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Evidence-based practice in Interventional Radiology

A mixed methods study exploring how evidence is incorporated into practice with a particular focus on blood glucose requirements for vascular patients with peripheral artery disease undergoing peripheral angioplasty.

Delia Rose Linton

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Abstract

Background: Evidence-based practice was established to align patient care with the best available evidence. At Waikato Hospital, vascular patients undergoing peripheral angioplasty are required to have a pre-procedural blood glucose level of less than 11 mmol/L. However, there is no guideline outlining this requirement or the underlying evidence supporting this criterion, the absence of which has led to confusion amongst staff. This research project seeks to explore how evidence for pre-procedural blood glucose requirements for vascular patients undergoing peripheral angioplasty is incorporated into practice and how the evidence is disseminated to relevant services.

Participants: The quantitative phase reviewed the clinical records of vascular patients (n=93) who had undergone a peripheral angioplasty in the 2022 – 2023 calendar year. Due to incomplete datasets, a total of 50 patient clinical records were included in analysis. The qualitative phase involved interviews with health professionals (n=9) involved in the care of vascular patients undergoing peripheral angioplasty.

Methods: This mixed-methods two-phase research project involved an initial retrospective clinical records audit of vascular patients diagnosed with diabetes mellitus who had undergone a peripheral angioplasty in the 2022 – 2023 calendar year. A regression analysis was undertaken to determine the correlation between the change in creatinine levels and (i) patient diagnoses and (ii) pre-procedural blood glucose levels. Qualitative data were gathered through semi-structured interviews with health professionals. These interviews were analysed using a general inductive method of inquiry to identify key overarching themes.

Findings: There was no observed statistically significant association using ANOVA between the change in creatinine levels and patient diagnoses ($p=0.31$) or pre-procedural blood glucose levels in vascular patients following a peripheral angioplasty ($p=0.14$). Although a one-unit increase in pre-procedural blood glucose levels was observed to result in an associated increase of 3.5 mg/dL in creatinine levels, this was not statistically significant ($p=0.25$). Analysis of the qualitative interview data from interviews with health professionals produced three themes relating to the implementation of evidence-based practice: (i) Dissemination of evidence; (ii) Balancing practicality with evidence in healthcare delivery; and (iii) Enhancing evidence-based practice in clinical contexts.

Conclusion: Although the research reported a relationship between raised pre-procedure blood glucose and creatinine levels, it was not statistically significant. More meaningful results arose, however, from the stakeholder interviews, which indicated a lack of communication and support around the rationale for the pre-procedural blood glucose cut-off value. It appeared that such miscommunication would be absent through the investment into staff education and the development of a clinical guideline.

Acknowledgements

Alone we can do so little; together we can do so much.

Helen Keller, 1880 – 1968

What a journey this has been. Upon reflection, the past 18 months have been filled with much learning, personal development and blessing; however, it has not been without its many challenges. Sickness, bereavement and the joyous news of the upcoming birth of our first child, together with the ups and downs of pregnancy, have added complexity to completing this thesis. First and foremost, I would like to acknowledge God's faithful provision throughout this time. The phrase, "Yet not I but through Christ in me," often came to mind as I was writing, reminding me that my hope and future are secure in Jesus Christ. God's constant presence never fails, and through my continued dependence on Him, He will strengthen me and help me to face whatever challenges come my way. It is my prayer that the knowledge and skills I have gained from this journey will be used to fulfil God's purpose for my life.

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Contribution

I, the researcher undertook all aspects of this study under the direct guidance of my supervisors. This entailed selecting the appropriate research design, the data collection and analysis, and the publishing of the findings in this thesis.

Dedication

To my husband, Jonathan Linton, for his unfailing love and support.

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Chapter I: Introduction

Little by little, one travels far.

J. R. R. Tolkien, 1892 – 1973

The modern world is experiencing an explosion in the discovery and accessibility of new information, and healthcare is no exception (Dang et al., 2022). However, the exponential growth in new evidence often outpaces its application to practice. In fact, it can take an average of 17 years for research to be incorporated into clinical practice (Hanney et al., 2015). Evidence-based practice is one of the best strategies health professionals can use to stay up to date with developing research and incorporate relevant evidence into their daily practice (Dang et al., 2022).

Evidence-based practice is a well-established concept that is widely accepted around the world. Its fundamental purpose is to guide clinical decision-making and encourage health professionals to consider whether current practice provides patients with the highest quality and most effective interventions possible (Craig & Dowding, 2020). Evidence-based practice provides a clearly defined process of collecting, analysing and implementing research findings into practice (Hoffmann et al., 2017). It involves locating and synthesising the best available evidence, including empirical research and non-research evidence to make informed decisions about the most evidence-based approach for patient care (Hoffmann et al., 2017).

Successfully incorporating evidence into practice can be challenging for healthcare organisations and health professionals. Many interrelated factors can positively or negatively influence the implementation of evidence within a clinical context. Li et al. (2018) identified how leadership, culture, collaboration, communication, training and resources can promote evidence-based practice in various ways. The presence of these factors not only contributes to the implementation of evidence-based interventions but also their sustained use in a clinical setting. Hailemariam et al. (2019) found that ongoing supportive leadership, training, and staff buy-in were key sustainment strategies for evidence-based practice. Whilst such factors enable evidence-based

practice, they can also become substantial barriers when lacking or distorted. Williams et al. (2015) demonstrated that a lack of leadership, a culture resistant to change and insufficient resources were commonly experienced deterrents of evidence-based practice.

The process of evidence-based practice is often initiated when health professionals encounter an issue or identify an area for improvement in clinical practice. One such example is the pre-procedural blood glucose requirements for vascular patients with peripheral artery disease undergoing peripheral angioplasty. Peripheral artery disease affects over 200 million people globally and is an independent marker for coronary artery disease and stroke, the leading causes of mortality worldwide (Lin et al., 2022; Song et al., 2019; World Health Organization, 2023). Peripheral artery disease impedes blood flow to the lower extremities, causing extreme pain, impaired mobility and severe limb complications, including non-healing wounds, gangrene and amputation (Wipke-Tevis et al., 2019). Individuals presenting with peripheral artery disease often have concomitant diabetes mellitus, which not only accelerates the progression of peripheral artery disease but is associated with worse outcomes (Thiruvoipati et al., 2015). Peripheral angioplasty is a minimally invasive procedure in which contrast media and a specialised catheter are used to visualise and treat peripheral artery disease (Wipke-Tevis et al., 2019). The use of peripheral angioplasty restores blood flow to the affected limb, resulting in symptom relief, improved mobility and higher rates of limb salvage (Aboyans et al., 2018). However, the use of contrast media has been associated with acute kidney damage, also known as contrast-induced nephropathy, particularly in patients with diabetes mellitus and elevated blood glucose levels (Kewcharoen et al., 2020). Thus, there has been exploration into whether maintaining normal blood glucose levels immediately before contrast-based procedures, such as peripheral angioplasty, reduces this risk.

The impetus behind incorporating evidence into clinical practice is rooted in the pursuit of optimal patient care. Evidence-based practice involves providing clinical interventions at the best possible standard and ensuring that they are safe and effective, resulting in more good than harm (Craig & Dowding, 2020). As such, the requirement for pre-procedural blood glucose levels to be less than 11 mmol/L before a peripheral

angioplasty was implemented to address the potential risk to patient safety and improve outcomes. This research study seeks to explore how evidence is incorporated into practice within Interventional Radiology and the dissemination of evidence to Ward M14 at Waikato Hospital. More specifically, it will address the following research questions:

1. How does evidence inform the requirement for blood glucose levels to be less than 11 mmol/L prior to a peripheral angioplasty?
2. How is evidence concerning pre-procedural blood glucose requirements disseminated between Interventional Radiology and Ward M14?
3. How does evidence-based practice impact service delivery and patient outcomes?

Chapter II: Literature review

If I have seen further, it is by standing on the shoulders of giants.

Sir Isaac Newton, 1643 – 1727

2.1 Literature review introduction

The starting point for any researcher is to determine where their research fits within the current literature (Moule et al., 2017). A literature review provides a summary and critical evaluation of previous research on a particular topic. It brings together the results from similar studies, provides a benchmark for comparing results with published findings and identifies gaps in knowledge (Creswell & Creswell, 2018). In essence, a literature review enables a researcher to create a ‘research space’ for their study and links it to the ongoing dialogue in the existing literature.

This chapter aims to evaluate the current literature surrounding two distinct themes. Firstly, it will examine how evidence is incorporated into clinical practice (Part I). Secondly, it will explore blood glucose requirements for vascular patients with peripheral artery disease undergoing peripheral angioplasty (Part II). A comprehensive literature search will be undertaken to locate and review relevant research studies, and emerging themes will be explored and critically evaluated. This process will allow specific research aims and questions to be proposed, which will be outlined at the end of this chapter.

2.1.1 Search methodology

To address the aims of this research study, a comprehensive database search of Google Scholar, CINAHL Plus and PubMed was undertaken by the researcher. Two primary search strategies were developed for Part I and Part II of this literature review with support from an expert librarian at the University of Waikato. The search terms used for Part I included a combination of ‘evidence-based practice’ with ‘healthcare’, ‘nursing’, ‘health’, ‘importance’, ‘benefit’, ‘advantage’, ‘challenge’, ‘barrier’, ‘incorporation’ and ‘application’. The search terms used for Part II included a

combination of 'vascular' with 'disease', 'disorders', 'peripheral artery disease', 'diabetes mellitus', 'percutaneous transluminal angioplasty', 'pre-procedural', 'blood glucose', 'glycaemic control', 'hyperglycaemia', 'complications', 'contrast-induced nephropathy', 'association', 'connection' and 'impact'. Other relevant literature was acquired through the references found within articles and a grey literature search. The results were limited to articles published within the last ten years for relevance; however, some significant seminal works have been included. Further exclusions were made for articles not published in English and if the full text was unavailable. These search strategies provided an extensive amount of literature, which was narrowed based on the title and abstract relevance of each article. This literature review is not intended to be an exhaustive collection of all relevant literature. It provides a comprehensive overview of the common themes from current, published literature surrounding evidence-based practice and pre-procedural blood glucose requirements for vascular patients undergoing peripheral angioplasty. A significant amount of grey literature has also been utilised to contextualise this research study.

2.1.2 Definitions of terms

The following terms surrounding evidence-based practice and pre-procedural blood glucose requirements for vascular patients undergoing peripheral angioplasty will be addressed throughout this research study. Clear definitions of the terms used within this study are provided below.

Evidence-based practice refers to the use of the best available, current, valid and relevant evidence in making decisions about the care of individual patients, in combination with clinical expertise, contextual clinical information and patient preferences. In the context of evidence-based practice, **evidence** is considered to be knowledge derived from a variety of sources, including research studies, clinical experience, patients' perspectives and the clinical environment, that has been tested and found to be credible. **Practice** simply refers to the exercise of the profession of medicine, nursing or one of the allied health professions.

Vascular patients refer to a cohort of patients who present to healthcare services with various disorders occurring in the arteries and veins of the vascular system. **Peripheral**

artery disease is a common disorder in vascular patients caused by a gradual reduction in blood flow to one or more of the limbs due to atherosclerotic build-up in the arteries. **Peripheral angioplasty** is a minimally invasive, endovascular procedure used to treat peripheral artery disease by opening the narrowed artery and restoring blood flow to the affected limb. Finally, **blood glucose levels**, also referred to as **glycaemic control**, encompasses the amount of glucose in the blood, which are typically higher in vascular patients with co-existing diabetes mellitus.

Part I: Exploring evidence-based practice

2.2 Evidence-based practice

2.2.1 History of evidence-based practice

The idea that research and evidence should underpin clinical decision-making has a long history in healthcare (Rolfe, 2016). In 1972, Archibald Cochrane, a medical doctor and researcher, was the first to voice concerns about the health profession administering treatments unsupported by evidence. Cochrane strongly advocated for the use of evidence from randomised controlled trials when determining preferred treatment options (Cochrane, 1972). Two decades later, the term ‘evidence-based medicine’ was the seminal conceptualisation of this theory. It was coined by medical practitioners as an educational approach to teach junior practitioners to search for and appraise clinical research in order to challenge current practice (Guyatt et al., 1992). However, it was later redefined as,

“the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research”

(Sackett et al., 1996, p. 71).

As such, evidence-based medicine was centred on practitioners assessing the credibility of research, specifically from randomised controlled trials, understanding the results of clinical studies and determining how to appropriately apply these results in their daily practice (Djulgovic & Guyatt, 2017). These formative concepts laid the foundation for evidence-based practice and led to the development of the Cochrane Collaboration and the Joanna Briggs Research Institute in the late 20th century, facilitating the global dissemination of sound scientific evidence to inform clinical decision-making (Dang et al., 2022).

2.2.2 Defining evidence-based practice

The term, ‘evidence-based practice’ was derived from the concept of evidence-based medicine. It has been individualised and adopted by many health disciplines and broadly refers to the use of evidence to guide the practice of doctors, nurses or the

multidisciplinary team (Godshall, 2015; Rolfe, 2016). Fundamentally, evidence-based practice is a problem-solving approach to clinical decision-making. While there are many differing interpretations of evidence-based practice, most definitions include the use of research-based evidence, clinical expertise and patient needs or preferences to inform patient care (Godshall, 2015). Evidence-based practice uses a deliberate approach to consider the various influences on practice and encourages critical thinking in applying evidence to implement the best interventions and improve patient outcomes. According to Sackett et al. (2000), the process of evidence-based practice involves five steps: (i) Formulating clinical problems into clear questions; (ii) Seeking evidence to answer those questions; (iii) Evaluating the evidence for validity and usefulness; (iv) Integrating findings with clinical expertise, patient needs and values to determine the optimum course of action, and (v) Evaluating the outcome. In essence, evidence-based practice integrates the use of current empirical research with experiential evidence, information from the clinical context and patient preferences to ensure clinical decisions are based on all available evidence, thus promoting best practice and the provision of safe, high-quality care (Craig & Dowding, 2020; Dang et al., 2022). Figure 1 illustrates the integrative nature of evidence-based practice.

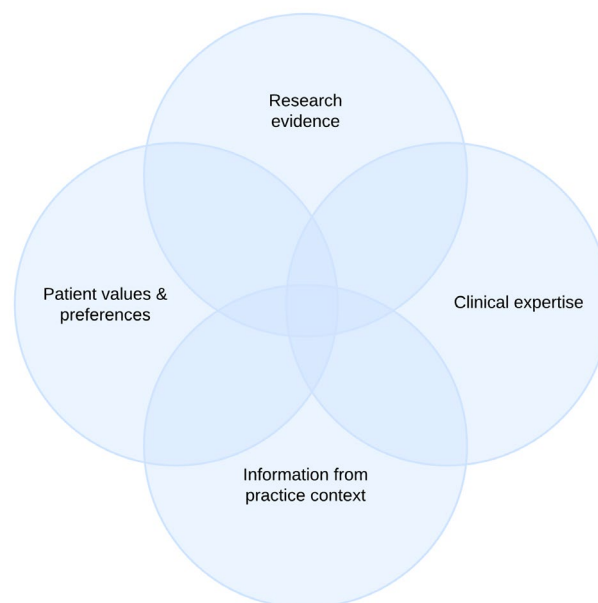


Figure 1: Evidence-based practice, adapted from (Hoffmann et al., 2017).

2.2.3 Sources of evidence

There has been much debate concerning what constitutes ‘evidence’ within evidence-based practice. In the early days, both Archibald Cochrane and David Sackett, the pioneers of evidence-based practice, believed that evidence referred solely to findings from research, particularly those from randomised controlled trials (Rolfe, 2016). As such, evidence-based practice established that not all evidence was equal. It endorsed using the highest quality evidence in medicine, alongside considering the totality of evidence available rather than simply selecting research that supported a particular claim (Djulbegovic & Guyatt, 2017). These overarching principles adhered to the belief that the higher the quality of evidence, the more trustworthy the results. Thus, evaluating available evidence for the rigour of research methods, the presence of bias or poor research practices was central to the process of evidence-based practice (Djulbegovic & Guyatt, 2017). Evidence-based practice presents a hierarchical structure for the quality of evidence, which has been developed over the years (Garrett, 2016). The hierarchy of evidence, as outlined in Table 1, aims to provide a simple comparison between an array of evidence generated by various research methods, promoting a level of trust in recommendations or alerting the user when caution may be required (Evans, 2003). It arranges and ranks evidence using a top-down approach according to the rigour of their research methods (Dang et al., 2022).

Table 1: Hierarchy of evidence, adapted from (National Health and Medical Research Council, 2009).

Level of evidence	Study design
I	Evidence obtained from a systematic review of all relevant randomised controlled trials.
II	Evidence obtained from at least one properly designed randomised controlled trial.
III-1	Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method).
III-2	Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group.
III-3	Evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without a parallel control group.
IV	Evidence obtained from case series, either post-test or pre-test and post-test designs.
V	Evidence gained from non-analytic studies (case reports), expert opinion and formal consensus documents (position statements).

Evidence gained from experimental research designs has long been considered the highest level of evidence (Dang et al., 2022). Randomised controlled trials use the traditional scientific method in which one experimental group is exposed to an intervention, alongside a comparison group, which is not exposed to the intervention. The evidence gained from randomised controlled trials is considered the most reliable because its research design minimises the risk of error or bias influencing the results. The process of randomisation and strict inclusion criteria in randomised controlled trials contributes to high internal validity, or the extent to which the evidence supports the cause-and-effect relationship being studied (Djulbegovic & Guyatt, 2017). While randomised controlled trials are regarded as the ‘gold standard’ research design, particularly for determining the effectiveness of treatment interventions, their findings are often limited to a narrow spectrum of patients and cannot be generalised to the wider population (Evans, 2003). Additionally, evidence may be of lower quality if the findings are based on a single population, limited by small sample sizes, or there is questionable application of clinical findings based on a surrogate endpoint (Djulbegovic & Guyatt, 2017).

Evidence from non-experimental, observational research designs has traditionally been considered lower quality due to the greater risk of systematic error and the distortion of treatment effects (Evans, 2003). Observational studies observe the effectiveness of an intervention in clinical practice. They typically fall into three broad categories: descriptive studies, which describe a naturally occurring relationship between two variables; correlational studies, which measure the relationship between two variables; and qualitative univariate studies, which describe the frequency of one variable (Dang et al., 2022). Observational studies have lower internal validity due to potential differences between comparison groups. However, these studies are firmly based in the real world, and findings often reflect the realities of clinical practice and can be generalised to the wider population (Evans, 2003). As both experimental and non-experimental studies can contribute valid evidence to the effectiveness of an intervention, the strengths and weaknesses of both should be considered when evaluating the best available research (Dang et al., 2022).

Over time, systematic reviews have gained increasing popularity and have started to replace randomised controlled trials as the best source of evidence (Evans, 2003). Systematic reviews are distinct from other forms of research as they merely summarise the available evidence. In contrast, randomised controlled trials and observational studies are the study designs used to conduct research. The use of systematic reviews supports the process of evidence-based practice by summarising the best available evidence. It also promotes the consideration of the totality of evidence on a particular topic (Djulbegovic & Guyatt, 2017). However, systematic reviews must be evaluated for the rigour and transparency in their search strategies, appraisal methods and if conclusions are based on a critical evaluation of the results (Dang et al., 2022). The development of the Cochrane Collaboration and the Joanna Briggs Institute have contributed to the growing collection of systemic reviews summarising evidence from randomised controlled trials and observational studies. Consequently, systemic reviews have become the most cited type of clinical research and are essential for developing clinical guidelines and guiding evidence-based practice (Djulbegovic & Guyatt, 2017).

The use of non-research evidence can be overlooked when incorporating evidence into practice. However, the original concept of evidence-based practice identified a far wider context for evidence. Alongside empirical evidence, the importance of clinical expertise and patient values were included in the concept of evidence-based practice (Dang et al., 2022; Garrett, 2016). While Cochrane and, later, Sackett used the term 'evidence' to refer to findings from research, they emphasised that the implementation of evidence involved utilising individual clinical expertise to determine whether it applied to the individual patient (Rolfe, 2016). Clinician experience is gained through first-person involvement and observation of clinical practice. Time and exposure to various practice situations build this experience, enabling an intuitive and holistic understanding of patients and their care needs. Collaboration with experienced healthcare professionals in the pursuit of evidence-based practice provides opportunities for collegial discussion and sharing of past experiences (Dang et al., 2022). Similarly, collaborating with patients allows their lived experiences, unique needs and preferences to be incorporated into care. It also provides clinicians with insight into whether the research evidence is relevant to the particular needs of the

patient (Dang et al., 2022). Fundamentally, evidence-based practice involves health professionals integrating quantitative and qualitative evidence with other forms of knowledge, including clinical expertise and patient preferences, wisely within their clinical context (Garrett, 2016).

Other forms of non-research evidence, while considered low quality in the hierarchy of evidence, are often used to guide evidence-based practice in clinical settings. Two such examples are clinical practice guidelines and quality improvement reports. Evidence-based clinical practice guidelines have been essential to quality healthcare for many years (Kredo et al., 2016). They provide recommendations for clinical practice based on a systematic review of the best available evidence on a topic of interest. The purpose of clinical practice guidelines is to optimise patient care, decrease gaps in staff knowledge, improve the quality of care by reducing practice variations and foster accountability of practice (Glasofer & Townsend, 2021). However, they are not classified as research evidence as they are often not comprehensive and may not consider the quality of findings included in the guideline (Dang et al., 2022). Similarly, quality improvement projects seek to systematically improve patient care delivery within an organisation. These projects involve a continuous process where improvement initiatives are applied and monitored within a particular area to secure positive change (Dang et al., 2022; Glasofer & Townsend, 2021). They produce valuable evidence and report on whether an intervention improves local practice. However, as their purpose is to achieve change at an organisational level, the results cannot be generalised to other clinical settings (Glasofer & Townsend, 2021). The extensive amount of available research and non-research evidence enables health professionals to make informed decisions about the most evidence-based approach for each patient. To fully embrace evidence-based practice, practitioners must assess the accuracy and trustworthiness of the best available evidence to determine suitability and efficacy within their clinical context (Hoffmann et al., 2017).

2.2.4 Importance of evidence-based practice in healthcare

Evidence-based practice can be described as doing the right things right. It involves doing things to the best possible standard and ensuring that the interventions are proven to be effective for that clinical situation, resulting in more good than harm

(Craig & Dowding, 2020). Evidence-based practice promotes an attitude of inquiry, encouraging health professionals to consider if their practice is informed by the best available evidence, thus avoiding conventional or habitual practices (Hoffmann et al., 2017). By following the process of evidence-based practice, the best available evidence is intentionally reviewed, and links between healthcare interventions and outcomes are examined to inform decisions, improving quality of care and patient safety (Dang et al., 2022).

2.3 Incorporating evidence into practice

The process of searching for and appraising a variety of research is central to evidence-based practice. However, this alone does not change patient outcomes or improve clinical practice. To achieve evidence-based change, health professionals face the challenge of implementing evidence into practice (McCluskey & O'Connor, 2017). Incorporating evidence into healthcare and subsequent changes to clinical practice is a dynamic process dependent on many variables. Continuous advances in scientific knowledge have significantly improved health professionals' ability to achieve better patient outcomes. However, the rapid growth and changing nature of evidence have resulted in health organisations struggling to stay abreast with research being published on a daily basis (Bucknall & Rycroft-Malone, 2010). Moreover, successfully implementing evidence into practice requires changes in attitudes, systems and behaviours by individuals, teams and organisations (McCluskey & O'Connor, 2017). It is, therefore, not surprising that the process is often protracted, involving multiple steps and varying degrees of complexity depending on the context (Bucknall & Rycroft-Malone, 2010).

2.3.1 Models of evidence-based practice

Numerous models and frameworks have been developed to guide the process of incorporating evidence into clinical practice. Many of these models follow David Sackett's original five-step process for evidence-based practice inquiry to varying degrees. However, while these five steps may appear simple, there are numerous ways to review research and countless approaches to successfully implement findings into practice (Dusin et al., 2023). The use of an evidence-based model establishes a

standardised approach to implementing evidence-based care within an organisation. To select the most appropriate model, the fit and feasibility of various available frameworks must be considered, including their strengths and weaknesses, ease of use, expertise of staff involved in the project and applicability to the clinical situation being investigated (Dang et al., 2022). Researchers, practitioners and organisations utilise these models to manage the complexity of evidence-based practice by establishing research strategies, determining resource needs, identifying barriers and facilitators and guiding processes (Dusin et al., 2023). Table 2 provides an overview of three widely used evidence-based practice models within healthcare settings.

Table 2: Evidence-based practice models

Name	Description
The Johns Hopkins Evidence-Based Practice (JHEBP) Model for Nurses and Healthcare Professionals	This model provides an inquiry-based learning framework in which individual healthcare professionals or interprofessional teams actively control their own learning to gain new knowledge and update existing knowledge. It involves an ongoing cycle of inquiry, practice and learning, and involves a three-step process: Practice question; Evidence, and Translation (PET). A spirit of inquiry and curiosity prompts individual or teams of health professionals to question whether current practices are efficient, effective and based on the best available evidence. They then embark on the PET process by developing a practice question, seeking, appraising and synthesising the best available evidence and translating this evidence into practice where feasible. As health professionals move through this process, they are continually learning, gaining insight and reflecting on the outcomes of changed practice. As a result, new questions may be generated during this process, which require further investigation (Dang et al., 2022).
The Advancing Research and Clinical Practice through Close Collaborating (ARCC) Model	This model provides a framework for system-wide implementation and sustainability of evidence-based practice in healthcare organisations and clinical settings to achieve quality outcomes. It has five key steps: (i) Assessing the culture and readiness of an organisation to implement evidence-based practice; (ii) Identifying key facilitators and barrier to evidence-based practice; (iii) Identifying mentors and equipping them with the knowledge and skills to facilitate change within their clinical context; (iv) Implementing evidence into point-of-care practice, and (v) Evaluating the outcomes from changed clinical practice (Melnik & Fineout-Overholt, 2010).
The Iowa Model of Evidence-Based Practice	This model provides a framework is to guide practitioners in the use of evidence to improve healthcare outcomes. It involves a step-by-step process by which practitioners identify practice or patient care that can be improved, assemble and critique existing research, consult non-research forms of evidence or conduct clinical research if existing evidence is insufficient, integrate and sustain changes to practice and disseminate the findings (Buckwalter et al., 2017; Titler, 2010).

2.3.2 The process of incorporating evidence into practice

The final two steps in David Sackett's five-step process for evidence-based practice – applying research findings to clinical practice and evaluating the outcomes of change – pose the biggest challenges for healthcare professionals (Dusin et al., 2023). In fact, evidence-based changes can take an average of 17 years to be incorporated into routine clinical practice (Bauer et al., 2015; Hanney et al., 2015). To address the gap between research and practice, the field of implementation science was developed to specifically explore factors affecting the uptake of evidence into routine clinical practice (Bauer & Kirchner, 2020). Implementation science is “the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practice into routine practice and, hence, to improve the quality and effectiveness of health services.” (Eccles & Mittman, 2006, p. 1). Several systematic frameworks within implementation science guide the process of implementing evidence into practice. While the approach and steps of these frameworks vary, most include four key steps to assist health professionals in identifying and understanding the causes of implementation problems and designing corresponding implementation strategies. These steps are outlined in Table 3.

Table 3: Implementing evidence into practice, adapted from (McCluskey & O'Connor, 2017).

Steps of implementation
1. Identify the evidence-practice gap and specify the evidence-based change or clinical intervention needed to close the gap.
2. Identify which factors need to be addressed, including barriers to and enablers of change within the clinical context.
3. Select and deliver intervention components that are most likely to overcome the identified barriers and enhance the enablers to bring about and sustain the implementation of evidence-based practice.
4. Evaluate whether the implementation of evidence into practice was effective.

2.3.3 Creating an evidence-based practice environment

Evidence-based practice is considered the ‘gold standard’ of care and is now an expectation of governmental agencies, regulatory bodies and health consumers alike. However, despite the abundance of research available to inform clinical practice, patients often do not receive evidence-based care; meanwhile, frontline health professionals face the challenging task of providing care alongside locating, appraising

and implementing new evidence into their daily practice (Duff et al., 2020). A standardised approach to incorporating evidence into practice is central to providing reliable, evidence-based care. This is often achieved through the explicit use of an evidence-based model and an implementation framework (Dang et al., 2022). However, to enhance effectiveness, these must be combined with the optimisation of the practice environment (Duff et al., 2020). In a recent systematic review of 36 studies, Li et al. (2018) identified several key organisational and contextual factors that influence evidence-based practice outcomes in a clinical context. These factors include leadership, organisational culture, interprofessional collaboration and communication, provision of training and access to information and resources.

