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How evidence-based clinical practice guidelines for Venous Leg Ulcers impact on patient safety.

A thesis submitted to the School of Nursing & Midwifery, National
University of Ireland, Galway in fulfilment of the requirements for the
award of the degree of Doctor of Philosophy.

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Declaration

I, Justin Kerr, declare that this work is submitted to fulfil the requirement of the degree of Doctor of Philosophy at the National University of Ireland Galway. I have not obtained a degree in the National University of Ireland Galway, or elsewhere, based on the work completed in this thesis. I am the author of this thesis and the principal author of the included manuscript.

Signature:

A handwritten signature in black ink, appearing to read "Justin Kerr", written in a cursive style.

Date: June 2022

Core Modules

This dissertation is submitted to the School of Nursing & Midwifery, National University of Ireland, Galway in fulfilment of the requirements for the degree of Doctor of Philosophy [Structured PhD].

Five core modules (90 ECTS) were completed in years 1-3 of the programme in fulfilment of the requirements for the degree of Doctor of Philosophy [Structured PhD] as follows:

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NU636	Health Economics & Influencing Policy	20
NU639	Systematic Review & Research Synthesis	20
NU1103	Leadership & Interprofessional Collaboration	20
NU1104	Research Practice	10

Publications and Presentations

Publication

Kerr J, Devane D, Ivory J, Weller C, Gethin G. Effectiveness of implementation strategies for VLU guidelines: A systematic review. *J Tissue Viability*. 2020 Aug;29(3):161-168. doi: 10.1016/j.jtv.2020.03.002. Epub 2020 Mar 13. PMID: 32340716.

Oral Presentation

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Abstract

Introduction

Patient safety is central to nursing practice. It is the connecting term in the Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives in Ireland (NMBI, 2021). However, it would appear that patient safety remains rooted in the avoidance of harm by minimising errors from actions. The author explores the concept of patient safety from the perspective of omission of care, particularly with regards to the application of national evidence-based clinical practice guidelines in patients with Venous Leg Ulcers (VLUs). This approach has not been considered before in a community setting with this patient cohort. It, therefore, contributes to the body of knowledge on patient safety. This thesis aims to ascertain if evidence-based clinical practice guidelines impact on patient safety in patients with VLUs. This work is structured around the Framework for patient safety research and Improvement (Pronovost et al., 2009).

Aim

The overall aim of this research thesis is to determine how evidence-based clinical practice guidelines for Venous Leg Ulcers impact on patient safety.

Objectives

- [1] To systematically review the literature to identify the most effective strategies to implement VLU guidelines.
- [2] To explore the safety attitudes of Public Health Nurses (PHNs) and Community Registered General Nurses (CRGNs) in the Republic of Ireland.
- [3] To understand the alignment of current practice in the management of VLUs against a national guideline amongst PHNs & CRGNs in Ireland.
- [4] Identify if PHNs and CRGNs consider clinical practice guidelines influence patient safety.

Methods

The Framework for Patient Safety Research and Improvement was the framework used to underpin this research. The framework was developed by Pronovost et al. (2009) to respond to an increasing need for improvements and progress in patient safety. The framework includes five domains:

- i) Evaluating progress in patient safety
- ii) Translating evidence into practice
- iii) Measuring and improving culture
- iv) Identifying and mitigating hazards
- v) Evaluating the association between organisational characteristics and outcomes.

A variety of research methods were used to deliver on the framework. A comprehensive literature review (Chapter 2) was undertaken to examine the progress in patient safety. The author then undertook a systematic review (Chapter 4) to explore the effective implementation strategies for the implementation of venous leg ulcer guidelines to understand the best methods to translate evidence into practice. A safety attitudes questionnaire (Chapter 5) was used to examine the attitudes of PHNs and CRGNs towards safety culture and climate and it was important to ascertain if published evidence based clinical practice guidelines are used in practice. This was followed by a panel group discussion (Chapter 6) to explore the findings from the survey, which was informed by the literature review. The data from the survey was analysed using a number of statistical techniques and the qualitative data from the survey and the panel discussion was analysed using directed content analysis.

Key findings

The key findings in this study reflect the view that patient safety is central to nursing practice. It also confirmed that within the Republic of Ireland CPGs do inform how PHNs and CRGNs deliver nursing care. Themes such as dissemination and implementation must be considered if we are to maintain and improve standards of care through evidenced based practice. While the findings do acknowledge that patient safety appears to be central to nursing work the results do reflect a passivity in practice in accepting the status quo – i.e.,

as to how things are done: particularly in relation to the structure and process of care, potentially resulting in delayed care.

Conclusion

It is the case that nurses do not practice with the intention to harm their patients and that patient safety remains at the core of the work that nurses do; the finding from the questionnaire and the panel discussion reflected this while recognising the challenging environments in which they practice. Patient safety is an important concept that has been underexplored in the community/PHN practice setting. If we are to expand the perimeter of patient safety as we currently understand it is important to understand the context in which care is delivered and the professional constructs in how care is delivered.

Unforeseen circumstances

There were unforeseen situations that were beyond the control of the author. These are presented at the end of the thesis, namely the onset and impact on the thesis of the global Covid 19 pandemic, a cyber-attack on the HSE and a cyber-attack on the National University of Ireland Galway.

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Firstly, I want to thank my primary supervisor Professor Georgina Gethin. Professor Gethin has been a constant support throughout this entire journey. Professor Gethin's expertise is remarkable and delivered with interest, understanding, enthusiasm and care; she had such generosity of spirit when things got tough.

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I thank all the respondents to the questionnaire and the panel members who were so generous of their time. I appreciate this study was undertaken at the peak of the COVID-19 pandemic, yet they so generously supported this work, and for that, I am grateful.

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I thank the Atlantic Technological University for the support in funding this PhD and my colleagues for their encouragement.

I thank my parents Michael Kerr (RIP) and Una Kerr (RIP), for encouraging me to pursue my dreams.

Lastly, and most importantly, I thank my wife, Yvonne, who has been a constant, unwavering support throughout this entire journey. This simply would not have been possible without her. I thank my two boys, Ryan, and Evan, who have unknowingly sacrificed so much of their time, I promise I will make it up! and I hope this work answers their question, *'How can one person have so much homework!'*

Glossary of Terms

Community Registered General Nurses: are registered nurse who support and contribute to community services.

Nurse Practice Development Coordinator: The role of the Nursing Practice Development Coordinator (NPDC) is to ensure the highest standard of patient focused care throughout the service through leading and managing practice development projects.

Public Health Nurses: are registered nurses with a specialist nursing qualification. They provide the core nursing and midwifery care in the community.

List of Abbreviations

ABPI	Ankle brachial pressure index
ADPHN	Assistant Director of Public Health Nursing
AWCP	Advanced wound care practitioner
CPG	Clinical Practice Guideline
CRGN	Community Registered General Nurse
DVT	Deep vein thrombosis
EPOC	Effective Practice and Organisation of Care
EU	European Union
GCP	Good Clinical Practice
GP	General Practitioner
HSE	Health Service Executive
IOM	Institute of Medicine
NPDC	Nurse Practice Development Coordinator
PHN	Public Health Nurse
SAQ	Safety Attitudes Questionnaire
SIGN	Scottish Intercollegiate Guideline Network
UK	United Kingdom
USA	United States of America
VLU	Venous Leg Ulcer
WHO	World Health Organisation

Dedication

This work is dedicated to my sons, Ryan, and Evan. They were much younger when I started this journey and believe anything is possible...

and to my wife Yvonne for making it all possible.

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Chapter 1 **Introduction**

1.1 Chapter Introduction

The purpose of this chapter is to introduce this thesis. The author will briefly introduce the origins of this study, how his experience from practice informed it, and why it was considered essential to undertake this study. This chapter will contain an outline of the main elements of the study, i.e., patient safety, clinical practice guidelines and Venous Leg Ulcers (VLUs). It will include a short overview of the chapters to follow and outline the structures therein.

1.2 Origins of the study

The author is a registered nurse who has worked in the acute hospital sector for many years, particularly in Emergency Nursing. The author recently transferred to the education sector, having undertaken administrative and management roles, including nursing and general management positions, clinical risk management, and nurse practice development. The latter roles spurred an interest in patient safety, expanded practice, and clinical practice guidelines (CPGs). Having worked as a Clinical Risk Manager for an acute general hospital, it was clear from ongoing trend analysis that most patient safety reports resulted from deviations from existing clinical practice guidelines, policy documents or standard procedures, or a disregard for policies and procedures and guidelines within the unit. It was often the case that it was not the custom and practice within a unit or a department to routinely refer to policy or guideline documents.

For many years, the author chaired a Nursing Policy, Procedure, and Guideline committee to review practice documents, and occasionally new policy documents were created following patient safety events. The author was seconded to chair a working group to develop a new national CPG; namely the Health Service Executive (HSE) National Policy for the administration of intravenous medication by registered nurses and midwives. The new guideline was to support the expansion of the scope of practice for registered nurses across all practice settings. It became apparent during this work that a narrative concerning practice that was not based on evidence remained the dominant narrative, and therefore practice remained unchanged. This was surprising and disappointing given two years of work and a solid

evidence base for a change of practice that would have improved the patient experience, improved patient outcomes, and improved patient safety through the appropriate application of evidence-based care. This highlighted an issue regarding the implementation of the guideline document. On reflection, it was evident that an implementation strategy got much less attention than creating the evidence base to inform the new practice.

It is well regarded that evidence-based practice is not implemented widely in routine practice, and nurses rely on experience more so than research and protocols (Friesen-Storms, Moser, van der Loo, Beurskens, & Bours, 2015). Given the authors experience from clinical practice in emergency nursing and experiencing first-hand the revolving door of patients admitted from the community, coupled with experience in risk management and patients safety, it important to explore the relationship of evidence-based guidelines and patient safety in much closer detail.

1.2.1 Patient Safety

Research into patient safety by its very nature has many layers to it (Gallego et al., 2012). Patient safety is a complex and abstract concept. Although it is recognised that the concepts associated with patient safety are broadening (Vincent & Amalberti, 2015); it is noted that the terms associated with patient safety remain firmly rooted in descriptions such as harm, adverse events and incidents all of which reflect an action of doing something untoward as opposed to reflecting any omission in care - a key focus of this thesis.

The World Health Organisation (WHO) recognises that patient safety is a global health concern and in high-income countries, one in 10 patients is harmed while receiving hospital care caused by various adverse events, with as many as half being preventable (WHO, 2019). It is acknowledged that most of the research into patient safety has taken place within the acute hospital sector resulting in little understanding about what needs to happen to improve safety in primary and community care (World Health Organisation, 2016). For this thesis, the author will explore patient safety in the community setting as this is the environment where the care of this patient group takes place.

Chapter 1 Introduction

Several key international authors and key opinion leaders have influenced the development of the patient safety agenda and have been recognised as ‘Gurus’ elsewhere (Pedersen, 2017) they will be referred to throughout this thesis, they include but are not limited to Don Berwick, founder and ex-President and CEO of the Institute of Healthcare Improvement (IHI) in the United States of America (USA); Lucian Leape, Harvard Professor and member of a number of key patient safety committees and agendas; James Reason creator of the Swiss Cheese Model, the dominant model for accident causation used in aviation and healthcare; Professor Charles Vincent Emeritus Professor Clinical Safety Research, Imperial College London; Avedis Donabedian former physician and researcher and creator of the Donabedian Model of quality improvement in healthcare and Professor Eric Hollnagel recognised for his work in progressing the patient safety agenda.

1.2.2 Clinical Practice Guidelines

CPGs offer an evidence-based approach for nursing, medical and other healthcare professionals in order to improve health outcomes through establishing standards of practice for care and to support improved clinical decision making and promote cost effective interventions (Maccatrozzo, Onida, & Davies, 2017). The main aims of CPGs are to:

- *“Synthesize and translate the highest quality of evidence into practice recommendations*
- *Optimize treatment outcomes and reduce the use of any harmful or unnecessary interventions*
- *Establish standards of care and reduce inappropriate practice variation*
- *Facilitate shared decision making among physicians, patients, and their caregivers*
- *Inform policymakers in their decisions about the allocation of health care resources” (Tetreault et al., 2019, p. 54S)*

There are a plethora of guiding documents available that direct the reader in the care and management of VLU, including the European Wound Management Association publication “Management of Patients with VLU: Challenges and current best practice” (Franks et al., 2016), The Scottish

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Intercollegiate Guidelines document “Management of chronic VLUs” (Scottish Intercollegiate Guidelines Network, 2010), the “Australian and New Zealand Clinical Practice Guideline for Prevention and Management of VLUs “ (Australian Wound Management Association, 2011) and the HSEs “HSE National Wound Management Guidelines 2018”.

Maccatrozzo et al. (2017) note that one would expect consensus across guidelines in the management and treatment of VLU’S given the prevalence and chronic nature of the condition. However, despite the availability of guidelines in the management and treatment of VLUs significant heterogeneity exists across the recommendations (Franks et al., 2016; Maccatrozzo et al., 2017).

1.2.3 VLUs

VLUs are the most common cause of lower limb ulceration in community settings (Weller, Team, Ivory, Crawford, & Gethin, 2018), resulting in a significant burden to the healthcare care system and the individual patient. Patients report feeling isolated, embarrassed, negative emotions, loss of sleep, loss of self-worth, anxiety and depression (Raffetto, Ligi, Maniscalco, Khalil, & Mannello, 2020).

Although delayed or difficult healing is experienced in practice, and there is an extremely high rate of recurrent ulceration in this patient group (Raffetto et al., 2020; Ratliff, Yates, McNichol, & Gray, 2016), wounds can heal with good evidence-based care (Raffetto et al., 2020). Correctly applied compression therapy is the cornerstone of treatment for VLUs (Andriessen et al., 2017; Kelechi et al., 2020; Ratliff et al., 2016).

