values for either L or R leg</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>--------------------------------</td>
<td>------------------------------</td>
<td>--------------------------------------</td>
</tr>
<tr>
<td>Sex</td>
<td>1</td>
<td>0.3%</td>
<td>0</td>
</tr>
<tr>
<td>Age Band</td>
<td>1</td>
<td>0.3%</td>
<td>0</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>3</td>
<td>1.0%</td>
<td>2</td>
</tr>
<tr>
<td>Socio-Economic Quintile</td>
<td>53</td>
<td>18.3%</td>
<td>42</td>
</tr>
<tr>
<td>High Needs</td>
<td>58</td>
<td>20.0%</td>
<td>39</td>
</tr>
<tr>
<td>Total*</td>
<td>290</td>
<td>116</td>
<td>22</td>
</tr>
</tbody>
</table>

*Total= total amount of patients with at least one ABPI of that value
3.3.6 Ethical Considerations

The study gained ethical approval by the University of Otago Human Ethics Committee (see Appendix A).

This study has also been through the Department of General Practice and Rural Health scientific review process prior to commencement (see Appendix B). The reviewers commented that the research uses appropriate research methodology. They approved the research following minor revisions undertaken whereby methodology was described in more detail as it was described very broadly initially.

The study protocol was also reviewed and responded to by the Ngāi Tahu Research Consultation Committee (Te Komiti Rakahau Ki Kāi Tahu) who considered the research to be of importance to Māori health, and have recommended that this research should be disseminated to Māori health organisations (see Appendix C). It was important for the researchers to have undergone this process to be aware of any cultural considerations present. There are a small number of Māori patients making up the sample examined by the quantitative arm, but all implications of the research are relevant to both Māori and non-Māori.

Within the amended New Zealand Health Information Privacy Code 1994, Rule 2: Sources of Health Information states that the health agency or researcher “must collect the information directly from the individual concerned” (rule 2.1). However, Rule 2.2 states that 2.1 is not necessary where the information used will be used for research purposes [that have gained ethics committee approval] and will not be published in a form that could reasonably be expected to identify the individual concerned. This clearly describes the legal ability of this health data to be used for this research, when used in a de-identified manner.

Authorisation of data was granted by MHC (see Appendix D) and a confidentiality statement was signed by both the MHC and by the candidate (see Appendix E). Most data provided to the candidate had already been anonymised using a unique randomised patient code, meaning only quasi-identifiers (such as date of birth, clinic visit, ethnicity) were supplied. All identifiable details were kept strictly confidential and used for research purposes only.
3.4 Results

3.4.1 Demographics and Characteristics

The demographics of the ‘total enrolled MHC population alive at 25/04/2015’ and ‘enrolled patients who have had an ABPI at MHC’ (and who were alive at 25/04/2015) are compared on Table 15 below:

Table 15: Demographics and Characteristics of the Total Enrolled MHC Population, Enrolled Patients who have had an ABPI at MHC, and the Total Enrolled MHC Population who have Never had an ABPI before

<table>
<thead>
<tr>
<th>Demographic Characteristics</th>
<th>Total enrolled MHC population*</th>
<th>Enrolled individual patients who have had an ABPI at MHC*</th>
<th>Total enrolled MHC Population who have never had an ABPI before*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>% (2dp)</td>
<td>n</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F</td>
<td>5,139</td>
<td>51.96%</td>
<td>156</td>
</tr>
<tr>
<td>M</td>
<td>4,751</td>
<td>48.04%</td>
<td>86</td>
</tr>
<tr>
<td>Total known</td>
<td>9,890</td>
<td>100.00%</td>
<td>242</td>
</tr>
<tr>
<td>Age Band</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-9</td>
<td>909</td>
<td>9.19%</td>
<td>0</td>
</tr>
<tr>
<td>10-19</td>
<td>1,152</td>
<td>11.65%</td>
<td>0</td>
</tr>
<tr>
<td>20-29</td>
<td>922</td>
<td>9.32%</td>
<td>0</td>
</tr>
<tr>
<td>30-39</td>
<td>848</td>
<td>8.57%</td>
<td>0</td>
</tr>
<tr>
<td>40-49</td>
<td>1,214</td>
<td>12.28%</td>
<td>3</td>
</tr>
<tr>
<td>50-59</td>
<td>1,315</td>
<td>13.30%</td>
<td>11</td>
</tr>
<tr>
<td>60-69</td>
<td>1,297</td>
<td>13.11%</td>
<td>28</td>
</tr>
<tr>
<td>70-79</td>
<td>1,134</td>
<td>11.47%</td>
<td>74</td>
</tr>
<tr>
<td>80-89</td>
<td>880</td>
<td>8.90%</td>
<td>91</td>
</tr>
<tr>
<td>90-99</td>
<td>216</td>
<td>2.19%</td>
<td>34</td>
</tr>
<tr>
<td>100+</td>
<td>3</td>
<td>0.03%</td>
<td>1</td>
</tr>
<tr>
<td>Total known</td>
<td>9,890</td>
<td>100.00%</td>
<td>242</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NZ European/ Pakeha</td>
<td>9,128</td>
<td>92.30%</td>
<td>236</td>
</tr>
<tr>
<td>NZ Māori</td>
<td>476</td>
<td>4.81%</td>
<td>4</td>
</tr>
<tr>
<td>Pacific</td>
<td>95</td>
<td>0.96%</td>
<td>1</td>
</tr>
</tbody>
</table>
### Demographic Characteristics

<table>
<thead>
<tr>
<th>Demographic Characteristics</th>
<th>Total enrolled MHC population*</th>
<th>Enrolled individual patients who have had an ABPI at MHC*</th>
<th>Total enrolled MHC Population who have NEVER had an ABPI before*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>% (2dp)</td>
<td>n</td>
</tr>
<tr>
<td><strong>Socio-economic Quintile</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (most affluent)</td>
<td>3,388</td>
<td>34.26%</td>
<td>47</td>
</tr>
<tr>
<td>2</td>
<td>2,051</td>
<td>20.74%</td>
<td>60</td>
</tr>
<tr>
<td>3</td>
<td>1,799</td>
<td>18.19%</td>
<td>42</td>
</tr>
<tr>
<td>4</td>
<td>2,030</td>
<td>20.53%</td>
<td>74</td>
</tr>
<tr>
<td>5 (least affluent)</td>
<td>583</td>
<td>5.89%</td>
<td>19</td>
</tr>
<tr>
<td>Total known</td>
<td>9,890</td>
<td>100.00%</td>
<td>242</td>
</tr>
</tbody>
</table>

| **High Needs**              |    |         |    |         |    |         |
| High Needs                  | 1,106 | 11.18% | 23 | 9.50% | 1,083 | 11.23% |
| Not High Needs              | 8,784 | 88.82% | 219 | 90.50% | 8,565 | 88.77% |
| Total known                 | 9,890 | 100.00% | 242 | 100.00% | 9,648 | 100.00% |

*alive as at 25/04/2015

#### 3.4.1.1 Demographics of the Total Enrolled MHC Population

It was found that 22,328 individual patients received a service from MHC between 2006 and 25/04/2015. Of these, 9,895 were enrolled. All other patients were non-enrolled ‘casual’ patients or were in the process of being enrolled. Five of the 9,895 enrolled patients were recorded as being deceased as on the 25/04/2015, leaving 9,890 as the total enrolled MHC population alive at 24/04/2015 (see Section 3.3.4.1 Population Definitions). These 9,890 patients are described in the first column of Table 15 (above).

The MHC population at 25/04/2015 had a mean patient age of 46.7 years, with a first quartile of 24 years and 3rd quartile of 68 years. The range varied between 0 (new-borns) to a maximum of 102 years (oldest patient).
The ethnic make-up of this population was mainly NZ European/Pakeha (92.30%).

As shown in Figure 12, 73.19% of the total enrolled MHC population lived in an area of socio-economic quintile 1-3. Less than 6% of the same population lived in quintile 5.

Figure 12: Socio-Economic Distribution in the Total Enrolled MHC Population, by Quintile

There were 1,106 (11.18%) High Needs patients.

There was no missing demographic data (see Section 3.3.5 Missing Data).

3.4.1.2 Demographics of the ABPI Group

There were 379 recorded ABPI assessments completed at MHC during the time period. The 379 recorded ABPI assessments were attributed to 338 individual patients (see Section 3.3.4.3 ABPI Group Definitions and Figure 13).
Figure 13: Number of Individual ABPI patients and Total ABPI Assessments Completed at MHC between 01/01/2006 and 25/04/2015

- Individual ABPI Patients = 338
  - Enrolled ABPI Patients = 324
  - Non-enrolled (casual) Patients = 14

- Total ABPI Assessments = 379
  - Total ABPI assessments on enrolled patients = 365
  - Total ABPI assessments on non-enrolled (casual) patients = 14

- Alive at 25/04/15 = 242
- Dead at 25/04/15 = 82

- ABPI assessments on patients who were alive at 25/04/15 = 268
- ABPI assessments on patients who were dead at 25/04/15 = 97
There were 268 ABPIs completed on patients who were alive at 25/04/2015 and 97 assessments on patients who were recorded as being deceased at 25/04/2015 (see Section 3.4.6 Deceased ABPI patients).

For comparability, only the 242 enrolled MHC patients who were alive at 25/04/2015 and who had an ABPI before that date were included in the comparison in Table 15 above.
Demographics of patients who have had ABPI assessments

Table 16 displays the demographics and characteristics of patients having the 379 ABPI assessments. It also distinguishes 365 ABPI assessments of enrolled patients from 14 ABPIs of patients not enrolled in MHC.

Table 16: Demographic Characteristics of Enrolled and Non-Enrolled patients who have had an ABPI at MHC for Total ABPI Assessments

<table>
<thead>
<tr>
<th>Demographic Characteristics (at time of ABPI)</th>
<th>ABPI assessments completed on enrolled patients</th>
<th>ABPI assessments completed on non-enrolled “casual” patients</th>
<th>Total number of ABPI assessments completed on patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>% (1dp)</td>
<td>n</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F</td>
<td>235</td>
<td>64.4%</td>
<td>11</td>
</tr>
<tr>
<td>M</td>
<td>130</td>
<td>35.6%</td>
<td>2</td>
</tr>
<tr>
<td>Total known</td>
<td>365</td>
<td>100.0%</td>
<td>13</td>
</tr>
<tr>
<td>Total</td>
<td>365</td>
<td>100.0%</td>
<td>14</td>
</tr>
<tr>
<td>Age Band</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>40-49</td>
<td>3</td>
<td>0.8%</td>
<td>0</td>
</tr>
<tr>
<td>50-59</td>
<td>11</td>
<td>3.0%</td>
<td>0</td>
</tr>
<tr>
<td>60-69</td>
<td>32</td>
<td>8.8%</td>
<td>0</td>
</tr>
<tr>
<td>70-79</td>
<td>84</td>
<td>23.0%</td>
<td>2</td>
</tr>
<tr>
<td>80-89</td>
<td>144</td>
<td>39.5%</td>
<td>6</td>
</tr>
<tr>
<td>90-99</td>
<td>85</td>
<td>23.3%</td>
<td>5</td>
</tr>
<tr>
<td>100+</td>
<td>6</td>
<td>1.6%</td>
<td>0</td>
</tr>
<tr>
<td>Total known</td>
<td>365</td>
<td>100.0%</td>
<td>13</td>
</tr>
<tr>
<td>Total</td>
<td>365</td>
<td>100.0%</td>
<td>14</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NZ European/Pakeha</td>
<td>358</td>
<td>98.1%</td>
<td>7</td>
</tr>
<tr>
<td>NZ Māori</td>
<td>5</td>
<td>1.4%</td>
<td>0</td>
</tr>
<tr>
<td>Pacific</td>
<td>1</td>
<td>0.3%</td>
<td>0</td>
</tr>
<tr>
<td>Chinese</td>
<td>1</td>
<td>0.3%</td>
<td>1</td>
</tr>
<tr>
<td>Total known</td>
<td>365</td>
<td>100.0%</td>
<td>8</td>
</tr>
<tr>
<td>Total</td>
<td>365</td>
<td>100.0%</td>
<td>14</td>
</tr>
</tbody>
</table>
Demographic Characteristics (at time of ABPI)

<table>
<thead>
<tr>
<th>Socio-economic Quintile</th>
<th>ABPI assessments completed on enrolled patients</th>
<th>ABPI assessments completed on non-enrolled “casual” patients</th>
<th>Total number of ABPI assessments completed on patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>% (1dp)</td>
<td>n</td>
</tr>
<tr>
<td>1 (most affluent)</td>
<td>59</td>
<td>21.2%</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>71</td>
<td>25.5%</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>45</td>
<td>16.2%</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>84</td>
<td>30.2%</td>
<td>1</td>
</tr>
<tr>
<td>5 (least affluent)</td>
<td>19</td>
<td>6.8%</td>
<td>0</td>
</tr>
<tr>
<td>Total known</td>
<td>278</td>
<td>100.00%</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>365</td>
<td>100.00%</td>
<td>14</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>High Needs</th>
<th>ABPI assessments completed on enrolled patients</th>
<th>ABPI assessments completed on non-enrolled “casual” patients</th>
<th>Total number of ABPI assessments completed on patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>% (1dp)</td>
<td>n</td>
</tr>
<tr>
<td>High Needs</td>
<td>23</td>
<td>8.3%</td>
<td>0</td>
</tr>
<tr>
<td>Not High Needs</td>
<td>255</td>
<td>91.7%</td>
<td>10</td>
</tr>
<tr>
<td>Total known</td>
<td>278</td>
<td>100.00%</td>
<td>10</td>
</tr>
<tr>
<td>Total</td>
<td>365</td>
<td>100.00%</td>
<td>14</td>
</tr>
</tbody>
</table>

Of all 379 ABPI assessments, 246 (64.9%) were completed on female patients and 132 (34.9%) performed on male patients.

The mean age of patients at the time of ABPI completion was 77.6 years (range: 38.0-99.4 years).

The mean year of ABPI classification for patients was 2010. The earliest ABPI recorded was on 03/05/2006 and most recent on 31/03/2015.

Of the 379 ABPI tests, the majority (365, 97.9%) were performed on NZ European Pakeha, 5 (1.3%) on NZ Māori, 2 (0.5%) on Chinese and 1 (0.3%) on Cook Island Māori. As shown in Table 16, there is a smaller percentage of NZ Māori having an ABPI than in the total enrolled MHC population (4.81%).

Most (63.3%) patients who had ABPI assessments live in the least socioeconomically deprived neighbourhoods (quintiles 1-3). Only 6.8% live in an area of most socio-economic deprivation. In comparison, 5.89% of the total MHC population live in the most deprived neighbourhoods and 73.19% live in lesser deprived areas (quintiles 1-3).

Eight percent of patients who had ABPIs were in the High Needs patient category.
In regards to healthcare providers; 28 (7.4%) ABPIs were completed by nurse “NC”, 2 (0.5%) were completed by nurse “MH”, while the rest of the ABPIs, 349 (92.1%) were completed by Dr Hywel Lloyd (see Section 3.3.2.3 ABPI Data Collectors).

Demography of individual patients who have had (one or more) ABPIs

There were 338 individual patients who have ever had an ABPI completed. Of the 338 individual patients, 82 (24.3%) patients were recorded as being deceased at 25/04/2015.

Figure 14 is a graph showing the 338 individuals, and the number of ABPIs they have had, by left-sided and right-sided ABPIs. The most ABPIs that any one patient had completed was four (on both left and right sides).

**Figure 14: Number of ABPIs that Individual Patients Have Had Completed**

There were no large differences in demographics of the 338 individual patients who have had one or more ABPIs and of the patients who had the 379 ABPI assessments. Table 17 shows very similar proportions within each demographic variable to Table 16 earlier:
Table 17: Demographic Characteristics of Enrolled and Non-Enrolled Patients who have had an ABPI at MHC for Individual Patients

<table>
<thead>
<tr>
<th>Demographic Characteristics (at time of ABPI)</th>
<th>Enrolled patients who have had an ABPI</th>
<th>Non-enrolled &quot;casual&quot; patients who have had an ABPI</th>
<th>Total patients who have had an ABPI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>% (1dp)</td>
<td>n</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F</td>
<td>203</td>
<td>62.7%</td>
<td>11</td>
</tr>
<tr>
<td>M</td>
<td>121</td>
<td>37.3%</td>
<td>2</td>
</tr>
<tr>
<td>Total known</td>
<td>324</td>
<td>100.00%</td>
<td>13</td>
</tr>
<tr>
<td>Total</td>
<td>324</td>
<td>100.00%</td>
<td>14</td>
</tr>
<tr>
<td><strong>Age Band</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>40-49</td>
<td>3</td>
<td>0.9%</td>
<td>0</td>
</tr>
<tr>
<td>50-59</td>
<td>11</td>
<td>3.4%</td>
<td>0</td>
</tr>
<tr>
<td>60-69</td>
<td>32</td>
<td>9.9%</td>
<td>0</td>
</tr>
<tr>
<td>70-79</td>
<td>78</td>
<td>24.1%</td>
<td>2</td>
</tr>
<tr>
<td>80-89</td>
<td>124</td>
<td>38.3%</td>
<td>6</td>
</tr>
<tr>
<td>90-99</td>
<td>71</td>
<td>21.9%</td>
<td>5</td>
</tr>
<tr>
<td>100+</td>
<td>5</td>
<td>1.5%</td>
<td>0</td>
</tr>
<tr>
<td>Total known</td>
<td>324</td>
<td>100.00%</td>
<td>13</td>
</tr>
<tr>
<td>Total</td>
<td>324</td>
<td>100.00%</td>
<td>14</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NZ European/ Pakeha</td>
<td>317</td>
<td>97.8%</td>
<td>7</td>
</tr>
<tr>
<td>NZ Māori</td>
<td>5</td>
<td>1.5%</td>
<td>0</td>
</tr>
<tr>
<td>Pacific</td>
<td>1</td>
<td>0.3%</td>
<td>0</td>
</tr>
<tr>
<td>Chinese</td>
<td>1</td>
<td>0.3%</td>
<td>1</td>
</tr>
<tr>
<td>Indian</td>
<td>0</td>
<td>0%</td>
<td>0</td>
</tr>
<tr>
<td>Other Asian</td>
<td>0</td>
<td>0%</td>
<td>0</td>
</tr>
<tr>
<td>Other Ethnicity</td>
<td>0</td>
<td>0%</td>
<td>0</td>
</tr>
<tr>
<td>Total known</td>
<td>324</td>
<td>100.00%</td>
<td>8</td>
</tr>
<tr>
<td>Total</td>
<td>324</td>
<td>100.00%</td>
<td>14</td>
</tr>
</tbody>
</table>
Demographic Characteristics (at time of ABPI)

<table>
<thead>
<tr>
<th>Socio-economic Quintile</th>
<th>Enrolled patients who have had an ABPI</th>
<th>Non-enrolled “casual” patients who have had an ABPI</th>
<th>Total patients who have had an ABPI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>% (1dp)</td>
<td>n</td>
</tr>
<tr>
<td>1 (most affluent)</td>
<td>49</td>
<td>19.8%</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>61</td>
<td>24.6%</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>42</td>
<td>16.9%</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>77</td>
<td>31.0%</td>
<td>1</td>
</tr>
<tr>
<td>5 (least affluent)</td>
<td>19</td>
<td>7.7%</td>
<td>0</td>
</tr>
<tr>
<td>Total known</td>
<td>248</td>
<td>100.00%</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>324</td>
<td>100.00%</td>
<td>14</td>
</tr>
</tbody>
</table>

High Needs

<table>
<thead>
<tr>
<th></th>
<th>Enrolled patients who have had an ABPI</th>
<th>Non-enrolled “casual” patients who have had an ABPI</th>
<th>Total patients who have had an ABPI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>% (1dp)</td>
<td>n</td>
</tr>
<tr>
<td>High Needs</td>
<td>23</td>
<td>9.3%</td>
<td>0</td>
</tr>
<tr>
<td>Not High Needs</td>
<td>225</td>
<td>90.7%</td>
<td>10</td>
</tr>
<tr>
<td>Total known</td>
<td>248</td>
<td>100.00%</td>
<td>10</td>
</tr>
<tr>
<td>Total</td>
<td>324</td>
<td>100.00%</td>
<td>14</td>
</tr>
</tbody>
</table>

Patients not enrolled in MHC

Of the 379 patients who had ABPI assessments, there were 14 ‘casual’ non-enrolled patients, all of whom only had 1 ABPI each. Therefore the second columns on Tables 16 and 17 are exactly the same.

Of patients not enrolled in MHC, 84.6% were female (compared to 62.7% for enrolled ABPI patients).