Supportive leadership is a crucial component influencing the successful implementation of evidence-based practice (Dang et al., 2022). Recent research has shown that frontline leadership, particularly nurse managers, play a crucial role in creating a supportive environment and empowering team members to embrace and utilise evidence-based practice. Bianchi et al. (2018), in an integrative literature review of 28 studies, found that nurse managers facilitate an evidence-based practice environment by allocating time and resources for nurses to learn about new research findings. Frontline nurses are acutely aware of issues and opportunities for improvement in their clinical area, thus placing them at the forefront of providing evidence-based patient care (Duff et al., 2020). Studies conducted by both Bianchi et al. (2018) and Duff et al. (2020) demonstrated that nurses were more likely to implement evidence-based practice on an ongoing basis when they felt supported by their manager, particularly when utilising evidence to change practice and mitigating resistance to change from other team members. Bianchi et al. (2018) also demonstrated that nursing managers should not only be facilitators of evidence-based practice but also active participants, leading by example and incorporating evidence into their daily practice.

The management style of leaders plays a crucial role in developing and promoting evidence-based practice. Harvey et al. (2019), in a descriptive study across four countries, explored the use of different leadership styles, namely transformational and transactional leadership, to facilitate evidence-based practice. Transformative leaders

utilise a facilitative approach by working closely with frontline staff, supporting and enabling the identification of clinical problems, seeking solutions and implementing evidence-based changes (Scott et al., 2017). They also lead by example, incorporating evidence into their daily clinical practice, thus demonstrating their commitment to and value of evidence-based practice and inspiring a sense of trust, acceptance, enthusiasm and shared purpose from their team (Aarons, 2006; Dang et al., 2022). Transactional leadership utilises a formal managerial approach by focusing on meeting specific goals or performance criteria (Aarons, 2006; Scott et al., 2017). They manage and monitor the utilisation of and adherence to evidence-based standards and may encourage team members to undertake activities that foster evidence-based practice by rostering time, providing remuneration and physical resources and recognising and rewarding their accomplishments in a timely manner (Scott et al., 2017). Harvey et al. (2019) concluded that finding a balance between these two styles, particularly balancing incorporating evidence-based regulatory requirements with cultivating an environment of learning and a sense of shared responsibility to create positive change, was the key to achieving evidence-based practice.

The effective implementation of evidence-based practice requires input from leaders at all levels (Li et al., 2018). Senior leadership can support evidence-based practice by ensuring all administrative decision-making, including policies, procedures and standards, are based on evidence (Dang et al., 2022). Senior leaders are also essential to ensuring new evidence and subsequent clinical changes are integrated as 'business as usual' and facilitate the involvement and buy-in from hospital staff and stakeholders across many different services. In addition, the support, involvement and commitment to evidence-based practice from senior leadership has a top-down effect, influencing middle and line managers to engage in implementing and facilitating evidence-based practice changes at the coalface (Li et al., 2018; Williams et al., 2015).

The presence of informal leaders, such as mentors or champions, is another important component contributing to implementing evidence-based practice (Dang et al., 2022). Informal leaders influence the practice of health professionals within their clinical working environment. The presence of a clinical champion provides a safe and supportive environment for staff to learn and implement new skills into their clinical

practice. Mathieson et al. (2019), in a systematic review of 22 studies, found that continued support from a clinical champion after initial training encouraged the sustained adoption of evidence-based practices.

Organisational culture influences attitudes towards evidence-based practice and the process of change (Scott et al., 2017). Culture shapes the beliefs and behaviours of those delivering healthcare alongside the norms and expectations about how work is performed within an organisation (Scott et al., 2017; Thompson & Quinlan, 2020). Li et al. (2018) found that organisations that demonstrated an openness to trialling innovations, positive staff attitudes towards change and an environment focused on continuous learning were highly associated with the successful implementation of evidence-based practice. Healthcare organisations can vary immensely within and between each other, often with distinct overarching cultures and diverse subcultures within different services. Thus, establishing a culture responsive to evidence-based change requires commitment from leaders at all levels (Dang et al., 2022). Senior leaders influence organisational culture by developing clear vision and mission statements incorporating evidence-based practice. Additionally, allocating resources, such as people, time, money and education, significantly contributes to creating and developing an evidence-based practice environment (Dang et al., 2022). Middle and line managers greatly influence the culture within their clinical area. By challenging tradition, setting expectations, modelling the use of evidence in daily practice, providing mentorship and holding their teams accountable for the use of evidence-based care, they can foster a culture that embraces evidence-based practice (Dang et al., 2022). Ultimately, a culture that supports learning, an openness to innovation and strong leadership lays the foundation for integrating evidence into clinical practice (Li et al., 2018).

Evidence-based practice changes involve all members of the healthcare team and often include health professionals working in different services within an organisation. Thus, interprofessional collaboration and communication are crucial for evaluating, disseminating and incorporating evidence in clinical practice (Dang et al., 2022). Interprofessional collaboration in healthcare involves an active and ongoing partnership between health professionals from diverse clinical backgrounds working

together to problem-solve, make decisions and provide care that benefits and meets the needs of patients (Busari et al., 2017; Schot et al., 2020). It occurs when there is mutual respect and a willingness to work together collaboratively (Green & Johnson, 2015). Li et al. (2018) described how collaborative relationships between services promote the sharing of resources needed for implementing evidence-based changes alongside facilitating support from a wider network of health professionals. Communication is the key to effective interprofessional collaboration (Busari et al., 2017). Li et al. (2018) found that communication significantly impacted the implementation of evidence-based practice. The use of various communication techniques, including meetings, debriefings, emails and announcements, all contribute to successfully implementing evidence-based practice across various clinical settings. Furthermore, Bianchi et al. (2018) identified the significant contribution of clinical leaders and managers in promoting communication within the interdisciplinary team regarding evidence-based practice, thereby fostering improved collaboration.

For evidence-based practice to work in a clinical setting, health professionals need training and access to evidence-based information (Scott et al., 2017). Li et al. (2019), in a systematic review of 20 articles, found that numerous teaching approaches, including small group exercises, case studies and simulation training, improved nurses' knowledge of and attitudes towards evidence-based practice. The provision of training on existing clinical practice and upcoming changes to practice provides health professionals with the knowledge and skills required to participate in evidence-based practice (Scott et al., 2017). Mathieson et al. (2019) demonstrated that training nurses to use an evidence-based innovation before it was implemented in practice contributed to its successful incorporation. Furthermore, the increasing availability of readily accessible, electronic literature, clinical practice guidelines and policies has great potential to assist evidence-based practice. However, many health professionals lack the skills, knowledge and confidence to read and appraise research findings and implement them into practice (Dang et al., 2022). Williams et al. (2015) identified that evidence-based literature should be readily available, and health professionals should receive guidance on accessing and comprehending studies to effectively incorporate evidence into their daily practice. In addition, utilising library resources and librarians'

skills to search for and evaluate information further contributed to evidence-based practice and better-informed clinical decisions (Dang et al., 2022).

The successful implementation of evidence-based practice in healthcare settings is linked to supportive leadership and organisational culture, mutually respectful interprofessional networks and the provision of resources. However, these factors are not independent but are interrelated and often influence each other in complex, dynamic ways (Li et al., 2018; Scott et al., 2017). Furthermore, while the combination of these components promotes the implementation of evidence-based practice, their absence or distortion can directly hinder the incorporation of evidence into practice (Li et al., 2018).

2.3.4 'Real-world' challenges of evidence-based practice

A variety of factors influence the successful implementation of evidence-based practice. Individual attitudes, experiences, biases, and organisational and workplace factors can act as barriers to incorporating evidence into clinical practice. In a scoping review of 49 studies, Williams et al. (2015) identified five major organisational hindrances to implementing evidence-based practice in healthcare settings. These barriers include a lack of supportive leadership, a workplace culture resistant to change, a lack of autonomy to implement evidence-based change into practice, high workloads, time pressures, insufficient staffing, and a lack of readily available resources.

Support from clinical leaders and managers can 'make or break' the implementation of evidence-based practice. Thus, a lack of leadership support makes it extremely difficult for health professionals to incorporate evidence into their clinical practice (Bianchi et al., 2018). Leadership that lacks authority, resists change or neglects to hold staff accountable for evidence-based care present significant barriers to implementing evidence-based practice (Li et al., 2018). Additionally, if health professionals do not feel that their managers value evidence-based practice, they are less likely to attempt to implement new ideas into routine practice (Williams et al., 2015). It is evident that the commitment to evidence-based practice exhibited by middle and line managers directly influences how frontline health professionals implement it. However, managers at this level need support from those in higher leadership positions to access

opportunities, resources, education and the mandate to facilitate a clinical environment that embraces and implements evidence-based practice (Bianchi et al., 2018). Insufficient backing from leadership at every organisational level leads to clinical managers and staff being left to cope with the complexity of implementing evidence-based practice without distinct guidance or support. In these situations, the pursuit of evidence-based practice may be abandoned altogether, especially when the lack of leadership support appears insurmountable to those working in a healthcare setting.

An organisational or workplace culture resistant to change poses similar barriers to implementing evidence-based practice. A lack of support from colleagues and a culture hampered by outdated practices and protocols does not encourage the flow of new ideas (Williams et al., 2015). An attitude of ‘this is how it has always been done’ is particularly damaging and is a significant barrier to evidence-based practice. Moreover, an organisational culture that functions with the belief that one particular group processes all the knowledge and autonomy to make decisions regarding patient care is often resistant to trialling innovations and does not recognise the expertise and input from interprofessional team members (Li et al., 2018; Williams et al., 2015). Negative perceptions of evidence-based practice arise when healthcare professionals feel they have limited autonomy to drive change in clinical practice and when their viewpoints and insights on patient care are disregarded or overlooked (Williams et al., 2015).

Heavy workloads, time pressures and insufficient staffing are frequently reported barriers to implementing evidence into routine clinical practice (Li et al., 2018; Williams et al., 2015). A heavy workload hinders evidence-based practice as patient-based tasks, such as routine clinical assessments, medication rounds, patients’ physical needs, discharge planning, liaising with family and clinical documentation, take priority. Consequently, this leaves little or no time in a health professional’s standard working day to locate evidence and integrate it into practice (Williams et al., 2015). Insufficient time due to more urgent, competing clinical demands often prevents evidence-based practice, especially when research is regarded as an additional activity on top of a normal workload (Li et al., 2018; Williams et al., 2015). To compound matters further,

insufficient staffing and high staff turnover create challenges in scheduling education sessions and study days outside of routine work days (Li et al., 2018).

A lack of easily accessible, evidence-based resources presents another barrier to evidence-based practice (Williams et al., 2015). Healthcare professionals with limited time were less inclined to actively search for evidence-based resources and implement evidence-based care if they perceive it to be more time-consuming than usual practice (Li et al., 2018). A lack of additional resources, including financial resources and clinical champions, to support evidence-based practice poses further barriers to evidence-based care (Dang et al., 2022).

There are many interrelated components which influence the implementation of evidence into practice. As previously noted, many of these factors can act as enablers or barriers to evidence-based practice depending on their context (Li et al., 2018). Barriers are best dealt with through prevention and planning to identify the needs of health professionals and devise strategies to overcome these challenges, thereby promoting the sustained implementation of evidence into clinical practice (Dang et al., 2022).

2.3.5 Sustaining evidence-based practice

The process of implementing evidence into practice should not simply stop when health professionals adopt evidence-based changes at the time. Rather, sustaining the use of evidence-based interventions in clinical practice is a critical component of ongoing quality care (Hailemariam et al., 2019). Understanding sustainability is challenging due to the lack of a clear definition in literature. Moore et al. (2017) recently explored over 200 articles to systematically develop a comprehensive definition of sustainability. Of these articles, just 24 included a definition of sustainability, encompassing five key constructs used to define the sustainment of evidence-based practice. Thus, 'sustainment' is defined as "after a defined period of time, the program, clinical intervention or implementation strategies continue to be delivered, and individual behaviour change is maintained; the program and individual behaviour change may evolve or adapt while continuing to produce benefits for individuals or systems." (Moore et al., 2017, p. 6). This definition allows the

sustainability of evidence-based practice to be viewed as an outcome, where quality care and improved patient outcomes are maintained, as well as an ongoing process, recognising the need to appropriately respond to factors that may facilitate or hinder the sustained use of evidence-based practice (Lennox et al., 2020).

In a systematic review of 26 studies, Hailemariam et al. (2019) investigated specific strategies to sustain evidence-based interventions in clinical practice. A total of nine sustainment strategies were identified among these studies. The most prominent of these were new or existing funding to support the continued use of evidence-based practice, support from organisational leadership, maintenance of staff buy-in, continued training to support the maintenance of workforce skills, mutual alignment between evidence-based interventions and organisational procedures and evaluating the effectiveness of evidence-based interventions. Dang et al. (2022) also identified that organisational leaders are crucial to supporting and sustaining evidence-based practice. Similarly, Aarons et al. (2016), in a mixed-methods study found that transformational leadership was significantly associated with sustained evidence-based practice. In contrast, passive and avoidant leadership was strongly associated with non-sustainment. In addition, a lack of funding, training and resources, leadership challenges, unfavourable organisational culture and lack of stakeholder support posed as barriers to sustaining evidence-based practice.

Additional factors influencing the sustainment of evidence-based practice included individual commitment from healthcare professionals, evident improvements in patient care and seeking feedback from health professionals involved in the change. Dang et al. (2022) suggested that to sustain evidence-based changes, frontline health professionals must own the change and work towards sustaining it in their individual practice. Furthermore, health professionals are more likely to continually integrate evidence-based practice changes if they see tangible improvements in patient care and outcomes (Dang et al., 2022). Lastly, Li et al. (2018) found that organisational leaders who facilitated ongoing communication, sought feedback and addressed the concerns of health professionals involved in evidence-based change resulted in higher success rates in implementing evidence-based practice.

Part II: Exploring blood glucose requirements for vascular patients with peripheral artery disease undergoing peripheral angioplasty

2.4 Vascular surgery patients

Vascular surgery specialises in the diagnosis and treatment of various disorders that occur within the arteries and veins of the vascular system. Most vascular disorders are classified according to their underlying pathology, which includes atherosclerotic disease, aneurysms and vein disorders. Vascular disease is considered a subset of cardiovascular disease, which encompasses any disease affecting the heart or blood vessels. However, vascular disease typically refers to blood vessel disorders outside the heart and brain (Hedin & Hansson, 2016). Commonly seen manifestations of vascular disease include abdominal aortic aneurysms, carotid artery disease, varicose veins and peripheral artery disease (Wipke-Tevis et al., 2019).

2.4.1 The vascular system

The vascular system, also known as the cardiovascular system, is comprised of an extensive network of vessels that play an integral role in the movement of blood throughout the body (Pugsley & Tabrizchi, 2000). The three major blood vessels – arteries, capillaries and veins – function together to deliver oxygen and essential nutrients to all body cells and remove metabolic waste products (Buckley, 2022b). The vascular system works in a closed-loop circuit, beginning and ending with the heart. It is divided into two separate circulatory systems: the pulmonary circulation, in which the right side of the heart pumps blood to the lungs; and the systemic circulation, in which the left side of the heart pumps blood to the rest of the body (Buckley, 2022b). These two systems are inextricably connected as the output from the former becomes the input for the latter. As the heart contracts, oxygenated blood flows into large arteries, which successively branch into smaller arterioles, leading to all parts of the body. The tiny arterioles ultimately merge into a fine network of capillaries, the smallest vessels, where nutrients, solutes, water and metabolic wastes are exchanged between the blood and cells (Marieb & Hoehn, 2015; Pugsley & Tabrizchi, 2000). The

deoxygenated blood then leaves the capillaries and enters tiny venules that progressively merge to form larger veins, returning it to the heart (Marieb & Hoehn, 2015). The blood is subsequently pumped to the lungs for re-oxygenation and returns to the heart for recirculation around the body. Figure 2 illustrates how these blood vessels relate to each other in the vascular system.

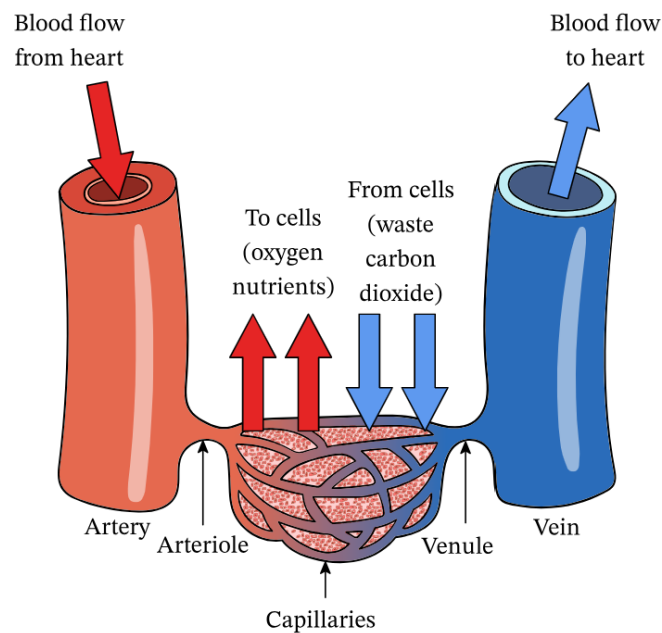


Figure 2: The vascular system (Nagwa, 2023).

For this intricate system to function effectively, the structure and composition of these blood vessels to remain intact (Pugsley & Tabrizchi, 2000). In most cases, blood vessels comprise of three distinct regions surrounding the blood-containing lumen. The tunica intima is the innermost region, consisting of a thin layer of endothelial cells, which provides a slick surface for blood flow (Marieb & Hoehn, 2015). The second region is the tunica media, which consists of circularly arranged layers of smooth muscle and elastin fibres. This layer supports the movement and regulation of blood flow through the vessels by either vasoconstriction or vasodilation and is vital for maintaining adequate circulation (Marieb & Hoehn, 2015). The outermost region is the tunica adventitia, composed of fibrous elastic connective tissue that protects, reinforces and anchors the vessel (Marieb & Hoehn, 2015). While most blood vessels

share the same anatomy, there is variability in the cellular components of each region based on a vessel's physiological function (Pugsley & Tabrizchi, 2000). Figure 3 provides a visual illustration of the basic composition of a blood vessel.

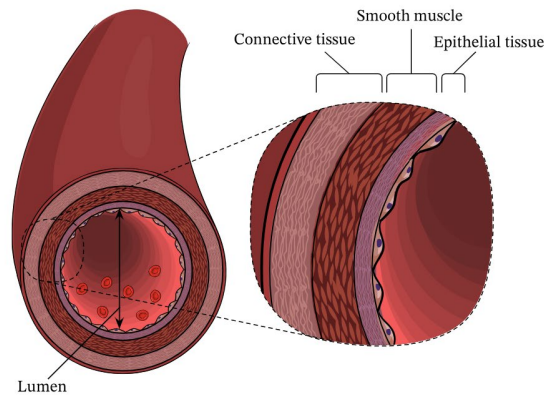
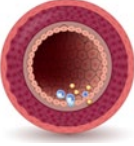
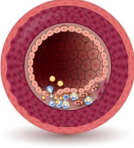
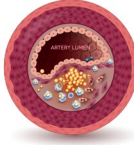
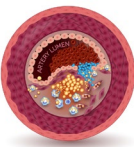


Figure 3: The anatomy of blood vessels (Nagwa, 2023).

2.4.2 Vascular disease

The dysfunction or disease of blood vessels compromises the effective functioning of the vascular system. The most common cause of vascular disease is widespread atherosclerosis, which can simultaneously affect a multitude of body organs and tissues. As such, individuals with vascular disease in one body region are likely to have it in other high-risk vascular tissue (McMonagle & Stephenson, 2014; Thiruvoipati et al., 2015). Atherosclerosis is caused by soft deposits of fat, known as plaque, within the tunica intima of vessel walls that harden over time. It results in a gradual thickening of the affected vessels and a progressive reduction in blood flow (Buckley, 2022a). The initiation and progression of atherosclerosis are complex, involving interactions between the components of the blood and the composition of the vessel wall (Shaffer et al., 2019). The development of atherosclerosis can be broken into four key stages, which are detailed in Table 4.

Table 4: The development of atherosclerosis

Stages of atherosclerosis	Description
1. Endothelial injury 	Damage can occur to endothelial cells lining vessel walls from various causes, including smoking, hypertension, dyslipidaemia and diabetes mellitus. Endothelial cells become inflamed, losing their ability to facilitate smooth blood flow through vasodilation and preventing unnecessary clotting. As a result, platelets aggregate at the site, causing increased clotting, and the vessel begins to constrict, leading to decreased blood flow (Buckley, 2022a).
2. Fatty streak 	A fatty streak is the earliest lesion of atherosclerosis. It occurs when the inflamed endothelial cells express adhesion molecules that bind various white blood cells, inflammatory and immune cells to the site, causing further damage to the vessel wall. This process results in significant amounts of lipid-containing cells accumulating and penetrating the intima of the vessel, forming a lesion (Buckley, 2022a).
3. Fibrous plaque 	Following the formation of a fatty streak, the arterial wall thickens, and collagen is produced, which migrates over the lesion, forming a fibrous plaque. The plaque may calcify and protrude into the vessel lumen, obstructing blood flow (Buckley, 2022a).
4. Complicated lesion 	As the fibrous plaque grows, it becomes unstable and prone to rupture. When a plaque ruptures, the vessel's inner wall is compromised, leading to rapid accumulation of platelets, coagulation and the formation of a thrombus. The thrombus may adhere to the vessel wall, leading to further narrowing, or it may completely occlude the vessel (Buckley, 2022a).

Atherosclerotic vascular disease is systemic and manifests in various vascular beds (McMonagle & Stephenson, 2014). One of the most common types of vascular disease is peripheral artery disease, in which the arteries perfusing the upper and lower limbs become narrowed or occluded, primarily as a result of atherosclerosis (Frank et al., 2019; Shaffer et al., 2019; Wipke-Tevis et al., 2019).

2.4.3 Peripheral artery disease

Peripheral Artery Disease (PAD) is a prevalent and debilitating vascular disease affecting approximately 200 million people globally (Aday & Matsushita, 2021; Lin et al., 2022; Song et al., 2019). It is characterised by a gradual reduction in blood flow to one or more of the limbs due to atherosclerosis (Buckley, 2022a; Lin et al., 2022). PAD

is the third most common manifestation of atherosclerosis, following coronary artery disease and stroke, but is generally underappreciated in comparison (Aday & Matsushita, 2021; Lin et al., 2022). However, PAD is an independent marker for coronary artery disease and cerebrovascular disease, the leading causes of mortality worldwide (McMonagle & Stephenson, 2014; World Health Organization, 2023).

The most significant risk factors for PAD are advanced age, smoking, diabetes mellitus and hypertension (Aday & Matsushita, 2021; Limnili & Ozcakar, 2021). The development of atherosclerotic PAD can begin in early life, remaining latent and asymptomatic for many years before progressing into its advanced stages (Song et al., 2020). As such, one of the strongest risk factors for PAD is older age, with most becoming symptomatic in the sixth to eighth decades of life (Aday & Matsushita, 2021; Wipke-Tevis et al., 2019). Smoking is another potent risk factor for PAD as it promotes endothelial dysfunction, initiating the development of atherosclerosis. Smoking increases the likelihood of PAD up to 10-fold, with heavy smokers being more likely to develop PAD than light smokers (Limnili & Ozcakar, 2021). Diabetes mellitus is a major risk factor for atherosclerotic disease and increases the risk of PAD up to two to four times (Limnili & Ozcakar, 2021; Thiruvoipati et al., 2015). The risk of PAD increases proportionally with the severity and duration of diabetes mellitus, and poor glycaemic control is also associated with an increased incidence of PAD (Thiruvoipati et al., 2015). Hypertension is strongly associated with the development of atherosclerosis as the stress of elevated blood pressure contributes to endothelial dysfunction (Limnili & Ozcakar, 2021). Other risk factors include dyslipidaemia, obesity and a familial history of cardiovascular disease (Limnili & Ozcakar, 2021; Wipke-Tevis et al., 2019).

PAD most commonly affects the arteries perfusing the lower extremities, including the iliac, femoral, popliteal and tibial arteries, or any combination of these arteries (Aday & Matsushita, 2021; Quatromoni & Wang, 2017; Wipke-Tevis et al., 2019). Figure 4 illustrates the common anatomical locations of atherosclerotic lesions in the lower extremities.

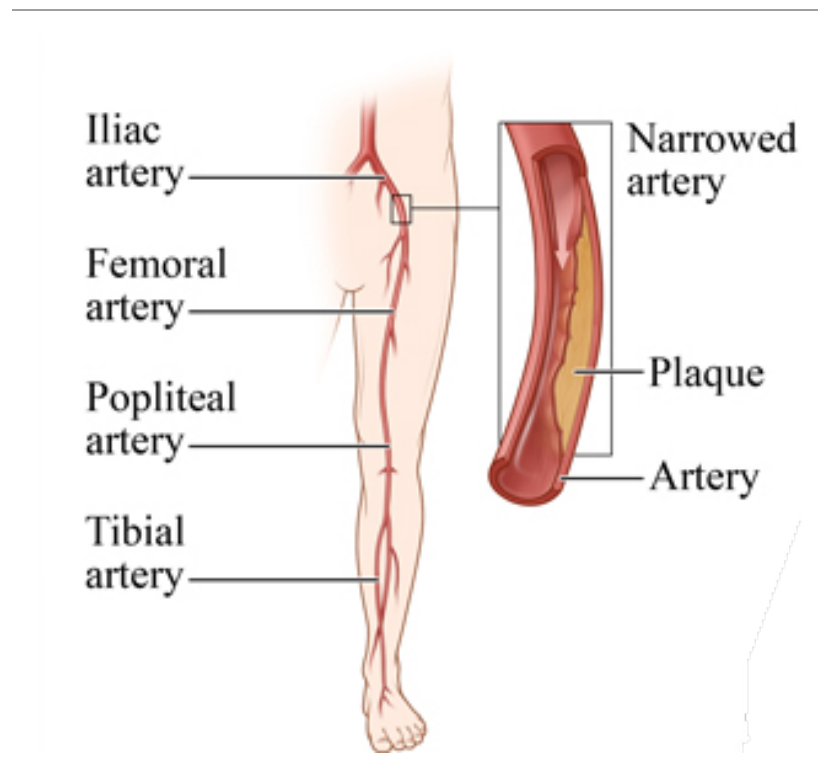


Figure 4: Peripheral artery disease of the lower extremities (Healthwise, 2023).

The severity of PAD can vary and generally depends on the location and extent of the occlusion, as well as the amount of surrounding circulation (Wipke-Tevis et al., 2019; Yorulmaz & Dirik, 2021). As such, individuals with PAD may present with a myriad of symptoms, ranging from no symptoms to a non-healing ulcer and gangrene (Beckman, 2013). The progression of symptoms commonly experienced by individuals with PAD are described in Table 5.

Table 5: Progression of peripheral artery disease symptoms

Symptoms of PAD	Description
1. Asymptomatic	No symptoms present.
2. Intermittent claudication	Intermittent claudication is the classic symptom of lower extremity PAD. It is an ischaemic muscle pain that occurs with ambulation, resolves within ten minutes and is reproducible. It is caused by a reduced supply of oxygenated blood required to meet the exercise demands of the limb. As a result, pain is caused by a buildup of lactic acid from anaerobic metabolism which subsides when ambulation ceases. Intermittent claudication is typically caused by a narrowed peripheral artery (Wipke-Tevis et al., 2019).
3. Ischaemic rest pain	Rest pain occurs as PAD progresses and involves multiple arterial segments. It is caused by insufficient blood flow to meet the basic metabolic needs of the limb, and generally occurs in the foot and toes (Wipke-Tevis et al., 2019).
4. Critical limb ischaemia	Critical limb ischaemia combines chronic rest pain for more than two weeks with non-healing ulcers or gangrene (Wipke-Tevis et al., 2019).

Further, the physical appearance of the limb is often altered due to impaired blood flow. Common physical changes include: alterations in skin colour; thickened or brittle nails; thin, shiny and taut skin texture; cool skin temperature; hair loss; decreased capillary refill time; and decreased or absent peripheral pulses (McMonagle & Stephenson, 2014; Wipke-Tevis et al., 2019).

Due to the variety of clinical symptoms in PAD, objective forms of diagnosis are crucial for an accurate diagnosis (Aday & Matsushita, 2021). Assessing an individual with suspected PAD begins with taking a clinical history to identify any established risk factors, a review of symptoms to assess for exertional leg symptoms, rest pain or walking impairment and a physical examination to palpate pedal pulses and identify any non-healing wounds (Aboyans et al., 2018; Gerhard-Herman et al., 2017). Table 6 describes the various diagnostic methods used to further assess the vascular system and blood flow.