However, the overall management of patients with Chronic Venous Disease (CVD) and VLUs remain less than adequate (Kelechi, Johnson, & Yates, 2015; Tan, Luo, Onida, Maccatrozzo, & Davies, 2019). This is despite decades of work focussing on the causes, treatment, management, and prevention of chronic venous disease (CVD), resulting in consensus statements, national and international evidence-based CPGs. Perhaps more importantly, given the understanding that VLU’s have a significant detrimental effect on the patient's individual life suffering from a VLU,

patients are still not receiving evidence-based care (Franks et al., 2016; Weller et al., 2020).

1.3 Gaps in care

There is a gap in the care that patients receive and the utilisation of available evidence for given conditions or illnesses; it is referred to as the Knowledge Translation (KT) gap (Gaddis, Greenwald, & Huckson, 2007) this is further acknowledged where very recently Eckert & Carter assert that there is a “glaring gap between evidence and clinical practice” (Eckert & Carter, 2021, p. 328).

The author can source no evidence of the relationship between the use or lack of use of CPGs and patient safety in the community, albeit CPGs are considered one of many levers to improve patient safety (Nieva & Sorra, 2003). Specifically, concerning VLUs, the value of developing and implementing CPGs for VLU management should be to improve the quality of care for patients (O'Donnell et al., 2014).

Fischer et al. (2016) report that approximately 30% - 40% of patients experience a treatment that is not evidence-based and that 20% - 25% of patients receive interventions that are harmful or not needed and they recommend that:

“ more research on the implementation of guidelines is needed to promote the systematic translation of current research evidence into routine practice... and that the focus of management and research in this area has changed from the development to the implementation of guidelines...and knowledge regarding appropriate strategies to implement guidelines remains sparse and no implementation strategy has been identified that is effective in all circumstances” (Fischer et al., 2016, p. 2)

The omission of standardised application of guidelines to practice may impact on patient safety. It is concerning that despite the extensive evidence regarding the treatment and management for VLUs, the ease of availability and access to national and international clinical practice guidelines, and the understanding we have of the impact that this condition has on patients, inconsistencies remain (Weller et al., 2020).

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A gap analysis exploring guidelines for the management of VLUs undertaken by Van Hecke et al (2008) identified that CPGs will have an important role in health care delivery. However, it noted that most of the guidelines that they reviewed did not consider dissemination and implementation in practice (Van Hecke, Grypdonck, & Defloor, 2008). Effective implementation plans should promote guideline adherence in practice and improve patient outcomes (Lugtenberg, Burgers, & Westert, 2009). Weller et al. (2020) recommend that implementation strategies are needed to maximise VLU guidelines in primary care practice. The implementation of CPGs can improve patient safety and improve the quality of care patients receive (Hovde, Jensen, Alexander, & Fossum, 2015). The author cannot source any studies that examine the impact of CPGs on patient safety in patients with VLUs this is important as it highlights the need for this study and to understand CPG's impact on patient safety in patients with VLUs.

1.4 Aim of the study

This study aims to identify how evidence-based clinical practice guidelines for Venous Leg Ulcers impact on patient safety.

1.4.1 Objectives

- [1] To identify the most effective strategies to implement VLU guidelines through a systematic review of the literature.
- [2] To explore through an online survey the safety attitudes of PHNs and CRGNs in the Republic of Ireland.
- [3] To ascertain from the survey results the alignment of current practice in the management of VLUs against a national guideline amongst PHNs in Ireland.
- [4] To identify if PHNs consider clinical practice guidelines influence patient safety, informed through the findings from the survey and the panel discussion.

1.5 Overview of following chapters

Chapter One offers an introduction to the thesis and provides an overview of the study. The rationale for the study is introduced and the aims and

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objectives are listed followed by an overall outline of how the thesis is organised.

Chapter Two presents a review of the literature. A literature search strategy is presented. The author then presents a comprehensive critical review of the literature in three distant chapter subsections: patient safety, CPGs, and VLUs. Donabedian's conceptual framework of structure process and outcome is explored in the context of this thesis.

Chapter Three presents an introduction to nursing research in the context of this study. The methodological approach taken in the context of nursing research is presented and will frame the research paradigm selected. The Framework for Patient Safety Research (Pronovost et al., 2009) is introduced.

Chapter 4 is presented in three distinct sections.

Section (A) provides an introduction, overview, and rationale for undertaking a systematic review.

Section (B) presents the preparation for the systematic review.

Section (C) presents of the final published manuscript.

Chapter 5 is divided into two distinct sections.

Section (A) - presents an introduction to survey research, and a rationale for this methodology is offered. An in-depth exploration of suitable questionnaires are presented, and a rationale for the final questionnaire is given. The issues of ethical approval, consent, validity, and reliability are discussed. Additional questions and the procedures in administering the survey are presented. The details on data collection presentation and data analysis are also provided.

Section (B) - presents the results in terms of response rates, respondent characteristics and demographics.

Chapter 6 provides an overview of the approach taken in engaging with the discussion panel. Verbatim responses are included as appropriate.

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Chapter 7 present an overall discussion and conclusion to this thesis. The strengths and limitations are defined and the implications for practice and implications for research are also outlined.

Chapter 8 provides a chronology of the Covid-19 pandemic, the cyber-attack on the HSE; the cyber-attack on the National University of Ireland Galway and their impact on the approaches in this study.

1.6 Chapter Summary

This chapter provided the introduction and rationale for this research study. The following chapter will provide a comprehensive review of the literature in relation to patient safety, CPGs and VLUs. They will be presented in three distinct subsections.

Chapter 2 Literature Review

2.1 Introduction

This chapter explores the literature from several areas related to the research question: Do clinical practice guidelines impact on patient safety in patients with VLUs? It aims to provide background to the research, identify gaps in the literature, and critically review what is known in this area.

Patient safety is not a new concept in health care or nursing. Indeed, patient safety is the connecting term in the Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives in Ireland (NMBI, 2021). Traditionally the terms adverse events and error are synonymous with patient safety. However, this work will not focus on adverse events or errors but on the broader elements of what contributes to patient safety and the role of CPGs. Pronovost et al., (2009) state that the omission of evidence based interventions may result in patients experiencing preventable harm and that capturing and reporting compliance with evidence based practice is important.

Evidence is abundant regarding the management of patients with VLU's; however, despite the availability of CPGs, implementation can be limited and inconsistent (Kelechi et al., 2020). The current health related burden of VLU is significant both for the patient and the health service. It is suggested that greater use of evidence-based care would result in significant financial savings and improve the care of patients (Kelechi et al., 2020; Phillips et al., 2020). It is essential, therefore, to undertake this research study now. It is important to ascertain if CPG's impact on patient safety in patients with VLUs.

A literature search strategy will be presented in section 2.2 and subsequently offers a structure to each of the three subsections of this literature review, namely:

- **Subsection 2.3** Patient Safety, page 13
- **Subsection 2.4** Clinical practice guidelines, page 35
- **Subsection 2.5** VLUs, page 44

Chapter 2 Literature Review

The literature review begins with an exploration of the elements associated with the CPGs - subsection 2.3 and presents these through the subheading of evidence-based practice leading into CPGs, guidelines repositories & grading systems and concludes with an understanding of the Appraisal of Guidelines for Research and Evaluations (AGREE).

The concept of patient safety is presented in subsection 2.4. It begins with presenting a brief historical context of patient safety, leading to an Irish context, and bringing the reader up to the present time. Definitions of patient safety are explored, and the relevant key concepts such as patient harm and safety culture are explained. While exploring the concept of patient safety, there was a strong interface between patient safety and quality; therefore, the relationship between safety and quality is briefly explored.

As VLUs are the clinical condition of interest in this study, subsection 2.5 will include a comprehensive overview of VLUs, including classification, anatomy and physiology epidemiology, and patients presentation. The recommendations contained within VLU guidelines will be presented from an international and a national perspective. The diagnostics, treatments, impact, and costs of VLU's will be considered.

2.2 Literature search strategy

This study aims to identify if clinical practice guidelines have an impact on patient safety. Specifically, the author explored this concept concerning the care of patients with VLUs.

The literature review continued to evolve throughout the development of the thesis. The major themes for the literature review have been taken from the research question, namely a) clinical practice guidelines, b) patient safety, and c) VLUs. It emerged from the literature review that there was an overlap between safety and quality; therefore, quality was explored as an extension of patient safety. It became apparent during the literature review that the application of CPG's to practice is underpinned by an evidence base supporting the delivery of quality care; therefore, an appreciation of the interconnectedness between CPG's, evidence-based practice, safety, and quality is important. Interestingly Smith & Valenta, (2018) report that it was

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only in 2013 that the term ‘patient safety’ was added as a term to the medical subject heading vocabulary as a MeSH term through the US National library of medicine.

The search strategy involved searching several electronic databases several times throughout the conduct of the study. The following electronic databases were searched: Cumulative Index to Nursing and Allied Health Literature (CINAHL 2000 - 2021), Medical Literature Analysis and Retrieval System Online (Ovid Medline 2000 – 2021), Excerpta Medica (Embase 2000 – 2021), Scopus, Cochrane Library and Google scholar using the advanced search methods appropriate to each database. Other PhD thesis were searched in the digital collection of open access scholarly publications from the National University of Ireland Galway (ARAN). The author explored reference lists of key articles and books to identify further relevant information. The date of the last search was November 2021.

Search terms used in the literature search for each of the main thematic areas based on the question were:

Clinical Practice Guidelines: Evidence based practice, clinical practice guidelin*, clinical guidelin*, polic*, Procedur*, guidelin*, Protoco*, standar*, pathway, CPG, CPGs, clinical consensus,

Patient Safety: patient safety, patient safety culture, safety culture, safety climate, risk management, patient harm, adverse event, public health, quality of care, quality of nurs*,

VLU: VLU*, Venous ulcer*, Leg Ulcer, VLU, Varicose ulcer, Venous insufficiency, compression

Given that VLUs are primarily managed in the community, the following terms were also included: community nurs*, public health nurs*, nurse specialist*, nurse practitioner*, tissue viability nurs*

The search was limited from 2000 onwards following the publication of the seminal report into medical error from the Institute of Medicine (IOM) in 1999. The search was limited to publications in English given that is the only language spoken by the author. There was no limitations in terms of study

Chapter 2 Literature Review

design or type of publication. The appropriate Boolean/search operators, proximity operators, truncation/wildcards, key words/MeSH terms/search by topic and phrase searching styles were used as appropriate to the database. Grey literature was searched in terms of national documents that may be of relevance

All references were managed in Endnote©.

2.3 Patient Safety

2.3.1 Defining patient safety

The term safety may be interpreted by most people as the absence of unwanted events such as incidents or accidents; the term safety is used in everyday language in healthcare and we assume that safety means the same thing to everyone and therefore the definitions of safety are rarely explored and considered (Hollnagel, Wears, & Braithwaite, 2015). It is important for this thesis that the author explores the definitions of patient safety and how they might relate to this thesis. Recognising the complexities associated with patient safety, Emanuel et al.,(2009) noted that

"...patient safety has become a discipline, complete with an integrated body of knowledge and expertise, and that it has the potential to revolutionize health care, perhaps as radically as molecular biology once dramatically increased the therapeutic power in medicine." (Emanuel et al., 2009, p. 13)

The term patient safety may conjure words such as harm, error, unsafe care, and adverse events and incidents (Jha, Prasopa-Plaizier, Larizgoitia, & Bates, 2010). The definitions of patient safety are vast and varied. The WHO recognises patient safety as:

"the prevention of errors and adverse effects to patients associated with health care" and "to do no harm to patients" (WHO, 2008).

A broader definition recognises patient safety as:

"a discipline in the health care sector that applies safety science methods toward the goal of achieving a trustworthy system of health care delivery. Patient safety is also an attribute of health care systems; it minimizes the incidence and impact of and maximizes recovery from, adverse events" (Emanuel et al., 2008).

Definitions of patient safety can be complex as the science and technology surrounding patient safety issues continue to grow and new definitions emerge. Measuring avoidable harm such as death rates, medication errors, including prescribing and administration errors, are more directly measurable areas of harm. Other areas of harm are not so straightforward and can be challenging to measure. Measuring less specific harm, such as non-adherence

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to practice guidelines and deviation from standard processes, are more challenging (Vincent, Burnett, & Carthey, 2013). More recently, harm in the context of patient safety can be considered as:

"impairment of structure or function of the body and/or any deleterious effect arising there from, including disease, injury, suffering, disability and death, and may be physical, social or psychological" (Cresswell et al., 2013).

The definition of patient safety offered by Vincent (2006), which the author considers particularly supports the focus of this thesis is:

"The avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare" (Vincent, 2006, p. 31)

Emanuel et al., (2009) recognise the personal nature of patient care and the progression of illness and acknowledge that failure to provide a correct intervention is considered every bit as much patient harm as well as the obvious harm of actions taken by health care practitioners and Mannion & Braithwaite, (2017) recognise the process of healthcare includes commission (active failure such as a medication errors) and omission of care (such as the failure to provide recommended care).

2.3.2 The international historical context of patient safety

It is essential to appreciate its emergence through an international historical context to understand patient safety. It is only in the last 25 - 30 years that medical error and patient safety have been acknowledged within medical and nursing professional practice, and terminology regarding medical error began to appear in journal texts (Vincent, 2010).

The 'Quality in Australian Health Care Study' was commissioned in New South Wales, Australia in 1994 to examine the proportion of hospital admissions associated with adverse events (Wilson et al., 1995). The report found that 16.6% of over 14,000 admissions to hospitals in the state of New South Wales were associated with adverse events. An adverse event is defined as: "An incident which results in harm to a patient" (WHO, 2008).

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The publication from the (IOM) in 1999 from the United States of America (USA) 'To err is human: building a safer health system' (Institute of Medicine, 1999) catapulted the notion of patient safety into the public domain, reporting that between 44,000 and 98,000 Americans die each year as a result of medical errors in hospital. This report acutely raised awareness concerning patient safety amongst healthcare professionals, politicians and the public at that time (Leape & Berwick, 2005). This report brought to prominence the significance of building a culture of safety in health care in order to protect patients from errors (Sorra, Khanna, Dyer, Mardon, & Famolaro, 2012).