All 14 patients were 70-99 years of age, with 46.2% making up the ‘80-89’ year age band. Similarly, most enrolled ABPI patients were in the ‘80-89’ year age band. The mean age for casual patients was 85.5 years, compared to 79.0 years for enrolled ABPI patients.

There were some missing data for ethnicity, socio-economic quintiles and High Needs categories for casual patients because this information was not collected by MHC (see Section 3.3.5 Missing data).
3.4.1.3 Demographics of the Total Enrolled MHC Population who have never had an ABPI before

There were 19,017 individual patients recorded as being seen at MHC who had never had ABPIs. Only 9,648 individuals of the 19,017 were enrolled, making up the total enrolled MHC population who have never had an ABPI before (see Table 15).

3.4.2 Medical Conditions and Risk Factors

Prevalence for PAD, other medical conditions and risk factors were found for the total ABPI group and total MHC population.

3.4.2.1 PAD

There were 131 (1.3%) patients with recorded PAD between 2006 and 25/04/2015 in the total enrolled MHC population.

In the ABPI group, 43 of 338 (12.7%) individual patients had PAD between 2006 and 25/04/2015. There were 52 recorded sets of ABPIs completed on these 43 individual patients. Of these 43 patients who have had both PAD and ABPIs, 9 (20.9%) patients had 2 ABPIs each while the rest had 1 ABPI each.

There was a significantly larger proportion of patients with PAD in the ABPI population (12.7%) than in the total enrolled MHC population (1.3%).

Demographics of patients who have had ABPIs with and without PAD

The mean age of the 43 patients who have had ABPIs and have PAD was 81.8 years. This was made up of 16 patients (37.2%) aged 80-89 years, 11 (25.6%) aged 70-79 years and 9 (20.9%) aged 90-99 years at 25/04/2015. The mean age at the time of the ABPI for this group was 77.9 years. Age distribution was fairly similar in patients who have had ABPIs but without PAD.

A slightly larger proportion of patients who had ABPIs with PAD lived in quintiles 1-3 than patients who have had ABPIs without PAD living in quintiles 1-3 (65.1% vs 61.0%)

Similarly, of patients who have had ABPI, those with PAD were more likely to be in a High Needs category than those without PAD (11.6% vs 8.4%).

There was no large difference between any characteristics of patients who have had ABPIs with PAD compared to patients who have had ABPIs without PAD (see Table 18).
Table 18: Characteristics of Patients who have had an ABPI with PAD versus without PAD

<table>
<thead>
<tr>
<th>Characteristics of PVD patients</th>
<th>ABPI patients with PAD</th>
<th>ABPI patients without PAD</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F</td>
<td>27</td>
<td>62.8%</td>
<td>187</td>
</tr>
<tr>
<td>M</td>
<td>16</td>
<td>37.2%</td>
<td>107</td>
</tr>
<tr>
<td>Total</td>
<td>43</td>
<td>100%</td>
<td>295</td>
</tr>
<tr>
<td>Age Band</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-49</td>
<td>0</td>
<td>0%</td>
<td>3</td>
</tr>
<tr>
<td>50-79</td>
<td>17</td>
<td>39.5%</td>
<td>106</td>
</tr>
<tr>
<td>80+</td>
<td>26</td>
<td>60.5%</td>
<td>185</td>
</tr>
<tr>
<td>Total</td>
<td>43</td>
<td>100%</td>
<td>294</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NZ European/ Pakeha</td>
<td>42</td>
<td>97.7%</td>
<td>282</td>
</tr>
<tr>
<td>Other Ethnicity</td>
<td>1</td>
<td>2.3%</td>
<td>7</td>
</tr>
<tr>
<td>Total</td>
<td>43</td>
<td>100%</td>
<td>289</td>
</tr>
<tr>
<td>Quintile</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-3</td>
<td>28</td>
<td>65.1%</td>
<td>128</td>
</tr>
<tr>
<td>4-5</td>
<td>15</td>
<td>34.9%</td>
<td>82</td>
</tr>
<tr>
<td>Total</td>
<td>43</td>
<td>100%</td>
<td>210</td>
</tr>
<tr>
<td>High Needs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High Needs</td>
<td>5</td>
<td>11.6%</td>
<td>18</td>
</tr>
<tr>
<td>Not High Needs</td>
<td>38</td>
<td>88.4%</td>
<td>197</td>
</tr>
<tr>
<td>Total</td>
<td>43</td>
<td>100%</td>
<td>215</td>
</tr>
</tbody>
</table>

Mean ABPI Results in patients who have had ABPIs and have PAD

The mean ABPI results for patients who have had a PAD classification in MHC between 2003 and 25/04/2015 were 0.73 (s.d. 0.26) and 0.81 (s.d. 0.24) for right and left legs respectively. These values are lower than the mean ABPI values for the entire ABPI group.
### 3.4.2.2 Other Medical Conditions and Risk factors

Prevalence of other medical conditions and risk factors was calculated for the total enrolled MHC population and the total ABPI population. This is summarised on Tables 19 and 20 below:

<table>
<thead>
<tr>
<th>Medical Conditions</th>
<th>Total Enrolled MHC Population (9,890)</th>
<th>ABPI Group (338)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Arteriosclerotic disease</td>
<td>225</td>
<td>2.3%</td>
</tr>
<tr>
<td>PAD</td>
<td>131</td>
<td>1.3%</td>
</tr>
<tr>
<td>Ischaemic heart disease</td>
<td>819</td>
<td>8.3%</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>423</td>
<td>4.3%</td>
</tr>
<tr>
<td>Venous disease</td>
<td>233</td>
<td>2.4%</td>
</tr>
<tr>
<td>Peripheral oedema</td>
<td>64</td>
<td>0.6%</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>635</td>
<td>6.4%</td>
</tr>
<tr>
<td>Chronic leg or skin ulcers</td>
<td>50</td>
<td>0.5%</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>162</td>
<td>1.6%</td>
</tr>
<tr>
<td>Gout</td>
<td>396</td>
<td>4.0%</td>
</tr>
</tbody>
</table>

Most medical conditions were over-represented in the ABPI group. There were 53 individual patients who had ABPIs (15.7%) who also had arteriosclerotic disease. In comparison, only 2.3% of the total enrolled MHC population were recorded as having the same condition.

Of patients who had both a history of having ABPIs and a classification of arteriosclerotic disease, PAD was the commonest form of arteriosclerotic disease (43 of 53), eight patients had a non-ruptured abdominal aortic aneurysm, two had a ruptured abdominal aortic aneurysm, two had generalised atherosclerosis, two had claudication, and two had Raynaud’s syndrome recorded.

Over a quarter of the ABPI population had ischaemic heart disease, compared with 8.3% in the total enrolled MHC population.
Of the 88 individual patients who had ABPIs and a recorded classification of IHD; 77 had 'ischaemic heart disease not specified', eight had a record of acute myocardial infarction, two had a record of angina pectoris, and one had a record of unstable angina.

Following a similar trend, cerebrovascular disease was more prevalent in the ABPI population (12.4%) than the total enrolled MHC population (4.3%) between 2006 and 25/04/2015.

Venous disease was also over-represented in the ABPI group (12.7% vs 2.4%). Of the 20 patients who had an ABPI and have had a ‘chronic leg or skin ulcer’; nine had chronic skin ulcers, five had venous ulcers of the leg, three had varicose veins with associated ulceration, two had leg ulcers (not specified), and one had a mixed venous and arterial leg ulcer recorded.

<table>
<thead>
<tr>
<th>Medical risk factors</th>
<th>Total Enrolled MHC Population (9,890)</th>
<th>ABPI Group (338)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Hyperlipidaemia</td>
<td>110</td>
<td>1.1%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>2,044</td>
<td>20.7%</td>
</tr>
<tr>
<td>Smoking status-heavy or very heavy</td>
<td>143</td>
<td>1.4%</td>
</tr>
</tbody>
</table>

Hyperlipidaemia was not very prevalent in both total enrolled MHC and ABPI samples (1.1% vs 2.4%) but was greater for the ABPI group. The prevalence of hypertension in the ABPI group was over twice that the total enrolled MHC population.

Heavy or very heavy smoking status was not very prevalent in either group, with less than 1% of the ABPI population attributed this risk factor.

### 3.4.3 ABPI Values and Subgroups

There were 379 individual sets of ABPI data recorded as being completed at MHC between 2006 and 25/04/2015. One ‘set’ of ABPI data (from a single assessment) comprises 6 possible values including the right and left brachial pressures, the right and left PT pressures and the right and left DP pressures (see Section 3.3.3 ABPI Test Method).
3.4.3.1 Segmental Arterial Pressures

The mean segmental systolic arterial pressures as shown in Table 21 below:

Table 21: Mean Segmental Arterial Pressures among the ABPI Group

<table>
<thead>
<tr>
<th>Segmental arterial pressure</th>
<th>Mean systolic pressure</th>
<th>s.d.* (2dp)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right Brachial Artery Pressures</td>
<td>146.6</td>
<td>22.24</td>
</tr>
<tr>
<td>Left Brachial Artery Pressures</td>
<td>146.4</td>
<td>22.76</td>
</tr>
<tr>
<td>Right Posterior Tibial (PT) Artery Pressures</td>
<td>136.9</td>
<td>33.12</td>
</tr>
<tr>
<td>Left Posterior Tibial (PT) Artery Pressures</td>
<td>140.8</td>
<td>33.66</td>
</tr>
<tr>
<td>Right Dorsalis Pedis (DP) Artery Pressures</td>
<td>133.5</td>
<td>38.06</td>
</tr>
<tr>
<td>Left Dorsalis Pedis (DP) Artery Pressures</td>
<td>133.7</td>
<td>36.14</td>
</tr>
</tbody>
</table>

*Standard deviation (s.d.) is calculated only for known values; unobtainable/non-occludable pressures were excluded in calculation of s.d.

The brachial blood pressures were normally distributed as shown in Figure 15:

Figure 15: Right and Left Brachial Systolic Pressures

The PT and DP pressures are normally distributed as well (see Figures 16 and 17). However in the ABPI population, a larger proportion of patients had low DP and PT pressures (under 100mmHg) than that of brachial pressures.
3.4.3.2 Calculated ABPI Values

The mean ABPI values were 0.96 (s.d. 0.23) for right-sided ABPI values and 0.97 (s.d. 0.20) for left-sided ABPI values. Over 65% of right and left-sided ABPIs fell in the 0.9-1.2 range.

In regards to the 379 right-sided ABPI values, 24.5% had a value of <0.9, diagnostic of PAD. This was made up of 7.4% of values 0.8-0.89, 12.1% of values 0.5-0.79 and 5.0% of values <0.5.

In comparison, of the 379 left-sided ABPIs, 21.6% had a value of <0.9, made up of 4.7% of values 0.8-0.89, 15% of values 0.5-0.79 and only 1.8% of values <0.5.
ABPI values >1.2 made up 6.3% and 6.6% of right and left-sided ABPIs respectively.

Right and left-sided ABPI values were calculated using sets of segmental pressures and are summarised in Table 22:

**Table 22: ABPI values**

<table>
<thead>
<tr>
<th>ABPI Value Ranges</th>
<th>No. right-sided ABPI values (%*, %**)</th>
<th>No. left-sided ABPI values (%*, %**)</th>
<th>Total no. ABPI values</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥0.9</td>
<td>271 (74.5%, 71.5%)</td>
<td>283 (77.5%, 74.7%)</td>
<td>554</td>
</tr>
<tr>
<td>&lt;0.9</td>
<td>93 (25.5%, 24.5%)</td>
<td>82 (22.5%, 21.6%)</td>
<td>175</td>
</tr>
<tr>
<td>&lt;0.5</td>
<td>19 (5.2%, 5.0%)</td>
<td>7 (1.9%, 1.8%)</td>
<td>26</td>
</tr>
</tbody>
</table>

**ABPI Intervals‡**

<table>
<thead>
<tr>
<th></th>
<th>No. right-sided ABPI values (%*, %**)</th>
<th>No. left-sided ABPI values (%*, %**)</th>
<th>Total no. ABPI values</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;1.2</td>
<td>24 (6.6%, 6.3%)</td>
<td>25 (6.8%, 6.6%)</td>
<td>49</td>
</tr>
<tr>
<td>0.9-1.2</td>
<td>247 (67.9%, 65.2%)</td>
<td>258 (70.7%, 68.1%)</td>
<td>505</td>
</tr>
<tr>
<td>0.8-0.89</td>
<td>28 (7.7%, 7.4%)</td>
<td>18 (4.9%, 4.7%)</td>
<td>46</td>
</tr>
<tr>
<td>0.5-0.79</td>
<td>46 (12.6%, 12.1%)</td>
<td>57 (15.6%, 15.0%)</td>
<td>103</td>
</tr>
<tr>
<td>&lt;0.5</td>
<td>19 (5.2%, 5.0%)</td>
<td>7 (1.9%, 1.8%)</td>
<td>26</td>
</tr>
</tbody>
</table>

**Totals**

<table>
<thead>
<tr>
<th></th>
<th>No. right-sided ABPI values (%*)</th>
<th>No. left-sided ABPI values (%*)</th>
<th>Total no. ABPI values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obtainable ABPI</td>
<td>364 (94.9%)</td>
<td>365 (94.7%)</td>
<td>729</td>
</tr>
<tr>
<td>Unobtainable ABPI values†</td>
<td>15 (4.0%) of total</td>
<td>14 (3.7%) of total</td>
<td>29</td>
</tr>
<tr>
<td>Total ABPI sets</td>
<td>379</td>
<td>379</td>
<td>758</td>
</tr>
</tbody>
</table>

*% of obtainable ABPI values (1dp)
**% of total ABPI tests (1dp)
‡Implications of different values include:
  >1.2 Normal or potential abnormality due to calcified vessels
  0.9-1.2 Normal ABPI value
  <0.9 PAD
  0.8-0.89 Mild abnormality
  <0.5 Severe abnormality
†Unobtainable values= where the artery was non-occludable or unobtainable
The following graphs in Figure 18 show the distribution of ABPI values for right and left sides respectively. Most ABPI results fell in the 0.9-1.2 subgroup for both sides.

**Figure 18: Right ABPI Value Distribution**

![Right ABPI Value Distribution](image)

**Figure 18: Left ABPI Value Distribution**

![Left ABPI Value Distribution](image)

Unobtainable and non-occludable values

There were 15 right-sided and 14 left-sided ABPIs in which a value could not be found. Of the 15 right-sided ABPIs, 9 were non-occludable, 2 were unobtainable, 4 did not state whether unobtainable nor non-occludable. Of the 14 left-sided ABPIs, 11 were non-occludable, 2 were unobtainable and 2 did not state why a value was not recorded.

3.4.3.3 Demographics of ABPI Subgroups

The sex distribution of patients who had an ABPI value of 0.9-1.2 was similar to that of the total ABPI group. However, there were more males in the group of patients with ABPIs <0.9 than in the group with ABPIs 0.9-1.2.

In the subgroup 0.9-1.2, males made up 32.76%, however, made up 45.46% of the <0.5 subgroup. This was not statistically significant (p-value=0.591).

The mean age for right and left ABPIs 0.9-1.2 were 76.2 and 76.3 years (s.d. 10.4). This was slightly younger than the mean age for the ABPIs with values <0.9- with mean ages for right and left ABPIs being 79.9 and 80.2 years respectively. Therefore, patients with ABPIs 0.9-1.2
were on average younger than those with ABPIs <0.9. All subgroups except for ABPI values <0.5 display normal distribution for age. The median age for left and right ABPIs <0.5 were 81.4 and 83.3 years.

The ethnic distribution among ABPI subgroups was found to be fairly similar, as shown in Table 23. Each group is made up nearly entirely of NZ European patients. All patients with ABPI results <0.5 were NZ European.

Table 23: Ethnic distribution in ABPI Subgroups

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>ABPI results 0.9-1.2 (Normal)</th>
<th>ABPI results &lt;0.9 (Abnormal)</th>
<th>ABPI results &lt;0.5 (Severely Abnormal)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NZ European</td>
<td>285 (99.3%)</td>
<td>112 (98.2%)</td>
<td>22 (100%)</td>
</tr>
<tr>
<td>Other Ethnicity</td>
<td>2 (0.7%)</td>
<td>2 (1.8%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Total no. patients with an ABPI of that value*</td>
<td>287</td>
<td>114</td>
<td>22</td>
</tr>
</tbody>
</table>

*with data on ethnicity

Patients from all subgroups covered all socio-economic quintiles (see Table 24). There did not seem to be skewing of ABPI results to any specific quintile.

The second and fourth quartiles tend to have larger proportions in each of the subgroups. Almost a third of patients with an ABPI result of 0.9-1.2 lived in quintile 4, and over 40% lived in quintile 1 or 2. Nearly 30% of patients who had an ABPI result of <0.9 lived in quintile 2 and 30% lived in quintile 4.

In contrast, nearly 35% of the total MHC population were living in an area of quintile 1, so there is more even spread of patients who have had ABPIs among different socio-economic quintiles, than in the total MHC population.

The proportions of High Needs to Non-High Needs patients were similar among patients with ABPI results 0.9-1.2 and those with ABPI results <0.9 (see Table 25).

Only 5.9% of patients with ABPI results <0.5 were of High Needs category. There were missing data for this group however (see Section 3.3.5 Missing Data).
### Table 24: Socio-economic Distribution in ABPI subgroups by Socio-economic Quintile

<table>
<thead>
<tr>
<th>Socio-economic Quintile</th>
<th>ABPI results 0.9-1.2 (Normal)</th>
<th>ABPI results &lt;0.9 (Abnormal)</th>
<th>ABPI results &lt;0.5 (Severely Abnormal)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>52 (21.9%)</td>
<td>17 (23.0%)</td>
<td>4 (23.5%)</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>54 (22.8%)</td>
<td>21 (28.4%)</td>
<td>7 (41.2%)</td>
</tr>
<tr>
<td>3</td>
<td>37 (15.6%)</td>
<td>8 (10.8%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>4</td>
<td>67 (28.3%)</td>
<td>23 (31.1%)</td>
<td>5 (29.4%)</td>
</tr>
<tr>
<td>5</td>
<td>27 (11.4%)</td>
<td>5 (6.8%)</td>
<td>1 (5.9%)</td>
</tr>
<tr>
<td>Total no. patients with an ABPI of that value*</td>
<td>237</td>
<td>74</td>
<td>17</td>
</tr>
</tbody>
</table>

*with data on socio-economic quintiles

### Table 25: High Needs patients in ABPI subgroups

<table>
<thead>
<tr>
<th>High Needs Categories</th>
<th>ABPI results 0.9-1.2 (Normal)</th>
<th>ABPI results &lt;0.9 (Abnormal)</th>
<th>ABPI results &lt;0.5 (Severely Abnormal)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Needs</td>
<td>20 (8.6%)</td>
<td>6 (7.8%)</td>
<td>1 (5.9%)</td>
</tr>
<tr>
<td>Not High Needs</td>
<td>212 (91.4%)</td>
<td>71 (92.2%)</td>
<td>16 (94.1%)</td>
</tr>
<tr>
<td>Total no. patients with an ABPI of that value*</td>
<td>232</td>
<td>77</td>
<td>17</td>
</tr>
</tbody>
</table>

*with data on High Needs categories

### 3.4.4 Indications for Having the ABPI

Of the 379 ABPI assessments completed, most (213, 56.2%) were used to guide management of a venous-related issue, 45.6% (173) were completed to investigate suspected PAD, and a minority (10.6%, 40) completed for an ‘other’ reason. These groups are not mutually exclusive and therefore percentages did not exactly add up to 100%.