Table 6: Diagnostic methods for peripheral artery disease

Diagnostic tests	Description
1. Ankle-brachial index (ABI)	An ABI has good validity as a first-line test in the diagnosis of PAD. It is obtained by measuring the systolic blood pressures at the arms and ankles with a Doppler. The ABI of each leg is calculated by dividing the ankle measurement from the respective arm measurement. A result of less than 0.09 indicates the presence of PAD (Gerhard-Herman et al., 2017).
2. Duplex ultrasound	A duplex ultrasound is often used for both vascular screening and diagnosis and is considered the first-line imaging method for PAD. It provides extensive information on the arterial anatomy and the degree of blood flow. The results are typically combined with the ABI measurement (Aboyans et al., 2018).
3. Treadmill test	A treadmill test is used to assess functional capacity. Individuals are assessed walking at a speed of three kilometres per hour on a 10 percent slope until they cannot continue because of pain. It is useful for diagnosing moderate arterial stenosis and determining the location of ischaemia (Aboyans et al., 2018).
4. Digital subtraction angiography (DSA)	A DSA is considered the standard reference for vascular imaging. It allows blood flow to be visualised by injecting contrast media into the appropriate arteries and using serial x-ray images to detect the presence of PAD. However, due to its invasive nature, it is often replaced with less invasive diagnostic methods (Aboyans et al., 2018; DiSabatino Herman et al., 2019).
5. Computed tomography angiography (CTA)	CTA and MRA scans both utilise injected contrast medium to obtain images of the vasculature and blood vessels. They are often used to develop individualised treatment plans and determine appropriate invasive interventions (Aboyans et al., 2018; Gerhard-Herman et al., 2017).
6. Magnetic resonance angiography (MRA)	

The treatment approach for individuals with PAD is two-fold. Firstly, medical interventions focus on improving limb symptoms, addressing contributing atherosclerotic lesions and limb salvage (Aboyans et al., 2018). Multiple minimally invasive and open surgical procedures are available to revascularise, or restore blood flow, and preserve a limb. The most common surgical procedures are outlined in Table 7.

Table 7: Treatments for peripheral artery disease

Treatment options	Description
1. Percutaneous transluminal peripheral angioplasty	A minimally invasive, catheter-based procedure in which a specialised catheter containing a cylindrical balloon at the tip is inserted into the femoral artery. The catheter is moved into the narrowed, or stenosed, artery, and the balloon is inflated to compress the atherosclerosis lesion into the intima of the artery. Expandable stents are often positioned within the diseased area to stabilise the artery and prevent re-occlusion (Wipke-Tevis et al., 2019).
2. Peripheral artery bypass surgery	An open surgery technique in which an autogenous vein or synthetic graft is used to bypass the atherosclerotic lesion. These surgeries can range from local procedures for small lesions to long full-leg bypasses (Aboyans et al., 2018).
3. Endarterectomy 4. Patch angioplasty	An endarterectomy and patch angioplasty are often performed in conjunction. An endarterectomy is an open surgery technique in which the occluded artery is opened, and the atherosclerotic lesion is removed. The patch angioplasty then involves sewing a patch to the opening to widen the lumen of the artery (Wipke-Tevis et al., 2019).
5. Amputation	Amputation is considered if tissue death is extensive, gangrene develops, or all major arteries are occluded, precluding the option for successful revascularisation. The goal of amputation is to preserve the length and function of the limb while removing all infected or diseased tissue. Common amputation surgeries due to PAD include the toes, forefoot, below-knee or above-knee amputations (Aboyans et al., 2018; Wipke-Tevis et al., 2019).

The second aspect of treating PAD is managing and reducing cardiovascular risk factors (Aboyans et al., 2018). This typically involves both lifestyle changes and medication therapy. Lifestyle recommendations include smoking cessation, improved nutrition and increased physical activity (Limnili & Ozcakar, 2021). Hypertension is a significant risk factor and increases the prevalence of both asymptomatic and symptomatic PAD (Limnili & Ozcakar, 2021). Lowering systolic blood pressure with antihypertensive medications and non-pharmacological methods reduces the risk of cardiovascular events (Aboyans et al., 2018). Dyslipidaemia is another risk factor for the progression of PAD. Evidence gained from observational studies and limited randomised controlled trials in patients with PAD showed that the use of statin medications to decrease low-density lipoprotein cholesterol and triglyceride levels reduces the risk of cardiovascular morbidity and mortality (Aday & Matsushita, 2021; Agnelli et al., 2020). Lipid-lowering therapies have also been shown to slow the progression of atherosclerosis in individuals with PAD (King et al., 2022; Limnili &

Ozcakar, 2021). Diabetes mellitus is associated with the development of severe PAD and has been linked to an increased risk of lower extremity amputations (Aday & Matsushita, 2021). Thus, adequate diabetes management contributes to reducing the risk of PAD and its complications (Frank et al., 2019; Wipke-Tevis et al., 2019).

2.4.4 Interplay between diabetes mellitus and peripheral artery disease

Diabetes mellitus is one of the strongest risk factors for the development of PAD. It not only accelerates the progression of atherosclerosis but those with concomitant diabetes mellitus and PAD are more likely to have severe forms of PAD and worse clinical outcomes (Evinc & Ozcakar, 2021; Thiruvoipati et al., 2015). Around the world, the prevalence of diabetes mellitus is steadily increasing. In 2021, it was estimated that 537 million people had diabetes mellitus, which is projected to increase to 643 million by 2030 (International Diabetes Federation, 2021). Consequently, diabetes mellitus is projected to become an increasingly important contributor to the development and progression of PAD (Thiruvoipati et al., 2015).

The term ‘diabetes mellitus’ does not simply refer to one condition but rather to a group of complex, chronic metabolic diseases. All types of diabetes mellitus share the same underlying cause: the dysfunction or destruction of pancreatic beta-cells (Turton, 2018). An elevated blood glucose level, known as hyperglycaemia, is the characteristic and identifying feature in all types of diabetes mellitus (World Health Organization, 2019). Hyperglycaemia occurs when there are high levels of glucose in the bloodstream (Turton, 2018). Insulin, a hormone produced by pancreatic beta-cells, is required to maintain a stable, normal blood glucose concentration (Dickinson & Whitbread, 2019). Insulin promotes the uptake of glucose from the bloodstream into cells, where it can be metabolised as an energy source (Shepard-Wipiiti & Brennan, 2021). The damage diabetes mellitus causes to beta-cells results in insufficient or absent insulin production, disrupting normal glucose metabolism and leading to hyperglycaemia.

Most cases of diabetes mellitus can be classified into two broad categories: type 1 diabetes mellitus and type 2 diabetes mellitus (Mayer-Davis et al., 2018). Type 1

diabetes mellitus is a chronic autoimmune disorder in which the body progressively destroys the beta-cells in the pancreas, eventually leading to severe or absolute insulin deficiency and hyperglycaemia (Todorovic, 2022). The rate of beta-cell destruction is variable, often occurring more rapidly in children and slower in adults (ElSayed et al., 2022a). Individuals with type 1 diabetes mellitus generally become clinically symptomatic when 90 percent of beta-cells have been destroyed (Mayer-Davis et al., 2018). Type 2 diabetes mellitus is caused by insulin resistance and inadequate insulin secretion (Dickinson & Whitbread, 2019). Insulin resistance occurs when the insulin receptors on cells are unresponsive or insufficient in the presence of insulin. As a result, the entry of glucose into body cells is impeded, thereby causing hyperglycaemia (ElSayed et al., 2022a). In the early stages of insulin resistance, the pancreas responds to elevated blood glucose levels by secreting greater amounts of insulin. Over time, the beta-cells become fatigued and are unable to continue producing insulin. In longstanding type 2 diabetes mellitus, beta-cell mass decreases significantly, and the number of functional cells will progressively decline as beta-cells die (Turton, 2018).

Regardless of type, diabetes mellitus accelerates the progression of peripheral atherosclerosis. As a result, individuals with diabetes mellitus have a two-to-four-fold increase in the risk of PAD (Jakubiak et al., 2021; Limnili & Ozcakar, 2021). The abnormal metabolic state caused by diabetes mellitus, namely decreased insulin production, chronic hyperglycaemia and dyslipidaemia, renders the arteries of the vascular system susceptible to atherosclerosis (Thiruvoipati et al., 2015). As a result, derangements occur within the vessel walls through endothelial cell dysfunction and inflammation (La Sala et al., 2019). The endothelial cells within blood vessels mediate the interaction between the blood and vessel wall, influencing blood flow, nutrient delivery and coagulation (Thiruvoipati et al., 2015). These cells release various bioactive substances that are vital for the proper functioning and structure of blood vessels. Insulin plays a critical role in the production of these substances, which is inhibited in diabetes mellitus (La Sala et al., 2019; Thiruvoipati et al., 2015). In addition, hyperglycaemia impedes the bioavailability of these substances, contributing to endothelial dysfunction and leading to an increased susceptibility for atherosclerosis (La Sala et al., 2019).

Chronic hyperglycaemia contributes to the accelerated progression of atherosclerosis by causing oxidative stress, which is an imbalance between unstable molecules, called free radicals, and the stable antioxidants needed to counteract them (La Sala et al., 2019). Hyperglycaemia directly influences the overproduction of free radicals and the reduced activity of antioxidants (Poznyak et al., 2020). The presence of oxidative stress in individuals with diabetes mellitus promotes atherosclerosis through increased plaque size and inflammation (Poznyak et al., 2020). Dyslipidaemia is another contributor to oxidative stress, as increased levels of very-low-density lipoproteins are more susceptible to oxidation. These lipoproteins penetrate the intima of an artery, contributing to atherosclerotic plaque formation (Poznyak et al., 2020). Furthermore, these modified lipoproteins induce changes in the smooth muscle cells, which reside in the tunica media of arteries (Thiruvoipati et al., 2015). It is thought that the changes to arterial smooth muscle cells contribute to the development of medial calcification, which leads to reduced vessel compliance, increased stiffness and poor vasoconstriction and vasodilation (Forsythe et al., 2015).

Inflammation within blood vessels is central to the development of atherosclerosis, and diabetes mellitus is associated with increased circulating levels of inflammatory biomarkers (La Sala et al., 2019; Poznyak et al., 2020). These inflammatory markers are thought to impact the contractibility of arteries, impair normal clotting and bind to the surface of endothelial cells, promoting platelet aggregation. Chronic inflammation promotes instability of the atherosclerotic plaque, thus increasing the risk of rupture, subsequent thrombus formation and occlusion of the artery (Thiruvoipati et al., 2015). In many cases, these abnormalities are prevalent prior to a diagnosis of diabetes mellitus, and their severity increases with poor glycaemic control and duration of diabetes mellitus (Thiruvoipati et al., 2015). Consequently, individuals with diabetes mellitus tend to develop PAD faster, present with more severe disease and are more likely to have worse outcomes (Evinc & Ozcakar, 2021).

Diabetes mellitus is linked to various chronic vascular complications, which are typically divided into two broad categories: macrovascular complications and microvascular complications. Table 8 outlines the common conditions within these categories.

Table 8: Chronic complications of diabetes mellitus

Macrovascular complications	Microvascular complications
<ul style="list-style-type: none"> • Coronary artery disease • Cerebrovascular disease • Peripheral artery disease 	<ul style="list-style-type: none"> • Retinopathy • Nephropathy • Neuropathy

Macrovascular complications affect the large and medium-sized blood vessels and contribute to the earlier and more frequent onset of PAD in individuals with diabetes mellitus (Dickinson & Whitbread, 2019). As previously described, these larger vessel diseases are attributed to endothelial dysfunction and inflammation caused by atherosclerosis, and these processes are amplified with diabetes mellitus (Forsythe et al., 2015). PAD tends to develop in the popliteal and infrapopliteal arteries below the knee in those with concomitant diabetes mellitus. Atherosclerotic disease in these locations is thought to be linked to a significant increase in major lower-extremity amputation rates in those with diabetes mellitus (Chung & Mills, 2019). In addition, the presence of diabetes mellitus increases the likelihood of multivessel PAD, further contributing to critical limb ischaemia and an increased risk of ulceration, tissue loss and amputation (Frank et al., 2019). Microvascular complications are caused by damage to the smaller capillaries, venules and arterioles, commonly manifesting in the eyes (retinopathy), kidneys (nephropathy) and nerves (neuropathy). Microvascular complications are specific to diabetes mellitus and are caused by the thickening of the outer layer, or the basement membrane, of these vessels in response to chronic hyperglycaemia (Dickinson & Whitbread, 2019). As a result, the endothelium becomes more permeable, slowing blood flow and diminishing the delivery of nutrients and oxygen to tissue regions, thus making them more susceptible to breakdown. The thickened basement membrane also prevents normal vasodilation and constriction of the vessels, contributing to impaired blood flow (Forsythe et al., 2015). Further damage can occur to the small vessels through platelet aggregation, oxidative stress and increased inflammatory markers in response to hyperglycaemia (Forsythe et al., 2015; Papatheodorou et al., 2016).

Diabetic foot disease is another common chronic complication characterised by foot ulcers (Amin & Doupis, 2016). It is primarily caused by a combination of the macrovascular and microvascular disease processes (Dickinson & Whitbread, 2019).

The presence of macrovascular disease accelerates the process of atherosclerosis and contributes to the development of PAD. The decreased peripheral blood supply in PAD affects the body's normal response to injury, leading to impaired healing, infection, tissue breakdown and insufficient delivery of oxygen, nutrients and antibiotics (Amin & Doupis, 2016; Wipke-Tevis et al., 2019). Microvascular disease causes diabetic neuropathy, a condition that results in sensory nerve damage and often occurs in the feet. The underlying mechanism of diabetic neuropathy has been linked to chronic hyperglycaemia and the accumulation of carbohydrates and other sugars, which leads to nerve damage (Dickinson & Whitbread, 2019). The progression of diabetic neuropathy can range from abnormal sensations to partial or complete loss of sensation (Amin & Doupis, 2016). As a result, individuals are less likely to be aware of minor trauma, ongoing pressure, calluses or injury to their feet. Diabetic foot ulcers usually develop from small, unnoticed wounds that worsen over time. The combination of diabetes mellitus, PAD and sensory neuropathy leads to an increased risk of infection, which can spread to the bone, impaired skin integrity and tissue dieback (Chung & Mills, 2019; Makrilakis, 2019). Individuals with PAD whose course is complicated with diabetic foot ulcers are at a greater risk of poorer wound healing and the subsequent need for amputation (Forsythe et al., 2015; Makrilakis, 2019; Thiruvoipati et al., 2015).

2.4.5 Peripheral artery disease in New Zealand

The prevalence of PAD is reported to be steadily increasing globally, with estimated numbers increasing from approximately 202 million people affected in 2010 to 236 million people in 2015 (Fowkes et al., 2013; Song et al., 2019). In New Zealand, there is a lack of data on the overall incidence, clinical presentation and outcomes of individuals with PAD (Hart et al., 2022). However, it is apparent that the major risk factors associated with PAD, specifically diabetes mellitus, unhealthy lifestyles and smoking, are prevalent in the New Zealand context. This is especially relevant for minority populations, including Māori and Pacific peoples, placing them at a higher risk of developing PAD. Furthermore, PAD has traditionally received less attention when compared with its counterparts, coronary artery disease and stroke, and individuals with PAD also received less risk-factor modification than those with coronary artery disease (Aday & Matsushita, 2021; Frank et al., 2019; Su et al., 2006).

Diabetes mellitus is one of New Zealand's fastest-growing chronic health conditions and an established risk factor for PAD (Limnili & Ozcakar, 2021; Ministry of Health, 2015). In recent findings, the estimated rate of diabetes mellitus has increased from 3.5 to 4.1 percent in the last decade. Overall, an estimated 292,400 people had diabetes mellitus in 2021 (Te Whatu Ora, 2021). Of this, approximately 90 percent of people have type 2 diabetes mellitus, with the remainder being type 1 or other specific forms of diabetes mellitus (Chepulis et al., 2021). Future projections indicate that the prevalence of type 2 diabetes mellitus alone will increase by up to 90 percent in the next 20 years (Shepard-Wipiiti & Brennan, 2021). New Zealand has a growing diverse mix of ethnic groups predisposed to developing diabetes mellitus (Shepard-Wipiiti & Brennan, 2021). In 2021, the Pacific population had the highest estimated rate of diabetes mellitus at 11.8 percent, followed by the Indian population at 10.1 percent and the Māori population at seven percent. By comparison, the European population had the lowest estimated rate at three percent (Te Whatu Ora, 2021). These findings pose significant inequities for these ethnic populations and are likely to worsen in light of the increasing prevalence of diabetes mellitus (Holder-Pearson & Chase, 2022). Furthermore, Pacific and Māori people have a two to four times higher risk of developing diabetes-related complications, such as PAD (Yu et al., 2021). The disparities in the rates of diabetes mellitus and its complications have been recognised for over two decades and remain as prominent now as ever before (Holder-Pearson & Chase, 2022; Jansen et al., 2020; Yu et al., 2021).

Unhealthy lifestyles, including a high-cholesterol diet, obesity and smoking are significant risk factors for diabetes mellitus and the accelerated development of PAD (Turton, 2018). From 2020 to 2021, the New Zealand Health Survey found that over one in three people were classified as obese, and 71.3 percent of Pacific adults and 50.8 percent of Māori adults were obese (Ministry of Health, 2021b). The increased rates of obesity and poor glycaemic control have been attributed to the shift away from the traditional, physical environment of the Māori and Pacific populations to a western, urbanised lifestyle (Barnes et al., 2004; Romana et al., 2022). In addition, the shift towards a diet high in protein, sugar, salt and animal fat has further contributed to diabetes mellitus, poorly controlled blood glucose levels and severe forms of PAD (Barnes et al., 2004). Findings from the 2008/09 New Zealand Adult Nutrition Survey

showed that Māori and Pacific people were more likely to eat fast food and drink soft drinks three or more times a week than European people (Beck et al., 2018). Smoking significantly contributes to the development and progression of PAD (Limnili & Ozcahar, 2021). While smoking rates are decreasing in New Zealand, Māori and Pacific populations remain disproportionately represented at 22.3 percent and 16.4 percent, respectively, compared with the European population at 8.3 percent in 2021 (Ministry of Health, 2021a).

Over the years, it has been consistently established that Māori and Pacific are more likely to develop diabetes mellitus with poorer glycaemic control, contributing to a higher risk of developing PAD and other diabetes-related complications than European New Zealanders (Tomlin et al., 2006). In a recent report on cardiovascular disease hospitalisations in the northern regions of New Zealand, the rate of Māori and Pacific hospitalisation rates for PAD had increased by seven percent and 45 percent, respectively, between 2010-2021. In addition, Māori and Pacific hospitalisation rates for PAD were 57 percent higher and 34 percent higher, respectively, than the European ethnic group in 2021 (Singh et al., 2022). Overall, it is a reasonable assumption that PAD imposes a significant health burden in New Zealand. As the risk of lower-extremity PAD increases with age, the rates of PAD are likely to increase as New Zealand's older population grows faster than the overall population (Hart et al., 2022). In addition, the increasing prevalence of significant risk factors is likely to contribute to a rise in the prevalence of PAD in years to come, disproportionately affecting New Zealand's Māori and Pacific populations.

2.5 Peripheral angioplasty

2.5.1 History of percutaneous transluminal angioplasty

Percutaneous Transluminal Angioplasty (PTA), together with stent implantation, plays an important role in the treatment of PAD (Jakubiak et al., 2021). It is a minimally invasive procedure in which a specialised catheter with a cylindrical balloon is used to widen the narrowing within an artery to improve blood flow (Wipke-Tevis et al., 2019). PTA is classified as an endovascular surgery and can be performed by a vascular surgeon or an interventional radiologist. In many cases, PTA procedures are

performed in a dedicated angioplasty suite within an interventional radiology service (McMonagle & Stephenson, 2014). The evolution of modern interventional radiology began over half a century ago and has progressed significantly in recent years. In 1953, a Swedish radiologist, Sven Ivar Seldinger, had the seminal breakthrough that made catheter-based angiography possible. He devised an elegant method to gain access to the body with only a needle, guidewire and catheter. In Seldinger's own words "I had a severe attack of common sense (...) needle in, guidewire in through the needle, needle out, catheter in over the wire, guidewire out" (as cited in Valji, 2021, p. 1256). Over the following decade, angiography was used to diagnose various conditions throughout the body. However, it was only when Charles Dotter envisioned the possibility of using angiographic techniques to treat patients that interventional radiology became a reality. In 1964, Dotter performed the first percutaneous transluminal angioplasty for an 82-year-old woman with painful leg ischaemia and gangrene. He successfully dilated the woman's narrowed femoral artery, restoring circulation to her leg and preventing the need for amputation (Rösch et al., 2003). Later, Dotter also introduced the idea of using expandable stents to keep arteries open (Rösch et al., 2003). Over the years, the use of PTA with or without stent placement has become an indispensable part of modern medicine. This technique is now widely used in treating many forms of cardiovascular, cerebrovascular and vascular diseases (Baum & Baum, 2014).

2.5.2 Types of percutaneous transluminal angioplasty

The wide range of vascular disorders has promoted the adaptation of PTA to accommodate the diverse anatomical locations of atherosclerosis. While these procedures share a similar technical approach, each has its own special set of clinical indications, procedural guidelines, techniques and interventions, monitoring and potential complications. Typically, the word angioplasty is preceded by the name of the area receiving surgical intervention. Common types of PTA include coronary angioplasty, cerebral angioplasty, carotid angioplasty, mesenteric angioplasty, renal angioplasty and peripheral angioplasty (Aboyans et al., 2018).

2.5.3 Clinical indications for peripheral angioplasty

The use of peripheral angioplasty to treat PAD provides effective symptom relief, restores blood flow and significantly contributes to limb salvage rates (Aboyans et al., 2018; Frank et al., 2019). However, it does not solve the underlying problem of chronic, progressive atherosclerosis. Endovascular procedures should always be accompanied by risk-modification strategies to improve atherosclerosis and promote the long-term success of revascularisation (Frank et al., 2019). The clinical indications for revascularisation via peripheral angioplasty are based on the severity of symptoms and the anatomical location and extent of atherosclerotic lesions (Aboyans et al., 2018). For those with intermittent claudication, occlusions tend to occur in the aorto-iliac and femoral-popliteal arteries. In many cases, conservative treatments, such as improving ambulation, smoking cessation and management of risk factors can be equally as effective as revascularisation using angioplasty or vascular surgery (Aboyans et al., 2018; Frank et al., 2019; Mohammad & Nypaver, 2017). However, revascularisation should be considered if these methods are unsuccessful, or the patient has significant discomfort or pain (Frank et al., 2019). If the atherosclerotic lesions are short, defined as less than five centimetres in the iliac arteries and less than 25 centimetres in the femoral-popliteal arteries, endovascular therapy provides long term patency. Larger arterial lesions may require open surgical techniques, such as an endarterectomy or bypass (Aboyans et al., 2018). Individuals with critical limb ischaemia often present with concomitant diabetes mellitus and the presence of a non-healing wound or infection. It is usually caused by a combination of femoral-popliteal with either aorto-iliac or below-the-knee disease (Aday & Matsushita, 2021). Revascularisation should always be attempted due to the high risk of limb loss (Forsythe et al., 2015; Mohammad & Nypaver, 2017). The type of procedure selected should be based on lesion complexity; however, an endovascular approach is usually the first approach due to lower levels of invasiveness and complications (Frank et al., 2019). In many cases of critical limb ischaemia, surgical wound debridement and minor amputations are required to wash out infection and remove dead tissue. A peripheral angioplasty is often required prior to amputation to improve blood flow and promote wound healing. This approach is accompanied by commencing proper wound care, treating infection and managing glycaemic control in those with diabetes mellitus to further improve limb outcomes (Aday & Matsushita, 2021).

2.5.4 Peripheral angioplasty procedure

The basic components of a PTA include: (i) Gaining arterial access; (ii) Placement of an introducer sheath through which a catheter and guidewire is inserted; (iii) Movement of catheter and guidewire to vessel of interest; (iv) Imaging; (v) Intervention; (vi) Re-imaging; and (vii) Removal of access and haemostasis (Lumsden, 2019; McMonagle & Stephenson, 2014). Figure 5 provides a visual illustration of a PTA with stent implantation.

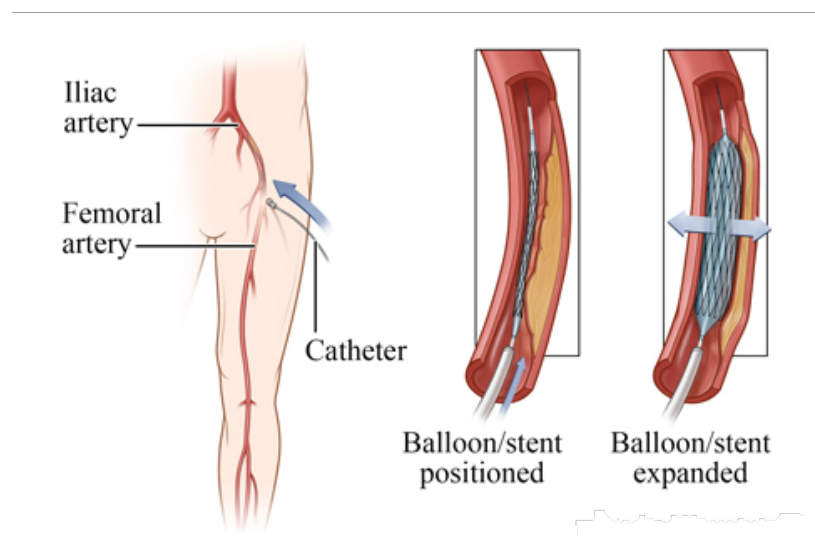


Figure 5: Peripheral angioplasty with stent implantation (Healthwise, 2023).

Gaining arterial access through the femoral artery is most commonly used for peripheral angioplasties, and the technique remains largely unchanged to the original Seldinger technique (Lumsden, 2019). Once the femoral artery is punctured, an introducer sheath is inserted, allowing easy passage of guidewires, catheters and interventional devices without vessel damage or excessive blood loss (Lumsden, 2019). The appropriate guidewire and catheter are then inserted through the sheath. The guidewire enables the catheter to move through the vasculature and cross atherosclerotic lesions. In turn, the catheter is used to deliver contrast media and assists in the placement of interventional devices at the target lesion (Lumsden, 2019). Imaging of different locations within the arterial system is obtained through the injection of contrast media, usually an iodine-based contrast agent or gadolinium, which is used for those with contrast allergies (McMonagle & Stephenson, 2014). A bolus of heparin, an anticoagulant medication, is also given during the procedure to

prevent acute thrombosis (McMonagle & Stephenson, 2014). Travel to the target vessel is navigated through a combination of the guidewire, catheter and real-time visualisation provided with fluoroscopy (McMonagle & Stephenson, 2014). Once the guidewire and catheter have been inserted into the narrowed area of the artery, the cylindrical balloon located on the tip of the catheter is inflated for approximately two minutes. This process may be repeated to physically dilate and mould the atherosclerotic plaque against the vessel wall, thereby improving blood flow (McMonagle & Stephenson, 2014). At this stage, an expandable stent may be deployed into the area to maintain patency (McMonagle & Stephenson, 2014). The removal of the catheter and guidewire is completed under fluoroscopy to prevent vessel injury. It is followed by the removal of the sheath, and haemostasis is regained by applying manual pressure for 10 to 20 minutes or through the deployment of a closure device (McMonagle & Stephenson, 2014). When clinically indicated, PTA offers several potential advantages over open surgical revascularisation. Individuals undergoing PTA receive local anaesthetic, so those at high risk of general anaesthetic can still undergo treatment. There are fewer associated complications with PTA, and the recovery time is much quicker when compared to open vascular surgeries (Robertson et al., 2017).

2.5.5 Common complications

As with any surgical procedure, PTA is associated with a number of potential complications. These complications may be related to the access site or treatment site, or they may be systemic (Beckman et al., 2021). Puncture site complications are common and may include excessive bleeding, the formation of a haematoma or the formation of a thrombus (Beckman et al., 2021; Kessel, 2008). Complications may also occur within the arteries during the procedure, including arterial perforation from the guidewire, pseudoaneurysm and, more rarely, vascular rupture during balloon dilation (Kessel, 2008). Common systemic complications may include stroke, vasovagal reactions, infection or allergic reactions (McMonagle & Stephenson, 2014). Contrast-induced nephropathy is another common complication of PTA. It is defined by a rise in baseline serum creatinine by more than 25 percent within 72 hours of exposure to contrast (Hossain et al., 2018). It is caused by the contrast media damaging the renal cells and impairing renal blood flow, thereby compromising renal function (Kewcharoen et al., 2020). Individuals with diabetes mellitus and pre-existing renal

impairment, which are common comorbidities alongside PAD, are at a higher risk of developing contrast-induced nephropathy (McMonagle & Stephenson, 2014).