Also, in the late 1990s in the United Kingdom (UK), several high-profile patient safety scandals gained attention at both an organisation and individual practitioner level. At an organisational level, the Bristol Royal Infirmary 'Bristol Heart Scandal' came to light where between 30 and 35 children died between 1991 and 1995. It is reported that approximately one-third of the children who received surgery at the hospital experienced sub-optimal care (Dyer, 2001). The report into the failings at Bristol Royal Infirmary noted that the most significant change needed was a change in organisational culture (Dyer, 2001). At an organisational and individual level for example The Lourdes Hospital Inquiry: an inquiry into peripartum hysterectomy at Our Lady of Lourdes Hospital, Drogheda, Ireland. Report of Judge Maureen Harding Clark S.C., / Department of Health & Children (Clark, 2006) investigated how the medical culture in Our Lady of Lourdes Hospital, Drogheda was different to other hospitals and how standards of maternity care were permitted to fall far below expected standards. This investigation also considered the practice of individual medical and nursing staff.

Following the IOM report and the scandals referred to above, a publication from the UK entitled 'An organisation with a memory: Report of an expert group on learning from adverse events in the NHS' (Donaldson, 2000) focused on establishing what was known concerning serious failures in the NHS. This led to establishing the National Patient Safety Agency (NPSA) in 2001. The NPSA was established to monitor patient safety incidents in the UK. A key aim of the NPSA was to promote incident reporting and the

Chapter 2 Literature Review

reporting of near misses in order to learn lessons from the reports and improve patient safety. A near miss is defined as: "an incident that did not cause harm" (WHO, 2008).

The National Reporting and Learning System (NRLS) was established in 2003 in the UK as part of the overall response to monitor and learn from incidents in England and Wales. The publication of 'An organisation with a memory' was considered a significant milestone on the patient safety agenda for England and Wales, resulting in measuring harm caused as a consequence of poorly managed or poorly delivered healthcare at a macro level (Vincent et al., 2013).

In 2004, the World Alliance on Patient Safety was formed through the WHO to raise awareness on the patient safety agenda to an international platform. In 2008 the Patient Safety First campaign was launched in the UK, with Australia and Ireland signing up to the principle 'to make the safety of patients everyone's highest priority' with the aim of the campaign to have no avoidable death and no avoidable harm.

In the years that followed, the UK, Australia and Ireland continued to monitor and respond to a variety of patient safety issues through various structures with findings on organisational culture a connecting theme in subsequent reports.

2.3.3 WHO

In March 2002, at the World 55th Healthcare Assembly, the WHO invited participating countries to pay close attention to the quality of care and patient safety agenda and recognised that "safety is a fundamental principle of patient care and a critical component of quality management" (World Health Organisation, 2002b) and recognised the need to standardise terminology associated with patient safety. The assembly passed the resolution WHA55.18 in May 2002. The assembly requested the Director-General of WHO, among other things, to promote framing of evidence-based policies that would improve patient care, with safe clinical practice in compliance with appropriate guidelines, considering the views of policy-makers, administrators and healthcare providers in developing global norms and

standards (World Health Organisation, 2002a). The World Alliance on Patient Safety was then launched in 2004 with the aim of facilitating the development of patient safety policy and practice in member states that would support a collaboration of knowledge and expertise to maximise the outputs required to improve the quality of care.

2.3.4 List of preferred terms and definitions for key concepts.

The WHO subsequently developed a conceptual framework for the International Classification for Patient Safety (ICPS) in order to promote learning in, and improve the patient safety agenda and to align patient safety concepts across the Member States (WHO, 2008), and to create a list of preferred terms and definitions of key concepts associated with patient safety Appendix 1.

2.3.5 Irish context of patient safety.

Noting the responses to patient safety concerns across the world as well as high profile publicised cases in Ireland such as The Lourdes Hospital Inquiry (Clark, 2006), the Health Information and Quality Authority (HIQA) was established in May 2007 as an independent organisation to promote quality and safety in public health and social services in Ireland. Its role is to develop standards, inspect and review health and social care services, and support informed decisions on how services are delivered (Health Information and Quality Authority, 2021).

It has been acknowledged in the Irish seminal report 'Building a culture of patient safety' (Madden, 2008), often referred to as the Madden Report that the care patients receive: "is not always consistent with evidence and so fails to secure the best possible outcomes" (Madden, 2008, p. 39).

The report contained 134 recommendations related to patient safety and quality of care in Ireland. It was delivered on behalf of the Commission on Patient Safety and Quality Assurance against a backdrop of patient safety incidents within the Irish health and social care sector.

Several national initiatives have continued to develop in Ireland since the publication of the Madden Report, with many initiatives outlined previously, including Patient Safety First.

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Patient safety continues to be a priority for the HSE. The HSE launched the first Board Patient Safety Strategy 2019 to 2024 in December 2019 (HSE, 2019), noting the patient safety initiatives that have taken place in the previous years and firmly stating the position to keep patient safety as a priority for the Irish health care system.

2.3.6 Progress in patient safety

Dr Charles Vincent, a leading authority in patient safety, accepts that much work has taken place and recognises where the developments and focus have been in the previous 20 years up to 2015; see Table 2-1

Vincent notes that harm remains the touchstone for patient safety but recognises that the umbrella terms for patient safety are now expanding and that the perimeter of safety is increasing to include areas that were previously considered consequences of care; to events which are considered preventable such as central line infections (Vincent & Amalberti, 2015).

Table 2-1 Progress in patient safety (Vincent & Amalberti, 2016)

	Where we were (1995)	Where we are now (2015)
Foundations	Incident reporting, continuous improvement, and development of best practice	Largely unchanged. More translation and use of industrial approaches to safety, increased attention to incident analysis, learning and feedback
Definition	Harm defined from a professional standpoint, rooted in a medico-legal and insurance perspective. Narrow vision of causality, direct association between technical care and harm	Patient safety still linked to a medico-legal perspective. Broader understanding of human error and organisational influences
Perimeter of Inclusion	Dominant technical vision of care, improved clinical protocols as main priority for improving safety	Recognition of the importance of human factors and human sciences. Organisational factors and safety culture are additional priorities for safety
Measurement	Counting incidents and adverse events	Largely unchanged

2.3.7 Safety-I and Safety-II

There is no question that patient care has become safer in the last 20 years, there have been reductions in common areas of harm, and there have been concerted efforts to measure and learn to improve patient safety. Ireland has played a significant role in progressing the patient safety agenda, particularly notable is that Ireland was the first country in the world to introduce a National Clinical Guideline for a National Early Warning Score (HSE, 2019) in order to quickly identify deteriorating patients. There are focussed efforts nationally and internationally in other areas of patient safety such as to reduce healthcare-associated infection rates, sepsis management, safer surgery.

The author has reflected on emerging new paradigms in patient safety and the focus on the acute hospital setting. The yardstick has been the measurement of adverse events. Essentially, the paradigm is situated in a model whereby adverse events can be found and fixed following a cause and effect approach

such as the Reasons swiss cheese model. Initially identified by James Reason in 1990, the swiss cheese model has been the dominant model to inform our understanding of accident causation, often referred to as Safety-I.

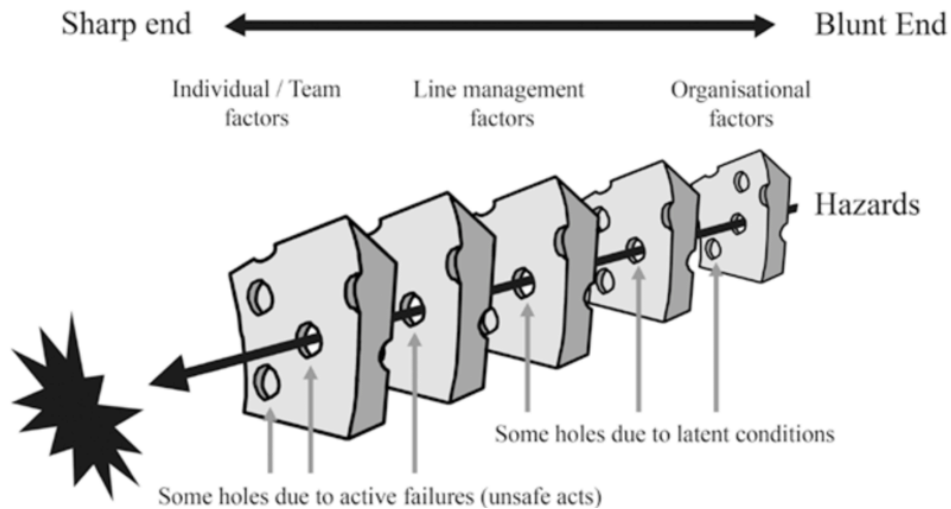


Figure 2-1 James Reason Swiss Cheese Model

Safety-I is said to focus on activities in patient care whereby underlying conditions are well understood, that issues can be deconstructed to their parts, the work environment is stable, controlled and well defined, and the influence of external influence is minimised (Braithwaite, Wears, & Hollnagel, 2015). The assumption is that this is a reactive approach and that the system is safe for those that engage with it and it is the people working within the system make it unsafe (Woodward, 2017).

New thinking is emerging regarding patient safety. This is being referred to as Safety-II, so rather than looking at patient safety through the lens of what goes wrong, Safety-II asks us to consider all of the times that things go right in healthcare and how we replicate those situations. Safety-II takes a much more proactive position and moves away from the perspective of ensuring 'as few things as possible go wrong' to a position of 'as many things as possible go right' (Hollnagel et al., 2015) with a particular emphasis on success within the system under various conditions. The people within the system are considered the gatekeepers of patient safety. It acknowledges that lots of

things go right every day; the focus moves from responding to a single adverse event to a focus on understanding what is going well and how to improve it.

Safety-I and Safety-II are considered complimentary as there is still the need to investigate and learn when things do go wrong, but there are also opportunities to learn when things are done well; understanding how we get things right and replicating this is an essential step towards new thinking in patient safety and move from a retrospective approach to a prospective approach in patient safety (Woodward, 2017) and to get an understanding the difference between the work as imagined and the work as done.

2.3.8 Work as imaged vs work as done

Work as imagined is based on the assumption that we expect people to do work as stated and work as they are expected to. Woodward (2020) describes the frequent day to day activities in clinical work as ‘work as done’, as clinicians adapt and adjust how they do their work depending on where they work and whom they care for, reflecting the unique and different circumstances they find themselves in. Safety-II acknowledges that there may be a difference in the assumption of what will be done and the reality of what is done in practice (Woodward, 2020).

2.3.9 Work as prescribed

Work as prescribed takes the form of guidelines, procedures, checklists and policies. It is acknowledged that the gap between work as prescribed and work as done may vary, e.g. policies regarding chemotherapy administration would require a very narrow gap between work as prescribed and work as done in order to maintain patient safety. Therefore, it is important to ensure that guideline documents try to reflect as closely a possible the day-to-day activity and understanding that the work in clinical practice is a combination of experience, expertise and judgement (Woodward, 2020). It is important to keep the gap between work as done, work as imagined, and as prescribed as narrow as possible. Therefore, approaching the delivery of care in the community in patients with VLU from a safety-II perspective may encourage best practice.

2.3.10 Patient safety and clinical practice guidelines

Concerns have been raised that the care provided to patients does not reach the expected standards of professional practice, particularly guideline or policy-driven standards which would be considered reasonable and achievable through professional consensus (Vincent & Amalberti, 2016). It is extremely difficult to identify comprehensive sources of evidence that benchmark care against CPGs, yet it has been reported previously (McGlynn et al., 2003) that just over 46% of patients did not receive recommended processes for their care across a wide variety of conditions.

In response to a growing recognition that considerable gaps exist between guideline driven care and the care patients receive; a seminal study - the CareTrack Australia study - was undertaken by Runciman et al., (2012). This study was one element of a National Health and Medical Research Council grant on patient safety. The four main aims of the study were:

- to determine the percentage of healthcare encounters at which Australians receive appropriate care;
- to determine the percentage of Australians who receive appropriate care;
- to identify factors influencing decisions to depart from appropriate care, from the perspectives of both participants and healthcare providers;
- to make recommendations on what would be necessary to set up sustainable systems for the surveillance of the appropriateness of healthcare in Australia. (Hunt et al., 2012)

The researchers selected 22 conditions from the most common estimates of the burden of disease and primary care activity. Following a retrospective review of medical records and telephone interviews they found that participants received 'appropriate care' at 57% of 35,573 eligible encounters. Appropriate care for the purpose of the study was defined as care in line with evidence-based or consensus-based guidelines (Runciman et al., 2012). The study concluded that consistent delivery of 'appropriate care' needs to be improved.

2.3.11 Patient safety in primary care

Sir Liam Donaldson, Chief Medical Officer, Department of Health in the UK, gave a lecture in 2002 at a risk management and clinical governance conference, he noted that the delivery of healthcare is changing, and in order to maximise the quality and safety of patients, we must be mindful of:

"the shift to a more primary care centred model of care the growth and complexity of clinical workload the ageing of the population the balance between centralisation of specialised services and public expectations for more convenient and local access to services" (Donaldson, 2002).

However, the focus on patient safety activity remains centred on acute hospital services. The first study of adverse events in Ireland (Rafter et al., 2017) focused on the acute hospital sector and found that the prevalence of adverse events in admissions taken from a retrospective chart review from 2009 was 12.2% (95% CI 9.5% to 15.5%), with an incidence of 10.3 events per 100 admissions (95% CI 7.5 to 13.1). Over 70% of events were considered preventable. Two-thirds were rated as having a mild-to-moderate impact on the patient, 9.9% causing permanent impairment and 6.7% contributing to death (Rafter et al., 2017). In exploring patient safety in primary care Panesar et al. (2016) recognised that much work has been undertaken to understand patient safety events in hospitals and that much less is understood regarding patient safety in primary care. They undertook a systematic review to investigate the frequency of patient safety incidents in primary care and how often those incidents were associated with patient harm; they did recognise incidents of omission as patient safety concerns; however, incidents of omission were excluded from their review; with the focus, therefore again being on active harm Panesar et al. (2016).