The specific indication categories are outlined in Table 26:
### Table 26: Indication Categories for completed ABPIs

<table>
<thead>
<tr>
<th>Indication Category Group*</th>
<th>Indication Category</th>
<th>Number of ABPIs</th>
<th>Percentage of Indication Category Group</th>
<th>Percentage of all 379 ABPIs</th>
</tr>
</thead>
<tbody>
<tr>
<td>To guide management of venous disease</td>
<td>Foot or leg ulcer</td>
<td>118</td>
<td>55.4%</td>
<td>31.1%</td>
</tr>
<tr>
<td></td>
<td>Traumatic foot or leg ulcer</td>
<td>41</td>
<td>23.9%</td>
<td>10.8%</td>
</tr>
<tr>
<td></td>
<td>Venous insufficiency</td>
<td>138</td>
<td>54.8%</td>
<td>36.4%</td>
</tr>
<tr>
<td>To investigate suspected PAD</td>
<td>Leg pain (intermittent or resting)</td>
<td>105</td>
<td>60.7%</td>
<td>27.7%</td>
</tr>
<tr>
<td></td>
<td>Intermittent</td>
<td>81</td>
<td>46.8%</td>
<td>21.4%</td>
</tr>
<tr>
<td></td>
<td>Resting</td>
<td>37</td>
<td>21.4%</td>
<td>9.8%</td>
</tr>
<tr>
<td></td>
<td>Clear history of classic vascular claudication or rest pain</td>
<td>51</td>
<td>29.5%</td>
<td>13.5%</td>
</tr>
<tr>
<td>Toe/foot pain</td>
<td></td>
<td>54</td>
<td>31.2%</td>
<td>14.2%</td>
</tr>
<tr>
<td>Sensation of unusually cold feet</td>
<td></td>
<td>7</td>
<td>4.0%</td>
<td>1.8%</td>
</tr>
<tr>
<td>Absence of pulse or very cold peripheries noted on examination</td>
<td>50</td>
<td>28.9%</td>
<td>13.2%</td>
<td></td>
</tr>
<tr>
<td>Discolouration to any of the lower extremities</td>
<td>8</td>
<td>4.6%</td>
<td>2.1%</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>To evaluate appropriate elective use of compression stockings for travel</td>
<td>7</td>
<td>17.5%</td>
<td>1.8%</td>
</tr>
<tr>
<td>Other**</td>
<td></td>
<td>34</td>
<td>85%</td>
<td>9.0%</td>
</tr>
</tbody>
</table>

* *In order of most to least prevalent Indication Category Group
**The “other” indication category included numbness in legs, numbness of feet, groin pain radiating into the legs, sensation of restless legs, strange lesions on the legs, tiredness in the legs, tingling in toes, and unspecified foot/leg problems.

### To guide management of venous disease

Among ABPIs completed to guide management of venous disease, 55.4% had indications related to a foot or leg ulcer, and 54.8% had indications related to venous insufficiency. Venous insufficiency included peripheral oedema, varicose veins and varicose eczema.

Under half of all foot or leg ulcers (41 of 118) were traumatic in aetiology. Ulcers that were not of traumatic cause may have been of venous insufficiency alone or diabetic neuropathy.
To investigate suspected PAD

Of patients who had an indication for an ABPI relating to investigating suspected arterial disease as shown on Table 26, the majority (60.7%) had either intermittent or resting leg pain.

With intermittent and resting leg pain considered separately, intermittent leg pain made up 46.8% of reasons for patients investigated for suspected PAD. Resting leg pain made up 21.4% of indications for patients who were investigated for suspected PAD.

Around 52% of patients who had an ABPI due to leg pain (intermittent or resting) had a clear history of classic vascular claudication or rest pain. Classic vascular claudication and rest pain made up 29.5% of all those who were suspected for PAD.

There was a large proportion of patients who had ‘toe/foot pain’ (31.2%), or ‘absence of pulse or cold peripheries on examination’ (28.9%) contributing to reasons why patients required an ABPI.

A minority (4.0%) of patients who were investigated for suspected PAD had sensation of unusually cold feet prompting ABPI investigation. Discolouration to the lower limbs was also a contributing reason for 4.6% of the ABPIs in this group.

There were 33 (8.7%) ABPIs that had both indications to investigate suspected PAD, and to guide management of venous disease. For instance, a patient who had a leg ulcer and discolouration of the lower extremities, requiring ABPIs.

‘Other’ indication category

Among ABPIs completed for other reasons, a significant subset (17.5%) were used to evaluate the appropriate use of compression stockings for travel as prophylaxis for DVT. This accounted for 1.8% of the total population.

Non-specific individual reasons were documented for 85% of patients who had ABPIs completed for ‘other reasons’. These included; numbness in the legs, numbness in the feet, groin pain radiating into the legs, and strange lesions on the legs.

3.4.5 Outcomes Following the ABPI

3.4.5.1 Outcome Category Groups and Categories

Of the 379 completed ABPI assessments, 30.9% (117) were managed as having venous disease without ulceration, 29.3% (111) were managed as having venous disease with ulceration.
Further, 23.2% (88) had nil further peripheral vascular management, which meant they were not treated for either venous or arterial disease, and were reassured that their ABPI result was normal. Out of all ABPIs, 17.7% (67) had ‘other management arranged’ and 16.9% (64) had been managed as having PAD alone (not mixed disease). Outcome category groups were not mutually exclusive and so percentages did not add to 100%.

Table 27 below outlines the outcomes of all ABPIs, grouped by the overarching methods of management (outcome category groups):

**Management of venous disease without ulceration**

Management of venous disease without ulceration was the most prevalent outcome category group among the ABPI group (117, 30.9%). Just under 70% of patients managed for venous disease without ulceration were managed via compression treatment (hosiery, layer bandaging) (80, 68.4%).

In contrast, 11.1% (13) were managed conservatively (such as pain management, antibiotics for cellulitic-looking legs, education regarding oedema and foot care etc.), 8.5% (10) required district nursing services for care of legs (e.g. peripheral oedema), and 8.5% (10) involved a referral to a secondary care vascular department. Only 5.1% (6) had nil further management (see later on in this Section).

**Management of venous disease with any lower limb ulceration**

Of all patients who had management of venous disease with any lower limb ulceration, more than half of all patients who had ABPI assessments were managed with compression (hosiery, layer bandaging) (66, 59.5%) or other conservative treatment (58.6%). Conservative treatment included redressing of the ulcer, antibiotics for wound infection etc.

Around half of all ABPI assessments managed for venous disease with ulceration were followed with patient referral to district nursing services (57, 51.4%) for wound care purposes.

In respect to referrals, 47 (42.3%) ABPI assessments involved a referral to a secondary care vascular department, and a few (3, 2.7%) involved a referral to another secondary care department. This included two referrals to dermatology for squamous cell carcinoma review or excision, and one rheumatology review for co-morbidities contributing to neuropathic pressure ulceration.

Only one (0.9%) had no further management (see later in this Section).
Table 27: Outcome Category Groups and Outcome Category Results

<table>
<thead>
<tr>
<th>Outcome Category Group*</th>
<th>Outcome Category</th>
<th>Number of ABPIs</th>
<th>Percentage of Outcome Category Group (%)</th>
<th>Percentage of all 379 ABPIs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Management of venous disease without ulcer</td>
<td>Nil further management</td>
<td>6</td>
<td>5.1%</td>
<td>1.6%</td>
</tr>
<tr>
<td></td>
<td>Compression treatment</td>
<td>80</td>
<td>68.4%</td>
<td>21.1%</td>
</tr>
<tr>
<td></td>
<td>Other conservative management</td>
<td>13</td>
<td>11.1%</td>
<td>3.4%</td>
</tr>
<tr>
<td></td>
<td>District nursing Services</td>
<td>10</td>
<td>8.5%</td>
<td>2.6%</td>
</tr>
<tr>
<td></td>
<td>Referral to secondary care Vascular Department</td>
<td>10</td>
<td>8.5%</td>
<td>2.6%</td>
</tr>
<tr>
<td>Management of venous disease with ulcer</td>
<td>Nil further management</td>
<td>1</td>
<td>0.9%</td>
<td>0.3%</td>
</tr>
<tr>
<td></td>
<td>Compression treatment</td>
<td>66</td>
<td>59.5%</td>
<td>17.4%</td>
</tr>
<tr>
<td></td>
<td>Other conservative management</td>
<td>65</td>
<td>58.6%</td>
<td>17.2%</td>
</tr>
<tr>
<td></td>
<td>District nursing Services</td>
<td>57</td>
<td>51.4%</td>
<td>15.0%</td>
</tr>
<tr>
<td></td>
<td>Referral to secondary care Vascular Department</td>
<td>47</td>
<td>42.3%</td>
<td>12.4%</td>
</tr>
<tr>
<td></td>
<td>Referral to secondary care other department</td>
<td>3</td>
<td>2.7%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Nil further management</td>
<td>Nil further peripheral vascular management</td>
<td>88</td>
<td>100.0%</td>
<td>23.2%</td>
</tr>
<tr>
<td>Other management arranged**</td>
<td>Conservative management</td>
<td>26</td>
<td>38.8%</td>
<td>6.9%</td>
</tr>
<tr>
<td></td>
<td>Investigations for other diagnoses</td>
<td>14</td>
<td>20.9%</td>
<td>3.7%</td>
</tr>
<tr>
<td></td>
<td>Dermatological investigation</td>
<td>5</td>
<td>7.5%</td>
<td>1.3%</td>
</tr>
<tr>
<td></td>
<td>Referral to secondary care vascular department</td>
<td>5</td>
<td>7.5%</td>
<td>1.3%</td>
</tr>
<tr>
<td></td>
<td>Referral to secondary care other department</td>
<td>22</td>
<td>32.8%</td>
<td>5.8%</td>
</tr>
<tr>
<td></td>
<td>District nursing services</td>
<td>1</td>
<td>1.5%</td>
<td>0.3%</td>
</tr>
<tr>
<td></td>
<td>Podiatry services</td>
<td>9</td>
<td>13.4%</td>
<td>2.4%</td>
</tr>
<tr>
<td></td>
<td>Compression treatment</td>
<td>8</td>
<td>11.9%</td>
<td>2.1%</td>
</tr>
<tr>
<td>Management of PAD</td>
<td>Nil further management</td>
<td>14</td>
<td>21.9%</td>
<td>3.7%</td>
</tr>
<tr>
<td></td>
<td>Other conservative management</td>
<td>15</td>
<td>23.4%</td>
<td>4.0%</td>
</tr>
<tr>
<td></td>
<td>Referral to secondary care vascular department</td>
<td>47</td>
<td>73.4%</td>
<td>12.4%</td>
</tr>
</tbody>
</table>

*In order of most to least prevalent Outcome Category Group

**Other management arranged= none of management for venous disease, management of PAD, nor nil further management.
As stated in Section 3.4.4 Indications for Having the ABPI, there were 41 traumatic leg ulcers reported as indicating factors for having an ABPI in the sample of 379 (10.8%). Of the 41, 26 (63.4%) had compression treatment following ABPI, 25 (61.0%) had other conservative management, 23 (56.1%) were referred to the district nursing service, and 16 (39.0%) were referred to a secondary care vascular department.

**Management of PAD**

Of patients who were managed as PAD based on the ABPI and clinical features (see Section 3.3.2 Data Collection), nearly three-quarters of cases were referred to a secondary care vascular department (47, 73.4%).

Approximately one quarter (15, 23.4%) of patients had other conservative management, such as prescription of pain medication, cardiovascular risk factor management, education about foot care etc. About 15.6% (10) of patients managed for PVD/arterial disease had both conservative management measures (such as pain medication) and were also referred to a secondary care vascular department.

Nil further management followed 14 (21.9%) ABPI assessments managed for PAD. Patients who had nil further management were individually managed taking into account age, co-morbidities, terminal illness, mobility and quality of life. For instance, some elderly patients (over 80 years) who had PAD based on ABPI results and mild symptoms did not receive any conservative treatment (e.g. to avoid discomfort of stockings) and no referral (e.g. as there was little point in seeing a vascular team due to significant comorbidities precluding them from interventions such as surgery).

In terms of patients who had a clear history of classic vascular claudication or rest pain, 35 of 51 (68.6%) were referred to a secondary care vascular department. Nine of the 51 patients (17.6%) had conservative management, while three (5.9%) had nil further vascular management.

Of the 54 who did not have a clear history of classic vascular claudication (either intermittent or rest pain), 13 (24.1%) were identified as having PAD following the ABPI and were managed accordingly. Eight of those 13 patients were referred to the secondary care vascular services. Five of the 13 had conservative management and one required nil further management following the ABPI. The remaining 41 of 54 were managed differently- under ‘other management arranged’ as they had ABPI results >0.9, excluding PAD.
Nil further management

Of all 379 ABPI consultations, 23.2% were not managed any further in regards to vascular treatment due to having a normal ABPI not suggestive of PAD, and having no restrictive vascular symptoms.

Other management arranged

Among patients who were managed under the outcome category group ‘other management arranged’, 32.8% (22) were referred to another secondary care department.

Patients in this category often had conservative management (26, 38.8%) involving pain medications, pharmacotherapy or education for cardiovascular risk factors, and foot care education as examples.

One in every five patients who were managed in ‘another way’ had investigations arranged for other possible diagnoses (14, 20.9%). Five of the 14 patients were referred for a dermatological investigation (i.e. punch biopsy) following ABPI assessment.

Of all patients who had ‘other management arranged’, eight (11.9%) had compression treatment for DVT prophylaxis for travel purposes (in patients with risk factors).

Five patients (7.5%) who had ‘other management arranged’ were referred to a secondary care vascular department (but not for PAD or venous disease). Reasons included referrals for symptomatic patients with normal ABPIs, or queries to the vascular lab for potential DVT.

3.4.5.2 Secondary Care Vascular Department Outcome Categories

There were 100 referrals made to the secondary care vascular department in total, equating to 26.39% of all ABPI assessments. Investigations and management categories were described for these referrals, as shown in Table 28:

Investigations

About a third (32%) of all referrals resulted in an arterial duplex scan for patients.

There were 27 (27%) patients who were referred to a secondary care vascular department and had formal vascular laboratory ABPIs completed, and 20 (20%) patients who had PVRs completed. Exercise ABPIs followed 6% (6) of referrals. The purpose of the vascular department’s requests for formal vascular lab ABPIs was generally to re-check all ABPIs, or to have up-to-date resting ABPIs to be compared with PVRs or exercise ABPIs. Most patients
were seen three to five months following referral, sometimes meaning that there were changes in clinical history reported and at times the requirement of a more current ABPI result, and had to be repeated.

Angiography was needed for 7% (7) of patients referred. Venous duplex scanning followed 5% of total referrals to the secondary care vascular department.

Table 28: Secondary Care Vascular Department Outcome Categories - Results

<table>
<thead>
<tr>
<th>Secondary Care Vascular Department Outcome Category</th>
<th>Number of ABPIs</th>
<th>Percentage of all Vascular department referrals (100)</th>
<th>Percentage of all 379 ABPIs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Investigations:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arterial duplex scanning</td>
<td>32</td>
<td>32.0%</td>
<td>8.4%</td>
</tr>
<tr>
<td>Formal vascular lab ABPIs</td>
<td>27</td>
<td>27.0%</td>
<td>7.1%</td>
</tr>
<tr>
<td>PVR</td>
<td>20</td>
<td>20.0%</td>
<td>5.3%</td>
</tr>
<tr>
<td>Angiography</td>
<td>7</td>
<td>7.0%</td>
<td>1.8%</td>
</tr>
<tr>
<td>Exercise ABPIs</td>
<td>6</td>
<td>6.0%</td>
<td>1.6%</td>
</tr>
<tr>
<td>Venous duplex scanning</td>
<td>5</td>
<td>5.0%</td>
<td>1.3%</td>
</tr>
<tr>
<td><strong>Other Management:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compression stockings or bandaging</td>
<td>35</td>
<td>35.0%</td>
<td>9.2%</td>
</tr>
<tr>
<td>Referral to the wound care nurse specialist or ulcer care clinic</td>
<td>9</td>
<td>9.0%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Bypass operation</td>
<td>9</td>
<td>9.0%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Nil</td>
<td>7</td>
<td>7.0%</td>
<td>1.8%</td>
</tr>
<tr>
<td>Waiting to be seen</td>
<td>7</td>
<td>7.0%</td>
<td>1.8%</td>
</tr>
<tr>
<td>Lower limb endarterectomy</td>
<td>5</td>
<td>5.0%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Ulcer or wound debridement</td>
<td>5</td>
<td>5.0%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Toe amputation</td>
<td>5</td>
<td>5.0%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Above-knee amputation</td>
<td>5</td>
<td>5.0%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Sclerotherapy</td>
<td>2</td>
<td>2.0%</td>
<td>0.5%</td>
</tr>
<tr>
<td>Other management</td>
<td>2</td>
<td>2.0%</td>
<td>0.5%</td>
</tr>
<tr>
<td>Below-knee amputation</td>
<td>0</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>
Other Management

After patients had been seen by the vascular service at the hospital, 35 (35%) were given compression treatment (hosiery or bandaging), and 9 (9%) were referred to the wound care clinic (with specialist input from a wound care nurse).

In regards to more invasive treatments, nine (9%) patients went on to have a bypass operation, five (5%) required debridement of a wound or ulcer and five (5%) patients had a lower limb endarterectomy.

There were five (5%) patients who had toe amputations, none who had below-knee amputations but five (5%) had above-knee amputations which all followed referral. Above-knee amputations were required in patients who were unresponsive to other treatments, or who had necrotic tissue where there was no other option available.

Only two (2%) patients required sclerotherapy for venous disease.

There were two patient referrals which resulted in “other management”. One of these patients had ulcer excision and skin grafting, and the other had thrombolysis. These were outlier cases which do not represent the majority of the management for secondary care.

Seven (7%) patients referred had nil further management and were re-referred back to the GP. The reasons for this are highlighted on Table 29 below.

Seven (7%) patients who had been referred were still waiting to be assessed by the vascular team as at 25/04/2015.
Table 29: Cases Referred to a Secondary Care Vascular Department which did not result in Further Management

<table>
<thead>
<tr>
<th>Case</th>
<th>Reason for referral (Outcome Category)</th>
<th>Reason for nil further management</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Other- Low left dorsalis pedis pressure, needed compressive therapy for travel</td>
<td>Patient was found to have normal ABPIs in clinic (no formal ABPIs) and was reassured that no further management was required.</td>
</tr>
<tr>
<td>B</td>
<td>Management of venous disease with ulceration</td>
<td>Patient declined any further intervention following discussion with the vascular team.</td>
</tr>
<tr>
<td>C</td>
<td>Management as PAD</td>
<td>Secondary care assessment found that the patient was asymptomatic and had atypical calf pain not typical of vascular pain. No further management necessary.</td>
</tr>
<tr>
<td>D</td>
<td>Management as PAD</td>
<td>The impression by the vascular team was that of spinal stenosis and a re-referral to neurology was made.</td>
</tr>
<tr>
<td>E</td>
<td>Management of venous disease with ulceration</td>
<td>The patient was referred with a non-healing ulcer and a reduced ABPI, but the ulcer had healed completely upon seeing the vascular team. Wait time was 2 months between referral and being seen.</td>
</tr>
<tr>
<td>F</td>
<td>Management as PAD</td>
<td>The impression by the vascular team was that of spinal stenosis and a re-referral to neurology was made.</td>
</tr>
<tr>
<td>G</td>
<td>Management of venous disease with ulceration</td>
<td>Patient declined any further intervention following discussion with the vascular team.</td>
</tr>
</tbody>
</table>
3.4.6 Deceased Patients

Total MHC population

There were relatively few deaths (‘dead’ statuses) recorded in the data (only five found upon data cleaning). Governmental funding is allocated in three month blocks only, and if patients die in that three month block, records are still recorded in the enrolled population. When a new three month block begins, because no dead patients are eligible for funding, patients’ records would be removed from the PMS. Therefore during the last three month block period, five patients died. This explains the scarce number of enrolled patients being classified as ‘dead’.

Upon cleaning the data, 58 of the total enrolled MHC patients had no “dead/alive” status, and their data has been included as they are assumed to be living.

ABPI Group

There were 82 individual patients who had been recorded as deceased as at the 25/04/2015, and who had been recorded as having at least one ABPI in the past. The mean age of these 82 patients at the time of their ABPI was 88.7 years (compared with 77.6 years for the entire ABPI group). There were 97 ABPI assessments recorded for these 82 individual patients.

Table 30: ABPI Values and Co-Morbidities among Deceased and Non-Deceased ABPI Patients

<table>
<thead>
<tr>
<th>ABPI Values and co-morbidities</th>
<th>Deceased ABPI patients (enrolled)</th>
<th>Non-deceased ABPI patients (enrolled)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Right</td>
<td>Left</td>
</tr>
<tr>
<td>ABPIs (ABPI result)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>0.91</td>
<td>0.94</td>
</tr>
<tr>
<td>Range (Min-Max)</td>
<td>0.10-1.39</td>
<td>0.30-1.71</td>
</tr>
<tr>
<td>ABPI Results (n)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;1.2</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>0.9-1.2</td>
<td>48</td>
<td>47</td>
</tr>
<tr>
<td>&lt;0.9</td>
<td>27</td>
<td>26</td>
</tr>
<tr>
<td>&lt;0.5</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Unobtainable or non-occludable</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>82</td>
<td>82</td>
</tr>
</tbody>
</table>
Of the deceased ABPI patients, 57% were female, and all but one patient was of NZ European/Pakeha ethnicity. There was substantial missing data on socio-economic quintile and High Needs for this population (see Section 3.3.5 Missing Data).

The mean ABPI results for right and left legs for deceased patients were 0.91 and 0.94 respectively (at the time of their ABPI). These mean results were lower than the mean results for non-deceased patients (0.98 and 1.00).