2.6 Impact of glycaemic control on peripheral artery disease and peripheral angioplasty outcomes

2.6.1 Glycaemic control

It is well established that diabetes mellitus contributes to the accelerated development and increased severity of PAD (La Sala et al., 2019; Thiruvoipati et al., 2015). Hyperglycaemia is the characteristic trait of diabetes mellitus and has been linked to both microvascular and macrovascular complications (La Sala et al., 2019). A few studies have addressed the association between glycaemic control and the development of PAD alone. Selvin et al. (2006), in a prospective cohort study of 1,894 people with diabetes mellitus, demonstrated that poor glycaemic control was associated with an increased incidence of PAD, independent of other risk factors. The findings from this study also showed that individuals with poorer glycaemic control were five times more likely to have severe manifestations of PAD, alongside increased hospitalisation rates and surgical interventions compared with those with good glycaemic control. Yang et al. (2020) confirmed these results in a recent retrospective cohort study of people with type 2 diabetes mellitus, demonstrating that elevated glycaemic levels and glycaemic variability are independently associated with the development of PAD. Despite these findings, studies on whether tight glycaemic control contributes to slowing the progression of PAD and reducing the incidence of other diabetes-related complications have produced mixed results. The Diabetes Control and Complications Trial (DCCT), a seminal study in the management of diabetes mellitus, demonstrated that intensive glycaemic control in patients with type 1 diabetes mellitus delays the onset and slows the progression of microvascular complications (Diabetes Control and Complications Trial Group et al., 1993). These findings were reinforced by the United Kingdom Prospective Diabetes (UKPDS) study, another landmark study, which demonstrated that intensive blood glucose control contributed to reduced microvascular complications in patients with type 2 diabetes mellitus (UK Prospective Diabetes Study Group, 1998). Both studies failed to conclusively demonstrate if tight glycaemic control reduced the incidence of macrovascular complications. The latter

study did show a reduced rate of myocardial infarction in patients with newly diagnosed type 2 diabetes mellitus; however, these results were inconclusive (UK Prospective Diabetes Study Group, 1998). Further studies were undertaken to evaluate the effects of intensive glycaemic control on reduced cardiovascular complications. These studies included the Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial, the Veterans Affairs Diabetes Trial (VADT) and the Action in Diabetes and Vascular Disease: Preterax and Diamicron MR Controlled Evaluation (ADVANCE) trial. All similarly showed that intensive glucose control did not reduce cardiovascular complications in patients with type 2 diabetes mellitus (Action to Control Cardiovascular Risk in Diabetes Study Group et al., 2008; Duckworth et al., 2009; Patel et al., 2008). However, several follow-up studies demonstrated that intensive glycaemic control had longer-term benefits for mitigating the risk of cardiovascular complications. Nathan et al. (2005), in a follow-up study to the DCCT, showed that intensive glycaemic control in patients with type 1 diabetes mellitus had long-term beneficial effects on the risk of cardiovascular disease. It suggested that the same glycaemic mechanisms that reduce the incidence of microvascular disease may extend to the development of atherosclerosis and resulting cardiovascular disease. Similarly, Holman et al. (2008), in a 10-year follow-up study to the UKPDS, showed that intensive glucose control at the time of diagnosis for people with type 2 diabetes mellitus was significantly associated with a reduced risk of myocardial infarction, alongside the well-established reduction in microvascular complications. Despite the contrasting evidence, the importance of glycaemic control for reducing the risk of both microvascular and macrovascular complications is widely accepted. In addition, many clinical guidelines on the management of diabetes mellitus advocate for maintaining blood glucose levels as near to normal as possible (Dickinson & Whitbread, 2019; Duckworth et al., 2009).

2.6.2 Glycaemic targets

Maintaining blood glucose levels within normal or recommended ranges provides strong benefits for microvascular complications. It may also provide macrovascular benefit, particularly in slowing the development of atherosclerosis and resulting PAD (Nathan et al., 2005). An individual's blood glucose level is typically measured through a capillary blood test or a Glycosylated Haemoglobin (HbA1c) blood test. A capillary

test is useful for monitoring patterns in the fluctuation of blood glucose levels in response to diet, medications or pathological processes. An HbA1c blood test reflects the average blood glucose level over a three-month period and is used for diagnosis and ongoing management (Dickinson & Whitbread, 2019). Table 9 outlines the recommended glycaemic targets for individuals with diabetes mellitus, compared with the normal ranges for those without diabetes mellitus.

Table 9: Recommended glycaemic targets

Measurement	With diabetes mellitus	Without diabetes mellitus
HbA1c	Less than 53 mmol/mol	Less than 40 mmol/mol
Fasting glucose levels	Less than 7.0 mmol/L	3.5-5.5 mmol/L
Two hours post-prandial glucose levels	Less than 10 mmol/L	4.0 – 7.8 mmol/L

Several studies have examined the relationship between HbA1c levels, capillary blood glucose levels and the risk of diabetic complications. In the DCCT, a 10 percent reduction in HbA1c was associated with 40 to 50 percent reductions in microvascular complications, specifically retinopathy, in patients with type 1 diabetes mellitus (Diabetes Control and Complications Trial Group et al., 1993). The UKPDS demonstrated that each one percent reduction in the average HbA1c level was associated with a 37 percent decline in microvascular complications and a 14 percent lower rate of myocardial infarction in patients with type 2 diabetes mellitus (UK Prospective Diabetes Study Group, 1998). Based on these findings, a target HbA1c level of less than seven percent, or less than 53 millimoles per mole (mmol/mol), is recommended for all patients with diabetes mellitus to reduce the risk of complications (Cosentino et al., 2020). The correlation between fasting and postprandial blood glucose levels and the risk of microvascular and macrovascular complications has been studied. Hirakawa et al. (2014) conducted a randomised controlled trial on the glycaemic variability in HbA1c levels and fasting glucose levels in the ADVANCE trial, which concluded that variability in glycaemic control predicted the future development of microvascular and macrovascular complications. Zhou et al. (2018), in a more recent, randomised controlled trial confirmed that variation in HbA1c levels and fasting glucose levels lead to an increased risk of cardiovascular events using data from the VADT. Some evidence suggests that elevated postprandial glucose levels are associated with an increased risk of cardiovascular complications (Cosentino et al.,

2020). The DECODE Study Group and European Diabetes Epidemiology Group (2003), in a collaborative prospective study of 22 cohorts in Europe, demonstrated that postprandial hyperglycaemia was a predictor for cardiovascular mortality. However, more recent studies have failed to corroborate these findings. Raz et al. (2009), in a randomised controlled trial of 1,115 patients with type 2 diabetes mellitus, compared the effects of hyperglycaemia on future cardiovascular events rates and found no difference between treatment groups. Furthermore, Borg et al. (2011) demonstrated that mean blood glucose and HbA1c levels are more strongly associated with cardiovascular complications than fasting glucose levels, postprandial glucose levels or glycaemic variability.

The use of intensive glycaemic control measures to reduce the risk of microvascular and microvascular complications significantly increases the risk of severe hypoglycaemia. In fact, the ACCORD study was discontinued after three years due to a rise in all-cause mortality in the intensive control group (Action to Control Cardiovascular Risk in Diabetes Study Group et al., 2008). Severe hypoglycaemia is associated with an increased risk of cardiovascular events and promotes clinical vulnerability in individuals with existing comorbidities (Cosentino et al., 2020; Westall et al., 2022). Thus, an individualised approach for glycaemic targets is advisable (ElSayed et al., 2022b). It is recommended that HbA1c targets be individualised according to age, comorbidities, duration of diabetes mellitus and perceived quality of life. In general, tighter glycaemic control is recommended for younger people early in the course of diabetes mellitus to reduce the incidence of long-term complications in the future (Cosentino et al., 2020). For the elderly, less rigorous targets should be considered, especially when treatment negatively impacts quality of life or the advantages of tight glycaemic control were considered neutral (Chin et al., 2008).

2.6.3 Pre-procedural blood glucose levels for peripheral angioplasty

The relationship between pre-procedural hyperglycaemia and outcomes following PTA has been explored in relation to the increased risk of adverse limb outcomes and contrast-induced nephropathy. Diabetes mellitus is considered a significant risk factor for loss of vessel patency, known as restenosis, and poorer rates of limb salvage following endovascular surgery (Forsythe et al., 2015). There is evidence, albeit limited,

on the relationship between glycaemic control and limb outcomes for patients undergoing peripheral angioplasty. DeRubertis et al. (2008) retrospectively studied 291 patients who underwent peripheral angioplasty for infrainguinal occlusions and demonstrated that the presence of diabetes mellitus and poor glycaemic control was linked to lower patency rates when compared with non-diabetics. Takahara et al. (2010) came to a similar conclusion when studying 278 patients undergoing peripheral angioplasty. This study found that HbA1c levels above six and eight percent were significantly associated with major amputation in patients with diabetes mellitus, mainly due to poor glycaemic control. Singh et al. (2014) conducted a single-centre retrospective study on the outcomes of diabetic patients following peripheral angioplasty for infrapopliteal occlusions based on their pre-procedural fasting blood glucose levels. Upon follow-up a year later, the rate of freedom from restenosis and the need for reintervention was 16 percent in patients who had glucose levels above eight millimoles per litre (mmol/L) at the time of the procedure, compared with 46 percent for those with glucose levels below eight mmol/L. In addition, amputation rates trended higher in patients with higher versus lower fasting glucose levels. Several more recent observational studies exploring the association between pre-procedural HbA1c levels and adverse limb events have come to similar conclusions. These studies all demonstrated that an HbA1c level above seven percent was associated with an increased incidence of adverse limb events and long-term amputations following peripheral angioplasty (Arya et al., 2018; Cha et al., 2020; Singh et al., 2019). Furthermore, they also demonstrated the relationship between the degree of glycaemic control and adverse limb outcomes. Patients with the poorest HbA1c levels, defined as higher than 10 percent were at a significantly higher risk of lower-extremity amputation than those with lower HbA1c levels (Arya et al., 2018; McGinagle et al., 2020). Despite the consistent association between elevated pre-procedural glycaemic control and adverse limb outcomes following peripheral revascularisation procedures in these studies, clinical guidelines on optimal pre-procedural glucose levels remain unclear (Singh et al., 2019). As such, randomised trials are needed to determine whether improved pre-procedural glycaemic control could reduce rates of restenosis and improve overall limb salvage rates among patients with PAD (Arya et al., 2018; Singh et al., 2019; Singh et al., 2014).

The relationship between pre-procedural hyperglycaemia and contrast-induced nephropathy following PTA has been explored mainly in relation to coronary angioplasty. Evidence from studies undertaken in recent decades show an association between pre-procedural hyperglycaemia and contrast-induced nephropathy. Kewcharoen et al. (2020), in a recent systematic review and meta-analysis, identified eight studies exploring this association in 10,991 cardiology patients undergoing coronary angioplasty. Of these studies, five were prospective cohort studies, two were retrospective cohort studies and one was a prospective randomised trial. There was some variation between studies in the definitions of contrast-induced nephropathy and pre-procedural hyperglycaemia. Contrast-induced nephropathy was defined as a 25 percent or 50 percent rise in serum creatinine from baseline within 48 to 72 hours after contrast administration. Pre-procedural hyperglycaemia was defined as a venous or capillary blood glucose of higher than 7.8 mmol/L to 11.1 mmol/L. The overall conclusion showed a strong association between contrast-induced nephropathy and pre-procedural hyperglycaemia. The risk of contrast-induced nephropathy increased by one and seven times when pre-procedural blood glucose levels were above 7.8 mmol/L and by two times if pre-procedural blood glucose levels were above 11.1 mmol/L. The combined result from these studies provides credence to establishing elevated pre-procedural glucose levels as a risk factor for contrast-induced nephropathy. However, further studies are needed to evaluate whether strict glucose control could reduce the incidence of contrast-induced nephropathy.

Individuals with diabetes mellitus are at risk of developing diabetic nephropathy, placing them at higher risk of contrast-induced nephropathy following PTA (Calvin et al., 2010). The progression of diabetic nephropathy and resulting chronic kidney failure is caused by the thickening and hardening of the renal capillaries in response to hyperglycaemia (Dickinson & Whitbread, 2019). The advanced age, comorbidities and renal risk factors common in patients undergoing peripheral angioplasty for PAD may predispose them to contrast-induced nephropathy. A few studies have addressed the incidence of contrast-induced nephropathy following peripheral angioplasty. However, they did not explore pre-procedural hyperglycaemia as a contributing factor. Schillinger et al. (2001) undertook a retrospective review of 213 patients with atherosclerosis undergoing femoropopliteal PTA to assess the incidence and

predictors of acute renal failure after peripheral angioplasty. This study concluded that transient acute renal dysfunction occurred in approximately 10 percent of patients with PAD following peripheral angioplasty. It did note that patients with contrast-induced nephropathy had higher HbA1c levels of six to eight percent at presentation compared to those with normal renal function, and HbA1c levels were associated with contrast-induced nephropathy in the logistic regression analysis. In a recent prospective cohort study, Sigterman et al. (2016) found that exposure to iodinated contrast media during endovascular procedures for patients with symptomatic PAD frequently resulted in contrast-induced nephropathy and longer-term renal decline. The conclusions from these studies, alongside the comorbid disease state common in patients with PAD, suggest that contrast-induced nephropathy may be a common occurrence, and pre-procedural hyperglycaemia may be a significant contributing factor. Although contrast-induced nephropathy usually presents as a mild, transient and reversible impairment, it has also been associated with an increased length of hospital stay, cardiovascular events and higher rates of long-term mortality. Therefore, efforts should be made to reduce the incidence of contrast-induced nephropathy, especially for vulnerable patients, such as those with PAD (Aurelio & Durante, 2014).

2.7 Research underpinning study

Organisational and contextual features have long been recognised as important determinants in implementing evidence-based practices across healthcare settings. Li et al. (2018) recently conducted an integrative review of 36 peer-reviewed empirical articles exploring the impact of organisational context on various implementation initiatives in a clinical context. The results from this study identified organisational culture, formal and informal leadership, interprofessional collaboration, communication and resources, including adequate staffing, education and time as the most commonly reported features influencing evidence-based practice. Importantly, 12 studies (33%) identified the presence of interrelationships between many of these features, highlighting the need for a multifactorial approach to promote the successful incorporation of evidence-based practice. Leadership influenced all other features in this review, and the synergy between interprofessional collaboration and communication promoted the process of implementing evidence into practice. Organisational culture provided the foundation for interprofessional teamwork, trust

and communication, positively contributing to the incorporation of evidence-based practice changes. Overall, leadership, culture, resources, interprofessional collaboration and communication contributed to the successful implementation of evidence-based practice in 50 percent of the selected studies.

The presence of similar contextual and organisational factors was also identified as sustainment strategies for evidence-based practice. Hailemariam et al. (2019) conducted a systematic review of 26 peer-reviewed studies exploring implementing evidence-based practice in a community health setting. Of these, 12 studies found that new or existing funding was a key factor influencing the sustainment of evidence-based interventions. Nine studies identified ongoing staff training was another crucial factor. Six studies reported that continued support from leadership was essential and four studies demonstrated that mutual alignment between evidence-based interventions and organisational values was vital. Furthermore, three studies reported the maintenance of staff buy-in was needed to support the sustained use of evidence-based practice. In addition, Li et al. (2018) and Hailemariam et al. (2019) found that the presence of organisational leaders who facilitated ongoing communication, sought feedback, addressed concerns of health professionals involved in evidence-based change and evaluated the effectiveness of evidence-based interventions resulted in higher rates of implementation success.

The retrieval of one recent systematic review and meta-analysis addressed the association between pre-procedural hyperglycaemia and the risk of contrast-induced nephropathy for patients undergoing coronary angiography. Kewcharoen et al. (2020) identified eight studies ranging from 2004 to 2019, which addressed the direct relationship between elevated pre-procedural blood glucose levels and an increased risk of contrast-induced nephropathy in 10,991 patients following coronary angioplasty. The meta-analysis results indicated that pre-procedural hyperglycaemia, defined as more than 7.8 mmol/L, was associated with an increased risk of contrast-induced nephropathy (pooled OR=1.71). The risk of contrast-induced nephropathy increased significantly when pre-procedural hyperglycaemia was defined as more than 11.1 mmol (pooled OR=2.83). In these studies, contrast-induced nephropathy was defined as a 25 to 50 percent rise in serum creatinine levels from baseline within 48 to

72 hours. The results from the individual studies included in this systematic review are discussed below.

Early studies investigated the relationship between hyperglycaemia and contrast-induced nephropathy in cardiology patients undergoing coronary angioplasty. Turcot et al. (2004), in a small single-centre study of 38 patients, were the first to document that acute hyperglycaemia was a potential independent risk factor for contrast-induced nephropathy in patients with diabetes mellitus undergoing coronary angiography. In this study, contrast-induced nephropathy occurred in 9 patients (24%) and its incidence was significantly higher in the group with hyperglycaemia (42%), defined as more than 8.3 mmol/L, than the group with normal blood glucose levels (5.3%). Marenzi et al. (2010) conducted a prospective cohort study of 780 patients with an ST-elevation myocardial infarction undergoing coronary angioplasty. This study focused on patients with acute hyperglycaemia, defined as more than 11 mmol/L, regardless of the presence of pre-existing diabetes mellitus. The results showed that 148 (19%) patients had acute hyperglycaemia, and 113 (14.5%) patients developed contrast-induced nephropathy. Patients with acute hyperglycaemia had a two-fold incidence of contrast-induced nephropathy (27%) than those without acute hyperglycaemia (12%). This study also explored the association between acute hyperglycaemia and contrast-induced nephropathy in patients with and without diabetes mellitus. Surprisingly, among patients with acute hyperglycaemia, the contrast-induced nephropathy rate was higher in patients without diabetes (38%) than in patients with diabetes mellitus (16%). This finding suggests that an acute rise in blood glucose levels, compared with chronically elevated blood glucose levels common in patients with diabetes mellitus, is a predisposing factor for contrast-induced nephropathy. Further analysis explored the association between acute hyperglycaemia and contrast-induced nephropathy. The authors computed relative risks (RR) for contrast-induced nephropathy associated with different blood glucose level cutoffs for patients with and without diabetes mellitus. In patients without diabetes mellitus, the RR researched the highest value at a threshold of 11.1 mmol/L, whereas the RR peaked at 16.7 mmol/L for patients with diabetes mellitus. In addition, the RR for contrast-induced nephropathy remained lower in patients with diabetes mellitus than those without diabetes mellitus. This finding suggests that a higher blood glucose threshold could be used for patients with

diabetes mellitus before an angiography. However, the most reliable pre-procedural glycaemic threshold for patients with diabetes mellitus should be estimated and validated in large, randomised control trials. Stolker et al. (2010) reported similar results in a retrospective cohort study of 6,358 patients with acute myocardial infarction undergoing coronary angiography. The results showed that the relationship between pre-procedural glucose levels and contrast-induced acute kidney injury varied markedly in patients with and without diabetes mellitus. Higher pre-procedural glucose levels were strongly associated with higher rates of contrast-induced acute kidney injury. However, while there was a strong association between elevated glucose levels and an increased risk of contrast-induced acute kidney injury in patients without diabetes mellitus, no significant relationship was observed in diabetic patients.

Almost a decade later, several further studies were conducted to explore the association between pre-procedural hyperglycaemia and contrast-induced nephropathy in diabetic patients undergoing coronary angiography. Qin et al. (2018) conducted a prospective randomised cohort study on 258 patients who underwent coronary angiography due to chest tightness or pain. The authors found that contrast-induced nephropathy occurred in 45 patients. They identified that pre-operative hyperglycaemia and an elevated HbA1c level in the contrast-induced group were significantly higher than in the non-contrast-induced nephropathy group. Furthermore, hyperglycaemia was identified as an independent risk factor for contrast-induced nephropathy (OR=2.815). Upon analysis, the incidence of contrast-induced nephropathy in patients with hyperglycaemia (25.0%), defined as a blood glucose level of more than 11.1 mmol/L, was significantly higher compared with the non-hyperglycaemia group (13.8%). In addition, the incidence of contrast-induced nephropathy in the elevated HbA1c group (26.1%) was significantly higher compared to the group without an elevated HbA1c level (14.3%). Further ROC analysis showed the ROC curves for the predictive value of blood glucose levels for contrast-induced nephropathy for all patients and for those with diabetes mellitus. The area under the curve value was relatively poor, indicating that blood glucose levels do not exhibit a strong predictive value for contrast-induced nephropathy in all patients (95%CI: 0.569). However, the area under the curve value was stronger in patients with diabetes mellitus (95%CI: 0.652). In another prospective cohort study, Lin et al. (2018) explored whether pre-procedural hyperglycaemia was

associated with contrast-induced kidney injury. This study included 558 patients with acute coronary syndrome undergoing emergency coronary angiography. Among them, 103 (18.5%) patients had pre-procedural hyperglycaemia and 89 (15.9%) patients developed contrast-induced acute kidney injury. The incidence of contrast-induced acute kidney injury was significantly higher in patients with hyperglycaemia (28.2%) than those without (13.2%). Similar to the findings in Qin et al. (2018), the presence of pre-procedural hyperglycaemia was an independent predictor for contrast-induced acute kidney injury (OR=1.971).

Additional studies investigated the relationship between hyperglycaemia and contrast-induced nephropathy in non-diabetic patients undergoing coronary angioplasty. In a retrospective cohort study, Shacham et al. (2015) explored the relationship between hyperglycaemia upon admission with the increased risk for acute kidney injury in non-diabetic patients with ST-elevation myocardial infarction undergoing coronary angioplasty. This study included 1,065 patients, of which 402 (38%) presented with hyperglycaemia. Upon analysis, admission hyperglycaemia, defined as more than 7.8 mmol/L, was a significant independent predictor of acute kidney injury. Patients with severe hyperglycaemia (20%), more than 11.1 mmol/L, had an increased incidence of acute kidney injury, compared with patients with mild hyperglycaemia (8%), between 7.8 to 11.1 mmol/L, and those without hyperglycaemia (7%). Khalfallah et al. (2020) conducted a prospective cohort study of 660 patients with an ST-elevation myocardial infarction and underwent a coronary angiography. This study specifically investigated patients with stress hyperglycaemia, defined as more than 7.8 mmol/L; thus, patients with known diabetes mellitus or elevated HbA1c levels were excluded. Patients were divided into two groups: Group I included 111 patients with stress hyperglycaemia; and Group II included 549 patients without stress hyperglycaemia. The results showed that contrast-induced nephropathy was more predominant in group I (P=0.020), with the incidence of contrast-induced nephropathy in group I was 22 (19.8%), compared with 64 (11.7%) in group II.

The results from these studies demonstrate that pre-procedural hyperglycaemia significantly increases the risk of contrast-induced nephropathy. However, the findings were specific to cardiology patients following coronary angioplasty. There

was a profound lack of literature exploring the association between pre-procedural hyperglycaemia and the increased risk of contrast-induced nephropathy in patient groups with diverse clinical conditions or following other types of percutaneous transluminal angioplasty. In fact, there was a complete absence of literature addressing the impact of pre-procedural blood glucose requirements for vascular patients undergoing peripheral angioplasty to treat peripheral artery disease. This review identified one older study, exploring the incidence and predictors of acute renal failure following peripheral angioplasty. Schillinger et al. (2001) conducted a retrospective review of 213 patients undergoing peripheral angioplasty. The resulting analysis identified that patients who developed post-angioplasty acute kidney failure had higher serum HbA1c levels at presentation ($P=0.002$) than patients with normal renal function. In the logistic regression analysis, HbA1c levels were significantly higher in patients who developed acute kidney failure following peripheral angioplasty ($OR=1.2$), but no independent association was found. The absence of literature exploring the association between pre-procedural blood glucose requirements and the increased risk of contrast-induced nephropathy for vascular patients following peripheral angioplasty establishes a knowledge gap.

2.8 Literature review summary

The successful implementation of evidence-based practice within a healthcare setting is influenced by many interrelated individual, organisational and contextual features, irrespective of the clinical intervention. Evidence-based practice is a complex process requiring health professionals to maintain an attitude of inquiry and a sense of personal responsibility. In addition, they must develop the skills to recognise a clinical problem, locate and appraise research, and incorporate evidence-based change into their practice. Moreover, many organisational and contextual features are required to enhance and sustain evidence-based practice changes. The presence of supportive leadership, a learning culture, resources and interprofessional collaboration and communication were all significant to creating an evidence-based practice environment.

The commencement of evidence-based practice occurs when health professionals recognise a clinical issue or an area for improvement within clinical practice. The

driving force behind incorporating evidence into practice is to ensure that patient care is effective and delivered to the highest standard. The exploration into the impact of pre-procedural blood glucose levels on vascular patients undergoing peripheral angioplasty is the result of health professionals at Waikato Hospital considering whether patient safety and quality of care could be enhanced in this area. The current evidence suggests that elevated pre-procedural blood glucose levels are an independent predictor of contrast-induced nephropathy. However, it is unclear if this evidence extends beyond cardiology patients undergoing coronary angioplasty to include vascular patients undergoing peripheral angioplasty. Ultimately, research conducted in this area would have the potential to address this knowledge gap and enhance evidence-based practice in this area.

2.9 Research aims and questions

This research study aims to address the current literature gap by exploring how evidence is used to inform the current requirement for pre-procedural blood glucose levels to be less than 11 mmol/L prior to a peripheral angioplasty. Furthermore, it aims to explore how this evidence is incorporated into practice within Interventional Radiology and the dissemination of evidence to Ward M14 at Waikato Hospital. More specifically, it seeks to address the following research questions:

1. How does evidence inform the requirement for blood glucose levels to be less than 11mmmol/L prior to a peripheral angioplasty?
2. How is evidence concerning pre-procedural blood glucose requirements disseminated between Interventional Radiology and Ward M14?
3. How does evidence-based practice impact service delivery and patient outcomes?

Chapter III: Methodology

Research is to see what everybody else has seen, and to think what nobody else has thought.

Albert Szent-Gyorgyi, 1893 – 1986

3.1 Methodology introduction

Research uses a methodological approach designed to answer questions, solve problems and gain knowledge that can benefit many people (Polit & Beck, 2022). Research methodology is the theoretical analysis of the methods used in research. It incorporates several research methods, namely qualitative, quantitative and mixed methods, which are used to structure a study and to gather and analyse relevant information (Polit & Beck, 2022).

This chapter will explore the theoretical methodologies underpinning this research study. A broad approach to conducting research involves the intersection of philosophical paradigms and research methods (Creswell & Creswell, 2018). Therefore, the positivist, interpretivist and pragmatist research paradigms and their corresponding methods will be discussed. The selection of the pragmatist paradigm was used to develop a mixed methods approach for this research study.

3.2 Research paradigm

A research paradigm is a philosophical worldview acknowledging a way of thinking about the world that includes ideas, beliefs, opinions and values (Kelly et al., 2018). These worldviews encapsulate how communities of researchers view and understand reality, the nature of knowledge and how it is created, and how research may be conducted (Harvey & Land, 2022; Houghton et al., 2012). Consequently, paradigms guide the approach to a research problem and provide suggestions for addressing it (Shannon-Baker, 2016). Many recognised research paradigms exist, with the positivist and interpretivist worldviews most commonly used in research relating to health and nursing (Polit & Beck, 2022). Positivism emphasises the use of systematic and

scientific methods to study society – the behaviours and actions of humans. This philosophy uses controlled testing of numerical variables to determine cause-and-effect relationships and objectively explain human behaviour, establishing absolute truth (Moule et al., 2017). The positivist worldview has been challenged as total objectivity and predicting cause-and-effect relationships that are true for all is problematic, especially when studying society (Creswell & Creswell, 2018). Such a change in thinking is reflected in the post-positivist paradigm, which maintains the use of controlled methods and strives for objectivity but seeks to obtain an approximation of the truth to the highest degree of likelihood (Kelly et al., 2018; Polit & Beck, 2022). As positivism and post-positivism focus on objective research, these worldviews are closely aligned with quantitative research methods (Kelly et al., 2018).

In contrast, interpretivism examines the interpretations and meanings humans place on their social behaviours. It recognises that truth consists of multiple realities that are subjectively perceived by individuals (Harvey & Land, 2022). Interpretivists focus on gaining insight into the unique experiences of individuals and groups. To achieve this, researchers work closely with participants, utilising interviews and observations to gather information (Creswell & Creswell, 2018). As a result, the findings are grounded in real-life experiences of people with first-hand knowledge of the situation being studied (Polit & Beck, 2022). Due to its subjective nature, the interpretivist worldview reflects qualitative research methods (Kelly et al., 2018).