The author can find no evidence in the literature that explores omissions in patient care in patients with VLU. The literature notes that a cohort of patients at particular risk of patient safety events in the community are older patients with multimorbidities (Scobie, 2011). Due to frailty, they are potentially more vulnerable to harm if they experience a patient safety incident (Hays et al., 2017). It is reported that for patients aged 65 years and over who experience a patient safety incident, are likely to be related to

clinical decision making, including assessment and treatment decision-making errors (Hays et al., 2017). The prevalence of VLU has doubled in the last 20 years, with over 65s having a higher prevalence (Gethin et al., 2021). Patients with VLUs are primarily managed in the community by PHNs or CRGNs. It is important therefore as part of this thesis that patient assessment and decision-making will be considered in measuring the safety attitudes of PHNs and CRGNs in Ireland, focusing on CPGs. The assessment of safety attitudes is discussed further in Chapter 5 section 5.4.

2.3.12 Enhancing patient safety – nursing practice

Patient safety research should consider safety as something more than just the absence of incidents and errors and should be considered as a concept that examines the organisational properties of patient safety and includes the safety attitudes, beliefs and knowledge of personnel within an organisation (Reiman, Pietikainen, & Oedewald, 2010).

In nursing practice, patient safety is enhanced through the Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives in Ireland (NMBI, 2021), which underpins the ethos in nursing regarding patient safety. The purpose of the code is:

"...to guide nurses and midwives in their day-to-day practice and help them to understand their professional responsibilities in caring for patients in a safe, ethical and effective way" (NMBI, 2021).

The code states five guiding principles, and each principle is connected with the term 'Patient safety' as detailed in Figure 2-2, and the stated focus is to support nurses in providing safe care in their day-to-day practice.

Designing systems for enhancing patient safety in healthcare delivery one must be cognisant that the focus for patient safety should be targeted at the point of care where the interaction between the patient and the nurse occurs. It must include having an appreciation of routine care that varies little and can best be managed with protocols where a deviation from a standard is not required (Emanuel et al., 2008). Once a guideline is implemented, quality measurements should be in place to ensure that the standard practice within the guideline is optimised. It is recognised that nurses play a pivotal role in

promoting patient safety simply by the very nature of their work (Ammouri, Tailakh, Muliira, Geethakrishnan, & Al Kindi, 2015)

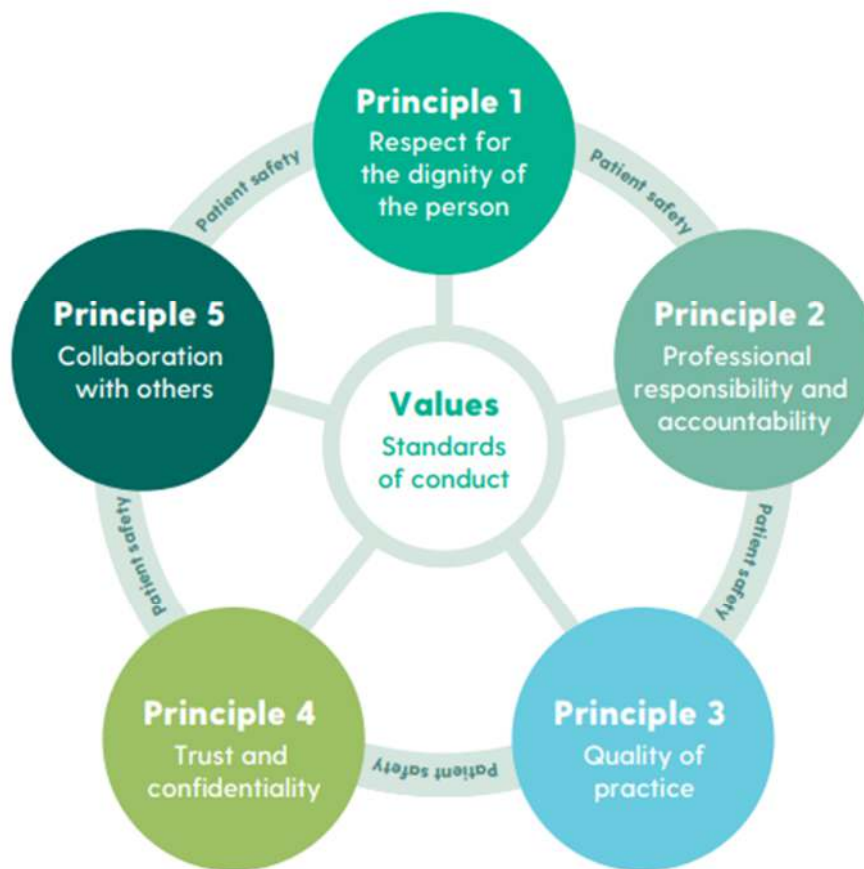


Figure 2-2 Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives (NMBI, 2021)

2.3.13 Donabedian's conceptual framework

Avedis Donabedian, a medical doctor, has written widely about quality of care and understanding systems in healthcare. It was in 1966 that Donabedian published “Evaluating the quality of medical care” and notes that “*the assessment of quality must rest on a conceptual and operationalized definition of what the "quality of medical care means"*”(Donabedian, 1966, p. 167). Here, he introduced the structure, process, and outcome framework often referred to as ‘the trinity.’

Structure is defined as to how care is arranged, most notably the infrastructure not limited to the personnel involved such as doctors, nurses and other members of the wider team, but also included are the qualifications of the team, the facilities, the equipment and the management framework of

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the organisation, essentially the conditions under which care is provided (Donabedian, 1988). Structure may be considered a significant influencing factor regarding the quality of care delivered or offered by the system. (Donabedian, 2003).

Process relates to the components of care i.e., the interaction between the caregiver and the patient. This relates to the actual delivery of care and extends to technical and non-technical elements of care delivery. It raises the question of whether good care has been delivered (Donabedian, 2005). Technical process elements consider the nurse's competency in providing care, including nursing diagnosis, treatment, education, and health promotion. Non-technical elements may include interdisciplinary communication and consideration as to how sociocultural factors influence how patients engage with the care system (Donabedian, 2005).

Outcomes are often what is measured when examining the quality of care delivered; they are often very tangible such as a wound healed or not healed. In this model, consideration ought to be given to other discriminating factors such as quality of life (Ayanian & Markel, 2016; Donabedian, 1966; Mormer & Stevans, 2019). An important element of an outcome measure is the effect the process of care has on the health and wellbeing of the individual receiving care. Caution is urged when one is making a correlation between outcomes measured and the care delivered, i.e., the process of care. Donabedian identified this as the “problem of attribution,” whereby the relationship between process and outcome may be inadequately known. However, outcome assessment is of value when considered in the totality of all processes of care, which includes patients, their families, and professionals and to note that not all outcomes are immediately measurable and visible and in measuring outcomes, one should consider if they are diagnosis-specific or inclusive and generic- for example quality of life (Donabedian, 2003)

Donabedian's 1966 publication is considered a landmark piece of work (Ayanian & Markel, 2016) and considered by some as a masterpiece that encapsulates everything that was known on quality management up to that date (Berwick & Fox, 2016) and structure, process, and outcome is widely

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accepted as a conceptual framework for outcomes research (Hakkarainen, Ayoung-Chee, Alfonso, Arbabi, & Flum, 2015).

Berwick & Fox (2016) state that some authors over-simplify Donabedian's conceptual framework and that it should be considered "far from reductionist," they assert that by today's standards, it remains an appropriate framework for measuring healthcare quality and note

"Donabedian's body of work remains significant for what is today an energetic international health care quality movement. The organizing concepts of structure, process, and outcome remain central to measuring and improving quality. No less important has been his insistence that research on quality and the use of findings from that research should emphasize measurement, analysis, management, and governance" (Berwick & Fox, 2016, p. 240).

Donabedian focused his work on health care quality and may not have anticipated the modern interconnectedness of quality and patient safety that we know today. However, it is evident that the best possible outcomes for patients were at the forefront of Donabedian's conceptual framework, and although not overtly referred to, it is implied in his work that he was embracing the concept of patient safety (Runciman et al., 2010). Reflecting on his work, Donabedian wrote in a personal correspondence referring to his model as the 'accursed structure – process – outcome paradigm' (Schiff & Rucker, 2001). However, he did not amend or change the original writings specifically regarding the model described above; his contributions extend to around 100 journal publications and seven books which brought him international recognition in the field.

In the original presentation of Donabedian's work in the 1966 publication, the conceptual framework was delivered as describing outcomes as the first approach, followed by process; structure is referred to as the third approach (Donabedian, 1966), in later text Donabedian himself, however, refers to the triad as structure, process and outcome and states that it was developed to assess clinical practice (Donabedian, 2003). Donabedian is clear in that structure, process, and outcome are not to be defined and applied as quality characteristics, but measurement and information in which quality can be

examined. There must be a predetermined relationship between all three elements. The framework should not be considered to be entirely linear and the complexities in which care take place need to be recognised in terms of cause and effect. It is not necessarily significant to define where structure, process and outcome begin and end, but to understand the interplay between structure and process and process and outcome and what information each approach offers to gather information that will allow one to determine the quality of care (Donabedian, 2003). The relationship between process and outcome comes from the process of care and an evidence base. If we know that evidence-based CPGs are implemented in practice, then the expectation is that clinicians deliver care to a high stand in the ‘process of care’ and achieve anticipated outcomes and therefore deliver good quality care (Donabedian, 2003).

2.3.14 Context of Donabedian’s conceptual framework

Donabedian’s structure, process and outcome model provides a framework when undertaking evidence-based service evaluation. It is essential to understand the differences and what is meant by structure, process, and outcome as this understanding offers a more comprehensive view of a service by moving beyond a focus on outcomes themselves to an understanding of what is contributing to the outcomes in the first place (Gentry, Powers, Azim, & Maidrag, 2018). Donabedian’s framework has been used previously in assessing the quality of VLU care. Bruwer, Botma, and Mulder (2020) undertook a descriptive quantitative design to evaluate leg ulcer care in Gauteng, South Africa. They conducted structured interviews using a questionnaire to gather data on the ‘structure’ of care provision and examined patients records to gather information on the process and outcome with the use of a checklist. They found from their survey that best practice guidelines were not fully implemented as staff were not adequately or fully trained to implement best practice guidelines and that adequate education was a factor in the process of care. They note that the consequences or outcomes for patients may be detrimental (Bruwer et al., 2020).

2.3.15 The interface between safety and quality

There is a challenge in demarcating safety and quality (Emanuel et al., 2008). There is a lack of clarity between the concept of safety in healthcare and the broader issues of health care quality (Leape & Berwick, 2005). It is noted particularly in the context of this thesis

"that patients who fail to receive needed treatments, or who are subjected to the risks of unneeded care, are also placed at risk for injury every bit as objectionable as direct harm from a surgical mishap." (Leape & Berwick, 2005, p. 2385)

the quality of patient care is directly linked to patient outcomes and ultimately patient safety, it is argued that poor-quality care is *"inherent in the very structures and processes of the healthcare system itself"* (Vincent, 2010, p. 16)

Vincent offers an interpretation of quality in healthcare as the *"proportional health gain actually delivered by a healthcare organisation for its' set of patients"* (Vincent, 2010, p. 34). The gap in quality healthcare is described as what *can* be achieved versus what *is* achieved, and the gap then is narrowed or widened depending on the quality of the service delivered. Significantly for this thesis, Donabedian suggests that in considering the effectiveness of care, the course of an untreated condition has a significant detrimental impact on the patient's health (Donabedian, 2003). This is in contrast to the lesser impact on the patient when they receive effective, timely and correct care, suggesting that when the correct care is delivered, it has a much better impact on the patient's overall well-being.

2.3.16 Developments in Donabedian's conceptual framework

Donabedian contributed widely to the area of quality, quality improvement and quality assurance. He acknowledges shortfalls in his framework if it is applied to activities other than clinical practice in that it may not perform so well. Viewing Donabedian's model from current perspectives in quality health care (Berwick & Fox, 2016) suggest there are three areas of note that Donabedian may not have anticipated in having such a significant influence on healthcare quality and patient safety. First, 'person-centred care' which

should be at the core of delivering quality patient care. Second, e-health & the digital age and its impact in healthcare, and third, although referring to systems of care in the framework, the broader understanding now suggests that this is considered in a much broader context. With that said, in seeking continuous improvements, understanding healthcare systems and redesigning the process of care is required if we are to achieve quality in care (Berwick & Fox, 2016)

2.3.17 Implementation Science

It is recognised that while methodologies used in implementation science and quality improvement can overlap, implementation science is explicitly focused on creating knowledge about the implementation or dissemination process (Kirchner, 2020). Whilst this thesis will consider the interface of quality and safety and the role of clinical practice guidelines, implementation strategies will be examined later in the context of a systematic review using an appropriate framework. Therefore as implementation science will narrow the focus to creating knowledge for implementation strategies rather than the broader focus required for this study of patient safety; implementation science is not examined in depth.

2.3.18 Safety culture

Culture has often been referred to as "the way we do things around here", whereby the "here" refers to a particular work unit (Pronovost & Sexton, 2005, p. 231). The term 'patient safety culture' was considered a relatively new but important concept in healthcare 12-15 years ago (Feng, Bobay, & Weiss, 2008), and Ammouri et al., (2015) state that "patient safety culture is a multifactorial framework that aims at promoting a system approach to preventing and reducing harm to patients". Patient safety culture in nursing is defined as:

"the product of nurses shared values and beliefs about patient safety. It is a set of common understandings of the group members in viewing patient safety and emerges from the dynamic reciprocal interaction among people, task and system" (Feng et al., 2008, p. 315)

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A culture of safety is considered a mainstay of overall patient safety, and the definition above is reflected in the psychometric properties of safety culture measurement tools (Nieva & Sorra, 2003). Following the publication of the IOM report and the recommendation that organisations need to focus on improving organisational culture, surveys on measuring patient safety climate began to emerge (Colla, Bracken, Kinney, & Weeks, 2005). It is important to note that the terms 'safety culture' and 'safety climate' are often used interchangeably in the literature (Alsalem, Bowie, & Morrison, 2018). The Madden report recognised that:

"a positive safety culture is characterised by open communication, mutual trust, shared perceptions of the importance of safety and confidence in the efficacy of preventative measures. In Ireland, increased efforts are required to improve national, professional and organisational culture so that patient safety is understood, promoted and supported at all levels." (Madden, 2008, p. 5)

The IOM report "To Err Is Human: Building a Safer Health System" identified safety culture as a distinct component to supporting organisations in minimising patient harm (Kohn, Corrigan, & Donaldson, 2000). The term safety culture first appeared in 1988 in the report on the then USSR's Chernobyl nuclear power station disaster. The term is associated with high reliability organisations (HRO); that is organisations that function in areas of potentially high-risk hazardous environments where a systems approach and staff attitudes and behaviours are critical to safety (de Wet, Spence, Mash, Johnson, & Bowie, 2010; Halligan & Zecevic, 2011) such as the aviation industry, the oil industry, air traffic control as well as nuclear power (Nieva & Sorra, 2003). Healthcare is also considered a HRO, however, unlike other HRO's, in healthcare, it is often the patient and not an employee that experiences the impact of unsafe practices (Colla et al., 2005).