**Figure 19: Percentage of ABPI Values for Deceased and Non-Deceased Groups**

Of all enrolled ABPI patients, a larger percentage of non-deceased patients had ABPI values 0.9-1.2 than patients who had died before 25/04/2015. Conversely, a larger percentage of patients who had died before 25/04/2015 had ABPI values <0.9 than those still alive. The proportions of ABPI values >1.2 were very similar among both deceased and non-deceased groups.
3.5 Chapter 3 Summary

This quantitative study describes the use of the ABPI in MHC over 2006-2015.

ABPIs were conducted by Dr Hywel Lloyd at MHC between 2006 and 2015. ABPI data collected showed that 379 individual assessments were completed on 338 patients during that time. The main reasons that ABPIs were completed were to aid in guiding management of venous disease and to investigate suspected PAD. Patients who had ABPI assessments had similar demographic characteristics to that of the total enrolled MHC population. However, patients who had ABPI assessments had higher prevalence of other non-communicable medical conditions than the total enrolled MHC population.

Nearly a third of patients having undergone ABPI assessments were managed as having venous disease without ulceration, a third were managed as having venous disease with ulceration, and about a quarter had no further peripheral vascular management. These categories were not mutually exclusive. Just over 16% of patients were managed as having PAD (without mixed disease). Of patients referred to a secondary care vascular service, 93% had further investigation or secondary care management.
Chapter 4: Interviewing Local Health Professionals Regarding the ABPI in Primary Care- The Qualitative Arm of the Study

4.1 Introduction

The benefits of conducting ABPIs in both primary and secondary care are well documented in the literature, yet the actual use of the ABPI in primary care is still limited. Internationally, quantitative and qualitative studies conducted among patients and health professionals in general practices acknowledge usefulness in using the tool but concerns have been raised regarding practical barriers such as taking too much time and being costly. To date, no research has examined the usefulness of the ABPI in New Zealand general practice.

To understand the possible practical barriers for undertaking ABPI assessment in primary care, a qualitative study involving interviews with health professionals in both primary and secondary care settings was conducted. This qualitative study gives insight into how and why the ABPI is or is not used currently by practicing clinicians, in order to identify the advantages and disadvantages of this assessment tool. This study examines the views of health professionals regarding the role of the ABPI in primary care, highlighting potential challenges to be addressed. If the ABPI is seen to be beneficial, then addressing and attempting to eliminate the barriers identified could help to enable future facilitation of this assessment in general practice.

4.1.1 Aims

- To explore perspectives of health professionals on the ABPI in general, and in terms of its role in primary care specifically.
- To understand the prior knowledge and experience that health professionals have had regarding the ABPI.
- To understand the perceived advantages of using the ABPI in general practice.
- To understand the challenges which hinder or prevent the use of the ABPI in general practice.
4.2 Study Design

The entire study is split into a quantitative analysis arm (Chapter 3) and a qualitative analysis arm (Chapter 4).

The study design of this arm is a qualitative analysis of a series of in depth face-to-face semi-structured interviews.

4.2.1 Study Participants and Setting

4.2.1.1 Participants, Inclusion Criteria

Participants were recruited using a snowball sampling technique.\textsuperscript{150}

Snowball sampling is a non-random sampling method in which members of the study population are engaged by recommendation from other members. This allows for acquisition of participants who may have been difficult to contact otherwise. Snowball sampling allows stakeholders and professionals in the field to determine suitable candidates, such as colleagues with a special interest or expertise in the topic. In practice, this meant asking participants about recommending colleagues (e.g. GPs, nurses) for invitation to the study, following their interview. Contact details were collected, and invitation emails sent.

Perspectives were also drawn from secondary care health professionals working in the vascular surgery department at Dunedin Public Hospital. Vascular referrals in the Otago Southland region are made to this service, and so it is prudent to appreciate opinions from this end of the referral pathway. Interviews with secondary health professionals also allowed a more holistic view to the subject, and to gain information from another viewpoint to supplement analysis of the other primary care health professionals’ interviews.

Each participant read and signed an information sheet and consent form prior to recruitment.

Inclusion Criteria

Inclusion criteria for participants included:

- Being situated in the wider Dunedin area
- Being available to be interviewed in person for roughly fifteen minutes to half an hour between June to September 2015
4.2.1.2 Sample Size

Sample size was determined based on the theoretical saturation point (when information redundancy was achieved). This was estimated to be at around 8-10 primary care participants initially.

Similarly, there was room to expand the number of participants interviewed should the researcher discover new themes or differences in data in order for information redundancy to be achieved (and more data on viewpoints to be shared).

4.2.1.3 Population Setting

The sample is confined to practitioners in the Otago/Southland region, in Dunedin. This is based on practical capabilities of the candidate being able to physically interview health professionals face-to-face.

4.3 Methods

4.3.1 Qualitative Methods Used

This qualitative arm of the study involved conducting face-to-face interviews with health professionals for evaluation of the ABPI in general practice.

4.3.2 Interview and Interview Design

Participants were interviewed using a semi-structured format. Open questions were chosen as a method of engaging a fuller response, and allowing flexibility for the interviewer (candidate) to probe for further clarification or information. An interview schedule was written as a guide for each interview (see Appendixes I and J) with pre-determined categories (topics) and questions to be explored.

Categories included prior experience of health professionals with the ABPI, views on advantages of the ABPI, views on barriers or challenges to using the ABPI, and views on the use of ABPI in the primary care sector.

Traditional interview techniques were incorporated into interviews to stimulate conversation and reasoning. Techniques used by the interviewer to establish rapport included reflective
listening, being unassuming, and using encouragers (such as nodding of the head). This helped to maximise the amount of information interviewees were willing to share.

Interviews were audio recorded using an Olympus digital voice recorder (model DS-2300), and audio files of all interviews were saved onto a secure computer. These audio files were used for manual transcription by the candidate into textual format, allowing for analysis and coding (see Section 4.3.3 Data Analysis).

Anonymised field notes were also written during the interview to note any thoughts, emotions, perceptions or pertinent ideas that the interviewer may have faced during the interview.

4.3.3 Data Analysis

A systematic Framework Method approach of qualitative data analysis was completed to reflect a true representation and interpretation of the data gathered.

Recorded interviews in audio file format were transcribed verbatim by the candidate manually onto a word document text format. Once interviews were transcribed, different opinions and subjects which arose in the transcribed interviews were coded in the text margins. Similar opinions and subjects are described as codes or ‘themes’. Data were read multiple times in order to add, collapse, expand, and revise codes. In addition, field notes were collated and analysed (coded) alongside transcribed interviews.

A process of triangulation was used whereby coded data was re-read by and discussed with an external analyst (in this case, a fellow research student) to validate and highlight the coding used by the candidate. This approach was used to improve reliability, and decrease subjectivity (researcher bias). Discussion with the secondary analyst also provoked further thought, scrutiny or justification for coding (see Section 5.3.1 Strengths).

The data analysis was carried out using a constant comparative method in which coded items were checked with the rest of the data already collected in order to match or distinguish codes. The constant comparative method allows categories to reflect as many nuances in the data as possible, to provide specificity in results. A split screen computerised approach facilitated comparative techniques.
A grounded theory approach was used to identify analytical categories as they emerged from the data.\textsuperscript{156} This means that hypotheses were developed as the analysis process continued, rather than defined \textit{a priori}.

Once a number of interviews had been analysed, charting was used to rearrange the data according to the thematic framework.\textsuperscript{154, 156} Charting involved generating a spreadsheet where themes were entered as headers. In order to illustrate and provide evidence of themes and to distil summaries of specific views and experiences, meaningful quotes were collected and grouped into the chart. Charting funnels evidence into a sorting system which can help check whether there is sufficient evidence for the proposed theme.

The charts were then used in a process of mapping and interpretation. This meant deriving similar and dissimilar features among categories and themes, mapping the range and nature of results, as well as defining any relationships between the data.

\subsection*{4.3.4 Sequential Analysis}

The process of data collection and data analysis occurred simultaneously, also known as interim or sequential analysis.\textsuperscript{156} This process allowed for the interviewer to begin assessing data as soon as it was collected, aiding familiarity and for the possibility of any interview questions to be refined, removed, or added.

\subsection*{4.3.5 Ethical Considerations}

The literature review highlighted the need for qualitative analysis in order to understand health care professionals’ reasoning for using or not using ABPIs as part of their service. This important aspect of the study was realised only after ethics approval had been gained solely for the quantitative arm. An amendment was made in writing to the ethics committee and ethical approval was obtained on the 28\textsuperscript{th} January 2015 for the interviews (see Appendix F).

Clinicians recommended for interview were given a Participation Information Sheet (see Appendix G) to inform them of the intentions of the study and purpose of the interview. A Participation Consent Form was subsequently signed if participants were happy to proceed (see Appendix H).
In order to protect the confidentiality of participants, all transcribed and analysed data were anonymous. Pseudonyms were used in place of real names. Following analysis, all digital recordings were deleted.

There were no anticipated harms of the study.

4.4 Results

The results are grouped into sections correlating to different aspects and views on the use of the ABPI.

4.4.1 Demography of Participants

In depth interviews with 13 health professionals (participants) were completed (see Table 31).

Table 31: Participants and Demographics

<table>
<thead>
<tr>
<th>Participant</th>
<th>Sex</th>
<th>Primary Occupation</th>
<th>Other current roles</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M</td>
<td>GP</td>
<td>Senior lecturer, Research, Guidelines group, Others</td>
</tr>
<tr>
<td>2</td>
<td>M</td>
<td>GP</td>
<td>Guidelines group</td>
</tr>
<tr>
<td>3</td>
<td>F</td>
<td>GP</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>F</td>
<td>GP</td>
<td>Management, GP5I</td>
</tr>
<tr>
<td>5</td>
<td>F</td>
<td>GP</td>
<td>Teaching, Others</td>
</tr>
<tr>
<td>6</td>
<td>M</td>
<td>GP</td>
<td>Management</td>
</tr>
<tr>
<td>7</td>
<td>M</td>
<td>Vascular surgeon</td>
<td>Research, Teaching, Others</td>
</tr>
<tr>
<td>8</td>
<td>M</td>
<td>GP</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>F</td>
<td>Vascular surgeon</td>
<td>Teaching</td>
</tr>
<tr>
<td>10</td>
<td>F</td>
<td>Clinical manager of vascular diagnostic laboratory (secondary care clinician)</td>
<td>Research</td>
</tr>
<tr>
<td>11</td>
<td>F</td>
<td>GP</td>
<td>Research</td>
</tr>
<tr>
<td>12</td>
<td>M</td>
<td>Wound care nurse specialist (secondary care clinician)</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>F</td>
<td>GP</td>
<td>Hospice medical officer</td>
</tr>
</tbody>
</table>

Of these 13, sex was divided fairly equally with six males and seven females interviewed.
Nine (69%) of the participants were health professionals in the primary care sector. All were general practitioners who had a Bachelor of Medicine and Bachelor of Surgery qualification.

No registered nurses, nurse practitioners or other allied health professionals in the primary care sector were interviewed.

Four (31%) of the participants were health professionals in the secondary care sector. Of these, two were vascular surgeons, one was a clinical manager of Otago Vascular Diagnostics and one was a wound care nurse specialist.

Many of the health professionals interviewed had many other roles. Some had unique clinical, medical or academic roles which were personally identifiable. Where this was the case, roles have been listed as ‘other’ in Table 31.

All of the health professionals interviewed practiced in Dunedin, New Zealand. None worked elsewhere except for one vascular surgeon and the wound care nurse specialist who completed clinical work in the wider Otago Southland region monthly.

4.4.2 Primary Care Health Professionals’ Use of ABPIs

Participants in primary care were asked whether they had access to a Doppler ultrasound at their practice, and whether they performed ABPIs themselves.

Six of the nine participants in primary care had access to a Doppler ultrasound. However, there were only two GPs identified who performed ABPIs regularly.

There were no health care professionals who stated that they had done them regularly in the past as a GP.

4.4.3 Previous Experiences with the ABPI

Participants were asked what their previous experience, if any, has been with using or observing the ABPI. There were varying levels of experience. Seven of the participants in primary care had some experience with ABPIs in the past. None said they had ever had any formal training on ABPIs. Of the seven who had some experience, four (31%) had heard of or seen it being done vaguely during their time at medical school:
“I’m sure I saw them at med school but not as house surgeon. I never worked for the vascular team, my surgical teams ended up being urology and yeah I never worked with the vascular team so I never saw them in action that way.” –GP

“I remember a little bit of the clinic stuff with venous ulcers and arterial ulcers and stuff like that, but not a big part of my surgical training as a med student” –GP

“No, I don’t think I actually ever did them. I just observed [at medical school].” –GP

Three (50%) had exposure when they were a house officer:

“I just used the vascular Doppler on the ward in the hospital as a house surgeon and [had] been shown how to do it when I got the machine. I think I rang the vascular technicians and just double checked what sort of thing you could do and I only think they just gave me a verbal description of what they did, and I didn’t’ think it was too hard so I just did it.” –GP

“I did a [house surgeon] vascular run, so yeah, we would be using equipment then, but that was a while ago... that’s a good many years ago now.” –GP

Two of nine professionals in primary care had no previous exposure to ABPIs.

“Well I’ve never even seen one done.” –GP

“No, I haven’t, no [in response to asking about previous exposure].” –GP

The two GPs who regularly do ABPIs both had minimal previous experience. One had experience with ABPIs as a general practice trainee and one had exposure while doing some emergency department work. Neither had any formal training. They began doing them for the reasons of venous ulcer disease treatment, and cardiovascular risk factor, in addition to their ability to diagnose peripheral vascular disease.

“I have been through GP training and did a number of attachments in geriatric medicine, or care of the elderly medicine as it is called here, and general medicine attachments, and wasn’t really familiar with it until I went into general practice and it was probably the mid-90s that I started doing them again for the same reasons, mainly around four-layer bandaging treatment of venous ulcer disease” –GP

“I would have used it for part time work in the emergency department but... I don’t know, I definitely never had any special training on it as such... Yeah, so there’s a couple of ways that I use it and the first thing that made me get a vascular Doppler
was, was some research around using ABPIs as an extra cardiovascular risk marker so if you could detect a, a low ABI it suggests that people have got vascular disease, so that’s one use. Another use is if we want to look at compression therapy for venous stasis, so we would have to make sure there is adequate arterial supply to the legs to make sure that they’re not contraindicated. And then you can use them as diagnostic for diagnosing peripheral vascular disease.” –GP

4.4.4 Beneficial Role of Using the ABPI

The potential or perceived benefits and advantages of using the ABPI in general practice were discussed with all participants. Themes included being able to diagnose peripheral vascular disease, to be able to check for mixed vascular disease in patients with venous disease presentations, ability to aid referral, decreasing the burden on secondary care, ability to manage patients in primary care, ease of use, and aiding cardiovascular risk factor education for patients.

4.4.4.1 Diagnose PAD

Many of the participants recognised firstly that the ABPI is able to evaluate and diagnose peripheral vascular disease in patients in conjunction with clinical symptoms. Professionals stated that it is a diagnostic tool helpful in defining disease as well as ruling out PVD in considering differential diagnoses.

“So probably the main critical clinical intervention area is when, is when a GP suspects that someone has got peripheral vascular disease, but they’re kind of not sure. The patient’s come in with vague symptoms of leg or foot pain that may not be classical claudicating pain, or even night pain and restless legs type syndrome.” –GP

“Low [blood] pressure, absent pulses you know you’d look for, patient presenting with intermittent claudication; clearly you’d think of that they’d need vascular studies to quantify [PVD]” -GP

“There’s a lot of overlap between lower leg cramps, pain, restless legs even peripheral neuropathy can be misinterpreted as vascular disease. The ABPI gives you pretty good reassurance that if the ratios are higher than 0.9, you can be pretty comfortable that there are no major blockage of any of the major arteries going down the leg” –GP
“I suppose in terms of clinical diagnostic purposes if I had somebody that was presenting with symptoms if I wasn’t sure if it was spinal or vascular claudication, then doing an ABI would help to differentiate that possibility.” –GP

“I think sometimes it’s handy to be able to say that there isn’t any obvious peripheral vascular disease to kind of clinically satisfy.” –GP

“Ensuring that somebody presenting with say leg pain and no clear no definite history of arterial problems just as part of the examination just to give confidence that the diagnosis is other than arterial disease.” –Vascular surgeon

Some professionals stated that using defined ABPI results to diagnose or rule out PVD can help to define the next step in management for patients in primary care.

“I think it makes a big difference in some patients, so say if you get a patient with leg pain and the history is not very clear whether it represents rest pain or leg pain or foot pain from another cause, if we have an ABI associated with it you can make a judgement call whether that patient needs to be seen as soon as possible in [a hospital outpatients] clinic if we think they’re having rest pain, or whether it’s more likely to be limb pain for another cause where we could have another appointment booked for an assessment. So from that point of view it’s very helpful.” –Vascular surgeon

“One [patient]… he must just be 65 now, would have been a few years ago when he presented with intermittent claudication, quite classical you know pain with walking, and resolving with rest, and he ended up, you know I referred him down there, and he ended up having ABIs and they ended up saying it wasn’t peripheral vascular disease. Whereas if we had availability of doing that, we could have screened him in the clinic and not wasted the resource of sending him down there.” –GP

One GP who does ABPIs stated that diagnosing peripheral vascular disease has been one of the most significant advantages for doctors in primary care.

“That’s the… most impact that can be generated by that, and doing it over the years, that’s probably where the most benefit has been gleaned from acute intervention and referral” –GP
4.4.4.2 Check for Mixed Vascular Disease

The ABPI was also seen as useful for many primary care professions in being able to evaluate whether there is arterial disease in patients with a venous disease presentation such as in patients with varicose veins, venous ulcers or dependent oedema. This was because it meant GPs were able to recommend compression treatments and immediately manage patients if no arterial disease was present, or conversely, to refer to secondary care services where there was arterial disease.

“That would be a great advantage to be able to check their flow and see whether [patients] were suitable for compression bandaging or not and it would have sped up the treatment process sometimes.” –GP

“If you have patients with venous changes or varicose veins and you’re thinking about, compressing them then again you could be reassured without necessarily having to refer for a specialist opinion.” –Vascular surgeon

Identifying whether patients are able to have compression earlier rather than later was seen to be beneficial for allowing faster healing times, reducing risk of complications and wasted health professional and patient time.

“You know, and if I [ruled out] arterial problems early, it would help [patients] in assisting definitely with compression bandaging, and compression support stockings and really, that’s most important for lower leg wounds that people go very quickly to support stockings or compression bandaging...” –Wound care nurse specialist

“Clearly treating venous disease is important. We see an awful lot of minor lower leg lacerations that get that don’t receive compression early enough that go on to form ulcerations or slowly heal, and that creates associated morbidity for patients, health, inappropriate use of health resources, doctor time, nursing time, patient time, using dressing without using compression” –GP

GPs commented that there was a substantial need for compression treatment in patients in primary care.

“Mostly, before we look at putting compression stockings on [which] would be the main way that I use it” –GP

“In my last practice, where I was full time, we had a lot of oldies with a lot of ulcers, non-healing ulcers, who we wanted to do compression bandaging on.” –GP
ABPIs were seen as helpful in aiding choice of compression stocking type (higher or lower levels of compression).

“It’s a really good assessment too for seeing the blood flow into the lower leg and give us an understanding of what type of compression we can use if any... we follow Australasian guidelines, so there’s a range between 0.8 and 1.2 where we say it’s a normal ABPI and we use full compression, where the compression is 40mmHg at the ankle...0.6-0.8, we would put some light compression on... between 0.6-0.8, you use light compression 20-30mmHg at the ankle site.” –Secondary care clinician

4.4.4.3 Aid Referrals Being Accepted

ABPI results included in patient referrals to secondary care professionals were seen as a significant advantage as it added more information to support the referral.