Traditionally, the combination of positivism and interpretivism was deemed incompatible due to their opposing views. However, they are now recognised as different ends on a continuum, with a pragmatist worldview – which incorporates both qualitative and quantitative approaches – residing in the middle (Harvey & Land, 2022). Pragmatism enables a mixed methods approach to research, thus allowing the researcher to select the most appropriate method for their study (Harvey & Land, 2022). As a result, it uses all approaches available to understand the problem, resulting in a more comprehensive view of the topic, and improves the validity of the findings through triangulation (Creswell & Creswell, 2018; Moule et al., 2017). Pragmatism is well-suited to the problem-solving nature of nursing research because it enables researchers to investigate complex issues in the most appropriate way (Harvey & Land,

2022; Kelly et al., 2018). For this reason, a pragmatist worldview, combining qualitative and quantitative research methods, was selected to formulate a mixed methods approach for this study.

3.3 Quantitative research

Quantitative research is an approach used to test objective theories by examining correlations between variables (Creswell & Creswell, 2018). These variables, in turn, are measured using various instruments to generate numerical data that can be analysed using statistics (Moule et al., 2017). A quantitative approach measures cause-and-effect relationships using deductive reasoning. Quantitative researchers usually begin with a hypothesis and use structured research strategies to test it by measuring the relationship between presumed causes and effects (Harvey & Land, 2022). Therefore, quantitative research addresses questions through objective measurement and observation of correlations between variables to establish statistically significant relationships and determine the most effective interventions (Ingham-Broomfield, 2014). In nursing research, experimental, quasi-experimental and non-experimental designs are commonly used to guide a quantitative approach (East et al., 2019). An experimental approach tests a cause-and-effect relationship using control, manipulation and randomisation. A quasi-experimental approach is similar and is utilised when factors in a study make true control or complete randomisation difficult to achieve (Moule et al., 2017). A non-experimental design is used to explore the interrelationship between certain variables without any active intervention from the researcher. Data are collected on several variables, and the results are then analysed and described (East et al., 2019; Shannon-Baker, 2016). This study utilised a non-experimental, quantitative approach to conduct a retrospective clinical records audit. As a result, the researcher explored the association between serum creatinine levels, patient diagnoses and pre-procedural blood glucose levels in vascular patients following a peripheral angioplasty.

3.3.1 Data collection and analysis

Quantitative data are gathered using formal instruments and numerous instruments exist, which tend to be categorised as physiological, behavioural or psychological

depending on the data they are designed to collect (East et al., 2019). Examples include biophysical instruments, structured observation or interviews, questionnaires and scales (Shannon-Baker, 2016). To select the most appropriate instrument, a researcher should consider the type of quantitative data to be collected and its validity and reliability (East et al., 2019). Validity refers to the degree to which an instrument measures what it says it measures, thus adequately reflecting the concept being examined (East et al., 2019). A reliable instrument measures the variable consistently and accurately across diverse settings. Without reliability, an instrument is not valid, and results may be incomplete; thus, a researcher cannot rely on the accuracy of their findings (Shannon-Baker, 2016). A standardised data collection tool was developed for this study. It was used to systematically gather categorical data on vascular patients who had undergone a peripheral angioplasty.

The purpose of quantitative data analysis is: (i) To measure differences between groups; (ii) To assess relationships between variables; and (iii) To rigorously test a hypothesis (Harvey & Land, 2022). Quantitative data are usually collected in the form of categorical or numerical data. However, as quantitative data analysis involves the use of statistics, data must be measurable and thus is always represented in numerical form (East et al., 2019). Data can be categorised into four levels of measurement: nominal; ordinal; interval; or ratio, which guide the statistical analysis performed on each variable. Descriptive and inferential statistics are the two main methods of analysis. Descriptive analysis focuses on describing and synthesising data (Polit & Beck, 2022). Frequency distributions, central tendency and variability are the common statistical methods used to describe variables. Frequency distributions organise numerical data, usually from lowest to highest, allowing a count or percentage of the variables to be determined and patterns to be identified. Central tendency provides an overall summary of the data by measuring the mean, median and mode. Variability considers how spread out the data are, and the most commonly used index of variability is the standard deviation (Polit & Beck, 2022). The standard deviation summarises the average deviation of values from the mean. A low standard deviation indicates the values are more similar, whereas a high standard deviation indicates that values are spread out over a wider range. Descriptive analysis is useful for organising and summarising data and portrays important features of the overall data (Moule et al.,

2017). However, it is seldom used to answer research questions; inferential analysis is usually used for this purpose (Polit & Beck, 2022). Inferential statistics takes the data beyond the specific sample and aims to make predictions for a wider population based on the data from a sample (Polit & Beck, 2022). Inferential analysis tests statistical hypotheses using various methods depending on the number of variables. Generally, t-tests are used for comparing two groups, whereas analysis of variance (ANOVA) assesses differences between multiple groups. Correlation analysis assesses the relationship between two variables, and regression analysis considers the cause-and-effect relationship between variables (Polit & Beck, 2022). Choosing the most appropriate method for quantitative data analysis depends on the research question, the data collected and how many variables and groups were considered (Moule et al., 2017). In this study, the categorical patient data were assigned numerical codes. Descriptive analysis was utilised to describe and make sense of the data. Through ANOVA and regression analysis, inferential analysis was used to investigate the association between post-procedural serum creatinine levels, patient diagnoses and pre-procedural blood glucose levels in vascular patients following a peripheral angioplasty.

3.4 Qualitative research

Qualitative research is an approach used to explore the subjective perspectives of individuals or groups regarding a research problem (Creswell & Creswell, 2018). It recognises that humans often perceive similar experiences differently and seeks to interpret the meanings they attach to their experiences (East et al., 2019). Qualitative researchers generally begin with a broad research problem and use flexible research strategies to comprehensively explore their participants' views (Harvey & Land, 2022). In nursing research, phenomenological, ethnographic and grounded theory designs are frequently used to guide a qualitative approach. Phenomenology aims to explore the lived experiences of individuals within a certain context, whereas ethnography seeks to understand the culture and social norms of particular people groups (Harvey & Land, 2022; Moule et al., 2017). Grounded theory examines a research problem based on data gathered from participants in their environment and uses it to develop a theoretical explanation and a hypothesis for further study (East et al., 2019). A qualitative approach was used to explore the perspectives and experiences of health

professionals working in Interventional Radiology and Ward M14 concerning the underpinning evidence and impact of the current pre-procedural blood glucose requirements for vascular patients undergoing peripheral angioplasty.

3.4.1 Data collection and analysis

Qualitative research considers the life experiences, beliefs, motivations, actions and perceptions of humans. Therefore, to enable an understanding of individual experiences, a researcher will work closely with participants and use interactive data collection methods (Moule et al., 2017). Unstructured or semi-structured interviews, observation, focus groups and personal diaries are commonly utilised, often taking place in the participants' natural environment (East et al., 2019). Qualitative data collection is usually undertaken with a small, relevant sample of participants (Harvey & Land, 2022). Researchers determine their ongoing data needs based on the information they have already gathered. As initial data collection may suggest further aspects to explore, researchers will use flexible and, at times, additional strategies to explore the data thoroughly. Data collection usually concludes when no new findings are uncovered (Harvey & Land, 2022). In this study, semi-structured interviews were conducted with medical and nursing health professionals working in Interventional Radiology and Ward M14.

Qualitative data collection usually generates large quantities of detailed data, which, in most cases, are turned into text format for analysis. Qualitative data analysis aims to understand meaning and accurately present it to others (Harvey & Land, 2022). A general inductive approach is commonly used to analyse qualitative data and was selected for this study. Inductive reasoning requires a researcher to become familiar with and understand the data. It is then coded, allowing similarities, differences, patterns and links to be identified and organised into categories and themes. This process continues until no new themes are identified (East et al., 2019; Harvey & Land, 2022). Inductive reasoning requires a researcher to become well acquainted with the raw data and the 'tone' of what has been discovered (East et al., 2019). As a result, they can be affected by the research and, in turn, affect the research findings. Throughout qualitative research, a researcher should continually reflect on any pre-conceived ideas and whether these impact their analysis of the findings (Harvey &

Land, 2022; Moule et al., 2017). In addition, consistency checks should be completed to enhance the trustworthiness of data analysis. This includes another researcher reviewing and coding the data into the established themes (Thomas, 2006). In this study, a general inductive method of inquiry was used to analyse the raw interview data and organise it into overarching themes, which were then linked to the objectives of this research.

3.5 Mixed methods research

Mixed methods research combines quantitative and qualitative approaches in a single study (Creswell & Creswell, 2018). As previously mentioned, mixed methods enable researchers to select different approaches to measure similar concepts. As a result, a mixed methods study will have structured research strategies in line with a quantitative approach alongside more flexible strategies in keeping with a qualitative approach (Harvey & Land, 2022). The use of mixed methods provides a more comprehensive understanding of the topic and can also enhance a research study's reliability, validity and trustworthiness, thus increasing its overall quality (Moule et al., 2017). Many research designs exist within mixed methods methodology to guide the order in which data are collected. Sequential and convergent designs are commonly used in nursing research (Polit & Beck, 2022). In a sequential design, quantitative and qualitative data collection occurs in separate phases. Preliminary data analysis is then undertaken following the first phase so that the findings can inform the second phase. A sequential design is further divided into two categories: exploratory, in which qualitative data informs the quantitative phase; or explanatory, where quantitative data informs the qualitative phase (Harvey & Land, 2022). A convergent design addresses one overarching research question, simultaneously gathering quantitative and qualitative data. The findings are then merged in the interpretation phase of the overall results. A convergent design is particularly useful for gaining a more complete understanding of the phenomena being studied (Creswell & Creswell, 2018; Doyle et al., 2016). An explanatory convergent mixed methods approach was most appropriate for this research study to explore the objective data gained from the clinical records audit and the subjective views of staff working within the wider vascular service. As a result, a more thorough understanding of the research problem was achieved.

3.6 Triangulation

Triangulation refers to combining research methods in one research study, as seen in a mixed methods approach. It generally involves researchers using qualitative and quantitative methods of data collection so that the findings can be mutually corroborated (Doyle et al., 2016; Moule et al., 2017). As a result, triangulation can confirm results and improve the accuracy of findings, thus strengthening the overall study (Harvey & Land, 2022).

3.7 Credibility and trustworthiness

Credibility refers to confidence in the truth of the collected data and its interpretations; trustworthiness relates to honesty and transparency in reporting research findings (Cronin et al., 2015; Polit & Beck, 2022). The researcher practised reflexivity during the qualitative stage of this study to ensure their interpretations did not impact the analysis of data or the findings. The researcher's supervisor also completed consistency checks during quantitative and qualitative data analysis to ensure the accuracy and validity of the findings. The quality of this research was strengthened further through the use of triangulation.

3.7.1 Researcher background

The researcher completed a Bachelor of Nursing at Waikato Institute of Technology in Hamilton. The researcher was accepted for the New Entry to Practice programme at Te Whatu Ora – Waikato and completed the required post-graduate paper through the University of Auckland, achieving top academic success. As a result, the researcher was offered a place in the Bachelor of Nursing with Honours Programme, provided in partnership with the University of Waikato and Te Whatu Ora – Waikato. The researcher currently has three years of experience working in the cardiothoracic and vascular surgical ward at Waikato Hospital.

This research study has been completed to meet the requirements for the Bachelor of Nursing with Honours. However, the researcher chose to complete this programme, not only to develop professionally as a registered nurse but to contribute to finding real solutions to meet the needs of patients within their clinical area.

3.8 Methodology summary

This chapter explored the pragmatist paradigm and associated mixed-methods design used in this research study, which incorporated both qualitative and quantitative approaches. This framework enabled the researcher to gather substantial data to comprehensively address the research questions underpinning this study.

Chapter IV: Methods

It is a capital mistake to theorise before one has data. Insensibly one begins to twist facts to suit theories, instead of theories to suit facts.

Arthur Conan Doyle, 1859 – 1930

4.1 Methods introduction

Research methods are the techniques researchers use to structure a study and include the plans, processes and strategies utilised in data collection and analysis (Polit & Beck, 2022). The pragmatist paradigm discussed in the previous chapter was used to formulate a mixed methods approach, and varying techniques were used to conduct the quantitative and qualitative phases.

This chapter will explore the design, population, data collection and data analysis of this study, alongside relevant ethical considerations. The specific methods discussed provided the framework for this research and will be followed by the study's findings.

4.2 Study design

This study utilised an explanatory convergent mixed methods approach, involving two phases: quantitative (Phase I); and qualitative (Phase II). It consisted of a larger quantitative phase and a smaller qualitative phase. Phase I involved a retrospective clinical records audit of vascular patients who underwent a peripheral angioplasty within the 2022 – 2023 calendar year. The audit aimed to investigate the association between raised post-procedural serum creatinine levels, patient diagnoses and pre-procedural blood glucose levels. Phase II involved semi-structured interviews with health professionals working in Interventional Radiology and Ward M14 at Waikato Hospital. The purpose of the interviews was to gain insight into the experiences and perspectives of health professionals on how evidence informs the current pre-procedural blood glucose requirement and how evidence-based change is implemented across clinical services. Both phases of this study aimed to address the overarching research questions. Data were collected separately but concurrently, and the results

were merged in the interpretation phase of this study. A brief overview of the research design and process used in this study is illustrated in Figure 6.

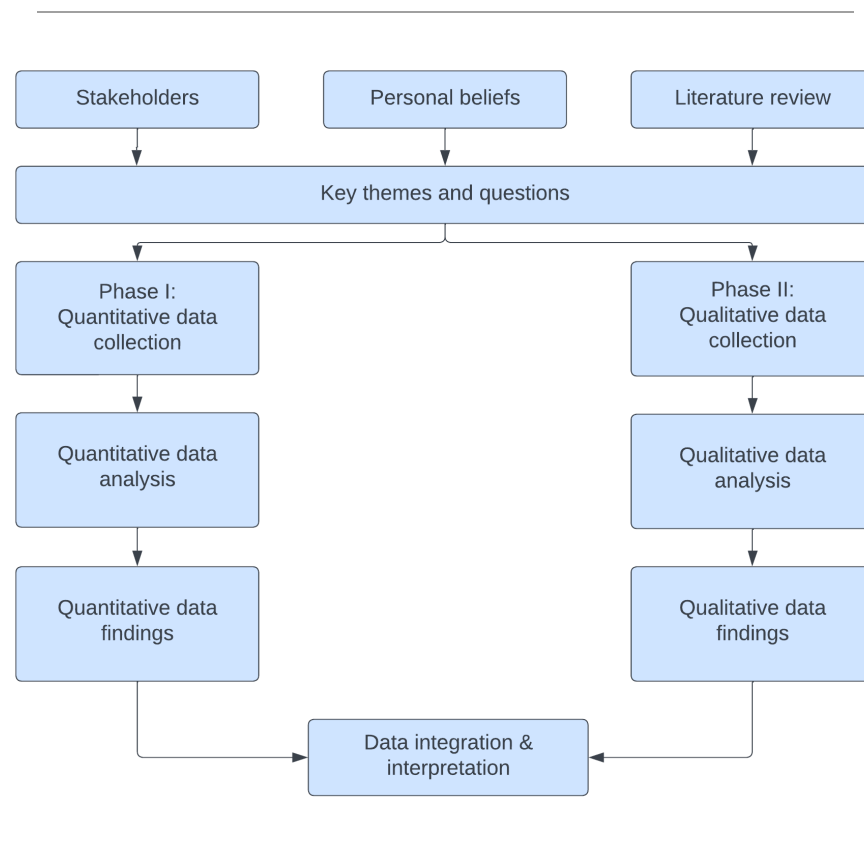


Figure 6: Research design

4.3 Setting

This research was conducted in Interventional Radiology and Ward M14, the cardiothoracic and vascular surgical ward, at Waikato Hospital. These services are key stakeholders in the care of vascular inpatients and work collaboratively on a daily basis. The topic of this study was identified as an area of interest to both parties due to a lack of understanding regarding pre-procedural blood glucose requirements and its impact on service delivery and patient care. As such, the researcher focused on exploring the utilisation and impact of evidence-based practice in these clinical areas, specifically in regard to this clinical issue.

4.4 Population

An appropriate sample of participants must be selected to accurately represent the population under examination and strengthen research outcomes and conclusions (Moule et al., 2017). A purposive sampling method was utilised for this study. This technique enables researchers to select participants who have knowledge or experience of the topic and will, therefore, be most informative for the study (Harvey & Land, 2022). Purposive sampling was selected for both phases of this research.

4.4.1 Phase I

Phase I of this study focused on obtaining quantitative data through a retrospective clinical records audit of patients who had undergone a peripheral angioplasty in the 2022 – 2023 calendar year. Purposive sampling was utilised to select patients admitted under the vascular speciality with a concomitant diagnosis of diabetes mellitus and who had undergone a peripheral angioplasty within this timeframe. Patients were excluded if they had been admitted under a different speciality, did not have diabetes mellitus or had undergone a different type of angioplasty other than a peripheral angioplasty.

4.4.2 Phase II

Phase II of this study involved gathering qualitative data through interviews with health professionals. Participants were required to care for vascular patients undergoing peripheral angioplasty in Interventional Radiology or in Ward M14 at Waikato Hospital. The selection of participants from both services enabled a variety of perspectives to be investigated. Interviews were continued until saturation plus one was achieved. Table 10 provides an overview of the sampling framework used in Phase II.

Table 10: Sampling framework

Clinical area	Medical health professionals	Nursing health professionals
Interventional Radiology	Up to three*	Up to three*
Ward M14	Up to three*	Up to three*

Note. * = Saturation plus one.

4.4.3 Recruitment strategy

Phase I of this study did not require any active participants; therefore, recruitment was not required. The recruitment process utilised in Phase II involved the ward administrator, who was independent of this study, sending an introduction email to potential participants, inviting them to participate. Those interested in participating were emailed the participant information sheet (Appendix 3) and consent form (Appendix 4). Once informed consent was gained, the researcher arranged a mutually convenient time to conduct the interview. In no instance was coercion used to recruit participants, and participants were assured that whether or not they chose to participate in this research would have no impact on their employment with Te Whatu Ora – Waikato.

4.5 Data collection

4.5.1 Quantitative retrospective clinical records audit

Once full sign-off was received from the Te Whatu Ora – Waikato Research Office, an i.Patient Manager (i.PM) report was requested from the analytics team on the 3rd of April 2023. The following codes were used by the analyst to identify potential participants for this study: ‘percutaneous transluminal balloon angioplasty’ and ‘percutaneous transluminal balloon angioplasty with stenting, single stent’ as the principal procedure; and ‘diabetes mellitus’ as one of the diagnoses. A list of 176 patients was securely emailed to the researcher’s organisational account on the 5th of April 2023. The list included patients’ National Health Index (NHI) number; admission; and discharge dates; principal diagnosis; diabetes mellitus description; principal procedure, and clinical specialty. The researcher conducted the clinical records audit from April to May 2023 using a standardised data collection tool (Appendix 1). The researcher input the provided NHIs into Clinical Workstation (CWS) to access each patient’s clinical profile on a secure computer at Waikato Hospital. No identifiable information, such as patients’ names, dates of birth or national index numbers, was recorded in the audit.

4.5.2 Qualitative semi-structured interviews

A set of seven questions and prompts were developed from themes identified in the literature review and from the stakeholder's input (Appendix 2). These questions were used to guide the interviews and encourage further discussion. Interviews were conducted from May to June 2023 at Waikato Hospital. Each interview was conducted in a quiet location, lasting approximately 30 minutes. The interviews were audio recorded with participants' consent to ensure an exact copy of verbal data was obtained.

4.6 Data analysis

4.6.1 Statistical concerns

The quantitative data gathered in the retrospective clinical notes audit were entered into a Microsoft Excel spreadsheet, and each variable was assigned a numerical code. Data analysis was then undertaken using the Statistical Package for the Social Sciences (SPSS) software with guidance from Mr Avinesh Pillai, a biostatistician from the University of Auckland. A regression analysis using a general linear model was carried out to explore the association and statistical significance between serum creatinine levels, patient diagnoses and pre-procedural blood glucose levels. The dependent variable was the change in creatinine levels (post-procedure creatinine levels minus pre-procedure creatinine), and the independent variables were the pre-procedural blood glucose levels and patient diagnoses.

4.6.2 General inductive method of inquiry

The qualitative data collected in the semi-structured interviews was analysed using a general method of inquiry. The audio-recorded interviews were transcribed verbatim into a written format to allow for accurate data analysis. The researcher used NVivo software to analyse and code the interview data. Firstly, data immersion was completed by reading the written transcripts several times to become familiar with and understand the content. The data were then coded, and as patterns and reoccurring ideas were identified, these were organised into categories and themes. Data analysis continued until no new themes were identified. Upon completion, the researcher's

academic supervisor reviewed the data and provided consistency checks, thus ensuring an accurate portrayal of the participants' perspectives.

4.7 Ethical concerns

This research study was conducted in partnership with the University of Waikato and Te Whatu Ora – Waikato. Prior to commencing this research, ethical approval was gained from the University of Waikato Human Ethics Committee on the 23rd of August 2022 (Ref No. HREC (Health) 2022#28). Authorisation was also gained from Te Whatu Ora – Waikato on the 11th of October 2022 (Ref No. RD022076) to undertake research within Waikato Hospital.

This research study addressed the ethical considerations regarding coercion, informed consent, the right to withdraw, confidentiality and privacy. In no instance was coercion used to recruit participants. All individuals involved in data collection were provided with participant information sheets, and written consent was gained before commencing interviews. These documents clearly outlined the participants' right to withdraw and the confidentiality measures in place. All information was stored securely to protect participants' privacy, and no identifiable information was used in the written research findings.

4.8 Methods summary

This chapter explored the research methods used to structure this study, including its design, setting, population, data collection and analysis, and relevant ethical concerns. These methods enabled the researcher to gather substantial data through a retrospective clinical records audit and interviews with relevant health professionals to comprehensively address the research questions underpinning this study.

Chapter V: Findings

Take nothing on its looks; take everything on evidence. There's no better rule.

Charles Dickens, 1812 – 1870

5.1 Findings introduction

The process of data analysis involves systematically applying statistical or logical techniques to evaluate, interpret, describe and present research data (Polit & Beck, 2022). As a result, the researcher can make sense of the raw data, and the findings can be utilised to answer the research questions underpinning a study. This research study aimed to explore the evidence underpinning the pre-procedural blood glucose requirement for vascular patients undergoing peripheral angioplasty, alongside how evidence is incorporated within Interventional Radiology and disseminated to Ward M14 at Waikato Hospital. A two-phase approach to data collection was employed. Phase I involved collecting quantitative data through a retrospective clinical records audit. Phase II involved collecting qualitative data through semi-structured interviews with health professionals from Interventional Radiology and Ward M14.

This chapter will present the findings from the quantitative and qualitative data collected in this research study. It will be comprised of two separate parts. Part I will outline the findings from the retrospective clinical records audit, which were analysed using descriptive statistics and regression analysis to identify correlations between the change in pre- and post-procedural creatinine levels, patient diagnoses and pre-procedural blood glucose levels. Part II will outline the findings from the semi-structured interviews, which were analysed using a general inductive method of inquiry to identify and explore significant themes.

Part I: Quantitative findings

5.2 Population characteristics

The patients included in the retrospective clinical notes audit were purposely sampled to include those admitted under the vascular speciality with a concomitant diagnosis of diabetes mellitus and who had undergone a peripheral angioplasty in the 2022 – 2023 calendar year. Out of the 176 patients provided by Te Whatu Ora – Waikato’s analytics team, 93 patients (n=93) met the criteria of this study. However, during the data collection phase, it became evident that there was significant variability in the monitoring and recording patients’ pre- and post-procedure creatinine levels and their pre-procedure blood glucose levels. In particular, there was a substantial lack of post-procedure creatinine levels recorded. Thus, data analysis was limited to patients with valid data for all variables in the model. As a result, a significantly smaller sample size of 50 patients (n=50) was taken forward for analysis. Table 11 provides an overview of the patients included in this study.

Table 11: Patient demographics

Patient details	Results
Count of gender (%)	50
Male	35 (70.0)
Female	15 (30.0)
Mean age (SD)	71.54 (11.17)
Male	71.51 (10.77)
Female	71.60 (12.44)
Count of ethnicity (%)	50
Māori	19 (38.0)
Asian	1 (2.0)
European	30 (60.0)
Mean pre-procedure creatinine levels (SD)	262.86 (283.62)
Mean post-procedure creatinine levels (SD)	274.80 (302.06)
Mean pre-procedure blood glucose level (SD)	8.61 (2.78)
Māori	8.37 (2.85)
Asian	5.80 (<i>unable to calculate SD</i>)
European	8.86 (2.75)

5.3 Regression analysis

5.3.1 Relationship between creatinine change and diagnosis

The first test analysed the association between the change in pre- and post-procedure creatinine levels by patients' diagnoses. Patients were organised into three categories based on the recorded severity of their peripheral artery disease: (i) Peripheral artery disease with ulceration and gangrene; (ii) Peripheral artery disease with rest pain; and (iii) Peripheral artery disease with intermittent claudication. Table 12 outlines the mean changes in creatinine levels according to these patient groupings.

Table 12: Patient groups by diagnosis

Patient groups	Mean change in creatinine	Standard deviation	Number of patients
1. Peripheral artery disease with ulceration and gangrene	20.03	70.97	27
2. Peripheral artery disease with rest pain	14.25	36.32	12
3. Peripheral artery disease with intermittent claudication	-10.45	27.10	11
Total	11.94	57.17	50

Table 13 illustrates the relationship between the three patient groups and the mean change in pre- and post-procedure creatinine levels. The standard deviations recorded in Table 13 demonstrate a high variability. As such, the results are difficult to interpret clinically. The limited sample size may have caused the high variability.

Table 13: Patient diagnoses and creatinine change

Source	Type III Sum of Squares	Degrees of freedom (df)	Mean Square	F	Statistical significance
Corrected Model	7488.82	2	3744.41	1.17	0.31
Intercept	3194.54	1	3194.54	1.00	0.32
Patient groups 1, 2 & 3	7488.82	2	3744.41	1.17	0.31

Note. Statistical significance was defined as a p-value of <0.05%.

In addition, Table 13 shows a p-value of 0.31, indicating that the association between patient diagnoses and the change in pre- and post-procedure creatinine levels is not statistically significant at the 5 percent level.

5.3.2 Relationship between creatinine change and pre-procedural blood glucose levels

The second test analysed the association between the change in pre- and post-procedure creatinine levels with pre-procedural blood glucose levels. Table 14 outlines the mean change in creatinine levels following a peripheral angioplasty. Again, the standard deviation indicates a high variability, possibly related to the limited sample size.

Table 14: Mean creatinine change

Mean change in creatinine	Standard Deviation	Number of patients
11.94	57.17	50

Table 15 demonstrates the association between the change in pre- and post-procedure creatinine levels and the pre-procedural blood glucose levels. Based on the p-value of 0.14, it is clear that this association was not statistically significant at the 5% level.

Table 15: Pre-procedural blood glucose levels and creatinine change

Source	Type III Sum of Squares	Degrees of freedom (df)	Mean Square	F	Statistical significance
Corrected Model	7086.25	1	7086.25	2.22	0.14
Intercept	11204.90	1	11204.90	3.51	0.06
Pre-procedural blood glucose level	7086.25	1	7086.25	2.22	0.14

Note. Statistical significance was defined as a p-value of <0.05%.

5.3.3 Relationship between creatinine change, diagnosis and pre-procedural blood glucose levels

The third test analysed the association between the change in pre- and post-procedure creatinine levels by the patient diagnosis groups and the pre-procedural blood glucose level. In accordance with the first and second tests, Table 16 demonstrates that these associations are not statistically significant at the 5% level.

Table 16: Pre-procedural blood glucose levels, patient diagnoses and creatinine change

Source	Type III Sum of Squares	Degrees of freedom (df)	Mean Square	F	Statistical significance
Corrected Model	11643.63	3	3881.21	1.20	0.32
Intercept	6147.43	1	6147.43	1.90	0.17
Pre-procedural blood glucose level	4292.75	1	4292.75	1.32	0.25
Patient groups 1, 2 & 3	4557.38	2	2278.69	0.70	0.49

Note. Statistical significance was defined as a p-value of <0.05%.

In addition, the negative beta coefficient illustrated in Table 17 indicates that a one-unit increase in pre-procedural blood glucose levels results in an associated increase of 3.5 mg/dL in creatinine levels. However, this finding was not statistically significant at the 5% level due to the limited sample size.