A number of patient safety measurement instruments are presented in Chapter 5 and the interface of patient safety culture and patient safety climate is contextualised.

2.3.19 Sub-dimensions of patient safety culture

Fang et al. (2008) propose a number of sub-dimensions of patient safety culture, namely:

- system sub-dimension
- personal sub-dimension
- task associated sub-dimension
- interactive sub-dimension (Figure 2-3)

System sub-dimension includes two major components, that is system integrity and management support. System integrity includes policies, procedures and guidelines, staffing levels, financial matters, and available equipment at a unit level. Management support is considered a key critical driver in shaping the attitudes towards patient safety within the work environment (Feng et al., 2008)

Personal sub-dimension includes personal competence and personal commitment. Personal competence relates to the professional or technical knowledge and skills to deliver patient care while maintaining patient safety, including a correlation between educational achievement and patient outcomes. Personal commitment relates to the motivation of nurses to patient safety and how involved they are in decision-making processes (Feng et al., 2008).

Task associated sub-dimension refers to the values and beliefs and is directly related to task-related safety behaviours, e.g. the nature of the task as related to one's own health and safety compliance is high such as the use of PPE in a COVID-19 environment (Feng et al., 2008)

Interactive sub-dimension refers to the interactions between nurses, patients, and the healthcare system focusing on communication and partnerships. Communication includes learning from errors, learning from the experience of others, building relationships with high-performing teams, including open communication in a supportive environment. Partnerships support a move towards person-centered care and support the patient in being an active participant in their care (Feng et al., 2008).

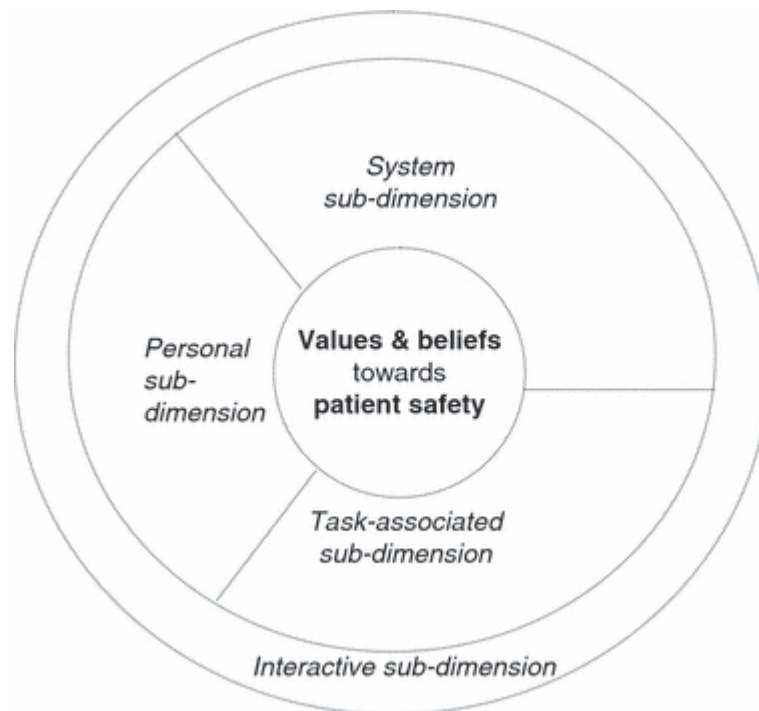


Figure 2-3 Diagram of the patient safety culture (Feng et al., 2008)

Understanding the sub-dimensions above are particularly important when measuring safety climates at an organisational level. Safety culture must be measured at a unit level as culture is essentially a context-specific local occurrence, there can be significant variation across an organisation level where the culture from unit to unit differs (Halligan & Zecevic, 2011; Pronovost & Sexton, 2005)

2.3.20 Safety climate

Safety climate therefore is described as the measurable elements of a safety culture and should be considered a subset of the safety culture (Colla, 2005). Safety climate provides a 'snapshot' of the culture related to a group's policies, procedures, and practices (de Wet et al., 2010). Safety climate can be measured using safety climate questionnaires which are cost-effective to administer, practical and do not require a significant amount of time to complete (Alsalem et al., 2018). The author will measure the safety attitudes of PHNs and CRGNs using a valid and reliable safety climate questionnaire. The detail regarding the questionnaire is presented in chapter 5.

2.3.21 Section Summary

In this section of the literature review, the author defined patient safety and demonstrated the complexities associated with the concept. Patient safety was examined within the context of this thesis. The historical background of patient safety was presented, followed by the international position on patient safety leading into the Irish situation. The role of patient safety in primary care was examined in relation to this thesis. The relationship between patient safety and quality cannot be ignored, and this was presented through Donabedian's conceptual framework.

The broader concepts of safety culture and safety climate were introduced as they are particularly relevant to the focus of this thesis this will be explored further in Chapter 5. The author has identified that there is clearly a need for this study in that a gap exists between care that happens in practice and standards of care as directed through CPGs. This has been clearly demonstrated by McGlynn et al., (2003) and Runciman et al., (2012) as evidences from the CareTrack study in Australia, and more recently by (Bruwer et al., 2020). The overlap between patient safety and CPGs was presented, focusing on a nursing perspective. Further detail on CPGs is expanded upon in the next section.

2.4 Clinical Practice Guidelines

2.4.1 Evidence based practice

Evidence based practice (EBP) is defined as:

'...a paradigm and life-long problem-solving approach to clinical decision-making that involves the conscientious use of the best available evidence (including a systematic search for and critical appraisal of the most relevant evidence to answer a clinical question) with one's own clinical expertise and patient values and preferences to improve outcomes for individuals, groups, communities, and systems' (Melnyk & Fineout-Overholt, 2011, p. 575)

and can be used to bridge the theory to practice gap (Mackey & Bassendowski, 2017).

EBP guidelines offer an opportunity to provide consistency among evidence based treatment options that lead to improved efficacy in the quality of care and a more cost effective service (O'Donnell et al., 2014). They are developed following a review of available evidence and may offer recommendations regarding treatment directions and a set of standards regarding treatment options (Johnston, Kelly, Hsieh, Skidmore, & Wells, 2019). According to Gaddis et al., (2007) the timely implementation of EBP at the point of care delivery resulting in appropriate and efficient care and has a direct impact on patient outcomes can be achieved through the use of CPGs

2.4.2 Clinical practice guidelines

CPGs are produced to decrease variation in practice and are particularly useful when various interventions are available (Gundersen, 2000) and to potentially streamline and standardise areas of practice (Abrahamson, Fox, & Doebbeling, 2012). CPGs serve many functions, such as standardising patient care, improving patient care effectiveness, and supporting clinical risk management functions to reduce preventable errors, adverse events, and avoidable patient harm (Kredo et al., 2016). The definition of CPGs offered by the IOM in 2011 states that they are:

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"statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options." (IOM, 2011, p. 4) .

A wide variety of guidelines exist on many topics, and some are based on methodological rigour, and some are based on the consensus of an expert group (Johnston et al., 2019).

The IOM states that trustworthy guidelines should:

- *"be based on a systematic review of the existing evidence*
- *be developed by a knowledgeable, multidisciplinary panel of experts and representatives from key affected groups*
- *consider important patient subgroups and patient preferences, as appropriate.*
- *be based on an explicit and transparent process that minimizes distortions, biases, and conflicts of interest*
- *provide a clear explanation of the logical relationships between alternative care options and health outcomes and provide ratings of both the quality of evidence and the strength of the recommendations and*
- *be reconsidered and revised as appropriate when important new evidence warrants modifications of recommendations."*

(IOM, 2011, p. 5)

For guidelines to improve patient care and improve patient outcomes, they must be relevant to the care setting, clear, easy to access and apply (Wall, 2016). It is indicated in the literature that guidelines are often not applied in practice and may lead to suboptimal care (Fischer et al., 2016; Storm-Versloot et al., 2012). Braithwaite (2018) states that only 50-60% of care is delivered in line with available guidelines; and that the stagnation within our healthcare systems has resulted in the rates of adverse events remaining steady. He notes the extreme complexity in delivering healthcare that is simply not experienced in any other industry and that it is incredibly challenging to translate evidence into practice.

Whilst it is recognised that the use of CPGs is low (IOM, 2011; Weller et al., 2020), it is the case that one of the most effective ways to apply evidence-

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based practice into clinical settings is through the use of CPGs (Pronovost, 2013). The development of CPGs are considered a high priority if there is:

- *"Significant disease burden and cost of management*
- *Controversy or uncertainty around the topic and supporting evidence*
- *New evidence arising that may impact current recommendations*
- *Potential to improve health outcomes and quality of life, reduce mortality and morbidity, and affect decision making*
- *Public or provider interest*
- *Potential to reduce variations in care and cost" (Tetreault et al., 2019, p. 55S)*

The benefits of using CPGs in practice include, a reduction in morbidity and mortality, improved efficiencies, a reduction in cost of care, greater consistency in practice and as a reference resource for practitioners (Woolf, Grol, Hutchinson, Eccles, & Grimshaw, 1999)

2.4.3 Guideline repositories

Nurses must have access to up-to-date relevant trustworthy guidelines to inform their practice. Several national and international repositories exist to support practicing clinicians, and each have their own approach to guideline construction and presentation, such as:

- World Health Organization (WHO)
- Scottish Intercollegiate Guidelines Network (SIGN)
- National Institute for Health and Care Excellence (NICE) (UK)
- Australian National Health and Medical Research Council (NHMRC)
- The HSE (Ireland)
- National Clinical Effectiveness committee (NCEC) (Ireland)

2.4.4 Grading systems for clinical practice guidelines

Numerous grading systems are available that support decision-making regarding assessing guidelines for the quality of evidence and the strength of recommendations. Atkins et al. (2004) identified six major grading systems that were appraised independently, namely:

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- The American College of Chest Physicians (ACCP) (Guyatt et al., 2001)
- Australian National Health and Medical Research Council (ANHMRC) (Glasziou, Irwig, Bain, & Colditz, 2000)
- Oxford Centre for Evidence-Based Medicine (OCEBM) (Ball, Sackett, Phillips, Straus, & Haynes, 1998)
- Scottish Intercollegiate Guidelines Network (SIGN) (Harbour & Miller, 2001)
- US Preventive Services Task Force (USPSTF), (Atkins, Best, & Shapiro, 2001)
- Force on Community Preventive Services (USTFCPS) (Briss et al., 2000)

In a review of guidelines on venous ulceration undertaken by Maccatrozzo (2017) they concluded that the difference in grading systems meant that guideline development groups could align recommendations to high, medium or low classification depending on their interpretation of recommendations resulting in variations of care provided.

2.4.5 Grading of recommendations, assessment, development and evaluation (GRADE)

The Grading of Recommendations, Assessment, Development and Evaluation (GRADE) system is a working group of individuals with interest in addressing the shortcomings of grading systems in health care and is now considered the standard in guideline development (GRADE) (Grade Working Group, 2022).

This system is emerging as one of two main approaches, which supports determining the quality of evidence and the strength of recommendations that underpins CPG's. The GRADE system is used by the WHO guideline review committee (World Health Organisation, 2011b). The Scottish Intercollegiate Guideline Network (SIGN) states that they are committed to the GRADE approach (Scottish Intercollegiate Guidelines Network, 2019).

Grading systems are important tools in developing CPGs and assessing published research (Irving, Eramudugolla, Cherbuin, & Anstey, 2017).

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However, confusion can occur when grading systems do not separate the quality of evidence from the strength of recommendations, Guyatt et al. (2008) notes that four key factors determine the strength of a recommendation, as presented in Table 2-2. This is significant as weighing up the effects of an intervention reflects the level of confidence we can have in that intervention. We must be confident that the quality of evidence is such that it supports the decision for or against an intervention (Guyatt et al., 2008). Guidelines panels need to consider the strength of the recommendations within the clinical contexts of variations in patient populations, it is acknowledged that there will always be trade-offs between interventions or therapies (Guyatt et al., 2008) resource implications need to be fully evaluated, the costs need to be considered in context of the setting of any guidelines document (Guyatt et al., 2008).

Table 2-2 Determinants of strength of recommendation (Guyatt et al., 2008)

Factor	Comment
Balance between desirable and undesirable effects	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. The narrower the gradient, the higher the likelihood that a weak recommendation is warranted.
Quality of evidence	The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted.
Values and preferences	The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted.
Costs (resource allocation)	The higher the costs of an intervention, the greater the resources consumed—the lower the likelihood that a strong recommendation is warranted.

2.4.6 Appraisal of guidelines for research and evaluations (AGREE)

GRADE is used in quality assessment of evidence in addition to its function as a CPG development tool. Regarding the quality assessment or critical

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appraisal of CPGs themselves specifically the development process of CPG's and assessment of that process is undertaken using the Appraisal of Guidelines for Research and Evaluation II (AGREE II) and this is considered the gold standard. The AGREE II tool reports how a guideline is formulated and presented from a methodological perspective (Tan et al., 2019). The tool is used to assess the methodological rigour of practice guidelines and is "used as a standard for evaluating the methodological quality and transparency of practice guidelines internationally" (Brouwers, Kerkvliet, & Spithoff, 2016).