“I think it might strengthen your referral letter, you know, if you show the surgeon, you’ve taken their problem seriously and particularly if you are referring to someone who always likes that measure that would be a good reason to do it.” –GP

“If you can, in a referral letter, say, well if this is what I already know about this person, you know, they are at high risk or you know, it would perhaps help with triaging to get appointments and stuff cause everybody is under pressure and secondary care is under pressure so anything that tries to help that would be good.” –GP

“Certainly, it’s some sort of scientific rigour to the referral rather than, often they’re quite vague” –Secondary care clinician

A secondary care clinician agreed that more information led to a better referral (where information was relevant) and that this improved the quality and overall standard of referrals:

“We reject those [poor] referrals because we want to change the culture. We want to change and get better referrals, so when I say, the Southern District Health Board, there’s a vascular consultant who grades that, they want to know more. So that is good practice to get us to think.” –Secondary care clinician
4.4.4.4 Decrease Burden on Secondary Care

ABPIs in primary care were believed to help reduce unnecessary referrals to the hospital. Participants believed that ABPIs allowed identification of patients with less severe or no disease to be managed in the community, and so aided in decreasing the number of patients seen in outpatient units or vascular laboratories in the secondary care setting:

“If we are doing them out here [referring to general practice], it saves another job in there for them that if they actually test out to be OK here, we don’t need to refer them further. So it leaves a system in the hospital if we are doing them in general practice.” –GP

“Anything, things that can improve outcomes and speed up referrals, or make more appropriate use of referrals then, yeah, that’s got to be good for both primary and secondary care” –GP

Some participants believed that ABPIs would allow more appropriate use of different types of referral, such as using an ‘advice only’ referral, rather than referral for full assessment:

“I suspect there would be more of a role for using the advice only part of our referrals that we can do... so you can say yes you want a clinic assessment or you can refer into a consultant saying ‘I just want some advice about this person and if you’d had this person saying ABPI’s 0.7 or whatever, what would you advise management given other comorbidities’ and [vascular surgeons] could have potentially spent 5 minutes reading that and saying that we wouldn’t do anything, it’s probably not severe blah, blah, blah, and sending that back” –GP

Correspondingly, secondary care professionals agreed with GPs. They discussed that having ABPI values in referrals would mean they would not have to evaluate patients who did not need to be seen (inappropriate referrals) and that it would improve waiting times for patients who did need to be seen.

“The biggest advantage I would see is that those who do not need to come through to the vascular lab would not attempt it.” – Secondary care clinician

“There is an issue with waiting times and trying to reduce number of people who don’t necessarily need a specialist assessment having come through... There is no doubt that reducing the waiting list for vascular lab assessment as well as clinical assessment, it would improve things.” – Vascular surgeon
“It saves your referrals, and in one setting, because we get a lot of referrals, just to do ABPIs.” –Vascular surgeon

This would mean that more appropriate spending would occur in secondary care services.

“It’s not good economics for us to being using top end to do stuff [secondary care services] for can you wear stockings or not, and there’s where I believe your practice nurse and in particular GP should have great confidence in doing.” –Secondary care clinician

4.4.4.5 Triaging in Secondary Care

Further to decreasing the burden of unnecessary referrals in secondary care, the ABPI result itself was seen to have an impact on triaging patients so that those with lower ABPI results would be seen more rapidly, and be treated quicker than those with less severe disease.

“I suppose the advantage is that you’d have an answer much quicker and refer to the vascular surgeons, yeah, so if someone needs bypass surgery, they’d get it done more quickly.” –GP

“It seems reasonable that if GPs had the resources then they would be able to do [the ABPI], the ABPIs would at least be a start and would enable the vascular department to triage a little better in terms of their appointments.” –GP

“Well clearly having a result and seeing if they are really compromised, clearly you’re going to refer them quicker but that would, [and] if they meet the criteria... they’re gonna be seen more quickly” –GP

Professionals thought that using ABPIs in general practice would help to qualify the neediest patients, and minimise waiting times to be seen and treated:

“It also speeds up referral so you can get much better access into secondary care if you’ve got ABPIs, ABPI results to prove the level of obstruction” –GP

“If we get a referral with an ABI because it helps us because the ABI is low. It means that the surgeon will immediately organise vascular studies, so that would speed it up” –Secondary care clinician

“I don’t think we’ve disadvantaged patients. I think we have aided patients so less waiting time for those who really need to get through the door” –GP
4.4.4.6 Ability to Manage Patients to a Greater Extent in Primary Care

There were views that general practice ABPIs could allow more patients to be managed in primary care, which was seen as beneficial to patients because of ease in seeing their established family doctor, reducing unnecessary travel to the hospital. Both primary and secondary care professionals thought this.

“Clearly being able to do things in your own practice with your own patients, they like that so they don’t have to go to the hospital, get their parking, and seeing someone else they don’t know, I think that’s a good thing.” –GP

“I think it’d be good to try and do as much as possible in the community” –GP

“That’s been the view by some for a long time - leave it to the experts. But at the other end of the equation, some of your patients may be hospital based, or rest care based or whatever it might be, or circumstances might be that that’s not feasible to commute into these secondary, tertiary, institutes because they’ve got limiting factors, be it whatever social circumstance.” –GP

“I don’t think patients would have any problem with having it done, you know, it’s non-invasive from their point of view and apart from having them to wear something, it means you can get to the leg, they’re used to having their blood pressure done, it’s not really different in that sense.” –GP

A GP summarises how being able to do ABPIs in general practice maintains patient-centred continuity of care without needing to rely on test results being sent back from the vascular laboratory:

“The gentleman I mentioned before who I did refer down, he ended up seeing [the] vascular lab well ahead of any other appointment, but we never got the information so when he came back saying what did that show, you couldn’t discuss it, whereas being in control of that information, you can, you’ve got that there to discuss what it means and what the impact’s gonna be, so that’s definitely better to keep things centred here for them if you can.” –GP

There was a perception that ABPIs completed in more rurally or distantly placed locations would aid in allowing patients to be managed in primary care, meaning patients would not necessarily need to go to distant hospitals to get assessed.
“So we’ve got quite a number of people trained already who do the ABIs. There are about four nurses in the community who do ABIs and they can do them at home. It’s not a problem because people train in Dunedin, Balclutha and in Oamaru. They do ABIs when there’s a need.” –Secondary care clinician

“It would make life a lot easier for patients, especially if they have to come a long way for appointments.” –Vascular surgeon

4.4.4.7 Ease of Use

Many professionals believed that the ABPI was generally easy to perform and was not a difficult skill to learn:

“From my understanding, it’s reasonably straight forward.” –GP

“I think it’s a very simple test” –GP

“Oh, it’s pretty straight forward, you know as long as you’ve got the cuffs that are the right size and things like that, it is fine.” –GP

In response to what amount of training and expertise was needed to be able to do the ABPI from secondary care professionals’ views, there were mixed responses. Some thought it was very simple:

“Very little. It’s easy-peasy... It’s easier than the stethoscope if you think about it. Because it doesn’t rely on your ears, how you put the thing in your ears, or whether you can hear you know. It is there in front of you” –Vascular surgeon

“It only takes 10 minutes to learn how to use it. With a little bit of practice, and an understanding of principles, but you can read about that in most books. Fourth year medical students can do it.” –Vascular surgeon

Others believed it required more experience to become proficient at performing the ABPI:

“Is it an easy test? I think when it’s a normal ABI I don’t think technically it’s a difficult test. I think what can happen depending on experience, you might, the less experience you have the longer it might take to do it, the harder it may be to... in patients with low ABI. But I guess on the positive side, a lot of patients who may not require referral for specialist opinion, that group will be the one with normal ABIs, so you can be reassured that if it was a normal ABI, even though you may not necessarily get the
very low ones which you can then refer on and have them rechecked, I think it would still be useful.” –Vascular surgeon

4.4.4.8  An Aid in Conveying Cardiovascular Risk

Some GPs believed that the ABPI result would allow them to communicate to patients whether they had any signs of PAD, or any physical manifestations of cardiovascular disease. This is in contrast to just using markers such as lipids which may be more difficult for patients to understand or relate to.

“It would probably be something more concrete for the patient, that they’re seeing a measure of end-organ damage as such. Like we are not just talking about their risk factors any more. It actually moves on to showing some disease.” –GP

“Some talk about how useful it is just to calculate cardiovascular risk all over, you know, overall risk...I think, it can be a good tool probably to educate those people and also for the GP to know this is what it is now and maybe, can do it again later and see what a difference there was, or you know, if things are deteriorated...and perhaps if you’re struggling to make them aware that they need to change some things, so do they need to stop smoking? Do they need to lose weight? Do they need to walk more?”

–GP

“I think it would be a really useful thing to do, you know you could also capture them, you know, if you get numbers telling them somethings starting to happen and you can kind of tell them what might evolve over the coming years, it might be motivation as well to get lifestyle change.” –GP

One GP who does ABPIs believed that screening patients with previous cardiovascular events for PAD using the ABPI could have a benefit:

“Should you be doing ABPIs on ... anyone who’s had a previous [cardiovascular] event, whether that be a TIA or stroke or a, or a cardiac event, you know, should you be assessing people for peripheral vascular disease using ABPIs, and there’s just a generally a blanket consensus that you should be looking for that” –GP
4.4.5 Challenges or Barriers to Using the ABPI

Participants were asked to identify challenges or barriers to using the ABPI in general practice in their view. The main themes were of the ABPI taking up too much time, being too costly, interviewees being unaware of its value, having a low patient need for ABPIs, and other practical issues.

4.4.5.1 Taking Too Much Time

Primary care participants often commented on how the ABPI would take too much time, and would impinge on the time needed to see other patients or on other work related activities. It wasn’t necessarily the time itself which was the barrier, but the view that time was better spent elsewhere such as with seeing the next patient.

“You don’t have much time [in general practice]. You have people coming through, and you don’t want something that’s gonna slow you down” –GP

“But yet you’ve got to balance that with doing the right thing in your consult, as well as not holding up the next person” –GP

“You know, if you do an ABI, it takes about 25 minutes, half an hour to do it proper. Which GP has that time? I dunno, not many.” –Secondary care clinician

“If someone comes in saying, yep I’m just here for this one thing, then you’d potentially have time within that consultation but actually if they come with their list, then they won’t be able to fit that in as well as everything else” –GP

GPs stated that other aspects of ABPI use would take up significant amounts of time too. This included time taken for patients to remove clothing, and for doctors to find the necessary equipment if not situated in the room.

“It’s time consuming, it’s really awkward for patients to strip them off, to get them up on the bed, and find a cuff that’s big enough to go around their legs, bits and pieces like that. So practically it’s not that easy.” –GP

“So, unless you’ve got the Doppler machine sitting in your room right there... if it’s somewhere else in the practice, you’ve physically got to spend a couple of minutes going and getting it... every little bit that delays your 15 minutes makes you run later, a morning, or whatever, your whole session” –GP
Further, performing the ABPI would take up the time of extra staff, or other resources such as room availability.

“Have you got enough time? [As in] staff time, room availability to actually do the measurement?” –GP

4.4.5.2 Being Too Costly

Another barrier to ABPI use mentioned by participants was the cost involved with doing the ABPI. This includes the capital cost of purchasing the Doppler ultrasound equipment itself, as well as the extra cost of a longer appointment (and so the opportunity cost of not having another paying patient instead). As general practices are businesses themselves, GPs tended to do a cost-benefit analysis regarding the test.

In response to what barriers or challenges were seen for primary care professionals in doing the ABPI, some said:

“The cost of the Doppler” –GP

“You [have] got to line up all your hats, your sort of evidence hat, your business hat, you know, can you make a business case to recover that initial cost and all the rest of it?” –GP

“Mainly money.” –Vascular surgeon

“You’d think of the cost in both dollar terms and in time, and if it’s gonna be expensive and it takes a long time, then you’re not generally going to be very interested, especially if it’s a condition you don’t really see much of.” –GP

The cost was not seen as being confined to just the Doppler ultrasound necessarily, but also the cost of the consequential treatment such as compression stockings:

“[There is] a cost factor, because compression bandaging itself is not cheap. So who would pay for this, you know the government at the moment, picks up the cost for dressings and compression bandaging in the community funding model at the moment where in the primary model, when you go to the GP you have to pay yourself, or you have to pay the nursing, and certainly compression bandaging” –Secondary care clinician
One GP mentioned that the choice of using a test was also influenced by whether there is funding by the PHO.

“We’re clearly running a business here and the funding issue, if we’d paid to do them by the, you know, PHO.” –GP

Another GP did a brief online search for new Doppler ultrasound machines upon finding that their practice’s Doppler did not work. They commented that buying a new one was too costly.

“I went to see how much a new one was and they were more expensive then I had expected so let’s put that by the way side.” –GP

Conversely, one GP who does ABPIs regularly believed that the Doppler ultrasound was not that expensive:

“They’re not cheap but they’re not that expensive and the clinical value you get from doing them is quite [good]” –GP

Another believed that things would become more affordable over time:

“Obviously the [machine] is obviously going to become cheaper as you know, as time goes [on].” –GP

4.4.5.3 Lack of Awareness of the ABPI’s Value

Some primary care professionals were unsure or unaware of the value that the ABPI brought to their practice. Some of these practitioners were unsure of the benefits of knowing the ABPI result, while others were unsure of how these results would change their management of their patients.

“Well [it’s] always useful having a test that is telling you what you don’t know already. I don’t specifically know the value of the ABI though.” –GP

“I don’t really see what specific advantages to find [ABPI results] out ourselves, rather than to refer them to the hospital.” –GP

“As to whether they have a good intrinsic value, you know I’m not really that sure to be honest. I never found them very useful clinically [regarding management].” –GP

One GP who performs ABPIs acknowledged that he was unsure of how useful the ABPI results he had put in his referrals were for the secondary care team receiving them.
A GP who had minimal previous experience with ABPIs (only doing them in medical school) had a lack of knowledge regarding the value of the ABPI:

“To be honest, I’ve never ever, ever, ever done it since then [laughs] so that’s kind of it, the limit of my knowledge.” –GP

4.4.5.4 Having a Low Patient Need for ABPIs

Many primary care professionals stated that they did not do ABPIs because there was little need to do them. Practitioners did not have enough patients presenting with reasons to do the ABPI. GPs reported a low number of patients who they believed warranted having ABPIs, so there has not been a great demand or need to consider the ABPI in their practice.

“My volume of patients isn’t that large I just probably don’t have the need to do them.” –GP

“I haven’t seen a patient with a good history of claudication for ages” –GP

“I don’t see all that many people with vascular disease, all my patients are younger and yeah it’s not, well peripheral vascular disease I should say.” –GP

“One GP suggested that the need is reducing due to better current care of vascular patients, and believed they were seeing less chronic leg ulcers as time went on:

“I think one, we are better at dealing with them, better at getting them healed than perhaps what they used to be, you know, even over the last 10-15 years things have improved. I think we’re better at chronic medicine control, you know, better at controlling peoples’ diabetes and whatever else is going on, so it’s in my view less common than it was.” –GP
Professionals in secondary care had mixed views regarding need. Two acknowledged that the ABPI would be used much less frequently than in secondary care, which poses a dilemma in whether it should be used in primary care:

“For someone like me, it’s my daily work, but for general practitioners, it’s an infrequent event. I have a brother who’s a GP who bought one… And now he’s telling me that he hardly uses it. So why should he have spent all that money on it, which is a fair question really. So it’s a bit of a catch twenty-two. –Vascular surgeon

“I’m not sure if we’ve got the, the critical mass for [ABPIs being done community wound clinics] to be honest.” –Secondary care clinician

Meanwhile, a secondary care health professional challenged the notion that there was a lack of patients presenting with vascular problems in primary care based on their experience:

“I find it hard it to believe that this population Dunedin not having much exposure to vascular patients when I know how many come through our laboratory” – Secondary care clinician

4.4.5.5 Confidence in Ability

Confidence in knowing how to perform the ABPI to proficiently was discussed as a challenge involved with doing the ABPI. Health professionals in primary and secondary care believed that a major barrier was lacking the confidence or ability to perform the ABPI:

“I couldn’t give you the technique. You know, if you asked me to do it tomorrow or today, I couldn’t actually do it myself, yeah.” –GP

“[The] training aspect of it [is a barrier] and having access to have somebody, to, to go through it with them and do a few cases with supervision so that you’re happy that your results are accurate, and there’s an awareness of what results mean” –Vascular surgeon

“I think it is confidence and reliability of being, you know, having the confidence in, reassurance of what you are doing is right and accurate” –GP

The technique of using an ABPI was seen to be a little difficult for some clinicians:
“Again there’s a degree of technique that’s used. It’s a bit like sort of patting your head and rubbing your belly… trying to maintain that co-ordination can be tricky sometimes.” –GP

“You don’t [want to] look too silly, and as though you don’t know what you’re doing” –GP

Accuracy of ABPIs was a concern for one GP who does ABPIs regularly:

“Do my readings compare with [the] vascular lab’s well, I don’t know, I have no idea!” –GP

Despite many current GPs expressing concern with their ability, a secondary care health professional believed that this is changing with new cohorts of medical graduates.

“I suppose part of that is becoming confident in examining, so I believe as part of the training for young med students nowadays is improving, and that young students are probably going out with a better knowledge base, I would hope, that allows them to have greater confidence as young practitioners, and thinking further in relation to this disease” –Secondary care clinician

4.4.5.6 Test Results Not Changing Management

Some participants mentioned that the ABPI test would not change their management of patients if completed in addition to taking a history and undertaking a thorough examination. Some practitioners felt that if they were worried about patients based on history and examination, they would refer them to secondary care anyway, despite a normal reading:

“I guess by the time you’re referring someone to the vascular clinic, you want a little more than an ABI, you want a specialist opinion or nurse or wound care’s opinion or input or follow-up and opinion on whether they need to be offered any other investigations or treatments so it’s kind of similar to that.” –GP

“If we think someone really needs it, we tend to refer them to the vascular clinic just because they have the expertise to go the next step…if you’re that worried about them you tend to send them in.” –GP

“I’d probably still do the ABPIs even if they had a good history of rest pain, knowing I’d probably be referring them in anyway.” –GP
One GP mentioned that ABPI use could influence management but due to the fact that some practices do not offer particular lines of management themselves, would have to refer patients to another service anyway. Below, the GP discusses how the ABPI could be used in identifying suitable candidates for compression therapy, however compression therapy is not offered by their practice, so referral to a district nurse or wound care clinic would be required:

“The problem is the next step, which is what compression therapy do you use, and for us to either stock or get experience with measuring up people’s legs and recommending different types of compression therapy or implementing it, and it’s a real big hassle, and it’s a cost risk. Whilst medicines are funded through Pharmac and that, the stockings of various strengths and that aren’t and so the other thing is that my practice is fairly small, a few doctors full time equivalent practice. To get enough doctor and nursing experience applying compression therapy just hasn’t been practical.” —GP

4.4.5.7 Not a Priority for Primary Care

Another barrier or challenge to using the ABPI in a primary care setting is that there are many other clinical or administrative tasks which are prioritised above its use. Practitioners stated that there were other tests or jobs which would be important to do first, and would demand the time of the professional above using ABPIs:

“I’m not sure that it is high on my list of priorities of things that could be done in general practice to reduce the burden on secondary care, so there’s lots of other things, like colposcopy, ultrasound, lots of things that with the right training and equipment would provide a, from my perspective anyway, would seem to provide a greater release of the burden on secondary care than ABPIs” —GP

“There would probably be other things that would be further up the priority list.” —GP

A GP states that in conjunction with their busy role as a senior manager of the practice, they have limited time and would have to prioritise use of their time with patients and other tasks:

“Because I’m sort of the senior person here, there’s a lot more of sort of management type things that you know, running the practice. From a practical point of view, you know, it’s not that I’m not interested in it.” —GP
The ABPI was compared to an ECG machine in one interview to illustrate the decision making process in choosing how to spend practice budget. There were pros and cons of using each, but the GP felt as if the ECG had more influence in changing clinical management:

“I mean compared to say ECG which I find incredibly useful as a tool for picking up rhythm disturbance which could change your management on the spot, or for people with chest pain and a few other things, I wouldn’t use [ABPIs] as much as our ECG machine. But on the other hand, it doesn’t cost as much as an ECG, it’s probably about as easy to do, if not easier to do an ABI than an ECG in some ways...” –GP

4.4.5.8 Inherent Limitations of the ABPI in Some Patients

Some primary and secondary care professionals have emphasised inherent limitations of the ABPIs themselves and how this may affect its use in a general practice setting. They acknowledge that the ABPI may not accurately reflect the true vascular status of some patients, including patients with diabetes mellitus or end-stage renal failure as examples. They suggest that ABPI results for these patients should be interpreted with caution.