Table 17: Pre-procedural blood glucose levels (beta coefficient) and creatinine change

Parameter	B	Std. Error	t	Statistical significance	95% Confidence Interval	
					Lower Bound	Upper Bound
Intercept	43.38	30.12	1.44	0.15	-17.25	104.03
Pre-procedural blood glucose level	-3.47	3.01	-1.15	0.25	-9.54	2.59
Peripheral artery disease with ulceration and gangrene	5.18	19.72	0.26	0.79	-34.51	44.88
Peripheral artery disease with rest pain	-19.59	24.13	-0.81	0.42	-68.16	28.98
Peripheral artery disease with intermittent claudication	0

Note. Statistical significance was defined as a p-value of <0.05%.

Part II: Qualitative findings

5.4 Population characteristics

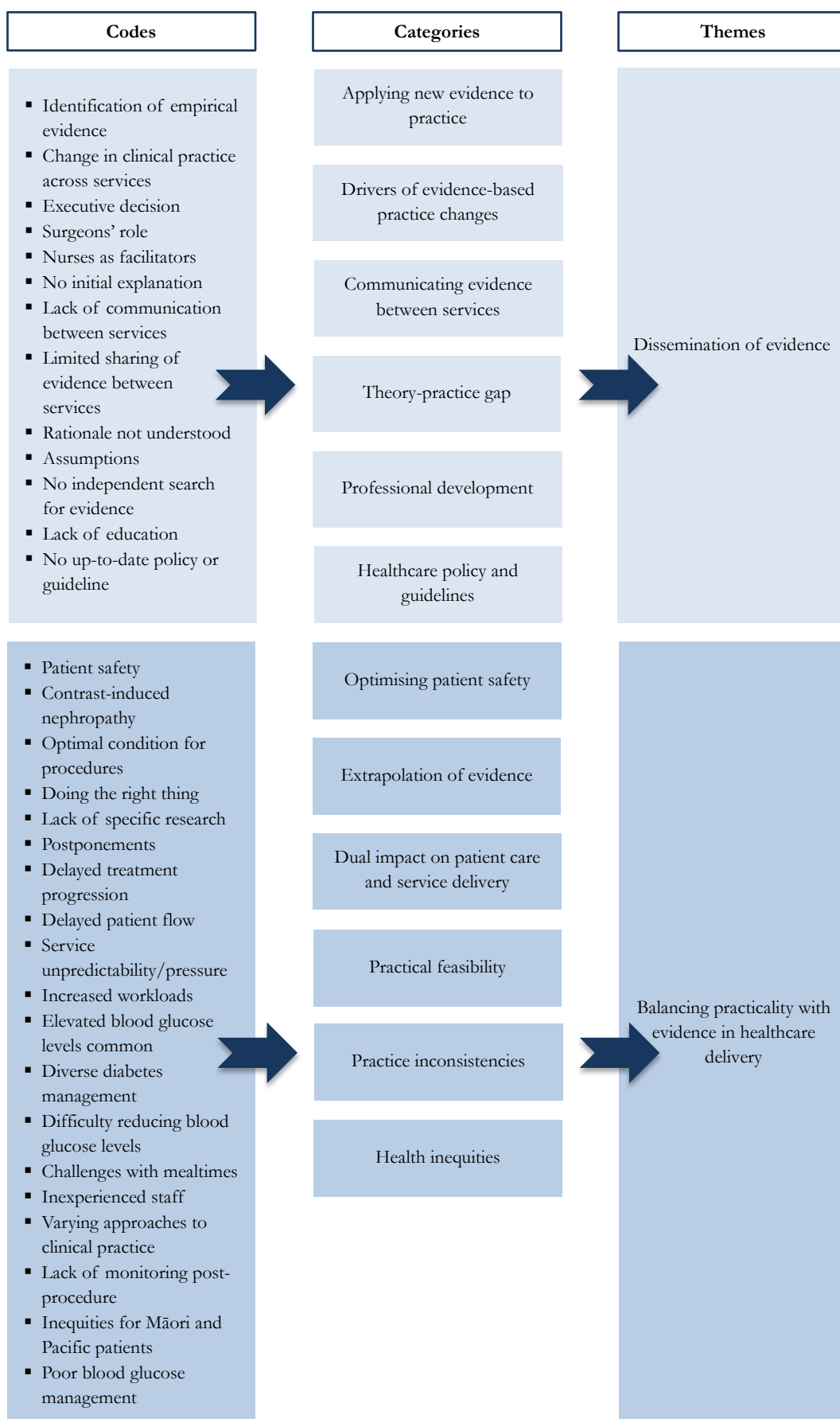
The health professionals interviewed were purposefully sampled to ensure participants were involved in the care of vascular patients in Interventional Radiology or Ward M14. The selected participants included medical and nursing staff from both clinical areas. A total of nine health professionals were interviewed, including one surgeon (n=1) and three registered nurses (n=3) from Interventional Radiology, and two surgeons (n=2) and three nurses (n=3) from Ward M14. Table 18 outlines the characteristics of the health professionals who participated in this study.

Table 18: Healthcare professional characteristics

Clinical area	Participants
Interventional Radiology	Count of participants (%)
Medical (%)	1 (11)
Nursing (%)	3 (33)
Ward M14	Count of participants (%)
Medical (%)	2 (22)
Nursing (%)	3 (33)
Experience in role	
1-3 years (%)	1 (11)
4-6 years (%)	5 (56)
7-9 years (%)	2 (22)
10+ years (%)	1 (11)

5.5 Thematic analysis

A general inductive approach was used to analyse the qualitative data gathered during the interviews. This process enabled the researcher to identify similarities, patterns and links within the data, which were organised into categories and themes. A total of 177 codes were identified during initial analysis, which was reduced to 53 codes upon further analysis. These codes were then grouped by similarity and organised into 18 categories with three overarching themes. These themes are: (i) Dissemination of evidence; (ii) Balancing practicality with evidence in healthcare delivery; and (iii) Enhancing evidence-based practice in clinical contexts. Figure 7 provides a graphic depiction of the inductive process that occurred in this study.



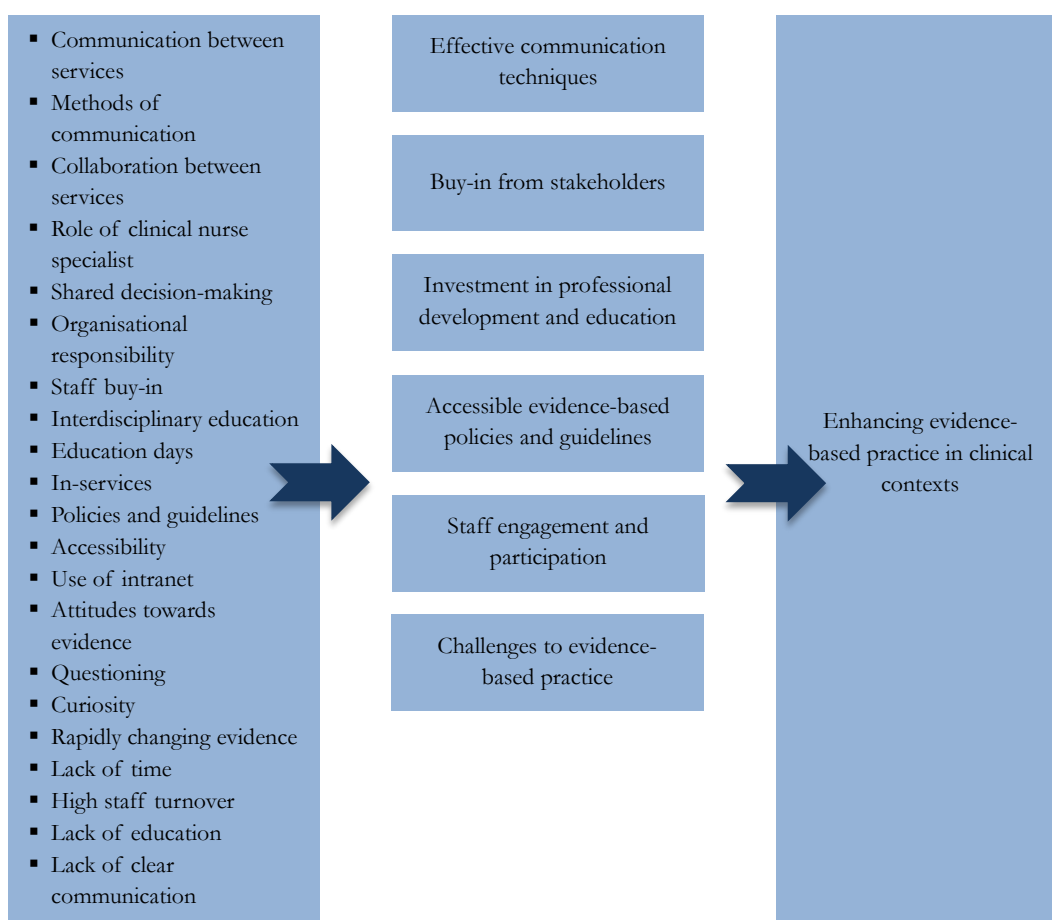


Figure 7: General inductive analysis of codes

5.5.1 Theme 1: Dissemination of evidence

The health professionals from Interventional Radiology and Ward M14 discussed the current requirement for blood glucose levels to be less than 11 mmol/L before a peripheral angioplasty and how it had been implemented in their clinical areas. The driving force behind this requirement was the identification of empirical evidence.

A blood sugar of 11 mmol/L has always been a cut-off in terms of the risk of contrast-induced nephropathy in patients, and it doesn't matter whether they're diabetic or non-diabetic. The evidence is out there, but it's primarily out of cathlab as more research has been done on cardiology patients. I can't find any evidence on peripheral vascular patients. Still, I think these groups of patients [cardiology and vascular] are probably fairly similar in terms of comorbidities, including cardiac disease, renal disease and diabetes. To me, it seems like a parallel group that we would use as they all have peripheral vascular disease.

There was also a meta-analysis in one of the journals in 2020 that, again, validated the 11 mmol/L cut-off for blood glucose levels. That journal article also referenced lots of research from almost a decade ago. For me, the risks are there, and there's more evidence if you look at other high-risk populations like patients with pulmonary embolism and acute blood vessel occlusions. They all have worse outcomes when they've got hyperglycaemia. So, typically, we use 11 mmol/L as our cut-off.

(Surgeon – Interventional Radiology)

The initiation of this strict requirement was described as an executive decision, which had then been carried out by frontline nursing and medical staff.

I think it started during my second year working here. One of our bosses said patients' blood sugars should be 10 mmol/L or below because, and this is from him, he said it makes the blood a little bit sticky with contrast and causes lactic acidosis.

(Registered Nurse – Interventional Radiology)

The clinical director came to us with some research that he had found about it and basically said that this is to avoid contrast-induced nephropathy. From my understanding, the blood becomes more sticky with more glucose in it, causing problems for the patients. So, for patients to have a good chance of the angioplasty working well with less complications, we need to get the blood sugars down to a certain level.

(Registered Nurse – Interventional Radiology)

It was just something that was started. The clinical director said, "This is what we're going to do now." As nurses, we just followed that instruction, which is probably not uncommon. Your boss makes a decision and then we follow it...no one ever worried about it either.

It didn't really feel like a change, it just felt like the surgeon came along and said they will operate under these conditions or this is what I require to do my procedure. Then the nurses...just enforced it and tried to make it happen. It's just one of those things.

(Registered Nurse – Interventional Radiology)

At times, when the new registrars come on, they've questioned it or I've heard them asking why we're doing this. I just tell them that this is the decision that's been made here and this is what we do. Talk to the boss about it if you've got any questions about it.

(Registered Nurse – Interventional Radiology)

Those working in Ward M14 also described how this requirement had been implemented in their clinical area.

I don't remember how the requirement was communicated between Interventional Radiology and the ward. I don't remember ever being told, I just remember suddenly, one day that was the rule.

(Registered Nurse – Ward M14)

I can't remember when the requirement for blood glucose levels to be less than 10 mmol/L started. It feels like it's always been that way. It just happened one day when Interventional radiology said they wouldn't take patients with blood glucose levels above 10 mmol/L and there was no real education provided around this.

(Registered Nurse – Ward M14)

When this started, I was new to the role and didn't understand the depth of why and wasn't able to grasp it. We worked closely with the charge nurse in Interventional Radiology to try and figure out a way forward.

(Registered Nurse – Ward M14)

While the requirement for pre-procedural blood glucose levels to be less than 11 mmol/L was communicated and implemented between services, the health professionals recounted a lack of education and sharing of evidence regarding its rationale.

Nothing was explained to us, not that I remember. I remember being told, or maybe it was an email or verbal instruction from my charge nurse, that blood glucose levels had to be less than 10 mmol/L for Interventional Radiology.

(Registered Nurse – Ward M14)

I'm not sure if there was an education session on blood sugar requirements.

(Registered Nurse – Interventional Radiology)

I don't think we've really had education about it amongst the team.

(Registered Nurse – Interventional Radiology)

Our boss had the evidence and knew all about it. I'm sure it would have been available had we asked but it was never something that was shared with the team.

(Registered Nurse – Interventional Radiology)

As such, it became evident that health professionals knew little about the evidence behind managing vascular patients' pre-procedural blood glucose levels prior to peripheral angioplasties. In addition, most could not relate any evidence to this requirement, and there was a discrepancy between whether blood glucose levels were required to be less than 10 mmol/L or 11 mmol/L.

With any kind of procedure, you should have evidence to back it up. I'm sure they [Interventional Radiology] have some kind of backing, I just don't know what it is.

(Registered Nurse – Ward M14)

I have no idea about the rationale behind it. I have no idea if elevated blood glucose levels increase the risk of contrast-based nephropathy. I've never even thought about it.

(Surgeon – Ward M14)

Furthermore, several health professionals voiced various assumptions about the rationale behind this requirement.

I believe it's to promote wound healing and the actual angioplasty working well.

(Registered Nurse – Ward M14)

I would assume that if you've got excess glucose in the blood then that's obviously not a good thing.

(Registered Nurse – Ward M14)

I believe it was to do with the viscosity of the blood and excess glucose making the blood thicker, resulting in difficulty during the procedure.

(Registered Nurse – Ward M14)

In my opinion, most patients coming to us [Interventional Radiology] for vascular work have poor kidney function and they're also diabetic. So, when we're giving contrast, it can induce contrast-induced nephropathy. If you give it to someone who's got poor kidney function, it affects them more and we may be harming that patient. That's just my own understanding.

(Registered Nurse – Interventional Radiology)

The requirement is for blood glucose levels to be less than 10 mmol/L before any angioplasty procedure. The reasons for this are there was an old paper about contrast and the interaction with getting good images. In the patient with hyperglycaemia, they thought it affected the quality of the images. I'm not sure about the mechanism though.

Another thing is that patients with higher blood sugars are more likely to go into a condition called contrast-induced nephropathy.

I've also seen evidence that suggests high blood sugars impact the success rate of the angioplasty procedure. And again, patients with high blood sugars are more likely to have more complications, like infection, ischemic events, strokes and heart attacks after the procedure.

(Surgeon – Ward M14)

As the interviews progressed, it became apparent that many frontline health professionals implemented this requirement in their clinical practice based on these assumptions. They had not undertaken an independent search for the evidence behind this requirement.

I haven't come across any evidence about it. I know I should as a senior nurse on the ward because I have a lot of people come up to me and ask me, especially students because I precept a lot of people. So, I should actually find the rationale behind it, but no, I haven't.

I think it's both the ward nurses and Interventional Radiology's responsibility to seek out the rationale behind this requirement...I think I should have researched a little bit into it or just asked, sometimes it's as simple as asking a question.

(Registered Nurse – Ward M14)

I think if I did my research, I could find the rationale behind why we're keeping it [blood glucose levels] below 10 mmol/L but I'm actually not sure. I don't know why we're doing it.

(Registered Nurse – Ward M14)

If they [Interventional Radiology] provided a good rationale behind this requirement then I could understand it but I don't know the rationale. I haven't seen any published articles about increased blood glucose levels and angioplasty procedures.

(Registered Nurse – Ward M14)

I've done angioplasties with a full range of blood glucose levels and I haven't noticed a difference but, to be fair, I probably haven't looked.

(Surgeon – Ward M14)

No, I haven't gone looking for any [evidence] specifically.

(Registered Nurse – Interventional Radiology)

I have not come across any research that backs up this requirement.

(Registered Nurse – Interventional Radiology)

Our boss said there's research about it but I'm still waiting for that research.

(Registered Nurse – Interventional Radiology)

In addition, no organisational resources, such as a policy or guideline, were available on the pre-procedural care of vascular patients to guide health professionals in their daily practice.

It may well be one of those things that no one's ever bothered to nail down as a policy or guideline.

(Surgeon – Interventional Radiology)

We [Interventional Radiology] have a general policy for angioplasties but the research for this requirement hasn't been included in it.

(Registered Nurse – Interventional Radiology)

There are no specific guidelines for Interventional Radiology. There's a surgical periprocedural guideline for managing glycaemic control but that's it.

(Surgeon – Ward M14)

We should have something on the ward with the rationale for this requirement. There's no information, nothing on the ward or on the information boards to say why.

(Registered Nurse – Ward M14)

However, despite the lack of evidence or rationale provided, health professionals seemed to accept the requirement and implemented it into their clinical practice.

It just started rolling. We just started checking the blood glucose level when we called for patients from the ward.

(Registered Nurse – Interventional Radiology)

We just, you know, started looking out for patients' blood sugars.

(Registered Nurse – Interventional Radiology)

I don't think there's been any sort of formal or informal education about the requirement in other areas. When we book a patient for an angioplasty, we tell the ward staff that the team need to make sure that the blood glucose level is less than 11 mmol/L. That's just how it's handed over.

(Registered Nurse – Interventional Radiology)

We just expect the registrars to get their patients ready...we don't own the patients. We [Interventional Radiology] are like a little shop and if the vascular teams want us to do something in our shop, they need to make sure their patients are good to go. We do the procedure and they look after the patients before and afterwards.

(Registered Nurse – Interventional Radiology)

5.5.2 Theme 2: Balancing practicality with evidence in healthcare delivery

The health professionals from both services voiced support for using evidence-based practice. Many condoned the requirement for pre-procedural blood glucose levels to be less than 11 mmol/L, especially if it optimised patient safety and outcomes.

We want optimal outcomes for people, so whatever is going to get us an optimal outcome should be the goal. If the research suggests that the blood glucose levels should be less than 10 mmol/L then we should be aiming for that.

(Registered Nurse – Ward M14)

Why shouldn't we be aiming for patients to have a normal blood sugar or at least a relatively normal blood sugar? In doing so, it reflects what we believe is best practice, in that patients who arrive here [Interventional Radiology] are more likely to get a better outcome if their blood sugars are normal, as opposed to abnormal.

(Surgeon – Interventional Radiology)

Keeping blood glucose levels within a normal range is the best thing for patients. No good comes from high blood sugars. In my mind, we should do everything we can to achieve optimal levels.

(Registered Nurse – Interventional Radiology)

In contrast, some health professionals questioned whether short-term glycaemic control had any perceived benefits for patients and if delaying angioplasties due to elevated blood glucose levels did more harm than good.

Glycaemic control over many months is important but acute short-term changes in glycaemic control isn't necessary.

(Surgeon – Ward M14)

Diabetes is a lifestyle disease. If we change it for a day, it doesn't necessarily change the long-term diagnosis.

(Surgeon – Ward M14)

Patients get cancelled days after day because their sugars are too high and, despite implementing as many interventions as we can to reduce the blood sugars, they don't get the care they actually do require.

(Registered Nurse – Ward M14)

I have very little opinion about whether optimal blood glucose levels are important for Interventional Radiology procedures. Honestly, I don't think blood sugars, in the grand scheme of things, makes the biggest difference for patients having vascular procedures. I don't think keeping a tight control is necessary. I think that delaying a procedure impacts patients more, more so than any perceived benefit of having tight glycaemic control for an angioplasty.

(Surgeon – Ward M14)

Several health professionals queried whether this requirement was necessary as there was little evidence specific to vascular patients. They also noted that other hospitals and services providing similar procedures had not implemented this requirement.

Since you started doing this project, I had a look for more research. I could only find research in cardiology, nothing specific to Interventional Radiology.

Now that this has all been brought to light, I do wonder if we the ones who are wrong. Why are other hospitals, like Christchurch and Auckland, not doing it? Shouldn't

everyone else be on board with this? And why aren't cardiology services doing it if it's been proven in cardiology research? Or are we just misled?

(Registered Nurse – Interventional Radiology)

There's no requirement for blood glucose levels to be less than 10 mmol/L prior to any of other scans using contrast or for coronary angioplasty, which is essentially the same procedure. These other procedures aren't postponed due to elevated blood glucose levels. I wonder why this research doesn't apply to other similar procedures.

(Registered Nurse – Ward M14)

I had never heard of this requirement before until I came here. In the other hospitals I worked in...there was no requirement for blood glucose levels.

(Surgeon – Ward M14)

However, others believed that the similarities between cardiology and vascular patients warranted the extrapolation of evidence. They spoke of promoting good glycaemic control while patients are engaging with healthcare services. In addition, they discussed the importance of setting a standard for evidence-based practice, regardless of the practices in other services.

...I think these groups of patients [cardiology and vascular] are probably fairly similar in terms of comorbidities, including cardiac disease, renal disease and diabetes. To me, it seems like a parallel group that we would use as they all have peripheral vascular disease.

...the evidence is not directly related to peripheral vascular patients but it doesn't take much to say it would apply to this cohort of patients.

(Surgeon – Interventional Radiology)

There's certainly no evidence to say that hyperglycaemia is a good thing in patients but there is enough parallel evidence to say it's a bad thing.

If you add elevated blood sugars into the equation, you're just adding more comorbidities to a patient. Most patients we see are comorbid – there's a high proportion with bad hearts, bad vessels, hypercholesterolemia and hypertension. It's just another thing they don't need.

It's hard to, in the context of limb salvage, argue that a blood sugar of 15 mmol/L is good for anyone.

(Surgeon – Interventional Radiology)

We always try to do the right thing – get the blood sugar sorted and then do the procedure as soon as possible. I think it's better for patient outcomes if their blood sugar is well controlled before the procedure.

(Registered Nurse – Interventional Radiology)

In the bigger context, Waikato is the tertiary referral centre for diabetic limb and critical limb salvage. I think the standard needs to be set and I think it's important that we don't ignore what evidence there is and say, "It's just easier to have blood sugars all over the show. I don't think that sends a good message to others working in Te Whatu Ora.

...the fundamental thing is whether we as a hospital think that blood glucose levels are worth normalizing before procedures and surgeries like this. I'm happy to be told that there's lots of research saying actually it doesn't matter, just let me just crack on. However, I find it very hard to find evidence that says that high blood sugars are a good thing and I don't think it's a standard we should be setting as a hospital.

(Surgeon – Interventional Radiology)

Throughout the interviews, the health professionals described how the requirement for pre-procedural blood glucose levels to be less than 11 mmol/L affected service delivery and patient care. The impact of postponed procedures was repeatedly mentioned.

I think this requirement impacts our patients because many have had their procedure delayed. No vascular patient gets better the longer they wait for surgery and the longer they stay in hospital.

(Surgeon – Ward M14)

If we don't have a patients' blood glucose level below 10 mmol/L before their procedure, they lose their slot in Interventional radiology and have to wait for another one. This impacts on the patient's length of stay.

The biggest issue is patient flow. We want patients to have their procedures in a timely manner so they can progress down whatever pathway they need to go down, such as having their next procedure in a timely manner and progressing to discharge.

(Registered Nurse – Ward M14)

Patients are often in pain and aren't getting any blood flow to their affected limb. The longer it takes to get treatment, the longer it takes for those things to heal.

(Registered Nurse – Interventional Radiology)

There's a ripple effect if a patients' procedure is cancelled. You also have to change all the bookings, so the booking clerks have to re-jig everything, orderlies have to change and nurses have to rush and get someone else prepped to come down. So, there's a massive spread of effect just for the sake of blood sugar. The effect of a cancellation is quite big but we've just come to deal with it.

(Surgeon – Interventional Radiology)

There are huge delays when a patients' procedure gets cancelled. By the time you send for another patient, it's been 45 minutes to an hour before we can start the next procedure. If we don't get through all the cases on that day and we've wasted an hour, we might have to come back later in the day, or over the weekend for that case.

(Registered Nurse – Interventional Radiology)

The health professionals also frequently highlighted the practical feasibility of this requirement. They spoke of many challenges, including patients commonly presenting with elevated blood glucose levels and difficulties reducing blood glucose levels prior to peripheral angioplasty.

Many of our patients come from a chronic disease profile and often come into hospital with elevated HbA1c levels and don't have good control of their blood glucose levels so trying to get it below 10 mmol/L can be incredibly difficult.

(Registered Nurse – Ward M14)

Obviously, we want everyone's blood glucose levels to be within a normal range but some people have never been in the normal range their whole life. How can you expect that to happen in a hospital, from day one, before having an angiogram. It's just a bit ridiculous. It's very difficult to manage.

(Registered Nurse – Ward M14)

I think it's an increasingly difficult target to reach in a population like ours.

(Surgeon – Ward M14)

Unpredictable procedure times, mealtimes and medication response times also posed challenges for staff trying to reduce patients' blood glucose levels.

You try to keep patients' blood glucose levels down but you can't because they're eating and drinking normally.

It's difficult get patients' blood glucose levels below 10 mmol/L because we don't have to keep them nil by mouth anymore. Oftentimes, Interventional Radiology will call for a patient after a meal, breakfast or lunch, and you check the blood glucose level and it's high so the patient doesn't get their procedure.

(Registered Nurse – Ward M14)

I think it's just a stupid rule, especially for a procedure where patients don't have to be kept nil by mouth but can be called at any time of day. For example, Interventional Radiology may call for a patient at 1330 hours. The patient has just had lunch but they will ask us to check the blood glucose level then and there. Often, it's a lot higher than 10 mmol/L because they've just eaten so they're not going to get their procedure.

(Registered Nurse – Ward M14)

We also allow our patients to eat before going to Interventional Radiology, which is not something I've seen in other hospitals that I've worked in.

(Surgeon – Ward M14)

Novorapid insulin is fast, but not that fast and you don't want to give too much.

Unfortunately, insulin takes time to work and each insulin is different. By the time we recognise that the patients' blood glucose level is high, give the insulin and check the blood sugar, there's already been a delay and often the level still hasn't come down. There's always this rush because if the patient loses that slot, they don't get their procedure.

(Surgeon – Ward M14)

The lack of policy or guidelines placed additional pressure on staff. In addition, the absence of a standardised approach contributed to the use of varied clinical interventions to reduce patients' blood glucose levels. The selected approach was often based on the skill, knowledge and experience of the staff on duty.

I think patients' angioplasties are postponed when we have medical teams on duty who don't understand the requirement for blood sugars to be less than 10 mmol/L. And there's no documentation for them to go to if they need guidance or education.

When patients' angioplasties are postponed due to elevated blood glucose levels, it often depends on which house officers or registrars are on duty, their awareness of the requirement for blood sugars to be less than 10 mmol/L and the way they decide to control patients' blood glucose levels.

(Registered Nurse – Ward M14)

If you have a patient on a Sunday evening who's booked for angioplasty on Monday morning, you often have an on-call house officer who doesn't understand the requirement for blood glucose levels to be less than 10 mmol/L or the best way to get the blood sugar down. They'll just do whatever they can, sometimes it'll be an insulin infusion, hourly novorapid insulin correction doses or keeping patients' nil by mouth. There are no set guidelines on what to do.

(Registered Nurse – Ward M14)

Sometimes we start patients on an insulin infusion if we're not managing to keep the blood glucose level below 10 mmol/L but that's usually determined on the day of the procedure. However, this is not standardised and often depends on the primary nurse noticing the patient's blood glucose levels, recognising that they need to be less than 10 mmol/L and contacting the medical team in a timely manner so something can be prescribed.

(Registered Nurse – Ward M14)

This requirement places a lot of pressure on staff trying to get the blood glucose levels down right before the procedure. If there was a guideline in place when we're preparing patients for peripheral angioplasties to help ensure that blood sugars would stay below 10 mmol/L then there would be less pressure on the staff. People would know what to do and could have worked that into their day prior, rather than everything being a shambles on the day. It just delays everything.

(Registered Nurse – Ward M14)

Furthermore, it became evident that there was a lack of routine monitoring for contrast-induced nephropathy in patients following a peripheral angioplasty

We always do the required bloods before a procedure but not routinely afterwards. Most patients will have these bloods repeated during their inpatient stay post procedure but it's not for us to check for differences between lab values related to Interventional Radiology procedures.