Despite the number of VLU guidelines available from respected organisations and professional groups it is suggested that assessment of available evidence using the AGREE II tool will provide the basis for the development of up to date, relevant and comprehensive information which will ultimately support decision making by clinicians on which intervention to use which may help to improve the quality of care to patients (Maccatrozzo et al., 2017) and to reduce the heterogeneity that is currently presented in VLU guidelines (Tan et al., 2019).

The AGREE II is comprised of 23 items organized into six quality domains:

- Scope and purpose
- Stakeholder involvement
- Rigour of development
- Clarity of presentation
- Applicability and
- Editorial independence.

It is the most commonly used guideline appraisal tool (Hoffmann-Eßer et al., 2018) and while it is recognised that a plethora of guidelines on the management of VLU's exist it is important to note that if one is to consider them as reliable for decision making in clinical practice then their methodological rigour and transparency need to be confirmed (Hoffmann-Eßer et al., 2018). The Agree II tool can be used by those developing guidelines as a measure of quality assurance during the development stage, funders may recommend organisations to demonstrate compliance of the

AGREE II checklist and they can be used retrospectively in assessing the methodological rigour of published guidelines (Brouwers et al., 2016).

2.4.7 Facilitators and barriers to clinical practice guideline use

There is an increased reliance on CPG's by clinicians, however, implementing CPG's and utilising them in practice is challenging, there are several internal and external factors that need to be considered, including the motivation of staff, if a practice change is required, the knowledge that a guideline exists at all, the workplace, the environment in which care is delivered, and the actual guideline itself (Abrahamson et al., 2012). With a particular focus on VLUs, Weller & Evans (2012) found that practice nurses' knowledge of managing patients with VLUs was suboptimal. Their practice did not reflect the EBP recommendation outlined in VLU CPGs.

To implement guidelines effectively and for guideline use to be optimal, more research evidence specifically from the unique perspective of nurses is essential (Abrahamson et al., 2012). Jun, Kovner, & Stimpfel, (2016) undertook an integrative review to appraise and synthesise the literature on barriers and facilitators in the use of CPGs by registered nurses. They categorised their finding into internal and external factors. Internal factors included nurses attitudes and perceptions and their knowledge of clinical practice guidelines. External factors included the format and usability of clinical practice guidelines, resources, leadership, and organisational culture.

Attitudes and perceptions were cited as the most frequently identified internal factors of barriers and facilitators to nurses using CPGs (Jun et al., 2016), reporting that there is a correlation between a negative attitude regarding the relevance and motivation towards CPGs and their decreased use in practice, they further found that nurses who reported a lack of motivation and resistance to change were less likely to use CPGs in practice (Jansson, Ala-Kokko, Ylipalosaari, Syrjälä, & Kyngäs, 2013). Interestingly they identified conflicting results from studies included in their review. Ebben et al. (2015) report that nurses with longer years of experience felt they had greater autonomy in practice and were less likely to use CPGs in practice, however Jansson et al. (2013) found no difference in the attitudes and perception of

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nurses based on their work experience (Jun et al., 2016). If nurses perceived the CPG offered little or no benefit from the guidelines this was also considered a barrier to use in practice however the contrary was also found in that if nurses felt that CPS improved and aided practice they were more likely to use them in practice and were more likely to advocate for their use among other nurses (Jun et al., 2016).

Jun et al. (2016) report discrepancies from their findings with some researchers reporting moderate to high knowledge of CPGs (Jansson et al., 2013; Koh, Manias, Hutchinson, Donath, & Johnston, 2008) while other researchers report a lack of knowledge as a barrier (Abrahamson et al., 2012; McCluskey, Vratisistas-Curto, & Schurr, 2013) and that this can be linked to disease specific CPGs and duration of service.

Knowledge regarding CPGs is considered a key factor in supporting their use. Jun et al. (2016) found that education both at the beginning and throughout the implementation process are recommended by nurses to increase the use of CPGs, with nurses demonstrating a willingness to undertake ongoing education regarding guidelines to increase their use in practice. They recommend that education at the time of implementation is required to increase knowledge of CPGs. Weller et al. (2020) used the Theoretical Domains Framework to identify barriers and enablers to implementing VLU guidelines in practice. They found that the main barriers included a lack of resources, busy working environments, and over reliance on experience. Interestingly they found that the majority of participants on their study were not aware that CPG's for VLUs were published and available. In order to enable update of CPG's in primary care practice, evidence-based implementation strategies are required (Weller et al., 2020).

The most cited external factor found by Jun et al. (2016) was regarding the CPGs themselves including ease of use, layout, content, and ease of access in the practice setting and that is it is recommended that CPGs should be practical simple and easy to follow flow charts/algorithms that can be reference quickly. Guyatt, Agoritsas, Lytvyn, Siemieniuk, & Vandvik (2019) refer to problematic guidelines and they identify three types of "problematic

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guidelines" for clinicians and specify them as: (1) guidelines that seriously violate standards of trustworthiness; (2) those that were once trustworthy but are now out of date; (3) guidelines that are current and meet many standards of trustworthiness but fail in some other important criteria, and that these may act as barriers to implementation. Other reported barriers included time, particularly time constraints during working hours; workload and staffing as it relates to availability of time, the lack of available equipment (Jun et al., 2016). Conversely, when functioning equipment was readily available and appropriate stock of supplies resulted in greater adherence to CPG use in practice.

Jun et al. (2016) found that leadership was a key element in both barriers and facilitators to the use of CPGs, however they examined it from the perspective of physicians adherence to guidelines and disagreement on their use and how that influenced uptake of guideline use by nurses. However, they did site that lack of feedback from managers contributed to a decreased use of CPGs. In contributing to a culture of enthusiasm, supportive successful leadership that believed in the use of CPGs were a significant facilitator in the use of guidelines in practice. A supportive work culture was a significant influencer and played a significant role in the use of CPGs (Jun et al., 2016) this extended to team work, communication and motivation.

Understanding barriers and facilitators to the use of CPGs to ascertain how best to implement guidelines in practice. As part of this thesis, the author has undertaken a systematic review to identify the effectiveness of implementation strategies for VLU guidelines; this is presented in Chapter 4, section 4.2.

2.5 VLUs

2.5.1 Introduction

In this section, the author will discuss chronic venous disease, chronic venous insufficiency and define VLUs, outline the clinical presentation and the classification scale associated with VLUs and the anatomy & physiology associated with them. The signs & symptoms, patient assessment, and treatment options will be presented. In this section, the author will present the evidence base, and CPGs for VLUs; the epidemiology associated with VLUs and the impact for the individual will be considered.

2.5.2 Chronic venous disease (CVD)

CVD is multifaceted, and there must be consistency in terminology both in clinical practice and academic literature. An international standardised classification system of chronic venous disease was created to bring consensus in terminology, reporting, diagnosis, and understanding to the severity of the condition. The classifications are referred to as the CEAP Classification Scale as they refer to four distinct headings, Clinical classification (C), Etiologic classification (E), Anatomic classification (A), and Pathophysiologic classification (P) (Beebe et al., 1996) this is presented in detail in Table 2-3

CVD is a broad term and is defined as:

"long-standing anatomic or functional changes within the venous system associated with clinical signs or symptoms that prompt investigation or care" (Carman & Al-Omari, 2019, p. 1).

CVD is considered to be underdiagnosed in clinical practice and can lead to chronic venous insufficiency (CVI) and VLUs (Nicolaidis & Labropoulos, 2019). CVD includes the entire spectrum of clinical presentations, ranging from telangiectasia at one end of the scale to venous ulceration at the other. The spectrum of CVD is visually depicted in Figure 2-4. and includes scoring according to the CEAP classification system (section 2.5.3) with relevant indicative prevalence rates referred to in the arrow underneath the images.

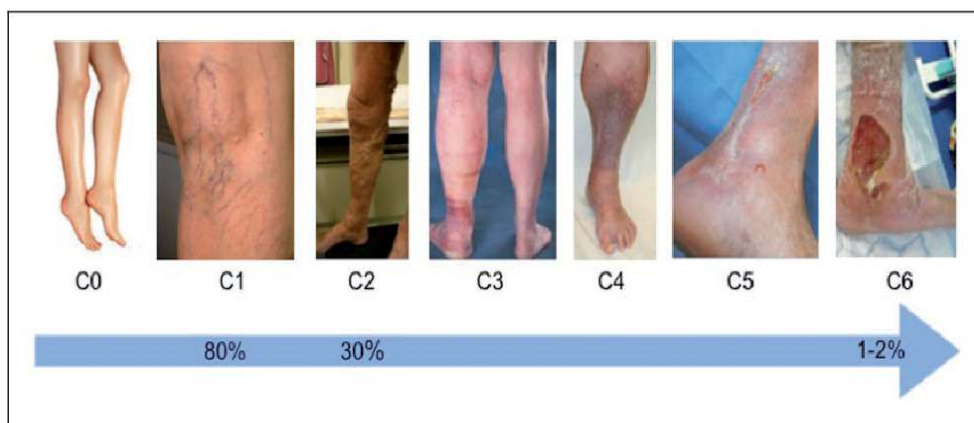


Figure 2-4 Spectrum of CVD according to the CEAP classification system with relevant prevalence rates (Onida & Davies, 2016)

2.5.3 CEAP classification

In 2004 the CEAP scale was further developed to offer more specific definitions (Eklöf et al., 2004) and denotes a broad categorisation of the aetiology, description of the affected veins and characterises the underlying pathophysiology (Youn & Lee, 2019). Interestingly, although the use of CEAP classification is recommended for all patients with VLU for disease characterisation (Chi & Raffetto, 2015) the CEAP classification system is not universally referred to in VLU management guidelines (Maccatrozzo et al., 2017).

The clinical classification should not be static in reporting of CVD. Following an initial assessment of the patient the classification should be noted in the patient's record. The patient's condition may deteriorate and may escalate through the scale and the record should be updated accordingly. The contrary is true also as healing of an active venous ulcer occurs, the classification moves in the opposite direction from C6 downwards to C5, the initial scoring is dependant as to when the patient engages with their health care professional for the initial assessment (Carman & Al-Omari, 2019). In relation to this thesis, the focus is on the latter end of severity focusing on C6 active VLUs.

2.5.4 CVI

CVI is considered an advanced venous disease (Carman & Al-Omari, 2019) and is the most common cause of lower leg ulcers (Vivas, Lev-Tov, & Kirsner, 2016). It is associated with more severe cases (Bergan et al., 2006).

Chapter 2 Literature Review

Table 2-3 CEAP Classification System (Youn & Lee, 2019)

Clinical classification (C)^a	
C ₀	No visible signs of venous disease
C ₁	Telangiectases or reticular veins
C ₂	Varicose veins
C ₃	Oedema
C ₄	Changes in skin and subcutaneous tissue ^b
	(A) pigmentation or eczema
	(B) Lipodermatosclerosis or atrophie blanche
C ₅	Healed ulcer
C ₆	Active ulcer
Etiological classification (E)	
E _c	Congenital (e.g., Klippel-trenaunay syndrome)
E _p	Primary
E _s	Secondary (e.g., post thrombotic syndrome, trauma)
E _n	No venous cause identified
Anatomical classification (A)	
A _s	Superficial
A _d	Deep
A _p	Perforator
A _n	No venous location identified
Pathophysiologic classification	
P _r	Reflux
P _o	Obstruction, thrombosis
P _{r,o}	Reflux and obstruction
P _n	No venous pathophysiology identified

^a The descriptor A (asymptomatic) or S (Symptomatic) is placed after the C clinical class.

^b C₄ is subdivided into A and B, with B indicating higher severity of disease and having a higher risk of ulcer development.

2.5.5 VLU

A VLU is defined as:

"an open lesion between the knee and the ankle joint that remains unhealed for at least four weeks and occurs in the presence of venous disease"
(Scottish Intercollegiate Guidelines Network, 2010, p. 1).

2.5.6 Epidemiology of VLUs

In developed countries, lower limb ulceration in the community is most commonly caused by venous leg ulceration (Weller et al., 2018). VLUs occur in 3-4% of the population over 65 years of age (Gethin et al., 2021) and in 1.5% of Western society's general population (Chi & Raffetto, 2015). It is expected that this will increase given that the population of over 65-year-olds continues to increase (Probst et al., 2021).

2.5.7 Anatomy & pathophysiology of VLUs

The lower leg consists of two main veins: superficial veins and deep veins. The superficial veins are contained within subcutaneous tissue and deep veins are found in deep fascia. The superficial veins and deep veins both contain venous valves to prevent venous reflux of the blood and are connected by perforator veins that pass through the muscle fascia. Alavi et al (2016) explains that the venous system is constructed like a ladder with the perforator veins acting as rungs whereby the calf muscle pushes blood towards the heart during the contraction of the calf muscle, the venous valves allow for blood to move in one direction i.e. towards the heart as shown in Figure 2-5

However, venous pooling may be present if there is damage to the valves from trauma, infection, or inflammation amongst other reasons and can result in reverse flow or leakage of blood around the valves; obstruction of blood flow may be caused by obesity or a Deep Vein Thrombosis (DVT). The reflux of blood may be experienced from valve dysfunction, outflow dysfunction, arteriovenous malformation and calf muscle pump failure which all contribute to the pathogenesis of venous disease leading to Chronic Venous Insufficiency resulting in a VLU (Alavi et al., 2016, p. 628). Fundamentally, whether the cause for the VLU is venous reflux or venous obstruction, both lead to increased venous pressure. The pathological response is inflammation

and increased hydrostatic pressure, resulting in increased ambulatory venous pressure progressing to a VLU (Chi & Raffetto, 2015).