A secondary care clinician notes the inherent limitations in simply doing a basic ABPI in general practice:

“Ankle pressure can be exaggerated in patients who have other issues for example end stage renal failure and that of the diabetic patient where the artery can be calcified as a consequence of those disease types ... So the ABPI has certain limitations therefore. And those limitations are reflected particularly in those two groups.” – Secondary care clinician

“The management advice that I [give]... usually has a guarded interpretation if the person has diabetes of a long duration, with the usual complications, microvascular complications of diabetes” –GP

“It also may have limitation where the patient has a very oedematous leg, be it for whatever reason and as a result of that making it clinically difficult to palpate a pulse, so the request is again try and identify the presence or absence of the index in a more formal [secondary] setting.” – Secondary care clinician
4.4.5.9 Having Enough Physical Space

One GP indicated that having limited physical space in practices was a barrier to doing the ABPI:

“The other thing for some practices is the space. We have the space now but actually having a room for privacy and stuff like that would be a consideration in general practice.” —GP

One GP who does ABPIs regularly also stated that space was a consideration, as well as needing to use another staff member:

“I just tend to like having one of my nurses rooms where I can get round both sides of the couch and just maybe have someone else to give me a hand to write down the numbers as I scoot around from, arm to leg to leg, or foot to foot, and so on so practically it’s not that big a deal to do it, but it is just nice to set aside a nurses room if you are planning it in advance and do it” —GP

4.4.5.10 A Lack of Barriers and Challenges

Conversely to the list of barriers and challenges described above, a few practitioners mentioned that there were not many barriers or challenges associated with using the ABPI in primary care. When asked, some stated:

“Not really” —GP

“I wouldn’t have thought so. No, it’s just a matter of doing it, and learning how to do it. Personally I mean.” —GP

“Nope, not that I can think of. I’ll probably brush up on how to do it, and what the results meant [laughs], just so I knew what I was doing.” —GP

4.4.6 Views of Primary Care Professionals who do Not Regularly do ABPIs

Of the nine GPs interviewed, seven did not regularly do ABPIs.

Of these, four had access to a Doppler ultrasound. The reasons for not doing them include many of the barriers mentioned in Section 4.4.5 Challenges or Barriers to Using the ABPI such as not having the knowledge to be able to do them, time, not having the current need for
them as they don’t see many patients presenting with vascular symptoms, and being able to refer to a colleague who does do them in a similar practice.

“I don’t do them myself, and that’s kind of on my target thing’s to do is actually to learn to do them properly.” –GP

“In a general busy practice setting, I don’t really see it as being that appealing, mainly because it’s time consuming.” –GP

“[I must] say I don’t have very many vascular patients at all. So I haven’t necessarily, just trying to remember if I’ve referred anyone down through the vascular service. But apart from like DVTs and things which I think still get covered by them don’t think I’ve made very many referrals at all.” –GP

Three GPs who did not regularly do ABPIs did not have access to a Doppler ultrasound. One stated they would do ABPIs if they had a Doppler ultrasound, while two would not. This was due to low patient need, and having extra commitments which would take up time.

“I suppose I would if I thought there was going to be enough need for it, I have to say I don’t.” –GP

“I probably wouldn’t do it because I, I’m already far too busy, like I am, because I am doing this surgical [skin excision] thing... I’m focusing on that rather than developing another new skill. But I wouldn’t be opposed to if someone else wanted to them in the practice or if the nurses had the opportunity to have education to do it, then I think that would be fine. But I think for me personally, I’ve already got enough already on. Yeah.” –GP

### 4.4.7 Views on the Role of ABPI in Primary Care

Participants commented on their overall views on the role of the ABPI in primary care. Questions asked included:

- What is the role of ABPIs in general practice overall and why?
- If there is a role for ABPIs in primary care, who should be responsible for doing the ABPIs?
Some practitioners believed the ABPI is a more specialised tool, and that a GP with a special interest should be doing the test. This way it would mean that some professionals could become very efficient with using this tool, and would be able to see a larger portion of patients with vascular patients than a ‘regular’ primary care professional or GP would.

“So we could refer them to someone you know like... or someone who, that would make more sense than really qualify everyone to do the job, because it’s quite specialised really isn’t it?” –GP

“It could be like a special interest that someone could, you know you could have a [GP with special interest] person to do that, you know, I could refer to a general practitioner who had a special interest that would be a good way to do that. You know we have ... here who does the musculoskeletal medicine and so if you had someone clearly who was qualified and interested in you know... that would be good.” –GP

“I wouldn’t probably be that inclined to do it myself in clinic because appointments are short but we could train nurses to do it, so I wouldn’t see it as a major issue to do it in the practice.” –GP

“If I was confused I’d grab... my colleague and we’d do it together, you know, if there was something that we were concerned about” –GP

One GP described how ABPIs may be better treated as GP special interest skill, so that referrals could be made within the community from GP to GP.

“I think that maybe if you had someone with a special interest in it, so that would be as general practitioners in the community there may be four five GPs who did it in Dunedin just like the sports medicine and the skin [excisions] -GP

Others felt that there is no reason why GPs couldn’t do the ABPIs themselves:

“I don’t think it needs to be a specialist general practitioner, particularly if you are thinking about screening the asymptomatic population, I think it should be part of adding value to our cardiovascular risk assessments and you know from that point of view, in theory all practices should be able to do it, it’s not that difficult, but it’s a resource issue and funding for equipment I guess across the board.” –GP

“It’s really if you have confidence, if you’re performing these tests, and you understand why you are doing them, then I believe you can teach people to do them it confidently.” – Secondary care clinician
Many practitioners believed that there was a role for nursing colleagues to be doing ABPIs:

“Because we have great practice nurses, I think they’d easily be able to do it, and that would resolve some of the time issues” –GP

“Probably makes it a bit cheaper for the patients too if we’re charging nurses fees for it rather than doctors’ fees for it.” –GP

“If I was needing to use it regularly, it would be something I’d teach nurses how to do and get them to do it because it is cheaper to get them to do time-consuming tasks like that.” –GP

“I’m a GP and I do them, but there’s no reason why you can’t train up a good competent nursing colleague to do them in the community I understand that some district nurses can do them. That was certainly the case before I came out to New Zealand.” –GP

Some believed that there was no one professional who was responsible for doing the ABPI, but perhaps just a dedicated clinician who is able to do them effectively to meet the demand of the population served, and on a regular basis:

“I think if you ask everybody to do it, it would be more of an issue with training and quality and standardising outcomes, but if you choose one or two individuals in each practice to, to train to do it, and do them, I think that’s probably the way forward. Who does it? I think it is whatever works in the circumstances.” –Vascular surgeon

“It’s how you utilise your staff” – Secondary care clinician

“Ideally in a [place] like a [large group practice]…, there should be one person to do the ABI to keep on top of it and to organise the compression bandaging and do the whole sort of thing… they probably should be done by one person…, somebody needs to do it on a regular basis.” –Secondary care clinician

Although no participants stated that it shouldn’t be done in primary care, there were some views that it wasn’t necessarily the responsibility of primary care to be doing all ABPIs:

“I think we’re quite fortunate here with the clinic at the hospital, the wound clinic, and if I had someone here with a chronic wound, and I would sort of liaise with them and they might organise the vascular studies. And with district nursing as well they would liaise with me” –GP
“It would be a huge shift within New Zealand to shift it back to primary care. It is purely a fact of education for primary care nurses, and then also for practicing it, because compression bandaging, [you] can teach it but you need to do it, and if you don’t do it often enough, you will forget, the same as the ABPI.” –Secondary care clinician

One GP discusses how they are satisfied with the secondary care vascular services they use in Dunedin, and believes they are handling ABPIs referrals well:

“I mean we’ve been pretty lucky in having reasonable access to the service in Dunedin, and I don’t have any big issues with them” –GP

4.5 Chapter 4 Summary

This interview study helped to reflect a large a number of views regarding the role of the ABPI in general practice.

Nine GPs and four secondary care providers from Dunedin were interviewed face-to-face about their experience and perspective on the use of the ABPI in general practice. Only two GPs of the nine identified with performing ABPIs regularly. Less than half of the nine GPs stated that they had experience with the ABPI during medical school, three said they had exposure as a house officer, with two having no previous exposure ever.

The main benefits that health professionals said the ABPI in general practice has includes the ability to diagnose PAD, being able to check for mixed vascular disease, and aids GP referrals to secondary care. ABPIs were perceived to help guide whether patients are appropriate for referral or not, and aid secondary care in triaging the most urgent patients. Other advantages such as being easy to use, and a supplement to conveying cardiovascular risk to patients were noted.

The main challenges to ABPI use in general practice were perceived as taking too much time, and being too costly in relation to the lack of patient need. Some GPs were unaware of the value of the ABPI and stated that confidence in their ability to perform or interpret the ABPI was a challenge. Further, challenges such as the test results not changing GP management of the patient and not being a priority for primary care were themes discussed. However, some GPs believed that there were not many barriers associated with ABPI use in general practice.
Overall, interviewees had mixed views regarding the role of the ABPI in general practice. While no health professional said there was absolutely no role for its use, there were many perspectives on whose role it would be to do them. Some believed that GPs themselves could do them, or perhaps a GP with special interest in vascular disease. Others believed that nurses were well equipped to perform ABPIs, and if nurses performed them, would allow the barriers of lacking GP time to be mitigated. Some stated that it didn’t matter who, as long as a dedicated professional was able to perform standardised ABPIs for a community group.
Chapter 5: Discussion

5.1 Discussion of Methodology

5.1.1 Electronic Health Records

The quantitative arm of the study used electronic health record data from MHC’s PMS. There were many reasons why electronic health record data was appropriately chosen for use.

Firstly, electronic health records are widely used in New Zealand general practice. Existing data allows the ability to harness ‘real-time’ clinical data without having to go through complex and often time-consuming processes of recruiting participants or undergoing tests in an artificial setting. Previous research has shown the value of data extraction for assessing efficacy of tests such as the ABPI within the health services research community.

Further, electronic health records enable extraction of a large amount of data in a small amount of time. Relatively few people in a single general practice need to undergo vascular and ABPI assessments in a ‘normal week’ relative to other investigations. By accessing the database of ABPI measures, more ABPI assessments than could be collected within one year were accessible (the time available for this work) (see Section 5.3.1 Strengths).

Routine practice data provide convenient, timely and easy access to demographic details and medical history notes that may impact on the interpretation of the results. The breadth of data supplements the ABPI database. Longitudinal data included follow up details, clinical letters and test results, which may not have not been gained otherwise from the doctor or patient in a one-off isolated intervention study.

Using routine practice data is also practical and does not require time, effort, or money from patients. No physical harms or added involvement are associated with this method. Using existing records did not require separate efforts by doctors, patients or researchers as the ABPI has already been completed, making the process more patient-centred. As the investigation has arisen from usual care, and the data are anonymous, using them for research avoids many ethical issues.

There ongoing benefits of harnessing electronic medical records for practices or GPs such as MHC. By collecting ongoing data that doctors and others know will be analysed, clinicians will be more motivated to record information accurately and comprehensively. There is a sense of “ownership of the data for success”. Quality note taking techniques are used not only for good GP practice, but can be used as quality data for future primary care research.
A major challenge of using routine practice data is in how to achieve appropriate levels of information security and privacy.\textsuperscript{158,160} In the quantitative analysis, data provided to the candidate was anonymised prior to being analysed before leaving the practice, or was secured on a digitally locked private database (see Section 3.3.6 Ethical Considerations). The candidate signed a confidentiality agreement with the practice where records were identifiable. An ethics committee had also evaluated the project.

Another challenge is data quality. All general practice staff need to be able to use the electronic health record competently so that the recording of information is complete and so there is reliability and consistency in the data. Further, practices require their medical staff to be able to correctly classify medical classifications based on accepted codes and coding systems. All staff at MHC had been trained and are competent at using the practice software, Medtech32 and Read codes (see Section 3.3.2 Data Collection).

5.1.2 Semi-Structured Interviews

The qualitative arm used semi-structured interviews. This allowed a naturalistic enquiry into understanding what using the ABPI would mean for primary health care professionals who work in general practice. Interviews allow for comprehensive and reasoned data to be collected, as well as a host of views, opinions and experiences.\textsuperscript{164} In this study, a qualitative enquiry gives insight into why general practitioners already do or do not conduct ABPIs, and their views on the use of the ABPI in general practice.

The semi-structured interviewing technique allowed for a flexible yet focused approach to be balanced, and a greater amount of exploration to be gained than via a more structured and narrow method.\textsuperscript{153}

A number of interviewing techniques were employed to encourage the collection of data. These included using anonymised field notes (rough notes written by the candidate during interviews), using encouragers and reflective listening to maximise data gained from interviewees (see Section 4.3.2 Interview and Interview Design).

5.2 Key Findings

Both arms of the study provided insights into the usefulness of the ABPI in a primary care setting. In both analysing real world data on ABPIs done in primary care, and engaging the
perspectives of health professionals, a number of key findings, benefits and challenges are discussed, as well as the role of the ABPI in general practice.

5.2.1 Characteristics of the ABPI group

It was found that 338 individual patients had a total of 379 ABPIs completed between 2006 and 25/04/2015. Most of these patients were enrolled MHC patients except for 14 who were patients referred to Dr Lloyd by GPs from other practices. Due to having a small number of non-enrolled patients, this study is limited to analysing the enrolled ABPI group.

When the ABPI group was compared with the total enrolled MHC population (alive at 25/04/2015), female patients made up 64% of the group (48% in the total enrolled MHC population). Despite this difference, no literature was identified regarding which sex ABPIs are done more commonly in, but global studies have found no significant sex variation in PAD prevalences.\(^{27,28}\) Age distribution of the ABPI group was skewed towards older ages, with those in the ‘70-79’ and ‘80-89’ year age bands making up the largest proportion of the ABPI group. This skewing is expected as age is a risk factor for PVD (PAD and mixed disease), especially those over 70 years.\(^{21}\) Socio-economic quintile distributions were different for both the total enrolled MHC population and enrolled ABPI group, with larger proportions of patients living in more deprived areas in the ABPI group. This may reflect socioeconomic inequality in disease prevalence, as indicated in the literature.\(^{21}\)

Ethnicity distribution was similar among both the total enrolled MHC population and enrolled ABPI group, with over 90% of both groups being NZ European/Pakeha. NZ Māori made up 4.81% of the total enrolled MHC population, but only 1.65% of the ABPI group. Similarly, NHC data shows a lower prevalence of PVD in NZ Māori.\(^{11}\) This could have been due to chance. However, it is documented in the literature NZ Māori have a higher prevalence of diabetes.\(^{113}\) Patients with diabetes and PAD generally have a longer asymptomatic phase than those without diabetes, meaning less Māori are presenting with PAD symptoms.\(^{67}\) Further, the NZ Māori population is younger than other populations.\(^{165}\) Deaths due to cardiovascular disease may have occurred before PAD was detected or had time to develop. As PAD generally affects those older, it could be suggested that there are less absolute numbers of older NZ Māori, and consequently less PAD being developed, or detected. All other ethnicities made up <1% of each group.

The mean age (at the time of ABPI) was lower for patients who were still alive at the end of the study period than those who had died before 25/04/2015. Conversely, those who had
died before 25/04/2105 were on average older when they had their ABPI. Being older increases the risk of PAD and PAD-associated morbidity and mortality.16

As expected due to selection bias, arteriosclerotic disease (including PAD), venous disease, peripheral oedema, diabetes mellitus, chronic leg or skin ulcers, congestive heart failure and gout were over-represented in the ABPI group with compared with the total enrolled MHC population. ABPI patients had double the proportion of hyperlipidaemia and hypertension than the total enrolled MHC population, although other characteristics were not controlled for. Having indications for ABPI increase the chances of having risk factors such as hyperlipidaemia and hypertension as predicted. However, ABPI patients had lower proportions of heavy smoking status reported. This may have been under-reported in general, as prevalence of heavy smoking was less than 1.5% for both groups. This percentage is lower than the national prevalence of heavy smokers being 3% in 2006.166 These results suggest that ABPIs are being completed on the correct population at-risk for PAD, who may have relating risk factors and diseases, such as venous disease, other cardiovascular diseases and diabetes.

5.2.2 ABPI Values and Subgroups

The mean segmental arterial pressures for the 379 ABPI assessments completed showed that mean DP and PT pressures were lower than mean brachial pressures. The brachial pressures were in the normal range for an average general practice.167 Lower DP and PT values were expected as patients who have ABPIs are inherently at higher risk of having PAD (the reason for having the test), and the distribution of the lower limb segmental pressures would be skewed to the left (lower pressures), compared with the total MHC population who had not had ABPIs.

Mean ABPI values, for both left and right-sided ABPI values were above 0.9, indicating that a majority of patients who had ABPIs did not have PAD. This correlated with 24.5% of right-sided and 21.6% of left-sided ABPIs <0.9. These findings indicated that of patients who have ABPIs, one in four to five will have PAD. Of the 379 patients who had an ABPI test, this would mean that 82-93 had PAD.

ABPI values <0.5 were more prevalent in right-sided ABPIs than left (5.0% vs 1.8%). There were a larger proportion of left-sided ABPI values 0.5-0.79 than right (15.0% vs 12.1%). The literature does not document whether one leg is more prone to severe PAD than the other, and so this could be explained by chance, but is currently unknown.
There were 15 right-sided and 14 left-sided ABPIs for which a value could not be found. A majority of these were non-occludable, most likely due to diabetic calcification (although not specifically stated in the data). A minority were unobtainable, and this is probably accurate as there are more patients with diabetes than with anatomical anomalies.

In regards to demographics of ABPI subgroups, mean ages of patients with ABPIs <0.9 were greater than for those with values 0.9-1.2. This was expected due to the increasing prevalence of PAD with age. Age in patients with ABPIs <0.5 were not normally distributed as there were not many ABPIs<0.5, and perhaps these patients had varying risk factors at different age groups.

In regards to deceased patients, mean ABPI results were lower for patients in the ABPI group who were dead at 25/04/2015 than patients not dead, suggesting that patients with lower ABPI results have a higher risk of mortality. These results correlate well with previous literature on risk factors, where indicates that lower ABPI results are correlated with higher risk of mortality in those with PAD.

5.2.3 Indications and Outcomes of ABPIs

Results about indications of the 379 ABPI patients showed that most (56.2%) were used to guide management of a venous-related issue, suggesting that this is a very common long-term condition seen at MHC. Investigation of suspected PAD due to PAD-related symptoms was the reason for 45.6% of the ABPIs. This left 10.6% of ABPIs completed for other reasons, with 1.8% of all ABPIs being done to evaluate the possible use of compression stockings for travel.

Knowing the distribution of indications is important to enable MHC and other similar practices to organise their resources better if offering an ABPI service. Having a relatively large proportion of venous disease requiring ABPI means that more compression bandaging of different grades may be required than expected. Further, this may have implication on costing for the practice, and management will need to decide whether (and how much) patients pay for the compression therapy measurement and service.

There were just as many patients who had the ABPI for venous disease with ulcers as without. Of the ulcers, just under half were reported as traumatic in aetiology. This is probably an underestimation as trauma may have happened without being reported by patients or recorded by clinicians.
Of patients who were investigated for suspected PAD and had leg pain, around 52% had classic vascular claudication or rest pain, leading to ABPI investigation. Without the ABPI, this group may have all been referred to the vascular laboratory or secondary care to have ABPIs, as would those with classic symptoms.

It was found that 8.7% of patients who had ABPIs had both an indication to investigate suspected PAD and to guide management of venous disease. Multiple vascular symptoms and signs may or may not be present in patients, so arterial and venous presentations should not be considered in isolation, as evidenced by the 8.7%.

In terms of outcomes for the 379 patients who had ABPIs completed, 100 (26.39%) patients were referred to the secondary care vascular department. This means that 73.61% of patients having ABPIs were not referred to the vascular department. If ABPIs were not available in general practice, secondary care could be overwhelmed by too many referrals- these findings suggest that if ABPIs were consistently provided in the community, then 73.61% of cases would remain in primary care.

Of all outcome categories, 23.2% patients required no further peripheral vascular management. These patients were investigated for suspected PAD but were found not to have evidence of PAD on ABPI testing. In addition, of patients who were identified with PAD, 21.9% had no further management, due to age and co-morbidities or patient preference, and 23.4% had other conservative management. Assuming all guidelines were followed, this means a subset of those who had ABPI-identified PAD did not require vascular referral. Again, these patients may have been inappropriately referred if ABPIs had not been done in general practice, increasing the burden on secondary care. Approximately one quarter of patients who had ABPI-identified PAD were not referred to the secondary care hospital vascular department.

Most patients who had ABPIs to guide management of venous disease were treated with compression treatment (59.5% of venous disease patients with ulcers, 68.4% without ulcers). Patients with venous disease who had co-existing arterial disease were appropriately not treated with compression, and may have been referred to other services such as secondary care.

Patients with traumatic leg ulcers were managed in similar proportions to non-traumatic leg ulcers, with 63.4% having compression treatment and 61% receiving conservative
management following ABPI. This suggests patients with traumatic ulcers have similar outcomes to all leg ulcers.

Among patients who had ‘other management arranged’, 32.8% (22) were referred to another hospital department, where another diagnoses may have been more likely than vascular disease. Many patients (38.8%) who had other management arranged were conservatively treated.

The results for hospital vascular department outcome categories showed that 93 of 100 patients referred had further investigation or treatment, leaving only 7% with no further treatment (see Section 3.4.5.2 Secondary Care Vascular Department Outcome Categories). Of those 7% (seven patients) who did not have any further treatment, two patients declined treatment offered by the vascular department. Of the other five patients, secondary care professionals believed two patients had spinal stenosis and re-referred them to neurology, one had informal ABPIs of normal value, one patient’s leg ulcer had healed completely when seen and one had atypical pain not recognised as vascular pain by the vascular department. It is difficult to say whether these patients’ referrals were inappropriate as PAD is able to progress and regress, and patients’ histories can change over time too.