(Registered Nurse – Ward M14)

I don't look for anything specifically or compare bloods post procedure. Creatinine I do care about because of the minimal evidence for contrast-induced nephropathy, but in my opinion, it's largely caused by dehydration rather than the ionic compound-based contrast.

(Surgeon – Ward M14)

We monitor blood results on a case-by-case basis. We check a patients' creatinine level during admission but if they had a quick angioplasty of the femoral artery, it's approximately just two shots of contrast so it shouldn't affect their kidney function.

(Surgeon – Ward M14)

During the interviews, the health professionals all discussed how the requirement for pre-procedural blood glucose levels to be less than 11 mmol/L had an inequitable impact on Māori and Pacific patients. However, in contrast, others believed that promoting good glycaemic control improved outcomes, thus improving equity for these population groups.

I think Māori and Pacific patients are probably more effected by this requirement. My experience so far is that their glycaemic control, long-term and short-term, is poorer for a variety of reasons. I think it's more difficult to get tightly controlled blood glucose levels in hospital. For example, someone who usually sits with a blood sugar of 20 mmol/L daily is not going to get to 10 mmol/L very easily, or safely.

(Surgeon – Ward M14)

The majority of our patient cohort are Māori and Pacific people and they inevitably miss out on their procedures because of their blood glucose levels. It's very inequitable.

(Registered Nurse – Ward M14)

Without looking at the numbers, it feels like they're [Māori and Pacific] a higher proportion of our angioplasty patients. I don't believe it's specifically an equity issue because any patient with diabetes and elevated blood sugars will get postponed. However, because there is such high number of that population coming through, it definitely ends up becoming an equity issue.

(Registered Nurse – Interventional Radiology)

We know there's double the diabetic rate in the Māori population and we've got one of the worst limb salvage rates in the country. However, I believe this requirement is pro-equity in terms of making sure that outcomes are improved.

(Surgeon – Interventional Radiology)

5.5.3 Theme 3: Enhancing evidence-based practice in clinical contexts

The health professionals described their perspectives on enhancing evidence-based practice in their clinical areas. Many spoke of effective communication between services and suggested various methods of communication.

In an ideal world, there would be a paper trail so we can go back and have a look at it. Maybe in the form of an email, or verbally contacting management staff and following up with an email. Everyone should also get this email, as this would ensure staff who are away or not on shift would also get the information.

(Registered Nurse – Ward M14)

Service to service communication, such as emails to managers, guidelines printed out and displayed in the nurses' station or medication room so it's easy to refer too.

(Registered Nurse – Ward M14)

Sending out the information behind clinical requirements would be a good way to do it.

(Registered Nurse – Ward M14)

Oh, we would definitely need to have a sit down with everybody and say this is what we currently do, this is some new evidence and this is what we would like to do from now. And then making sure the different parties knew about it and were on board with that.

(Registered Nurse – Interventional Radiology)

I think definitely going up to the ward face to face and chatting with them is really good. It's good to hear their stories, learn how it works for them and answer their questions.

(Registered Nurse – Interventional Radiology)

Those working in Interventional Radiology also discussed the essential role of their recently appointed clinical nurse specialist and how this had contributed to improved communication and teamwork between services.

Our clinical nurse specialist goes to visit each patient before their procedure and ideally catches up with the nurse also to just talk them through what we need and why we need it.

(Registered Nurse – Interventional Radiology)

Our clinical nurse specialist now goes out to the ward regularly and links in with staff, which we just don't have the time to do. The liaison between the ward and us [Interventional Radiology] has really improved. I've noticed that all the pre-procedural checklists have improved and, if there's an issue, it's flagged in advanced. I think this has resulted in improvements, not just with blood sugar levels, but across the board.

(Surgeon – Interventional Radiology)

Collaboration between services and buy-in from stakeholders were described as factors that could optimise evidence-based practice, particularly in implementing professional education and developing a clinical guideline.

It should be straightforward...everyone agrees that we need to address this issue, then looks at the evidence and comes up with a policy or guideline that's sensible. This would take away the kind of should-we-shouldn't-we about these patients and their blood glucose levels because actually that just doesn't help them.

All stakeholders should be involved, including nurses, physicians and medical-imaging technologists who use intravenous contrast. The communication of evidence has to be a wraparound thing where you say, "Here's the evidence. It's not directly related to peripheral vascular patients but it doesn't take much to say it would apply to this cohort of patients." I think everyone would get the message and would be responsive to a policy or guideline that was written and co-signed by the stakeholders.

(Surgeon – Interventional Radiology)

I think it would be more useful to have guidelines from the diabetes service to direct us. Interventional Radiology are not experts in diabetes mellitus and, as vascular doctors, we can do a few things to manage blood glucose levels. However, the important thing is...how to manage sugars effectively and safely, which the diabetes service does well. They should be guiding all of us on how to manage patients with diabetes well, both in general and how to manage sugars prior to procedures.

(Surgeon – Ward M14)

The health professionals also voiced that the organisation had an important role in ensuring evidence-based policies and education was provided to frontline staff.

Guidelines and protocols need to be streamlined, including information from the services involved, such as the diabetes service and Interventional Radiology, and should be in the form of hospital policy.

(Surgeon – Ward M14)

Often, people just see a number and they don't understand the reason why. It can be difficult for them to spontaneously go and do all the research themselves. I think that's where, you know, fundamentally it needs to be the organisation educating everyone to say, this is what we're doing and why we're doing it.

(Surgeon – Interventional Radiology)

In addition, health professionals frequently referred to the provision of evidence-based, readily accessible guidelines and education as an essential aspect of evidence-based practice.

Having a guideline for blood glucose levels and Interventional Radiology would be useful because I'd be able to say this is why we're doing it and I would probably buy in to why we're doing it, as opposed to this seems rather arbitrary.

(Surgeon – Ward M14)

A policy or guideline to say this is what we expect, this is why we expect it, a reference to the underlying research and this is what you need to do in this order to get to achieve it would definitely help. Firstly, for us to better understand and to then be able to better educate patients. It's very frustrating to say, "No, you can't go to Interventional Radiology for your procedure because of your blood glucose level." When patients ask why and we don't know or can't explain it, we end up making something up. It's good to keep patients well informed but if we're not well informed then we can't do that for others.

(Registered Nurse – Ward M14)

If I had the research, I would print it out and pin it to the notice board in the staff room and work in with the nurse educator to provide education on the ward.

If there was a guideline in place when we're preparing patients for Interventional Radiology to help make sure that, on the day, patients' blood glucose levels were well managed, there would be less pressure on the staff.

(Registered Nurse – Ward M14)

Having guidelines printed out around the ward. Nurses don't have time to sit down, type it out and look on the intranet. So having up to date guidelines that are there on a board, or in a folder would be very helpful.

(Registered Nurse – Ward M14)

In my opinion, anything that is a clinical requirement should be written down and readily accessible to all staff.

The major protocols of a service should be taught at orientations and at key moments throughout the year, such as when new medical and nursing staff start. A handbook which has the major ways things are done should exist as well.

(Surgeon – Ward M14)

For nurses, some kind of guideline would be extremely helpful so they know exactly what they need to do to prepare patients for procedures.

(Registered Nurse – Interventional Radiology)

We need a proper policy available online and education sessions in each relevant ward.

(Registered Nurse – Interventional Radiology)

Another factor influencing evidence-based practice and seeking information was staff engagement and interest.

I think it depends on your level of interest. If you're happy to turn up to work, do your job and go home then you're probably not going to seek out new evidence. You've got to have enough curiosity that if a question arises, you want to investigate it...it's just a case of being curious and wanting to improve clinical practice.

(Surgeon – Interventional Radiology)

However, health professionals also raised several challenges commonly faced in their clinical areas that hindered evidence-based practice. A lack of time and rapidly changing evidence were significant obstacles to seeking information, updating policies and staying up to date.

I've got so much going on in my job, I just don't have time to look into the science of blood sugars. I'm just trusting that the surgeons have done the background work.

(Registered Nurse – Interventional Radiology)

I don't have time to look for evidence during my workday. If I wonder about the rationale for something, I'll look it up at home in my free time.

(Registered Nurse – Interventional Radiology)

Most of my self-education has to be done after hours.

(Surgeon – Ward M14)

I think the biggest issue is keeping policies up to date. Most policies have a three-year life. However, as new evidence comes along, you could be updating them every six to twelve months, which is quite time consuming.

I struggle to keep our policies updated three-yearly. I can imagine everyone else is in the same boat.

(Registered Nurse – Ward M14)

High staff turnover was another barrier to providing education and sustaining evidence-based practice.

There's a very high turnover of staff in the wards at the moment so I can go there and do in-services, but often within six months those staff have all gone.

(Registered Nurse – Interventional Radiology)

Furthermore, health professionals voiced how the organisational process of implementing evidence into practice could present many challenges when attempting to implement evidence-based change.

Sometimes, finding robust evidence is the easy part. It's actually negotiating all the hoops in the hospital. So, there's clinical ethics procedure, clinical ethics committee and new procedures committee. There's getting all the equipment passed, business cases, referral pathways and post procedural pathways. It's easy to have the evidence, it's way harder to bring it to fruition. It can take years but you get there in the end.

(Surgeon – Interventional Radiology)

5.6 Findings summary

This chapter explored the quantitative (Part I) and qualitative findings (Part II) in this research study. Part I presented the findings from the retrospective clinical records audit, which were analysed using regression analysis. The dependent variable was the change in creatinine (post-procedure creatinine minus pre-procedure creatinine), and the dependent variables were patient diagnoses and pre-procedural blood glucose levels. Upon analysis, the patient diagnoses and pre-procedural blood glucose levels did not have a statistically significant association with the change in creatinine levels. The p-values were 0.31 and 0.14 respectively. In addition, the high standard deviations demonstrated a high variability in the data due to the limited sample size. The model

did suggest that a one-unit increase in pre-procedural blood glucose resulted in an associated increase of 3.5 mg/dl of creatinine levels. However, this result was not statistically significant at the five percent level (p-value = 0.25). Part II presented the findings from the semi-structured interviews with health professionals from Interventional Radiology and Ward M14. A general inductive method of inquiry was used to analyse the raw interview data, resulting in three overarching themes. The first theme addressed the dissemination of evidence between services. The second theme explored the realities of the healthcare environment and its impact on implementing evidence-based change. The third theme explored practical approaches to enhancing evidence-based practice within a clinical context.

Chapter VI: Discussion

It is often the small steps, not the giant leaps, that bring about the most lasting change.

Queen Elizabeth II, 1926 – 2022

6.1 Introduction

Evidence-based practice is centred on the provision of safe and effective patient care (Craig & Dowding, 2020). In a healthcare setting, the process of incorporating evidence into practice begins when a clinical issue or an area for improvement is identified. Locating and evaluating relevant evidence to address an issue and improve patient care is just one aspect of evidence-based practice. The more challenging task is successfully incorporating evidence into routine clinical practice, particularly when patient care is shared across different services and teams of health professionals. The everyday reality of healthcare organisations presents significant barriers to evidence-based practice. However, much can be done to mitigate these challenges and enhance an evidence-based practice environment, improving patient care and outcomes.

The aim of this research was to explore how the evidence underpinning blood glucose requirements for vascular patients undergoing peripheral angioplasty is incorporated into practice within Interventional Radiology and the dissemination of evidence to Ward M14 at Waikato Hospital. A comprehensive literature review revealed an association between elevated pre-procedural blood glucose levels and contrast-induced nephropathy in cardiology patients undergoing coronary angioplasty. However, it demonstrated a gap in current research regarding whether this association extends to vascular patients undergoing peripheral angioplasty. In addition, several organisational and contextual factors were identified as enablers and barriers to evidence-based practice in a healthcare setting. It is hoped that the findings from this research will contribute to this body of knowledge. This final chapter will interpret the findings from the current research study in the wider context of literature and will be divided into three parts.

Part I will interpret the findings to answer the following three research questions:

1. How does evidence inform the requirement for blood glucose levels to be less than 11 mmol/L prior to a peripheral angioplasty?
2. How is evidence concerning pre-procedural blood glucose requirements disseminated between Interventional Radiology and M14?
3. How does the requirement for pre-procedural blood glucose levels to be less than 11mmol/L impact patient outcomes and service delivery?

Part II will theorise the findings to explore the multifaceted nature of evidence-based practice and its impact on successfully incorporating evidence into practice. Lastly, Part III will address the limitations, conclusions and implications for future practice of this research.

Part I: Research questions

6.2 How does evidence inform the requirement for blood glucose levels to be less than 11 mmol/L prior to a peripheral angioplasty?

Incorporating research findings into routine clinical practice is the cornerstone of evidence-based practice. Health professionals enhance patient care by identifying areas for improvement, seeking relevant evidence and working to implement evidence-based change within their clinical context. The evidence underpinning the requirement for pre-procedural blood glucose levels to be less than 11 mmol/L was explored through the retrospective clinical records audit and the interviews with health professionals.

The clinical records audit investigated the impact of elevated pre-procedural blood glucose levels on vascular patients who had undergone a peripheral angioplasty. It specifically explored the correlation between the change in creatinine levels and: (i) patient diagnoses; and (ii) pre-procedural blood glucose levels. There was not a statistically significant association between the change in creatinine levels and patient diagnoses ($p=0.31$) or pre-procedural blood glucose levels ($p=0.14$) in vascular patients following a peripheral angioplasty at the five percent level of significance. A one-unit increase in pre-procedural blood glucose levels resulted in an observed non-statistically significant increase of 3.5 mg/dL in creatinine levels ($p=0.25$) at the five percent level of significance. Such a trend was aligned with the views of the health professionals from Interventional Radiology. Though the defined 11 mmol/L of blood glucose did not appear to be statistically significant, the higher the pre-procedural blood glucose level, the more likely the poorer outcomes post-intervention.

The interviews explored health professionals' perspectives on the evidence underpinning this requirement. The requirement for pre-procedural blood glucose levels to be less than 11 mmol/L was founded on evidence from cardiology research. Health professionals working in Interventional Radiology had located this research, which identified that a pre-procedural blood glucose level of more than 11 mmol/L

significantly increased the risk of contrast-induced nephropathy. They identified similarities between cardiology and vascular patient cohorts, thus warranting the extrapolation of this evidence into their clinical area and initiating this requirement. In addition, health professionals firmly believed that reducing vascular patients' blood glucose levels before a peripheral angioplasty enhanced patient safety and contributed to improving overall outcomes.

The association between pre-procedural hyperglycaemia and contrast-induced nephropathy, as indicated by increased serum creatinine levels of 25 to 50 percent, was established in cardiology patients undergoing coronary angioplasty. Kewcharoen et al. (2020) found that elevated blood glucose levels were associated with increased serum creatinine levels within 48 to 72 hours of a coronary angioplasty. In addition, the higher the blood glucose level, the higher the risk of contrast-induced nephropathy. A blood glucose level of more than 7.8 mmol/L was associated with an increased risk of contrast-induced nephropathy, and this significantly increased when blood glucose levels were above 11.1 mmol/L. This study observed an association between pre-procedural blood glucose levels and creatinine levels. While this finding was not statistically significant, it does suggest that higher pre-procedural blood glucose levels are associated with higher post-procedural serum creatinine levels within 72 hours of a peripheral angioplasty. An extrapolation of this result infers that elevated pre-procedural blood glucose levels may increase the risk of contrast-induced nephropathy in vascular patients following peripheral angioplasty.

The findings from this study did not establish whether the requirement for blood glucose levels to be less than 11 mmol/L before a peripheral angioplasty was warranted for vascular patients. However, the pathological similarities between cardiology and vascular patients suggest that extrapolating this threshold from previous cardiology research may be appropriate. Vascular disease is considered a subset of cardiovascular disease, sharing atherosclerosis as its primary cause (Hedin & Hansson, 2016). Patients with atherosclerotic vascular disease in one area of the body are likely to have it in other high-risk areas. It is well-established that peripheral artery disease is an independent marker of coronary artery disease (McMonagle & Stephenson, 2014). Furthermore, the basic components of a peripheral angioplasty and coronary

angioplasty are markedly similar (Aboyans et al., 2018; Baum & Baum, 2014). The current threshold for vascular patients' pre-procedural blood glucose levels could be considered arbitrary. However, the aforementioned factors, and the observed association between pre-procedural blood glucose levels and creatinine levels in this study, suggest that managing blood glucose levels before a peripheral angioplasty may positively benefit vascular patients.

6.3 How is evidence concerning pre-procedural blood glucose requirements disseminated between Interventional Radiology and Ward M14?

The dissemination of evidence is a critical aspect of evidence-based practice. It involves the targeted distribution of information to health professionals with the intent to spread knowledge and the associated evidence-based interventions (McCormack et al., 2013). The perspectives of health professionals on the dissemination of evidence and the implementation of the associated pre-procedural blood glucose requirement were explored during the interviews.

The health professionals in Interventional Radiology described the requirement as an executive decision verbally communicated to the nursing and medical teams. The health professionals in Ward M14 could not recall how the requirement had been passed on to them. They reported that Interventional Radiology had simply stopped performing peripheral angioplasties on patients with blood glucose levels above 11 mmol/L. Health professionals from both services described a lack of understanding regarding the rationale for this requirement and reported that no evidence had been provided alongside the initiation of this requirement. In addition, no policy or clinical guideline was available for health professionals to refer to in their daily practice.

Evidence-based practice changes involve many healthcare team members, often including those working in different services. This is especially pertinent in a large tertiary health organisation like Waikato Hospital. Li et al. (2018) demonstrated that interprofessional collaboration and effective communication are crucial for disseminating and incorporating evidence into practice. Interprofessional

collaboration requires active and ongoing partnerships between health professionals to understand, support and implement evidence-based interventions. Interprofessional collaboration is predominately facilitated through effective communication and the sharing of resources. Promoting these factors facilitates support and buy-in from all health professionals involved in patient care and contributes to consistently implementing evidence-based interventions across multiple health services. Furthermore, Hailemariam et al. (2019) found that maintaining staff buy-in led to the sustained use of evidence-based interventions. The findings from this study indicate a breakdown in clear communication between those working in Interventional Radiology and Ward M14. As a result, there has been confusion and frustration regarding the strict pre-procedural blood glucose requirement. The lack of understanding has caused health professionals, particularly in Ward M14, to question the relevance of this requirement and whether it positively contributes to improved patient outcomes.

The provision of education and easily accessible guidelines are paramount to disseminating evidence and supporting evidence-based change. Li et al. (2018) found that clinical education improved knowledge and attitudes towards evidence-based interventions. Hailemariam et al. (2019) also identified that continuing to educate health professionals on evidence-based interventions enhanced their knowledge and continued use of evidence-based practice. This study identified that no education had been provided for frontline health professionals in Interventional Radiology or Ward M14 on the rationale for the pre-procedural blood glucose cut-off value. A policy or guideline is one of the most effective ways to disseminate evidence, boost knowledge and support the implementation of evidence-based practice (Dang et al., 2022; Li et al., 2018). This study also found that no policy or clinical guideline existed in Interventional Radiology or Ward M14 endorsing the current requirement for pre-procedural blood glucose levels. As a result, health professionals could not easily locate the evidence underpinning this requirement. Consequently, most did not understand the rationale for the pre-procedural blood glucose threshold. It appeared that this requirement did not have staff buy-in and had simply been incorporated into practice to ensure vascular patients received their scheduled peripheral angioplasties. In addition, the lack of knowledge contributed to various incorrect assumptions

becoming attached to this requirement, further compounding the theory-practice gap and contributing to confusion amongst health professionals.

The results from this study indicated a breakdown in the communication of evidence among healthcare professionals working in Interventional Radiology and Ward M14. There was also no policy or guideline in either service outlining the rationale behind the requirement for blood glucose levels to be less than 11 mmol/L before a peripheral angioplasty. Developing an evidence-based clinical guideline could mitigate the current lack of knowledge and dispel incorrect assumptions. It could also facilitate support and buy-in from all health professionals involved in caring for vascular patients undergoing peripheral angioplasty, contributing to the informed and sustained use of evidence-based practice.

6.4 How does evidence-based practice impact service delivery and patient outcomes?

Implementing evidence-based practice should ultimately result in changed clinical practice to improve patient care. However, this process can be challenging for health professionals, particularly when their clinical area lacks the support required to incorporate evidence into routine practice successfully. During the interviews, the health professionals described commonly faced challenges to implementing the pre-procedural blood glucose requirement and the impact this had on staff and patients. They also shared their perspectives on how these barriers could be practically addressed to streamline the use of evidence-based interventions within their service. The two key themes that emerged were: (i) Balancing practicality with evidence in healthcare delivery; and (ii) Enhancing evidence-based practice in clinical contexts.

The everyday reality of the clinical environments in Interventional Radiology and Ward M14 posed challenges for evidence-based practice. The health professionals from both services frequently described the impact of postponing peripheral angioplasties due to elevated blood glucose levels. Prolonged admission times and delays between scheduled procedures affected service delivery, placed pressure on staff and contributed to delays in treatment progression for patients. Health professionals in

Ward M14 also described difficulties in effectively managing vascular patients' pre-procedural blood glucose levels due to factors beyond their control. These included patients frequently presenting with elevated blood glucose levels, unpredictable procedure times, mealtimes and medication response times. The lack of an evidence-based guideline resulted in the use of varied clinical interventions to reduce vascular patients' blood glucose levels, often at the last minute. Frontline health professionals relied on various subjective factors, including their memory, clinical skills and previous experience with patients undergoing peripheral angioplasty, to recognise when a patient's blood glucose level needed to be less than 11 mmol/L and implement necessary interventions. The lack of a policy or guideline contributed further to the lack of knowledge about the rationale for this requirement. In addition, patient care was impacted as health professionals could not easily identify the most effective clinical interventions to prepare vascular patients for peripheral angioplasty.

The health professionals in Interventional Radiology and Ward M14 described various practical approaches to mitigate the current challenges faced in relation to the blood glucose cut-off value. Clear communication and sharing of evidence between service managers, disseminating evidence to frontline staff and developing a guideline were frequently mentioned as enablers for evidence-based practice.

A clinical environment that supports and facilitates evidence-based change is crucial to evidence-based practice. Williams et al. (2015) described heavy workloads, time pressures and a lack of readily available resources as key barriers to incorporating evidence into practice. The findings from this study showed that health professionals in Interventional Radiology and Ward M14 frequently experienced these barriers in their daily practice. As a result, they felt disillusioned and frustrated by the pre-procedural blood glucose cut-off level. Many expressed the feeling that this requirement made their already difficult job harder. The lack of knowledge about the rationale for this requirement also caused health professionals to question its relevance and contributed to confusion, further compounding feelings of frustration. Despite this, all health professionals voiced positive attitudes towards evidence-based practice and supported the pre-procedural blood glucose requirement if it contributed to patient safety and improved outcomes. Many expressed that education, particularly

through the development of a clinical guideline, would significantly improve attitudes towards this requirement and understanding of its rationale. As previously discussed, Hailemariam et al. (2019) and Li et al. (2018) identified the importance of continued staff buy-in, training and resources in evidence-based practice. In addition, Dang et al. (2022) suggested that health professionals are more likely to commit to the routine use of evidence-based interventions when they perceive benefit for their patients.

The findings from this study show that health professionals in Interventional Radiology and Ward M14 have positive attitudes towards evidence-based practice. They also demonstrated a willingness to incorporate evidence-based interventions into practice within their clinical setting to enhance patient safety and improve outcomes. However, working in a ‘stretched’ healthcare organisation has posed many practical challenges. In addition, the lack of investment in staff education and the development of a guideline has contributed to confusion and frustration regarding the pre-procedural blood glucose cut-off level. Combining the positive attitudes of health professionals with tangible resources and support has great potential to strengthen the sustained use of evidence-based practice in this area. As a result, patient outcomes will be improved, and health professionals can be assured that the care they provide is truly in patients’ best interests.

Part II: The multifaceted nature of evidence-based practice

Evidence-based practice is considered the ‘gold standard’ of care in modern healthcare, the fundamental purpose of which is to align patient care with the best available evidence, thus ensuring that interventions are proven effective and provided to the best possible standard (Craig & Dowding, 2020). Whilst evidence-based practice is now well-established and accepted internationally, the interpretation and implementation are often fraught with challenges. Further, the process of incorporating evidence into practice involves multiple steps, each crucial to success, though such key steps can be frequently overlooked or missed when operating within a healthcare organisation.

The foremost steps in evidence-based practice involve locating and appraising relevant evidence to address a clinical issue or area for improvement. It requires health professionals to consider whether their practice or the practice within their clinical area, is informed by the best available evidence (Hoffmann et al., 2017). Intentionally evaluating current practice, reviewing the best available evidence and making links between how findings can be implemented to improve patient care is the cornerstone of evidence-based practice. However, evidence-based practice is not simply theoretical but requires practical application to improve the quality of care and patient safety (McCluskey & O'Connor, 2017). The subsequent steps involve incorporating evidence into current clinical practice, resulting in new or changed approaches to care. This process is arguably the most challenging for health professionals, and its success is significantly influenced by various enablers or barriers within the target context. As a result, breakdowns are more likely to occur in the latter phases of evidence-based practice.

This study explored the use of evidence in Interventional Radiology to inform the requirement for vascular patients’ blood glucose levels to be less than 11mmol/L before a peripheral angioplasty. The findings showed that executive clinical staff had identified empirical evidence deemed applicable for optimising the safety and outcomes for vascular patients. Its results were then extrapolated to establish the pre-

procedural blood glucose cut-off level. It is evident that the foremost steps of evidence-based practice were adhered to at this point. However, this research continued to investigate how this evidence was disseminated between Interventional Radiology and Ward M14, as these services shared vascular patients' pre- and post-procedural care. The results showed that frontline health professionals did not know the rationale underpinning this requirement. In fact, while the clinical requirement for pre-procedural blood glucose levels had been communicated, it had not been accompanied by the corresponding evidence. Furthermore, despite being implemented several years ago, neither the requirement nor the evidence had been taken into an organisational policy or guideline. It is clear that a breakdown occurred in the subsequent steps of evidence-based practice. As a result, there has been much confusion and frustration among frontline health professionals regarding the implementation of this requirement.

Incorporating evidence into practice is a dynamic process impacted by many interrelated factors. The theory behind evidence-based practice is the enhancement of patient care through the consistent use of best evidence. However, many specific factors that influence the success of evidence-based practice can pose significant barriers, depending on their presence or distortion within a clinical setting (Li et al., 2018). This study identified a breakdown in the sharing of evidence between decision-makers and frontline staff in Interventional Radiology. The resulting lack of knowledge contributed to miscommunications between these health professionals and those working in Ward M14. Enhancing collaboration between services sharing patient care has the potential to strengthen and streamline the use of evidence-based interventions (Busari et al., 2017). Clear communication and sharing of resources between interprofessional team members and different services are the most effective strategies for improving collaboration (Li et al., 2018). In addition, the nonexistence of an evidence-based guideline outlining the requirement and its rationale resulted in further miscommunications, confusion, practice inconsistencies and incorrect assumptions being shared among frontline staff. Tangible support and resources, such as staff education and easily accessible guidelines, promote staff buy-in and the consistent use of evidence-based interventions (Hailemariam et al., 2019). Enhancing the successful implementation of evidence-based practice requires consideration of the

factors that may facilitate or hinder change within that area and how these can be addressed. As a result, evidence-based interventions can be customised and implemented using a targeted approach to optimise enablers and overcome barriers to bring about lasting evidence-based change.

The findings from this study demonstrate the multifaceted nature of evidence-based practice. Identifying a clinical issue, seeking evidence, evaluating how evidence may improve patient care and working to implement evidence-based interventions into routine practice are the crucial steps of evidence-based practice. These steps can be conceptualised as a puzzle, as depicted in Figure 8. Together, these components make the ‘complete picture’ of evidence-based practice, contributing to the successful incorporation of evidence into practice.