2.5.8 Signs and symptoms of chronic venous disease

Signs and symptoms of chronic venous disease include aching and heaviness in the lower legs, restless legs, cramps, itch and pins and needles sensations, venous eczema, hyperpigmentation of skin of the ankle, atrophie blanche, and lipodermatosclerosis (Bergan et al., 2006). Patients may present with symptoms that are ongoing or symptoms that worsen towards the end of the day; there may be no visible sign of venous insufficiency. Clinical features include swelling, varicose veins, and lower leg discomfort whereby patients report feelings of a dull ache or throbbing or feelings of pressure after standing for long periods that is improved by walking and/or elevation of the legs, thus reducing venous pressure (Youn & Lee, 2019). However as the disease progresses there may be evidence of darkening of the skin and increasing pain and other symptoms (Nicolaidis & Labropoulos, 2019). Irrespective of the nature of the reported signs and symptoms, the condition is most probably directly related to venous hypertension (Bergan et al., 2006). VLUs are predominantly found at the medial aspect of the lower leg between the lower calf and the medial malleolus (Singer, Tassiopoulos, & Kirsner, 2017).

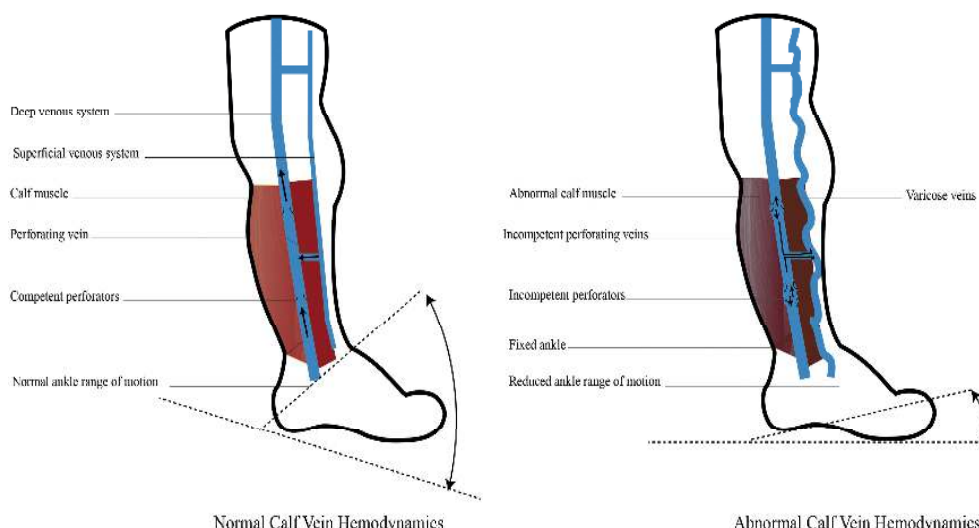


Figure 2-5 Venous disease/calf vein haemodynamics (Alavi et al., 2016)

2.5.9 Evidence for practice

The evidence base for the management of patients with VLU's can be summarised using CPGs. The author discussed the role and function of CPGs in section 2.4

The European Wound Management Association (EWMA) and Wounds Australia published a joint document in 2016 entitled Management of Patients with VLUs – challenges and current best practice (Franks et al., 2016) They presented an overview of eight evidence-based CPGs to support healthcare providers' decision-making (Franks et al., 2016) and are listed in Table 2-4.

It is acknowledged that there are variations in clinical practice and although there is a wealth of studies, guidelines, protocols and policies available there is also a variation and contradiction in evidence (Franks et al., 2016). Given the sociological & psychological impact on patients and the economic burden on the individual or the taxpayer, there is a need for standardised evidence-based CPGs to improve patient outcomes (Franks et al., 2016). The expert working group from EWMA also recognise and state that:

“there is an urgent need to improve leg ulcer management, to identify barriers to implementation and to provide facilitators to assist in the development of a leg ulcer service that enhance the patient journey in the healing of these debilitating ulcers” (Franks et al., 2016, p. S7).

Chapter 2 Literature Review

The author will consider the implementation strategies for VLU guidelines as part of this thesis. Importantly Franks et al., (2016) note that in the early stages of VLU development that patients are not receiving timely and appropriate treatment, the author considers this a patient safety issue and will explore this issue throughout the thesis.

It is noted in the literature that the management of patients with CVD varies despite the existence of national and international guidelines regarding referral pathways for patients with CVD. Davies (2019) and Andriessen et al (2017) note that of the guidelines, consensus & position papers and algorithms & clinical pathways they reviewed there was a distinct lack of information on the implementation of the guidelines and their impact on practice.

Clinical Care for patients should include accurate diagnosis based on assessment with the correct tools (Andriessen et al., 2017). A review of VLU guidelines undertaken by Andriessen et al. (2017) identified a total of 14 guidelines published (2008-2016). In addition, Andriessen et al. (2017) considered three consensus and position papers (published 2013) and three algorithms and clinical pathways (published 2010-2013) resulting in a total of twenty (n=20) documents; similarly the EWMA expert working group considered guidelines for the management of venous leg ulceration published or updated between 2010 – 2015 in English, however they excluded consensus or expert opinion documents. Andriessen et al. (2017) found that most of the guidelines reviewed were of an acceptable quality considering:

- *"Validated levels and grading of evidence*
- *They were clinically relevant and applicable*
- *They included a validated classification system for VLU*
- *They addressed multidisciplinary aspect of VLU management*
- *They had regular updates no later than 5 years" (Andriessen et al., 2017, p. 1564)*

A systematic review was undertaken by Tan et al., (2019) where they evaluated the quality of VLU CPGs that may assist clinicians in practice they identified 14 CPGs as published between 1999 – 2016. The 14 guidelines

identified were assessed using the AGREE II tool. It was reported that there was significant heterogeneity of scores between the guidelines in domains 1, 2, 3, and 5 namely, scope and purpose, stakeholder involvement, rigour of development and applicability respectively including overall quality. Less heterogeneity was seen in domain 4 - clarity of presentation and domain 6 - editorial response. Of most significance with regard to this thesis is that Tan et al (2019) note that most of the guidelines that they identified did not perform well in domain 5 – applicability; suggesting that VLU guidelines do not identify barriers to implementation and fail to offer ways to improve application to practice resulting in a reduction of clinical impact for the patient. They go on to say that it is imperative that future guideline developers consider ways to promote uptake of recommendations.

Interestingly between both studies Andriessen et al. (2017) and Tan et al. (2019) only five studies appeared in both reviews ((AAWC). 2010; Australian Wound Management Association, 2011; Neumann, 2017; Scottish Intercollegiate Guideline Network, 2016; Wittens et al., 2015) the EWMA also included the AAWC (2010), and the Scottish Intercollegiate Guideline Network (2010) documents as it fell within their inclusion criteria; this further demonstrates the vastness of the availability of CPGs for VLUs and further highlights the challenge regarding patient safety and the use of CPGs.

Many guidelines that exist are national guidelines such as:

- Scotland: Management of chronic VLUs. A national clinical guideline (Scottish Intercollegiate Guidelines Network, 2010)
- Australia and New Zealand: Australia and New Zealand clinical practice guideline for the prevention and management of VLUs (Australian Wound Management Association, 2011)

The UK's National Institute for Health and Care Excellence (NICE) refers the reader to the above two resources. In Ireland the HSE published wound management guidelines with a specific section on VLU's in 2018. The timelines of the publication of these guidelines also informed the need for this thesis.

Chapter 2 Literature Review

In examining all three reviews (Andriessen et al., 2017; Franks et al., 2016; Tan et al., 2019) it is acknowledged that the management of VLUs is complex, prevalence of VLUs is on the increase and while variations in practice do exist it would be expected that patient and clinical outcomes improve through the use of the best available evidence and it is recommended by that guidelines should incorporate expanding competency skills (Franks et al., 2016)

Table 2-4 Overview of guidelines identified in EWMA Document (Franks et al., 2016, p. SII)

Title	Organisation	Published/ updated	Country / international collaboration
Association for the Advancement of Wound Care (AAWC) venous ulcer guideline	Association for the Advancement of Wound Care	(2005) 2010	USA
Management of chronic VLUs (SIGN CPG 120)	Scottish Intercollegiate Guidelines Network (SIGN)	2010	Scotland
Varicose ulcer (M16) [Varicose ulcer (NL: Ulcus cruris venosum)]	Dutch College of General Practitioners (NHG)	2010	The Netherlands
Australian and New Zealand Clinical Practice Guideline for Prevention and Management of VLUs	Australian Wound Management Association and New Zealand Wound Care Society	2011	Australia and New Zealand
Guideline for management of wounds in patients with lower-extremity venous disease	Wound, Ostomy, and Continence Nurses Society (Professional Association)	(2005) 2011	USA
Guideline for Diagnostics and Treatment of VLUs	European Dermatology Forum	(2006) 2014	Europe
Management of VLUs: Clinical practice guidelines of the Society for Vascular	The Society for Vascular Surgery and American Venous Forum	2014	USA and Europe

Surgery and the American Venous Forum			
Management of Chronic Venous Disease, Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS)16	The European Society for Vascular Surgery	2015	Europe

2.5.10 HSEs national wound management guidelines 2018

The HSE in Ireland published National Wound Management Guidelines in 2018. The guideline aims to:

"support the implementation of standardised wound care in healthcare organisations nationally and the quality and safety of patients/clients in our care...and to...ensure that the most up-to-date evidence is available to support the standardisation of care and encourage best clinical practice, and to contribute to improved patient outcomes" (HSE, 2018, p. 2).

The guidelines detail the:

- Assessment of leg ulceration
- Management of venous leg ulceration,
- Management of Venous leg ulceration post healing.

As these guidelines were published in 2018 it provided the author with a unique and timely opportunity to explore the link between safety, and CPGs for the management of VLUs.

The HSE created an original grading scheme for the National Wound Management Guidelines and provide the grading system detailed in Table 2-5. The grading system was created by members of the HSE's Guideline Review Group (GRG), and recommendations graded using this system are noted as "HSE Recommendation Evidence Grade: A, B, C or D"

Table 2-5 HSE Recommendation Evidence Grade

Level of Evidence	Source of Evidence
A	Data derived from multiple randomised clinical trials or meta-analysis
B	Data derived from a single randomised clinical trial or large non-randomised studies
C	Recommendation comes directly from an existing guideline
D	Consensus of expert opinion and/or small studies, retrospective studies, registries

2.5.11 VLU guidelines - patient assessment

The diagnosis, management, and treatment of VLUs is complex. The diagnosis of chronic venous disease should be based on history, patient presentation, clinical examination and findings from appropriate tests to support diagnosis (Santler & Goerge, 2017).

It is important to identify the presence of CVD from the outset and have an understanding of the risk factors associated with VLU's as part of the patients history (Table 2-6) and to exclude potential differential diagnosis including arterial disease, diabetes, traumatic ulcers and mixed aetiology (Lim, Baruah, & Bahia, 2018), vasculitic leg ulcers and malignancy (Pannier & Rabe, 2013). Due to the mixed aetiological factors associated with leg ulceration, an assessment should be undertaken by a clinician with appropriate training (Franks et al., 2016; HSE, 2018).

Table 2-6 Risk Factors for VLUs (Lim et al., 2018)

Increasing age
Female
Lipodermatosclerosis
Previous ulcer
Family history of chronic venous disease or ulcers
High body mass index
History of venous thromboembolism
Physical inactivity (such as lower limb skeletal or joint diseases, occupational, sedentary lifestyle)
Increasing number of pregnancies
Severe leg injury or trauma

2.5.12 Patient assessment - ankle brachial pressure index

It is recommended that all patients have an ankle brachial pressure index (ABPI), or ankle brachial index (ABI) completed as part of their assessment (Andriessen et al., 2017; Franks et al., 2016; HSE, 2018). This is a non-invasive test used to assess peripheral perfusion in the lower limbs using a sphygmomanometer and a handheld ultrasound device (Kelechi et al., 2015) Figure 2-6. In a systematic scoping review undertaken by Weller et al, (2018) to analyse existing international CPG’s for VLU management on the recommendations for compression based on ABPI reading and clinical assessment found that of the 13 VLU CPG’s they reviewed that in relation to the specific ABPI range of compression therapy that can be safely applied clear guidance was lacking (Weller et al., 2018). This demonstrates a lack of consistency which may affect clinicians use of guidelines in practice.

The continuous-wave Doppler ultrasound is a readily available means to examine the veins of the leg as a screening test for chronic venous disease (Santler & Goerge, 2017). Doppler can be used where oedema may prevent palpation of the pedal pulses. It is a measure that supports clinical decision making in assessing for arterial disease (Wounds Australia, 2016).

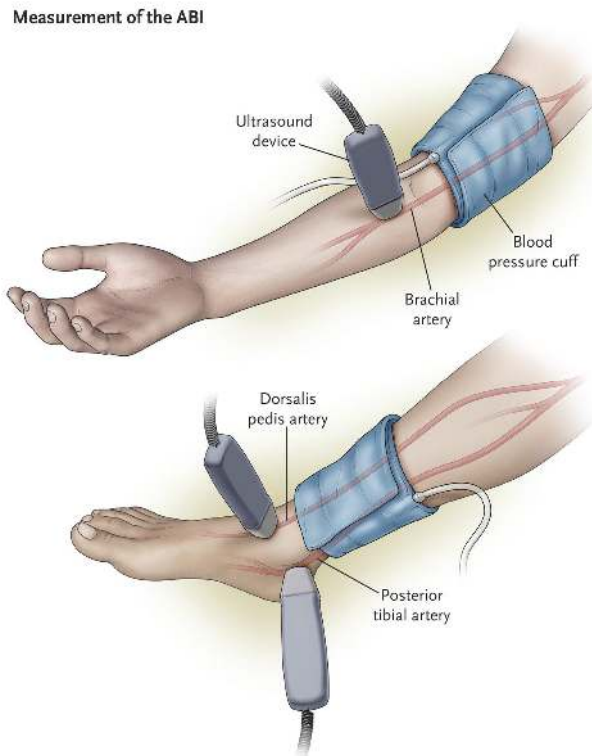


Figure 2-6 Measurement of ABPI (Singer et al., 2017)

The ABPI is determined by measuring the ratio of the highest brachial systolic pressure to the highest ankle systolic pressure as recorded in the arterial pulses of the leg and can be expressed as the formula:

$$\text{ABI} = \frac{\text{Ankle Systolic Pressure}}{\text{Brachial Systolic Pressure}}$$

The resting ankle brachial index's diagnostic criteria were standardised in 2011 (Kim, Wattanakit, & Gornik, 2012). Healthy adults are considered to have a value greater than 1. Diagnosis of peripheral arterial disease is typically excluded with an ABPI of ≥ 0.9 at rest. It is noted that referral to a vascular specialist should be considered for $\text{ABPI} \leq 0.90$ at rest before starting compression therapy (Andriessen et al., 2017). Andriessen et al (2017) provide guidance regarding arterial circulation and ABPI (Table 2-7) and this guidance is incorporated into the HSE National Wound Management Guidelines 2018. However, the Scottish Intercollegiate Guideline currently

states that compression therapy can be safely used in leg ulcer patients with an ABPI ≥ 0.8 (Scottish Intercollegiate Guidelines Network, 2010).