About a third of all referrals to the vascular department resulted in an arterial duplex scan. This could have meant that surgical intervention was a possibility in some of these patients as the duplex scan investigates sites of arterial blockage.

Of all referrals, 27% had formal ABPIs tested at the vascular laboratory. However, this number was probably under-reported as ABPIs completed in outpatient clinics may not have been recorded, or letters regarding formal ABPI testing may not have been returned to the GP. Further, there were many reasons for re-checking ABPIs, including if time between being seen and their last ABPI was extended, or whether symptoms reported did not match ABPIs completed in general practice. So it is difficult to assess what the meaning of re-testing ABPIs were for a population without discussing cases with the clinicians involved.

Compression bandaging was implemented in 35% of referred patients to the vascular department. Despite compression bandaging often being done in the community, referrals were applied consistently with guidelines. As the referrals were not inappropriate, this implies that specialist expertise considered benefits and risks of compression and concluded that it was worthwhile for use in those patients referred.
Only a minority of patients referred by GP to the vascular department received amputation (5% of referrals received above-knee amputation, none received below-knee amputation and 5% received toe amputation). It would be prudent to compare vascular department referrals from practices not doing ABPIs with those who do to see if ABPIs completed on at-risk patients in the community leads to relatively less invasive surgery.

5.2.4 Benefits Derived from Using the ABPI in General Practice

The ABPI is well established in the literature as being a simple, non-invasive and reliable test, which even medical students are able to do. The findings of this study reinforces the literature that there are benefits of performing the ABPI in general practice at both individual and population levels. Benefits are displayed from both quantitative and qualitative standpoints.

Most notably is the advantage of being able to begin compression bandaging immediately once mixed arterial and venous disease is ruled out in patients presenting with venous symptoms or ulcers. Over half of all ABPIs done at MHC between 2006 and 2015 were done to guide management of a venous symptom or complaint. Just under 70% and 60% of patients who were managed as having venous disease without or with ulcers respectively were treated with compression therapy. Many primary care professionals believed that this was the main advantage of using ABPIs in general practice.

Also, diagnosing and quantifying PAD was perceived by health professionals as an important advantage in being able to understand aetiology of symptoms, aid referrals in being accepted, allow for triaging of patients in secondary care, and identifying urgent cases to be immediately managed. The research shows that 73.4% of patients with PAD (diagnosed by ABPI) were referred to hospital. Conversely, just over 25% of patients with PAD were not referred, and were managed in primary care conservatively. Both are benefits as patients who required referrals had a numerical justification reinforcing clinical judgement to be referred. Patients who were not referred were managed conservatively based on objective measures, decreasing the need for unnecessary referrals.

Further, the ruling out of PAD was appreciated as a huge advantage by interviewed health professionals, conferring the benefits of preventing unnecessary referrals, allowing full management of patients in general practice and decreasing the (patient and financial) burden on the secondary care vascular service. Close to 40% of cases in the quantitative arm had
either ‘no further management arranged’, or ‘other management arranged’ when the ABPI values ruled out PAD. This correlates well with the literature stating that referrals based on a clinical history of intermittent claudication alone may be inappropriate. Performing ABPIs in general practice benefits patients by providing patients with immediate results, and eliminates the need for long waiting times where referrals could have resulted inappropriately.

There was a perception by GPs that ABPI results were highly valued by secondary care vascular departments, and having the ability to refer patients with values would aid referrals in being accepted. Those in the secondary care agreed by stating that the department encourages a high standard of referrals, which includes thinking about the problem at a deeper level, by using ABPIs and interpreting them.

Further, GPs believed that ABPI use may be of more benefit for rural practices located further away from hospital. This was because ABPI testing allowed for more patient-centred healthcare in their own communities, and may prevent long and perhaps unnecessary trips to a city to get a relatively simple test done. GPs believed it was easy to use. A vascular surgeon described the test as being easier to use than a stethoscope, used daily by GPs.

5.2.5 Challenges and Barriers to Using the ABPI in General Practice

The largest barriers to ABPI use in this setting included issues of taking too much time, being too costly and having a lack of patient need for the test, as defined in the research.

Consistently, GPs reiterated that they were part of a larger business entity and that all examinations, tests and new procedures and their clinical benefits are considered in relation to the opportunity cost of other patients and tests. Compared to the relatively low number of patients presenting with vascular symptoms in many Dunedin practices, GPs said that it would take at least another consultation-long appointment to be able to complete the ABPI, which would mean forgoing the opportunity to see another patient, as well as having another paying patient at the practice.

There are many other tasks which compete for the attention of primary care providers, and some GPs prioritised ABPIs lower on the list, under cervical screening, ECGs and other skills.

Further, some GPs discussed in interviews their lack of access to a Doppler, and how it would be too costly to buy one in relation to its estimated use. Doppler ultrasounds range between
$367 to over $1000 by New Zealand suppliers. MHC charged patients an additional consultation fee for the ABPI which could have deterred some patients from consenting to the procedure. There were no records of any patient declining the ABPI in the data extracted.

MHC had an average rate of 38 ABPIs completed per year, or around 3-4 per month which could be an overestimation of what an individual GP may encounter. Whether this is frequent enough to justify ABPI use would depend on the size of the practice, its financial situation and decisions of the owners (compared to the clinicians). Due to the variability of practice characteristics, it is unreasonable for this research to comment on whether this frequency is considered ‘enough for use’ for a single general practice. However, the result suggests that it could be more cost-efficient if one clinician completed the ABPI for an entire suburb or community, such as in Mosgiel (see Section 5.2.6 The Role of the ABPI in General Practice).

A few GPs lacked awareness of the ABPI and its theoretical and practical value. This was strongly related to minimal previous experience with observing or using the ABPI in the past. This was a large barrier in that GPs who had a less comprehensive understanding of the ABPI did not feel that it was a necessary part of vascular assessment. Those who had more past experience with ABPIs discussed the benefits of the ABPI in more detail. So, education sessions held for GPs or nurses to assist their understanding of vascular assessment tools is recommended to increase awareness of the ABPI.

Some GPs interviewed stated that they believed the ABPI results did not change their management of their patients. This was related to a lack of confidence or awareness of the ABPI’s value in some participants. A heavy reliance on patients’ clinical history and examination was stated by some GPs, and more weight was placed on these aspects than on the ABPI result. Further, some practices did not offer treatments such as compression bandaging which would mean that management itself was not possible despite an indication to do so via ABPI result. This was the case for one GP who did ABPIs regularly. Individual practices’ capabilities often determined the practical benefit of completing the ABPI.

Understanding the barriers and challenges to ABPI use were a major goal of the study. General practices need to consider their own priorities and financial situations before attempting to mitigate barriers.
5.2.6 The Role of the ABPI in General Practice

There were polarising thoughts among primary and secondary care professionals regarding the role of the ABPI is in general practice. Although most professionals acknowledged the theoretical benefit, the challenges were significant enough to prevent its use to many cases. Many professionals discussed not if there was a role, but whose role it should be.

Some study participants commented that all GPs are able to perform ABPIs due to its ease of use and relative simplicity, and should be using it themselves. This view has been reiterated in guidelines.52

Others have stated that it could be more appropriate for nursing colleagues to perform ABPIs in general practice. Reasons included saving GP time, allowing more patients to be seen by GPs, prevent the risk that an urgent case is missed, and that nurses were sufficiently competent do perform this test independently. Previous studies have showed low levels of variability in results and accuracy between professionals making this a viable option in regards to accuracy and reliability of use.108, 109

Some practitioners interviewed believed that the ABPI is a tool that an individual nurse or GP with a special interest could do for a practice or community. ABPIs were discussed by these practitioners as a special skill. Some GPs interviewed had little experience and little confidence in being able to perform and interpret the ABPI themselves, which could have contributed to this view. However, reasoning behind having a specialist clinician perform ABPIs in the community included the ability for GPs to refer to their specialist colleagues easily, mitigating barriers of Doppler costs, time and lack of patient need. One GP likened ABPIs to minor surgical procedures completed in general practice, as a specialised skill.

Rearrangement of how the ABPI is used in a community setting could be an appropriate solution to maximise its benefits while mitigating barriers. Primary and secondary care professionals described a concept of having one individual (GP, nurse) being responsible for completing ABPIs for a wider group or community (depending on population sizes). Again, this clinician would gain more experience and efficiency in doing ABPIs with a larger patient load than one would normally expect. Further, other GPs’ time would be preserved, while not delaying the test unnecessarily, and there would be no further equipment costs to smaller practices because referral could be made to the ABPI specialist primary care professional instead. This solution allows for an integrated multi-centred and multidisciplinary approach to vascular care in general practice. This is similar to the case for Mosgiel and MHC currently,
with Dr Hywel Lloyd seeing more ABPI patients than normal due to having a special interest in this area. The disadvantage of this concept is that there is a risk that no practitioner would be interested, and so a community could lack the ability to complete the vascular assessment.

Although no practitioners stated that there was no role for using the ABPI in general practice, several Dunedin GPs stated that it may not be a priority for GPs. This was because they were satisfied with existing vascular laboratory services in Dunedin and in turn may be because Dunedin has a relatively large university-owned vascular laboratory service at Dunedin Public Hospital. Other hospitals or regions in New Zealand may not offer a similar service (see Section 5.3.2 Limitations). Nevertheless, all interviewees believed that efforts to increase quality of patient management in primary care should be considered, and ABPIs in general practice could be a way to do so.

### 5.3 Strengths and Limitations

Both arms of the study had strengths and limitations that contribute to internal and external validity of the research.

#### 5.3.1 Strengths

The quantitative arm of the study evaluated 379 ABPIs completed over 10 years, and this long time span allowed a large sample of ABPIs to be analysed as they are not done as often as other tests in general practice. On average, 3-4 ABPIs were completed per month. Having only one year of results would not have yielded enough results to merit proper analysis.

Electronic patient records were used to harness a wealth of demographic information (see Section 5.1.1 Electronic Health Records), and there was minimal missing data for most enrolled patients at the MHC. Electronic data and minimal missing data allowed for more complete analysis of real world data of ABPIs conducted on patients with clinical need, rather than in an artificial research setting.

Due to being able to analyse all 379 ABPIs completed in the practice, no sample size calculations needed to be completed, as all 100% of ABPIs were included in the study, and not just a proportion hoping to represent the entire sample.

In regards to ABPI methodology, although the literature defines much variation, there was consistency in ABPI technique throughout the quantitative arm of the study. 100 Electronic
records showed that 349 of the 379 ABPIs were completed by Dr Lloyd, and a minority (30, 7.9%) completed by one of two nurses supervised by Dr Lloyd. Dr Lloyd based his techniques on NZ guidelines similar to that of international guidelines. The ABPI method followed is comparable to recommendations in international guidelines. Further, for non-enrolled patients referred to the clinic, patient notes were read only after completion of the ABPI to decrease collection bias. Therefore, consistency of methodology meant that risk of measurement bias would be reduced.

The qualitative arm of the study used a similar interview structure for all interviewees, meaning consistency was applied. Interviews were recorded to minimise interview bias and memory difficulties during transcription phases (see Section 5.1.2 Semi-Structured Interviews).

The setting of interviews encouraged maximum discussion and data collected. Interviews were completed in settings comfortable to interviewees, as the candidate travelled to most interviewees’ workplaces. Comfort encouraged maximum discussion when questions were asked. Interview techniques to encourage interviewee participation were used. Further, it allowed the candidate to observe the context in which statements were being made (e.g. sizes of individual practices, equipment available, vascular laboratory).

Data saturation was achieved after nine general practice interviews as many GPs discussed similar advantages and barriers of using the ABPI. Though there were not many secondary care practitioners interviewed, they provided a valuable alternative perspective to supplement the primary care perspective.

An external analyst was used to independently check and code transcribed interviews to reduce observer bias in the analysis period. A process of triangulation through discussion aided the candidate to code or recode certain aspects of interviews, as well as consider other points of view on how qualitative data was perceived and evaluated.

The use of both a quantitative and qualitative approach together had a synergistic effect to assess the usefulness of ABPIs in general practice. The quantitative arm allowed for characterisation of the types of patients who are currently being evaluated using the ABPI, and evaluation of reasons or indications for ABPI use. Further, the real world data meant that outcomes could be measured to define the consequence of having ABPIs done. The qualitative arm allowed for an understanding of reasons practitioners gave for wanting to do the ABPI or not and challenges that inhibited use of the ABPI in this setting. Interviews helped to confirm
and place quantitative data into a meaningful social context, determining the situations in which the ABPI could be used. The quantitative and qualitative arms support one another in finding a more valid answer to the research question that each could have alone.

No similar research to either the quantitative or qualitative arms has been completed in New Zealand before: it is the first of its kind in this setting. Therefore this research has bought new knowledge to the scientific community. Further, no quantitative research evaluating ABPI use clinically with patient follow-up over 10 years could be found during the research period–so this could be the longest retrospective ABPI group in general practice to have been analysed internationally.

5.3.2 Limitations

The quantitative arm of the study one evaluated data from one general practice, which limits generalisability to other practices although within the one practice there was consistency in technique and clinical judgement. The setting is one of an urban general practice in Dunedin, which has a different population to other regions in NZ and internationally. The findings can only be said to be applicable to this practice in this context and is not necessarily representative of the wider region or general practices in New Zealand, generally.

Further, because this was an observational study of electronic records and not a controlled study, there was no comparison group for outcomes data. There is no group who were eligible for ABPIs who did not receive ABPIs. It can only be speculated what outcomes would have arisen for participants who did not receive ABPIs. This means that conclusions stated within the research may not be as strong as if there were a defined comparison group.

There was a reliance on the electronic clinical notes and what was recorded in letters when determining indications and outcomes data for the ABPI group. Therefore any indications or outcomes were recorded in the study only if they had been previously recorded in the notes. This may have meant there is underreporting of some data, such as patients who received conservative treatment, as it was not recorded explicitly.

Similarly, investigations and management delivered in secondary care may have been underreported as study data were restricted to documentation sent from the hospital to MHC.

A further limitation was that because there was an arbitrary end-point for analysis of the MHC ABPI data, patients who were awaiting referral at 25/04/2015 did not necessarily have any outcomes recorded, and so no outcome was recorded for some ABPI patients. Therefore,
some patients may have had no further peripheral vascular management due to waiting for specialist consultation.

The PAD definition by ABPI measurement in this study may have also limited findings. As the ABPI takes the higher of brachial and distal arterial pulses, disease in collateral circulation may have been missed, underestimating prevalence and severity of PAD in the MHC population. The getABI trial compared different methods of determining the ABPI, and found that PAD identification was doubled if the lowest ankle systolic pressure used in the calculation of ABPI compared to the highest.\textsuperscript{31}

Similarly, the definition for severe disease was <0.5, which was a numerical boundary between severe and moderate disease. This may not fairly reflect reality, as patients may have severe disease with ABPI values 0.52 for instance. Further, other research have used a definition of <0.4 as severe disease.\textsuperscript{16} Different definitions may have resulted in different results.

The qualitative arm of the study also had limiting factors.

Due to time constraints on the candidate to be able to finish both arms within the year, the number of the interviewees was limited to people who were able to be interviewed between June and September 2015. The sample size was relatively small, with nine GPs and four secondary care professionals. The recruitment protocol of snowball sampling put pressure on the time allocated for this arm of the study as existing participants were asked to recommend further participants following their interviews, which meant a pool of health care professionals could not be invited at the commencement of research. Nonetheless, saturation of data was reached for GPs for many of the topics discussed.

Further, the time constraint meant that the demographic profile of interviewees was also limited to people who the candidate could interview face-to-face within the months mentioned. Only health professionals in the Dunedin region were interviewed, limiting the generalisability and context of findings to Dunedin, New Zealand. The research implies that more benefit may be gained if the ABPI was used in a setting further from a vascular laboratory or hospital such as in the rural GP setting because referral would entail patients travelling a larger distance. Interviews with GPs working in distance or rural settings would be useful to investigate potential ABPI utility. Participants in primary care were limited to urban GPs. There were no other primary care professions or allied health professionals represented in this arm of the study.
Interviews were all recorded and may have been seen as intrusive to participants. There was one instance when a participant wanted to mention other details and opinions after the recording was stopped. This was because they did not want to be identified discussing financial issues regarding ABPI use. It is possible the data were restricted to what participants were willing to share on tape to researchers, and could have limited the amount of contentious opinions gained.

Subjectivity and interviewer bias was minimised by having a structured interview with open-ended questions, as well as using an external analyst during analysis phases. However, subjectivity in the coding is still a possible limitation due to the nature of the study.

5.4 Implications and Recommendations

5.4.1 Implications

This research suggests that there is a role for ABPIs to be used in primary care, which has implications for patients both on individual and population levels as well as primary and secondary care systems. Practices that use ABPIs are able to gain an immediate answer to questions regarding patients have PAD or not. This may lead to the identification of appropriate cases needing referral. Moreover, it can convey level of severity and urgency to be seen by a secondary care vascular department without necessarily having to go through a lengthy waiting process, reducing morbidity for patients. Further, where disease is ruled out, unnecessary referrals are not sent, and patients are able to be reassured, treated using conservative management in primary care or investigated promptly for other diagnoses. Specifically, this means only patients with symptomatic or limiting PAD would be referred, and that compression bandaging would begin promptly for those with venous disease but without PAD in general practice. Doctors would be able to reinforce their clinical decisions to patients through ABPI results. These benefits are mirrored in both arms of the study (see Section 5.2 Key Findings).

In regards to secondary care, using ABPIs in general practice may decrease some of the burden on vascular laboratories, outpatient clinics and wound care clinics as patients may be managed more appropriately with an ABPI result. Further, it may decrease the frequency of harms happening within the referral period (while waiting to be seen).
As the ageing population continues to rise in New Zealand, it is predicted that PVD and other cardiovascular disease prevalence will rise. Using the ABPI in primary care is one way to better manage patients and decrease unnecessary use of health resources.

In order to implement ABPI testing more widely, practices may need to educate staff in using Doppler ultrasound, add another task to their lengthy list and incur additional expenses. Thoughts around whose role it is to do ABPIs should be discussed within or between practices of a community to mitigate and overcome the barriers identified in the study. Someone who is easily accessible to many practices and patients, who may have an interest or expertise in doing ABPIs, and who may be able to have access to an existing Doppler would be suitable. An adequate and accessible space would also be required to implement ABPIs in general practice.

Another issue that should be considered includes what reimbursement is required for the extra service. Practices would need to charge patients, incur costs, or gain reimbursements from local PHOs or District Health Boards. More research around cost-effectiveness from a population standpoint and inter-professional collaboration may be needed to make this recommendation practical from a business point of view.

There are potential issues of over-diagnosis and picking up PAD in asymptomatic individuals if the service is freely available to general practice. Clinicians with access to a primary care ABPI provider should discuss which patients should receive the test and clearly document this to provide guidelines to referring GPs for awareness. Clinical audits of recorded information using electronic data such as in this study, should be completed regularly to evaluate its effectiveness over time.

5.4.2 Recommendations

The findings have given scope for the following recommendations:

Future avenues of research are recommended to extend this research, including;

- Continuing the collection and analysis of ABPI data at MHC
- Evaluating similar quantitative data in other practices that perform ABPIs regularly to be able to compare findings, both in Dunedin and across New Zealand
- Conduct further interviews with more primary care health professionals in both urban and rural centres across New Zealand, comparing Dunedin to other centres
• Conduct further interviews with other primary care and allied health professionals to gain perspective

• Completing a health economics cost analysis of the burden of PAD in New Zealand and how many DALYs would be reduced if ABPIs were done in primary care

• Completing epidemiological research on the unmet need for ABPIs in primary care in different regions in New Zealand

• Discussion into the possible reimbursement strategies for diagnostic tests such as the ABPI

As suggested by the qualitative study, findings suggest that there could be a lack of knowledge and experience of ABPIs for GPs elsewhere. More information or education should be provided to GPs and GP trainees. For instance, an evening session provided by Departments of Primary Care in universities, or further publication of articles. Centres that train health professionals, practice educators or mentors should be encouraged to discuss the benefits, challenges and opportunity of using the ABPI in general practice to inform their decision of whether they should do them. This research recommends that GPs become cognizant of the capabilities and role of the ABPI.

Further, medical schools should review whether the use of ABPIs is sufficiently integrated into the curriculum, and perhaps could be added to a list of core clinical skills which could be learnt. This would raise awareness of the value of ABPIs for all medical graduates.