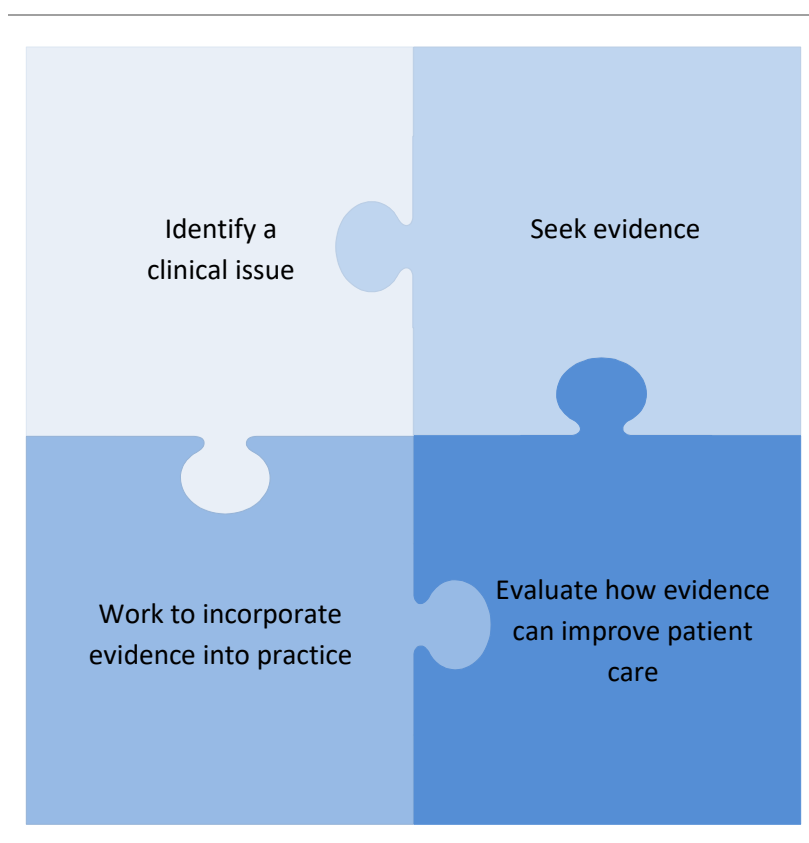


Figure 8: Key components of evidence-based practice

However, when a ‘puzzle piece’ is missing or attempts are made to these components in an isolated or fragmental way, very little can be achieved. In fact, it can result in many failed attempts to incorporate evidence into practice. These steps must be

utilised in unison to enhance the success of evidence-based practice. As a result, the sustained use of evidence-based practice will improve the quality of patient care, optimising safety and positive outcomes.

Part III: Limitations, conclusions and implications

6.5 Study limitations

Every research study has limitations (Boswell & Cannon, 2018). Researchers are best placed to identify and acknowledge any difficulties in the methodology or design of a study that may have impacted the quality of the results (Polit & Beck, 2022). Several limitations were detected during this study, potentially impacting the research findings. These include time constraints, limited sample size, selection bias, the researcher's role and generalisation of research findings, which will each be discussed in this section.

6.5.1 Time constraints

This research was completed to meet the requirements for the Bachelor of Nursing with Honours. As such, time constraints existed, mainly impacting Phase I of this study. In Phase I, it was anticipated that the researcher would gather data of up to 100 vascular patients during the clinical notes audit. The audit took place over four weeks and outside the researcher's clinical working hours. While 93 patients met the criteria for this research, only 50 patients could be included in the data analysis. Due to the specific timeframe in which this research was to be completed, the researcher could not extend the audit to include vascular patients from previous years. In Phase II, there were only a small number of potential participants for this research. Nine interviews were completed, giving the researcher perspectives from health professionals in Interventional Radiology and Ward M14 and achieving data saturation.

6.5.2 Sample size

As previously noted, approximately half of the vascular patients who had undergone a peripheral angioplasty between 2022 and 2023 had a complete dataset. The small sample size significantly limited data analysis and impacted the findings from the audit, possibly contributing to the high variability and statistical insignificance of the results.

6.5.3 Selection bias

Purposive sampling was used in both phases to select participants who met the inclusion criteria for this study. This approach was necessary as the research aimed to explore the use of evidence in Interventional Radiology and Ward M14 at Waikato Hospital, specifically concerning pre-procedural blood glucose requirements for vascular patients undergoing peripheral angioplasty. Purposive sampling is highly prone to bias as the researcher must judge who has sufficient knowledge or experience of the research question to be most informative for the study (Harvey & Land, 2022). To reduce the presence of bias and address any shortfall in the sample, the researcher sought to interview health professionals in medical and nursing roles with varied years of experience. As a result, a variety of different perspectives were explored, leading to well-rounded results.

6.5.4 Role of the researcher

It is unlikely that the researcher's role as a registered nurse within Ward M14 had a significant impact on the research within Phase I. However, the researcher's personal experience in the phenomena under investigation may be viewed as a limitation due to potential bias. Additionally, the researcher's clinical role may have influenced the responses obtained during the interviews in Phase II. Notwithstanding such issues, the researcher's knowledge and experience in the care of vascular patients undergoing peripheral angioplasty was significantly beneficial during the interviews as it facilitated in-depth discussion, thus contributing to more comprehensive findings.

6.5.5 Generalisation of research findings

This research was conducted in Interventional Radiology and Ward M14 at Waikato Hospital. The exploration into the cut-off requirement for pre-procedural blood glucose levels was specific to these services. It is unknown if this requirement is utilised in similar health services around New Zealand. As such, the researcher recognises that the results may only apply to Waikato Hospital services. However, the literature indicates that evidence-based practice, including its process, enablers and challenges, is pertinent in various healthcare settings. Thus, this study's conclusions may apply in other clinical settings.

6.6 Study conclusions

Evidence-based practice was established to align patient care with the best available evidence. It is well-established that health professionals can directly improve the quality and effectiveness of patient care by incorporating the principles of evidence-based practice into their daily routines. Incorporating evidence into practice involves identifying an area for improvement, locating and evaluating various relevant research to address the issue, and then working to implement an evidence-based change in practice. However, the exigent roles of health professionals, alongside the realities of working in an overextended healthcare organisation, can often impede the daily use of evidence-based practice. To mitigate this, tangible resources and support are required to enable health professionals to prioritise and intentionally incorporate evidence into practice.

This research aimed to explore the use of evidence-based practice in Interventional Radiology and the dissemination of evidence to Ward M14 at Waikato Hospital, specifically concerning blood glucose requirements for vascular patients with peripheral artery disease undergoing peripheral angioplasty. The results of this mixed methods study and existing literature indicate that evidence-based practice is a complex process influenced by many interrelated individual, organisational and contextual factors. Health professionals must consider various factors in their clinical area or the target area and how these may enhance or hinder the uptake of evidence-based practice. Consequently, strategies to enhance evidence-based practice can then be implemented, leading to the successful incorporation of evidence into practice.

The findings from the retrospective clinical records audit explored the impact of elevated pre-procedural blood glucose levels on vascular patients who had undergone a peripheral angioplasty between 2022 and 2023. The existing literature indicated that pre-procedural hyperglycaemia was an independent risk factor for contrast-induced nephropathy in cardiology patients undergoing coronary angioplasty. However, it was unclear if this evidence extended to vascular patients undergoing peripheral angioplasty. As such, data gathered from the audit were analysed to investigate the association between the change in creatinine levels and (i) patient diagnoses and (ii) pre-procedural blood glucose levels. While the findings were not statistically

significant, an association was observed between pre-procedural blood glucose levels and creatinine levels. This association suggests that an elevated pre-procedural blood glucose level increases the risk of contrast-induced nephropathy in vascular patients; however, it does not establish whether the 11 mmol/L blood glucose cut-off is warranted in this setting. Despite this, the similarities between cardiology and vascular patients suggest that extrapolating this threshold from previous cardiology research may be appropriate.

The findings from the semi-structured interviews explored health professionals' perspectives on the evidence behind this requirement and how it was disseminated between Interventional Radiology and Ward M14. Health professionals described a lack of communication and tangible support around the rationale for the pre-procedural blood glucose cut-off level. As a result, there was much confusion and misinterpretation concerning the evidence underpinning this requirement for frontline staff in both services. To resolve this issue, investment into staff education and the development of an evidence-based clinical guideline would prevent further miscommunications, encourage staff buy-in and enhance the sustained use of evidence-based practice in this area.

6.7 Implications for practice

The most pertinent practice implications from this study were improved collaboration and communication between Interventional Radiology and Ward M14. The main feedback received from health professionals was the need for an evidence-based guideline. Developing such a guideline would significantly improve staff knowledge of the rationale for pre-procedural blood glucose requirements. In turn, it would dispel incorrect assumptions and mitigate practice inconsistencies currently experienced in these areas. Several considerations were suggested to enhance the use and effectiveness of a guideline. Firstly, to facilitate its widespread adoption among health professionals at various clinical levels, it would be necessary for the involved services and the overarching organisation to endorse it. Secondly, easy and convenient access through the intranet and in paper format would significantly enhance frontline health professionals' use of a guideline.

Ongoing professional education could further enhance the aforementioned benefits of an evidence-based guideline. Education sessions involving Interventional Radiology and Ward M14 staff would enhance collaboration through a sense of shared purpose. It would also allow health professionals to ask questions, clarify concerns and provide feedback. Furthermore, investment in regular training sessions would ensure new staff members are educated and serve as a refresher for existing staff. It is the understanding of the researcher that management staff in Interventional Radiology are designing a study day for nursing staff involved in the care of vascular patients. Based on the findings from this research, implementing such an initiative would prove to be highly beneficial and would enhance the use of evidence-based practice in this area.

These implications are simplistic and already have a solid foundation in Waikato Hospital. However, the importance of these strategies has been overlooked in this particular area. As a result, health professionals in Interventional Radiology and Ward M14 have been left feeling disillusioned and frustrated by the pre-procedural blood glucose cut-off level. The findings from this study highlight the importance of each component in the process of evidence-based practice. Locating and evaluating relevant evidence to address a clinical problem and improve patient care is the foremost aspect of evidence-based practice. However, barriers must be addressed, and tangible support must be provided to facilitate the successful incorporation of evidence into 'real world' healthcare environments.

6.8 Future research

This research explored the use of evidence-based practice in Interventional Radiology and the dissemination of evidence to Ward M14 at Waikato Hospital, specifically concerning blood glucose requirements for vascular patients undergoing peripheral angioplasty. It was established that the evidence underpinning this requirement was based on the extrapolation of cardiology research, which indicated that pre-procedural hyperglycaemia was an independent risk factor for contrast-induced nephropathy following coronary angioplasty. As such, this association was explored concerning vascular patients undergoing peripheral angioplasty in this study. While an association between pre-procedural blood glucose levels and creatinine levels was observed, it was

not statistically significant due to the limited sample size. Furthermore, it did not establish whether the 11 mmol/L blood glucose cut-off was warranted in this setting. Future research is needed to explore this association further and validate whether strict glucose control in vascular patients could reduce the incidence of contrast-induced nephropathy following a peripheral angioplasty.

Appendices

Appendix 1: Phase I standardised data collection tool

Appendix 2: Phase II semi-structured interview questions

Appendix 3: Participant information sheet

Appendix 4: Participant consent form

Appendix 5: The University of Waikato ethics approval

Appendix 6: Te Whatu Ora – Waikato research approval

Appendix 7: Te Puna Oranga Māori Research Review Committee endorsement

Appendix 1: Phase I standardised data collection tool

PROJECT TITLE: **EXPLORING HOW EVIDENCE IS INCORPORATED INTO PRACTICE WITH A PARTICULAR FOCUS ON BLOOD GLUCOSE REQUIREMENTS FOR VASCULAR PATIENTS WITH PERIPHERAL ARTERY DISEASE UNDERGOING PERIPHERAL ANGIOPLASTY**



THE UNIVERSITY OF
WAIKATO
Te Whare Wānanga o Waikato

Researchers:

Delia Linton (Principal Investigator)

Professor Matthew Parsons (Academic Supervisor)

Nicola Syrett-Nyika (Clinical Supervisor)

Clinical Notes Data Collection Tool

Patient National Health Index (NHI) number: Admission & discharge dates:
Gender
Ethnicity
Age
Type of diabetes mellitus
Presence of chronic kidney disease
Diagnosis
Procedure details (type, date, time)
Most recent HbA1c level
Pre-procedure creatinine level
Post-procedure creatinine level
Blood glucose level immediately prior to procedure
Outcomes

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Appendix 2: Phase II semi-structured interview questions

PROJECT TITLE: **EXPLORING HOW EVIDENCE IS INCORPORATED INTO PRACTICE WITH A PARTICULAR FOCUS ON BLOOD GLUCOSE REQUIREMENTS FOR VASCULAR PATIENTS WITH PERIPHERAL ARTERY DISEASE UNDERGOING PERIPHERAL ANGIOPLASTY**



Researchers:

Delia Linton (Principal Investigator)

Professor Matthew Parsons (Academic Supervisor)

Nicola Syrett-Nyika (Clinical Supervisor)

Interview Questions for Health Professionals

1. Can you tell me about yourself?
 - What is your role?
 - What are your qualifications?
 - How long have you been working in your current area?

2. What is your perspective on optimal pre-procedural BGLs and the requirement for BGLs to be <10mmol/L prior to peripheral angioplasty?
 - What is the history behind this requirement? When and why was it started? Was there a different policy beforehand?
 - What was the rationale for this requirement?
 - What published evidence was this based on?
 - Are there policies around target BGLs ranges prior to peripheral angioplasty?
 - Have optimal pre-procedural BGLs been explored further?
 - Do you know if this requirement is used in other departments at Te Whatu Ora, i.e., Cathlab, CT, Theatre? Or in other IR services around the country or overseas?

3. Are you aware of any adverse reactions related to BGLs >10mmol/L during and/or after peripheral angioplasty?
 - If yes, what are they? How are they linked to elevated BGLs?
 - Are you aware of any specific assessments / monitoring that is routinely completed for diabetic patients before and after peripheral angioplasty, i.e., routine blood tests, extra insulin doses, NBM status, insulin infusions, specifically monitoring creatinine?

4. How does the requirement for BGLs to be <10mmol/L impact on patients' overall health outcomes?
 - Do you think this requirement has a positive or negative impact on patients' overall health outcomes, i.e. longer length of stay, delayed procedures, poorer limb outcomes?
 - Do you think Māori and Pacific patients are more likely to be impacted by this requirement?

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5. Are patients' angioplasties often postponed due to BGLs >10mmol/L?
 - Does it happen often, or just once in a while?
 - What kind of impact do delayed procedures have on your patients, i.e., frustration at staff / health system / longer hospital admissions / delayed wound healing?
 - What kind of pressures does this place on your department / staff?
6. What are the costs associated with postponing and rescheduling patients' angioplasties?
7. Evidence around clinical practice changes rapidly. How do you locate and incorporate evidence into your clinical practice?
 - How do you locate and review new evidence relevant to your clinical area, i.e., in-services, emails, policies/guidelines, independent searches?
 - How do you find time to review new evidence? Do you find this difficult?
 - How do you incorporate new evidence into your practice?
 - How do services communicate new/relevant evidence to each other?
 - Do you think new evidence is easily incorporated into practice in your service, and other services you work with?
 - Do you think policy and guidelines have a role in communicating evidence to others? If so, have you found it an effective tool within your service/services you work with?
 - In an ideal world, how would you like to see this done?
 - Do you have any recommendations to help medical and nursing staff locate new evidence and implement it into their practice?

Appendix 3: Participant information sheet

PROJECT TITLE: EXPLORING HOW EVIDENCE IS INCORPORATED INTO PRACTICE WITH A PARTICULAR FOCUS ON BLOOD GLUCOSE REQUIREMENTS FOR VASCULAR PATIENTS WITH PERIPHERAL ARTERY DISEASE UNDERGOING PERIPHERAL ANGIOPLASTY



Researchers:

Delia Linton (Principal Investigator)
 Professor Matthew Parsons (Academic Supervisor)
 Nicola Syrett-Nyika (Clinical Supervisor)

Participant Information Sheet

Researcher Introduction

My name is Delia Linton, and I am a registered nurse working in the cardio-thoracic and vascular ward (M14) at Waikato Hospital. I am currently completing the Honours Programme through the Te Whatu Ora Waikato and the University of Waikato. I will be working alongside Professor Matthew Parsons and Nicola Syrett-Nyika to complete this project.

Project Invitation and Description

We invite you to participate in a research study exploring the optimal blood glucose levels for patients with diabetes mellitus proceeding to peripheral angioplasty. The study will commence in August 2022 and finish in July 2023. Before you decide whether to participate in this study, it is important that you understand more about the research and what participation involves. In order to help you make your decision, please read this information sheet carefully.

The primary rationale for this research project is to better understand how pre-procedural blood glucose levels impact peripheral angioplasties, including complications during procedures, cancellations, adverse reactions and patient outcomes. The study has two phases; the first seeks the views and opinions of up to 12 people working within the vascular and interventional radiology services at Te Whatu Ora Waikato and the second is to conduct a clinical audit of patient notes who have undergone a peripheral angioplasty.

If you would like to participate, the researcher will arrange a time for an interview. The interviews will take place at Waikato Hospital in a quiet area and will take approximately 30 minutes. The interview will be recorded using an audio recorder and will later be transcribed. Your participation is entirely voluntary, and you will be provided with a consent form at the beginning of the interview.

Project Results

The findings of this study will be used to complete a Bachelor of Nursing (Honours) research thesis. The results may also be used for reports and publications for Te Whatu Ora Waikato. If you would like to receive a summary of the findings of this research, please indicate this on the consent form that will be provided to you before the interview commences.

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Researchers:
Delia Linton (Principal Researcher)
Professor Matthew Parsons (Academic Supervisor)
Nicola Syrett-Nyika (Clinical Supervisor)

Anonymity/Confidentiality/Risk

Taking part in this study is voluntary. Whether you decide to take part or not will have no effect on your employment at Te Whatu Ora Waikato. Your personal information and interview will be kept separately on a password-protected computer, and you will be assigned a pseudonym/code for data analysis. It will not be possible to identify you in any reports from the research.

No risks have been identified from participating in this research. However, if through taking part in the interviews, you experience stress or anxiety, you will be encouraged to talk further with your line manager or contact EAP services if required.

Right to Withdraw from Participation

During the interview, you have the right to refuse to answer any question without giving a reason. You have the right to withdraw your consent to participate at any time during the interview without giving a reason. Following your interview, you will receive a copy of your transcript. You will have the opportunity to amend your interview transcript and remove any traceable data from the study for up to two weeks after receiving your transcript. You can also withdraw your consent to participate in the study at any time up to two weeks after receiving your interview transcript by emailing the researcher. You do not need to give a reason for choosing to withdraw from the study. You can ask questions about the study at any time, either to the person organizing this study or if you wish to talk to someone not involved in this study, you have the right to raise ethical questions or report concerns with the University of Waikato Human Participants Ethics Committee.

Data Storage/Retention/Destruction

Participants' personal information and interview transcripts will be kept separately on a password-protected computer, and the information will be assigned a code for data analysis. The audio recording of your interview will be stored on a password-protected computer at The University of Waikato, and only the researchers will be able to access it. After one year, it will be destroyed. The transcript of your interview will be stored on a password-protected computer at the University of Waikato, and only the researchers will be able to access it. It will be destroyed after six years. Your signed consent form will be kept in a locked cabinet at The University of Waikato, and only the researcher will have access to it. It will be destroyed after six years. Thank you very much for your time and help in making this study possible. Should you require any further information, please do not hesitate to contact us.

PROJECT TITLE: EXPLORING HOW EVIDENCE IS INCORPORATED INTO PRACTICE WITH A PARTICULAR FOCUS ON BLOOD GLUCOSE REQUIREMENTS FOR VASCULAR PATIENTS WITH PERIPHERAL ARTERY DISEASE UNDERGOING PERIPHERAL ANGIOPLASTY



Researchers:

Delia Linton (Principal Researcher)

Professor Matthew Parsons (Academic Supervisor)

Nicola Syrett-Nyika (Clinical Supervisor)

Funding

The researcher received Health Workforce Directorate, Te Whatu Ora Waikato, post-graduate funding to complete a Bachelor of Nursing (Honours).

Approval Statement

"This research project has been approved by the Human Research Ethics Committee. Any questions about the ethical conduct of this research may be sent to the Secretary of the Committee, email fass-ethics@waikato.ac.nz, postal address, Faculty of Arts and Social Sciences, Te Kura Kete Aronui, University of Waikato, Te Whare Wananga o Waikato, Private Bag 3105, Hamilton 3240."

Contact Details:

Delia Linton

Email: delia.linton@waikatodhb.health.nz

Te Whatu Ora Waikato

Professor Matthew Parsons

Email: mparsons@waikato.ac.nz

Phone: +64 21 753 204

Te Whatu Ora Waikato / The University of Waikato

Nicola Syrett-Nyika

Email: nicola.syrett@waikatodhb.health.nz

Phone: +64 21 801 678

Te Whatu Ora Waikato

Appendix 4: Participant consent form

PROJECT TITLE: EXPLORING HOW EVIDENCE IS INCORPORATED INTO PRACTICE WITH A PARTICULAR FOCUS ON BLOOD GLUCOSE REQUIREMENTS FOR VASCULAR PATIENTS WITH PERIPHERAL ARTERY DISEASE UNDERGOING PERIPHERAL ANGIOPLASTY



Researchers:

Delia Linton (Principal Investigator)
 Professor Matthew Parsons (Academic Supervisor)
 Nicola Syrett-Nyika (Clinical Supervisor)

Participant Consent Form

Name of Participant: _____

- I have received a copy of the Information Sheet describing the research project. Any questions that I have, relating to the research have been answered to my satisfaction. I understand that I can ask further questions about the research at any time during my participation or by contacting the researcher and/or the researcher's supervisors.
- I am aware that I can withdraw my participation at any time during the interview without giving a reason and at any time up to two weeks after receiving my interview transcript by emailing the researcher.
- During the interview, I understand that I do not have to answer questions unless I am happy to talk about the topic. I can stop the interview at any time and ask to have the recording device turned off at any time.
- I understand that my identity will remain confidential in the presentation of the research findings.
- I understand that I can request a summary of the findings of this research.
- My participation in this study is voluntary.
- I agree to take part in this study under the conditions set out in the Information Sheet.

Please complete the following checklist by ticking [✓] the appropriate box.	YES	NO
I wish to receive a copy of the research findings. (If yes, please include an email address below).		

Participant: _____ Researcher: _____
 Signature: _____ Signature: _____
 Date: _____ Date: _____
 Contact Details: _____ Contact Details: _____

Appendix 5: The University of Waikato ethics approval

The University of Waikato
Private Bag 3105
Gate 1, Knighton Road
Hamilton, New Zealand

Human Research Ethics Committee
Roger Moltzen
Telephone: +64021658119
Email: humanethics@waikato.ac.nz



23 August 2022

Delia Linton
Te Huataki Waiora – School of Health
DHECS
By email: dl260@students.waikato.ac.nz

Dear Delia

HREC(Health)2022#28 : Exploring Optimal Blood Glucose Levels for Patients with Diabetes Mellitus Proceeding to Peripheral Angioplasty

Thank you for your responses to the Committee feedback.

We are now pleased to provide formal approval for your project.

Please contact the Committee by email (humanethics@waikato.ac.nz) if you wish to make changes to your project as it unfolds, quoting your application number with your future correspondence. Any minor changes or additions to the approved research activities can be handled outside the monthly application cycle.

We wish you all the best with your research.

Regards,



Emeritus Professor Roger Moltzen MNZM
Chairperson
University of Waikato Human Research Ethics Committee

Appendix 6: Te Whatu Ora – Waikato research approval

Waikato

Te Whatu Ora
Health New Zealand

Management and Resource Sign-offs

This study does not require HDEC review.

Locality Review – *the undersigned agree to the following statements:*

- The study protocol and methodology are ethical and scientifically sound.
- This researcher has identified that this study does not require Health & Disability Ethics Committee (HDEC) review.
- The local lead investigator is suitably qualified, experienced, registered and indemnified.
- Resources, facilities and staff are available to conduct this study, including access to interpreters if requested.
- Cultural consultations have occurred or will be undertaken as appropriate
- Appropriate confidentiality provisions have been planned for.
- Appropriate arrangements are in place to notify other relevant local health or social care staff about the study, and for making available any extra support that might be required by participants, where relevant.
- Conducting this research will have no adverse effect on the provision of publicly funded healthcare.
- There is a stated intent that the results of the study will be disseminated and where practical and appropriate the findings of the study will be translated into evidence based care.

Clinical Support Services Sign-offs

CROSS OUT/ADD SIGN-OFFS APPLICABLE TO THIS PROJECT

SIGNATORIES DECLARATION: We agree that appropriate resources are available in our service to support this project

Clinical Support Service	Name	Signature	Date signed
Pharmacy	Rajan Ragupathy OR Jieun Bae		
Pharmacy	Julie Vickers OR Jan Goddard		
Laboratory	Kay Stockman		
Radiology	Leigh Harvey		

RD022076 Blood Glucose Angioplasty (Linton) (1)

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Waikato

Te Whatu Ora
Health New Zealand

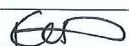
Medical Records Denise Jon  20/09/2022

Department/Service Sign-off

Dept/Servi ce/Org	Role	Name	Signature	Date signed
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As Clinical Director/Clinical Unit Leader, by signing this I confirm

- I have discussed the research project and resource implication for this department with the principal investigator and that the Principal Investigator has discussed these resource implications with any affected services / staff members.
- All researchers/students from the department involved in the research project have the skills, training and experience necessary to undertake their role.
- I support the research project being conducted; and confirm there are suitable and adequate facilities and resources for the research project to be conducted at this site.

Surgical	Nurse Director	Kim Holt		21/09/22.
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As Director / Executive Director, by signing this I confirm:

- All costs incurred by Waikato Unit/Service in regard to the research project are included in an approved research budget (including those costs which will be incurred by contributing units, eg laboratory). For studies involving researcher time only, the researcher has the time to undertake the study.
- Research is not commenced until all required approvals have been obtained.

Surgical & Director Critical Care		Michelle Sutherland		22/09/2022
Hospital & Community	Executive Director	Chris Lowry		23/9/22
Te Puna Oranga	Māori Research Review Ctte	Nina Scott	See attached letter	N/A

Please return to the Research Office (via Sarah Brodnax, Level 2 Hockin) along with required documents as identified in the checklist for final approval.

Office use only:

Quality & Patient Safety, Waikato

It is the responsibility of the Director of Quality & Patient Safety or Chief Medical Officer to ensure that the research approval process has been followed, that required internal and external approvals are evident and that the research project fits within the strategic direction of Waikato.

Signature:  Date: 9/11/2022

Waikato

Te Whatu Ora
Health New Zealand

Name: MARGARET FISHER Position: CMO

Appendix 7: Te Puna Oranga Māori Research Review Committee endorsement



Waikato

Te Whatu Ora
Health New Zealand

Te Puna Oranga Māori Research Review Committee

19 September 2022

Re: Māori Consultation for 'Exploring Optimal Blood Glucose Levels for Patients with Diabetes Mellitus Proceeding to Peripheral angioplasty'.

Name of Applicant: Delia Linton

Tēnā Koe Delia,

Thank you for submitting the above research proposal to the Te Puna Oranga Māori Research Review Committee for Māori consultation. The research application has been reviewed in order to support and prompt the researcher to think about how this research will improve health outcomes and eliminate inequity for Māori living within the Waikato region.

1. The Committee acknowledges the researchers for collecting ethnicity data as part of a demographic background of the participant to improve data collection for Māori in order to improve Māori health outcomes and reduce inequity for Māori.
2. The Committee encourages the research team to actively recruit equal numbers of Māori and Non-Māori. Any Research that involves Māori participation would require sufficient face to face time for fully informed consent to occur. Inclusion of the whānau of the Māori participant should be encouraged to support the continued engagement of the Maori participant in the research process.
3. The Committee encourages all research that involves participation of individuals, especially Māori participants to fully inform them regarding the detail of tissue collection. One consent form for the current use of Tissue. One consent form for the future use of tissue (this should be clear to the participant).
4. Studies using retrospective data must respect Maori data as outlined in Te Mana Raraunga: **5.1 Respect**. *The collection, use and interpretation of data shall uphold the dignity of Māori communities, groups and individuals. Data analysis that stigmatises or blames Māori can result in collective and individual harm and should be actively avoided.*

Reference: Te Mana Raraunga: Principles of Māori Data Sovereignty. Brief #1 | October 2018.

<https://static1.squarespace.com/static/58e9b10f9de4bb8d1fb5ebbc/t/5bda208b4ae237cd89ee16e9/1541021836126/TMR+Ma%CC%84ori+Data+Sovereignty+Principles+Oct+2018.pdf> (Accessed August 2019)

5. If cultural issues arise for the Māori participant during any research, they will inform the research team during the study that an issue has occurred. Cultural issues may not be obvious to the participant or the researcher prior to commencement of the research.
6. The Committee encourages the research team to continue to consult with Te Puna Oranga, Māori Health service at any time, should they have any further queries.
7. Feedback regarding this research is appreciated and can be shared back to the Kaunihera Kaumatua via Te Puna Oranga Māori Health Service

The Committee endorses this research proposal with the consideration of the above cultural recommendations where appropriate and requests the researcher to collect ethnicity data for all study participants seen at Waikato hospitals for our own internal records.

Dr Nina Scott
Te Puna Oranga-Maori Health Service

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