Results may be used in helping to influence guidance for primary care practitioners such as within clinical practice guidelines groups e.g. BPAC. Health professional associations, educational institutes or colleges should encourage those in primary care to perform ABPIs where there is a need. As suggested by the interviews with secondary care professionals, added commentary from secondary care vascular specialists to GPs via letters or articles may strengthen their recommendation of doing ABPI in general practice.

Inter-professional collaboration within practices or communities is recommended to develop a system to recruit a local individual with an interest in vascular care to perform ABPIs for a population, as suggested by the research.

This project has set a platform upon which other more focused research and discussion can now take place.
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Appendices
Appendix A: Statement of Ethical Approval, University of Otago

Professor S Dovey
Department of General Practice & Rural Health
Dunedin School of Medicine

2 December 2014

Dear Professor Dovey,

I am writing to you concerning your proposal entitled “Use of the Ankle Brachial Pressure Index (ABPI) in a General Practice over 11 years”, Ethics Committee reference number HD14/62.

The above research was submitted and reviewed as a ‘Human Ethics Committee (Health) Departmental Conditional Approval of Projects using Health Information’. The outcome of that consideration was that the proposal was approved.

The standard conditions of approval for all human research projects reviewed and approved by the Committee are the following:

Conduct the research project strictly in accordance with the research proposal submitted and granted ethics approval, including any amendments required to be made to the proposal by the Human Research Ethics Committee.

Inform the Human Research Ethics Committee immediately of anything which may warrant review of ethics approval of the research project, including: serious or unexpected adverse effects on participants; unforeseen events that might affect continued ethical acceptability of the project; and a written report about these matters must be submitted to the Academic Committees Office by no later than the next working day after recognition of an adverse occurrence/event. Please note that in cases of adverse events an incident report should also be made to the Health and Safety Office:

http://www.otago.ac.nz/healthandsafety/index.html

Advise the Committee in writing as soon as practicable if the research project is discontinued.

Make no change to the project as approved in its entirety by the Committee, including any wording in any document approved as part of the project, without prior written approval of the Committee for any change. If you are applying for an amendment to your approved research, please email your request to the Academic Committees Office:

gary.witte@otago.ac.nz
Approval is for up to three years from the date of this letter. If this project has not been completed within three years from the date of this letter, re-approval or an extension of approval must be requested. If the nature, consent, location, procedures or personnel of your approved application change, please advise me in writing.

Yours sincerely,

[Signature]

Mr Gary Witte
Manager, Academic Committees
Tel: 479 8258
Email: gary.witte@otago.ac.nz

c.c. Assoc. Prof. C Jaye  Head of Department  Department of General Practice & Rural Health
Appendix B: Statement of Scientific Review, Department of General Practice and Rural Health, University of Otago

**SCIENTIFIC PEER REVIEW: Letter to Head of Department to inform of results**

25/10/2015

Dear Associate Professor Chrys Jaye,

Re: Scientific Peer Review. Use of the Ankle Brachial Pressure Index (ABPI) in one general practice

Ding T (student), Dovey S, Lloyd H.

Department: General Practice and Rural Health, DSM

The above project has now been through the Department’s scientific peer review process. The two peer reviewers (two internal) considered this research to address an important clinical issue in primary care and to use an appropriate research methodology and recommended minor revisions to the protocol. These recommendations focused on refining the exact study methodology so that it was a descriptive study of current clinical practice. I can confirm that the revised protocol takes appropriate account of the peer review comments.

I recommend that this protocol now meets an acceptable standard for proceeding to the ethics review process (Category B).

Yours sincerely

[Signature]

Professor Tim Stokes
Research Convenor, Scientific Peer Review Committee,
Department of General Practice and Rural Health
Appendix C: Statement from Ngāi Tahu Research Consultation Committee

Wednesday, 17 December 2014.

Professor Susan Dowey,
Dunedin School of Medicine - General Practice and Rural Health,
DUNEDIN.

Tua Koe Professor Susan Dowey,

Use of the Ankle-Brachial Pressure Index (ABPI) in a general practice over 11 years.

The Ngāi Tahu Research Consultation Committee (the committee) met on Tuesday, 16 December 2014 to discuss your research proposal.

By way of introduction, this response from the Committee is provided as part of the Memorandum of Understanding between Te Rūnanga o Ngāi Tahu and the University. In the statement of principles of the memorandum it states "Ngāi Tahu acknowledges that the consultation process outlined in this policy provides no power of veto by Ngāi Tahu to research undertaken at the University of Otago." As such, this response is not "approval" or "mandate" for the research, rather it is a mandated response from a Ngāi Tahu appointed committee. This process is part of a number of requirements for researchers to undertake and does not cover other issues relating to ethics, including methodology they are separate requirements with other committees, for example the Human Ethics Committee, etc.

Within the context of the Policy for Research Consultation with Māori, the Committee based consultation on that defined by Juthoe McGechan:

"Consultation does not mean negotiation or agreement. It means: setting out a proposal not fully decided upon; adequately informing a party about relevant information upon which the proposal is based; listening to what the others have to say with an open mind (in that there is room to be persuaded against the proposal); understanding that such in a genuine and not cosmetic manner. Reaching a decision that may or may not alter the original proposal."

The Committee considers the research to be of importance to Māori health.

The Committee notes and comments that ethnicity data is to be collected as part of the research project and recommends the use of the questions on self-identified ethnicity and descent; these questions are contained in the latest census.

The Committee suggests including in the research team a researcher with expertise in analyzing and interpreting data by ethnicity.

The Committee suggests dissemination of the research findings to Māori health organisations regarding this study.
We wish you every success in your research and the committee also requests a copy of the research findings.

This letter of suggestion, recommendation and advice is current for an 18 month period from Tuesday, 16 December 2014 to 16 June 2016.

Nīhau noa, nū

Mark Brunton
Kawhakahaere Rangahau Māori
Research Manager Māori
Research Division
Te Whare Wānanga o Otago
Ph: +64 3 479 8736
Email: mark.brunton@otago.ac.nz
Web: www.otago.ac.nz
Appendix D: Statement of Data Authorisation, Mosgiel Health Centre

Dr Alan Mawhinney
Dr Grace McPherson
Dr Robert Morton
Dr Jackie Hughes
Dr Don Watson
Dr Kim King
Dr Ben Hayward
Dr Bob Chadwick
Dr Graham Johnston
Dr Jennifer Lee
Dr Hywel Lloyd
Dr Rachel Mansfield

Mosgiel Health Centre
21-23 Ingles Street, Mosgiel 9024
PO Box 349, Mosgiel 9053
Ph: 3489 5195 Fax: 34897700
e-mail: health@mosgiel@xtra.co.nz

29th November 2014

Dr Cheryl Jaya
Associate Professor and Head of Department
Department of General Practice and Rural Health
University of Otago
PO Box 915
Dunedin
New Zealand

Dear Dr Jaya,

Re: Use of the Ankle Brachial Pressure Index (ABPI) in a General Practice over 10 years

Student investigator
Name: Thomas Ding Level of Study: Finished 3rd year MB ChB
Department/School: Dept. General Practice and Rural Health, Dunedin School of Medicine

Mosgiel Health Centre is pleased to be part of the research project to be undertaken by Thomas Ding. We have read the research proposal and look forward to working with them in their chosen study activity. The project sees their research as being of significant value to Mosgiel Health Centre, our patients as well as informing national and international Primary Care Services of the role of Ankle Brachial Pressure Index.

We look forward to being involved with this important piece of research.

Yours sincerely,

Dr Alan Mawhinney
Partner, Mosgiel Health Centre
Appendix E: Confidentiality Statement with Mosgiel Health Centre

Confidentiality Statement

All patient Protected Health Information (PHI)—which includes patient medical and financial information, employee records, financial and operating data of the practice, and any other information of a private or sensitive nature—are considered confidential. Confidential information should not be read or discussed by any researcher unless pertaining to his or her specific job requirements. Examples of inappropriate disclosures include:

- Researchers discussing or revealing PHI or other confidential information to friends or family members.
- Researchers discussing or revealing PHI or other confidential information to other researchers without a legitimate need to know.
- The disclosure of a patient's presence in the office, hospital, or other medical facility, without the patient's consent, to an unauthorized party without a legitimate need to know, and that may indicate the nature of the illness and jeopardize confidentiality.

The unauthorized disclosure of PHI or other confidential information by researchers can subject each individual researcher and the practice to civil and criminal liability. Disclosure of PHI or other confidential information to unauthorized persons, or unauthorized access to, or misuse, theft, destruction, alteration, or sabotage of such information, is grounds for immediate disciplinary action up to and including termination.

Researcher Confidentiality Agreement

I hereby acknowledge, by my signature below, that I understand that the PHI, other confidential records, and data to which I have knowledge and access in the course of my employment with Mosgiel Health Centre is to be kept confidential, and this confidentiality is a condition of my employment. This information shall not be disclosed to anyone under any circumstances, except to the extent necessary to fulfill my job requirements. I understand that my duty to maintain confidentiality continues even after I am no longer attached to the practice.

I am familiar with the guidelines in place at Mosgiel Health Centre pertaining to the use and disclosure of patient PHI or other confidential information. Approval should first be obtained before any disclosure of PHI or other confidential information not addressed in the guidelines and policies and procedures of Mosgiel Health Centre is made. I also understand that the unauthorized disclosure of patient PHI and other confidential or proprietary information of Mosgiel Health Centre is grounds for disciplinary action, up to and including immediate dismissal.

Signature of Researcher

26 November 2014

Thomas Ding

Print Name

Supervisor: Dr Hywel Lloyd
28 January 2015

Professor S Dovey
Department of General Practice & Rural Health
Dunedin School of Medicine

Dear Professor Dovey,

I am again writing to you concerning your proposal entitled “Use of the Ankle Brachial Pressure Index (ABPI) in General Practice: a Mixed Methods Study”, Ethics Committee reference number HD14/62.

Thank you for your request for amendment to the above study. The Committee notes that you would now like to discuss with general health practitioners, and other health professionals, their views, past experiences and reasons behind why they perform ABPIs. The Committee is grateful for the detailed summary provided including the consideration given to any potential ethical implications. The Committee notes the assurance given regarding confidentiality and anonymity and that this is made clear on the Information Sheet.

The Committee also notes the change in title.

The Committee accepts and approves the amendments requested.

Your proposal continues to be fully approved by the Human Ethics Committee. If the nature, consent, location, procedures or personnel of your approved application change, please advise me in writing. I hope all goes well for you with your upcoming research.

Yours sincerely,

Mr Gary Witte
Manager, Academic Committees
Tel: 470 6250
Email: gary.witte@otago.ac.nz

cc: Assoc. Prof. C Jaya Head of Department, Department of General Practice & Rural Health
Appendix G: Participant Information Sheet

Use of the Ankle Brachial Pressure Index in General Practice: A Mixed Methods Study

Information Sheet for Participants

Research team

<table>
<thead>
<tr>
<th>Principal investigator and supervisor:</th>
<th>Professor Susan Dovey</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Department of General Practice and Rural Health</td>
</tr>
<tr>
<td></td>
<td><a href="mailto:susan.dovey@otago.ac.nz">susan.dovey@otago.ac.nz</a></td>
</tr>
<tr>
<td>Clinical supervisor:</td>
<td>Dr Hywel Lloyd</td>
</tr>
<tr>
<td></td>
<td>Department of General Practice and Rural Health</td>
</tr>
<tr>
<td></td>
<td><a href="mailto:hywel@bpac.org.nz">hywel@bpac.org.nz</a></td>
</tr>
<tr>
<td>Student researcher and interviewer:</td>
<td>Thomas Ding</td>
</tr>
<tr>
<td></td>
<td>BMedSc (hons) student</td>
</tr>
<tr>
<td></td>
<td><a href="mailto:dinth152@student.otago.ac.nz">dinth152@student.otago.ac.nz</a></td>
</tr>
</tbody>
</table>

Introduction

Thank you for showing an interest in this project. Please read this information sheet carefully. If you decide to participate we thank you. If you decide not to take part there will be no disadvantage to you and we thank you for considering our request.

What is the aim of this research project?

This research project aims to evaluate the use of the Ankle Brachial Pressure Index (ABPI). In addition to a quantitative investigation, we wish to explore the views and any past experience of general practitioners in regards to the procedure, and why they use it (or not).

This project will be undertaken by Thomas Ding as part of his BMedSc (hons) thesis.
Who is funding this project?

The project is being run under the University of Otago and the researcher, Thomas Ding has 2 scholarships to fund his research. This includes the Maurice & Phyllis Paykel Research Trust Award in Medical Sciences, and the Best Practice Advocacy Centre Scholarship.

Who are we seeking to participate in the project?

We are seeking to interview any health professionals in primary care who have had experience with ABPIs in the past, and/or who have an interest in discussing their views on the ABPI (even if they do not do it themselves). This may include, but not exclusively, general practitioners, nurse practitioners, practice nurses etc.

Also, other health professionals with an interest in the ABPIs in other settings e.g. vascular laboratory or secondary care, would be welcomed to take part as well.

If you participate, what will you be asked to do?

Participants will be interviewed at a place and time convenient to them (e.g. at their practice). This will include a discussion of approximately 30 minutes duration however may be shorter or longer if participants wish.

The discussion framework and questions will pertain to prior experience with and views on using ABPIs, the role of ABPIs in general practice, whether and why practitioners do ABPIs, challenges and barriers regarding the use of ABPIs and details on how it may be used. The discussions will be open-ended. In the event that the line of questioning develops in a way that makes you feel uncomfortable or hesitant, you may decline to answer any question's.

What about anonymity and confidentiality?

A digital audio recorder will be used to record the discussion, to allow the researcher to evaluate and transcribe discussions afterwards. This information will be all made anonymous. The audio recording and transcriptions will be stored on a secure system while being used. Once transcribed, the audio content will be deleted permanently. No aspects of the transcription will contain identifiable data. Any previous experiences and sensitive information discussed will remain strictly confidential and anonymised as with all other recorded information.

Is there any risk of discomfort or harm from participation?

No. Participation will only be required for an interview.

What data or information will be collected, and how will they be used?

All interview discussions will be recorded via a digital audio recorder so that discussions can be transcribed. Written (anonymised) notes may also be made during the interview. These
will be analysed to find a thematic matrix, and anonymised quotations may be used within a BMedSc (hons) thesis or other research publication.

The audio recording will be kept only up till the point which interviews are all transcribed, or when there is no more need for them, at which they will be destroyed. Data obtained as a result of this research may be retained for up to a maximum of five years in secure storage.

Participants will receive a copy of the findings if they wish.

Only Thomas Ding and his two project supervisors will have access to the raw data.

**If you agree to participate, can you withdraw later?**

You may withdraw from participation in the project at any time and without any disadvantage to yourself.

**Any questions?**

If you have any questions now or in the future, please contact either:

<table>
<thead>
<tr>
<th>Thomas Ding</th>
<th>021-268-3181</th>
</tr>
</thead>
<tbody>
<tr>
<td>Student Researcher, BMedSc (hons)</td>
<td><a href="mailto:dinth152@student.otago.ac.nz">dinth152@student.otago.ac.nz</a></td>
</tr>
<tr>
<td>Department of General Practice and Rural Health</td>
<td></td>
</tr>
<tr>
<td>Or</td>
<td></td>
</tr>
<tr>
<td>Professor Susan Dovey</td>
<td>03-479-4135</td>
</tr>
<tr>
<td>Principal Investigator and Supervisor</td>
<td><a href="mailto:Susan.dovey@otago.ac.nz">Susan.dovey@otago.ac.nz</a></td>
</tr>
</tbody>
</table>

*This study has been approved by the University of Otago Human Ethics Committee (Health). If you have any concerns about the ethical conduct of the research you may contact the Committee through the Human Ethics Committee Administrator (phone +64 3 479 6256 or email gary.witte@otago.ac.nz). Any issues you raise will be treated in confidence and investigated and you will be informed of the outcome.*
Appendix H: Participant Consent Form

Use of the Ankle Brachial Pressure Index in General Practice: A Mixed Methods Study

Principal Investigator and Supervisor: Professor Susan Dovey (susan.dovey@otago.ac.nz)
Clinical Supervisor: Dr Hywel Lloyd (hywel@bpac.org.nz)
Student Researcher and Interviewer: Thomas Ding (dinth152@student.otago.ac.nz)

CONSENT FORM FOR PARTICIPANTS

Following signature and return to the research team this form will be stored in a secure place for one year.

Name of participant:

1. I have read the Information Sheet concerning this study and understand the aims of this research project.
2. All my questions about the project have been answered to my satisfaction, and I understand that I am free to request further information at any stage.
3. I know that my participation in the project is entirely voluntary, and that I am free to withdraw from the project at any time without disadvantage.
4. I know that as a participant I will be interviewed, and a digital audio recording of the discussion will be made.
5. I know that transcribed discussions will be anonymised, and the digital audio recording destroyed once transcription is complete.
6. I know that if the line of questioning develops in such a way that I feel hesitant or uncomfortable I may decline to answer any particular question(s), and/or may withdraw from the project without disadvantage of any kind.
7. I know that when the project is completed all personal identifying information will be removed from the paper records and electronic files which represent the data from the project, and that these will be placed in secure storage and kept for up to five years.
8. I understand that the results of the project may be published and be available in the University of Otago Library, but that I agree that any personal identifying
Information will remain confidential between myself and the researchers during the study, and will not appear in any spoken or written report of the study.

9. I know that there is no remuneration offered for this study, and that no commercial use will be made of the data.

Signature of participant:  

Date:  

☐ Please tick if you would like to a copy of any publications which arise from this research.
Appendix I: Interview Schedule

Interview Schedule

Materials for interview

- Notebook/paper
- Digital audio recorder
- Patient Information Sheet
- Patient Consent Forms
- Watch or Timer (also on digital tape)
- Pens

Formalities (Beginning)

☐ Greetings- introduce self, role, and research topic briefly
☐ Explanation of interview, reiterate openness of questions, confidentiality and anonymous reporting
☐ Answer any questions
☐ Allow time for participant information sheet to be read
☐ Have consent form signed (give copy if wanted)
☐ Test digital audio recorder

Interview Guide

- Could you say your full name, occupation, and other roles you have related to clinical, medical or academic activities?

- Could you discuss what you know already about ABPIs? (If not stated specifically following open question, ask about.)
  - How ABPIs are used
  - Why they are used
  - Role in primary care
  - Role in secondary care

- Could you discuss any experience you’ve had with ABPIs? (If not stated specifically following open question, ask about.)
  - Training
  - Teaching- med school, house surgeon, registrar, GP training

- Do you perform ABPIs and why?
  - For those who do-
    - Why do you do ABPIs? What advantages do you see in doing ABPIs?
    - In what scenarios would you do ABPIs? (Routine with vascular patients/Case-based)
    - Discuss how you do the ABPI specifically.
    - What equipment do you use?
    - What disadvantages do you see in doing ABPIs, if any?
- Could you discuss any barriers/challenges that you've faced when considering ABPs?
- How have you dealt with these barriers/challenges?
  - For those who don't:
    - Have you ever considered it?
    - What advantages do you see in doing ABPs, if any?
    - What disadvantages do you see in doing ABPs, if any?
    - What are the barriers/challenges to doing ABPs, if any?
  - For those who have done it and decided not to anymore:
    - Why did you do ABPs? What advantages do you see in doing ABPs?
    - Why not anymore? What disadvantages do you see in doing ABPs, if any?
    - What were the barriers/challenges in doing ABPs, if any?

- Could you discuss the usefulness of ABPs in general practice?
  (If not stated specifically following open question, ask about):
  - If yes, who do you think should be responsible for doing so and why?
  - Barriers to general practitioners doing the test, other than for yourself?

- Summarize
- Do you have any additional comments to make?

Formalities (End)

☐ Thank you for your time
☐ Recommending other participants: snowball sampling
Appendix J: Interview Schedule for Interviews with Secondary Care Health Professionals

Interview Guide- Interviews with Secondary Care Health Professionals

• Name, occupation, major roles related to clinical, medical or activities

• Could you discuss your views on the use of the ABPI in general practice?

• How should ABPIs be used in general practice? Why?
  o When or how often should they be done?
  o Whose role would or should it be to complete ABPIs in general practice and why?

• What is your personal experience (if any) of ABPIs in the primary care?

• In your opinion, what are the main advantages of doing the ABPI in primary care?

• In your opinion, what are the main challenges or barriers of ABPI?

• Comment on the appropriateness of referrals you receive
  o What is the standard of referrals in this region?
  o What is required in referrals from your point of view?
  o What have the quality of referrals been like? Unnecessary items? Missed items?

• What level of training do you think is required to be able to do ABPIs satisfactorily from a secondary care point of view?

• Additional Comments?