Table 2-7 Arterial circulation and ABPI (Andriessen et al., 2017)

Ankle brachial pressure index	Arterial circulation	Compression treatment
ABPI > 1.00–1.3	Normal	Apply compression
ABPI = 0.8–1.0	Mild peripheral disease	Apply compression with caution
ABPI \leq 0.8–0.6	Significant arterial disease	Use modified compression with caution – refer to a specialist
ABPI < 0.5	Critical ischaemia	Do not compress – refer urgently to a vascular specialist
ABPI > 1.3	Refer to vascular/diabetic specialist	

ABPI measurement when done correctly, i.e., correct patient position, correct cuff position, and rest time, and when the practitioner has an understanding of the variables when performing the assessment, is considered to be clinically relevant and is a valid and reliable assessment to determine the appropriate use of compression therapy (Keen, 2008).

2.5.13 Treatment

Attaran (2018) acknowledges that compression therapy is the cornerstone of treatment for VLUs and describes the latest innovations in the treatment of venous disease including Endovenous Laser Ablation, Radiofrequency Ablation, Sclerotherapy, Mechanochemical Ablation and Cyanoacrylate. These require surgical intervention that may or may not be available and may or may not suit all patients. Compression therapy is more widely used, it is used in the community and delivered primarily by nurses.

2.5.14 Compression therapy

The gold standard for VLU treatment is compression therapy focusing on improving venous function and reducing interstitial pooling (Attaran, 2018;

O'Meara, Cullum, Nelson, & Dumville, 2012). Compression therapy is delivered via a bandaging system that includes elastic and inelastic compression systems that include two and four layer multi-layer bandaging, tubular bandaging and compression hosiery (Wounds International, 2013).

Compression increases the healing rates of VLU compared with no compression and multi-component compression systems are more effective than single-component systems (O'Meara et al., 2012). The focus of treatment for VLUs is in reversing the underlying venous hypertension and "pro-inflammatory milieu" using compression treatment in conjunction with other adjuvant therapies (Chi & Raffetto, 2015), and compression may also reduce pigmentation and pain (Attaran, 2018).

2.5.15 Classification of different types of compression

A systemic review was undertaken by O'Meara et al., (2012) specified the British Standards Institute classification of bandages as detailed by Thomas (1995):

- Class 1: retention bandages. Used to retain dressings
- Class 2: support bandages. Used to support strains and sprains. Bandages in this category can apply mild to moderate compression.
- Class 3a: light compression. These bandages exert 14 to 17 mmHg at the ankle when applied in a simple spiral.
- Class 3b: moderate compression. These bandages apply 18 to 24 mmHg at the ankle when applied as a simple spiral.
- Class 3c: high compression. These bandages apply 25 to 35 mmHg at the ankle when applied as a simple spiral.
- Class 3d: extra high compression. These bandages apply up to 60 mmHg at the ankle when applied as a simple spiral (O'Meara et al., 2012).

And compression stocking classification is also described:

- Class 1: light support, provides 14 to 17 mmHg at the ankle. Used to treat varicose veins

- Class 2: medium support, provides 18 to 24 mmHg at the ankle. Used to treat more severe varicosities, and to prevent VLUs
- Class 3: strong support, provides 25 to 35 mmHg at the ankle. Used to treat severe chronic hypertension and severe varicose veins and prevent VLUs. (O'Meara et al., 2012).

2.5.16 Impact of VLUs on the person

VLUs are difficult to heal and have a high recurrence rate, which significantly impacts the quality of life of patients with the condition (Lal, 2015). Quality of life can be defined as:

“a general perception of wellbeing, happiness, and satisfaction by an individual” (Woo, Santos, & Alam, 2018, p. 18)

Chronic venous disease is associated with a reduced quality of life, in terms of pain, physical function, and mobility (Bergan et al., 2006). Those living with chronic wounds find that it results in isolation and report increased levels of stress and depression (Woo, 2013). Several tools exist to assess the quality of life (QoL) in patients with venous disease, including the Aberdeen Varicose Vein Score and the Chronic Venous Insufficiency Quality of Life Questionnaire (Onida & Davies, 2016). Studies using these assessment tools report that patients with a CEAP classification of C5-C6 reported very poor quality of life and comparable to other chronic diseases such as heart failure and chronic lung disease (Andreozzi et al., 2005; Carradice et al., 2011).

A systematic review undertaken by Phillips et al., (2018) to identify qualitative research that looked at the symptoms and health-related quality of life themes from patients with VLU's reported that the symptoms associated with VLU's are broad and individualised to each patient highlighting the complex nature in caring for this group of patients.

The psychosocial impact of VLUs is significant for the individual manifesting in social isolation, depression, feelings of regret, loss of power and helplessness, and poor quality of life (Lal, 2015). Patients identified terms such as 'not giving in, keeping cheerful, not moaning, coping and avoidance, hiding leakage, and stoicism' in responding to the impact of VLU's (Phillips et al., 2018)

2.5.17 Measuring the cost of VLUs

The chronic nature of leg ulcers means that chronic venous disease utilises a significant amount of healthcare resources (Bergan et al., 2006) and creates a healthcare burden in the western world (Chi & Raffetto, 2015). It is reported that the prevalence of CVD accounts for 2% of the healthcare budget in western societies (Davies, 2019). Different health care systems have different funding approaches to the cost of treatment for VLUs. In the UK, the estimated costs associated with the management of patients with VLUs amounts to an annual cost of just over £2 billion GBP sterling, the primary cost driver being the number of district nurse visits, followed by dressings and compression bandages (Phillips et al., 2020) with the direct cost per patient per annum to be in the region of £7706 GBP sterling. In Australia, it is reported that the direct costs for treating VLUs are over US\$802.5 million dollars and that patients are not receiving evidence-based care (Barnsbee et al., 2019). In Ireland, it is not possible to detail the costs of VLUs separately from other chronic wounds. The estimated annual cost for wound care in Ireland is €614,691,970 (95% CI: €445,009,348, - €827,702,117) (Gillespie, Carter, McIntosh, & Gethin, 2019). It is recognised that greater adherence to evidence-based practice approaches and the use of guidelines in caring for patients with VLUs would result in significant financial savings (Barnsbee et al., 2019; Phillips et al., 2020).

2.6 Chapter summary

The literature review identified the need for patient safety to be high on the agenda for clinicians, policy makers, and care organisations, focusing on researching patient safety issues (Walshe & Boaden, 2005). CPGs are a vital support to clinicians in practice. They have an important role in providing evidence to those delivering direct patient care as well as to those responsible for policy decisions and health care costs. Implementing CPGs effectively can influence the quality of care that patients experience, particularly when the evidence of a recommendation has been rigorously assessed for strength/weaknesses that lead to changes in practice. Guidelines help to standardise practice and may have a direct relationship to patient outcomes.

Chapter 2 Literature Review

Regarding VLUs, adherence to CPGs may improve healing rates and guide nurses to support patients who experience malodorous wounds and pain.

Patient safety is the cornerstone of nursing practice and links to the five principles of the Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives. In recognising that patient safety extends to more than adverse events and errors in practice and encompasses the application of evidence to improve the quality of care necessitates further study in this area with this patient cohort.

Having undertaken this literature review, it is challenging to find a correlation between CPGs and patient safety. The author cannot identify any studies that particularly focus on patients with VLUs, given the burden of the disease for the healthcare providers and the patient.

The next chapter will present the methodological approach and the theoretical framework used in the study.

Chapter 2 Literature Review

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Chapter 3 **Methods**

3.1 Introduction

This chapter introduces the methodological approach taken in the context of the thesis and will frame the research paradigm selected, i.e., a positivist paradigm. This study aims to identify - Do evidence-based CPGs impact patient safety in patients with VLUs? The framework for patient safety research (Pronovost et al., 2009) is introduced. The application of the framework to this thesis is presented and justified. The author details each step on the framework and the relationship to the research methods chosen; for ease of reference, the section of the framework is highlighted at the introduction of each future chapter.

In Chapter 4, Chapter 5 and Chapter 6, the author outlines three different research studies used to answer the primary question. For ease of reading, each chapter will be presented as methods and results consecutively within the chapter.

3.1.1 Chapter 4

Chapter 4 is divided into three sections:

Section (A) presents an introduction to systematic reviews.

Section (B) will present the preparation for the systematic review, and

Section (C) will present the final systematic review manuscript accepted for publication.

3.1.2 Chapter 5

Chapter 5 is divided into two distinct sections.

Section (A) will introduce the reader to survey research and provide a comprehensive overview of the methodological approach taken, including an overview of the selected questionnaire and issues such as validity and reliability will be addressed as it pertains to the survey. The creation of the survey will be described, including the application of additional questions. Ethical considerations related to the survey will also be addressed. The process of data collection and presentation of results will be provided.

Chapter 3 Methods

Section (B) will present the results of the survey. The presentation of the results will be described in more detail.

3.1.3 Chapter 6

Chapter 6 will present the rationale for the panel discussion and the results of same. The role and constitution of the discussion panel are presented, and the approach to the structure of the facilitated discussion is noted. The process of data collection and presentation of results are provided

3.2 Methodological approach.

Different research paradigms can be used to support the pursuit of systemic approaches to gain knowledge to understand how the world operates (Park, Konge, & Artino, 2020). The word paradigm was coined by Thomas Kuhn, an American philosopher in his work *'The Structure of Scientific Revolutions'* in 1962, to mean a philosophical way of thinking (Kivunja & Kuyini, 2017). Kivunja & Kuyini (2017) state that:

"a (research paradigm) is the lens through which a researcher looks at the world. It is the conceptual lens through which the researcher examines the methodological aspects of their research project to determine the research methods that will be used and how the data will be analysed." (Kivunja & Kuyini, 2017, p. 26).

It is essentially the belief system that underpins the methodological position taken by the researcher (Polgar & Thomas, 2020). Creswell and Creswell recognise the term 'worldview' as a *"basic set of beliefs that guide action"* (Creswell & Creswell, 2017, p. 5); they specifically state that other authors refer to the philosophical underpinnings of research as; paradigms, epistemologies and ontologies or broadly conceived research methodologies (Creswell & Creswell, 2017).

Paradigms are influenced by ontological positions (Slevitch, 2011). The positivist ontological perspective reflecting the nature of reality underpinning the philosophical position of positive paradigm assumes that a single reality exists in the research phenomenon. It can be measured, identified and understood irrespective of the researchers perspective or belief (Park et al., 2020). Therefore, in conducting research, the investigator adopts a controlled and structured approach which includes a precise research topic, adopting a suitable research methodology while remaining detached from the participants.

The author adopted a quantitative methodological approach to this thesis as this method supports the notion that data can be analysed using numerical methods (Quick & Hall, 2015) and that quantitative research incorporates a variety of methods to investigate a phenomenon of interest, thus supporting

the analysis of trends and relationships from simple measurements to more complex phenomenon such as attitudes and beliefs (Watson, 2015). Researchers have several tools available when using quantitative methods, including systematic reviews, questionnaires, and Randomised Control Trials, amongst many others. Given the research question is to identify if evidence-based clinical practice guidelines impact on patient safety in patients with VLUs the author has used three specific methods to ensure a multifaceted approach answers the research question in this thesis:

- (i) a systematic review as numerical data can be pooled to draw conclusions from previous studies,
- (ii) a purposive sample survey methodology and
- (iii) a discussion panel (established by the author). The author acknowledges that panel discussions are not aligned to the quantitative methodological approach. However, the rich data available from the survey must be contextualised to promote a deeper understanding of the phenomenon being studied.

The survey data for this thesis is quantitative. One open-ended question in the survey asks the respondent to include any additional information that they feel is relevant. This provides the author with context for the findings.

3.3 Framework for patient safety research

A Framework for Patient Safety Research and Improvement was developed by Pronovost et al. (2009) to respond to an increasing need for improvements and progress in patient safety. The framework includes five domains:

- i) Evaluating progress in patient safety
- ii) Translating evidence into practice
- iii) Measuring and improving culture
- iv) Identifying and mitigating hazards
- v) Evaluating the association between organisational characteristics and outcomes.

It is recommended by Pronovost et al. (2009) that healthcare organisations address technical (science) and adaptive work (culture) to sustain improvements in patient safety and note that patient safety research is an

applied science; therefore, technical and adaptive activities are inextricably linked. They offer the example of clinicians' adherence to evidenced-based practice as a means of demonstrating technical work and adaptive work (Pronovost et al., 2009)

While it is recognised that it is challenging to translate evidence into practice, particularly in the form of clinical guidelines; this study aims to identify if evidence-based clinical practice guidelines impact patient safety in patients with VLUs, the Framework for Patient Safety Research will be used to guide the methods chosen. The author selected this framework as it is underpinned by Donabedian's structure, process, and outcome paradigm, with one of four distinct areas of focus being – how often do clinicians provide appropriate, evidence-based interventions? Importantly in the context of this thesis, Pronovost et al., (2009) in describing 'translating evidence into practice' specifically recognise that errors in omission (that is failure to provide evidence based care) can result in significant preventable harm to patients.

3.3.1 Relationship of the Framework for patient safety research to this thesis

The relationship of the framework to the thesis and the connection to the methods selected is illustrated in Figure 3-1. the author then presents further detail of the context of the framework under each domain as particularly applied to the thesis.

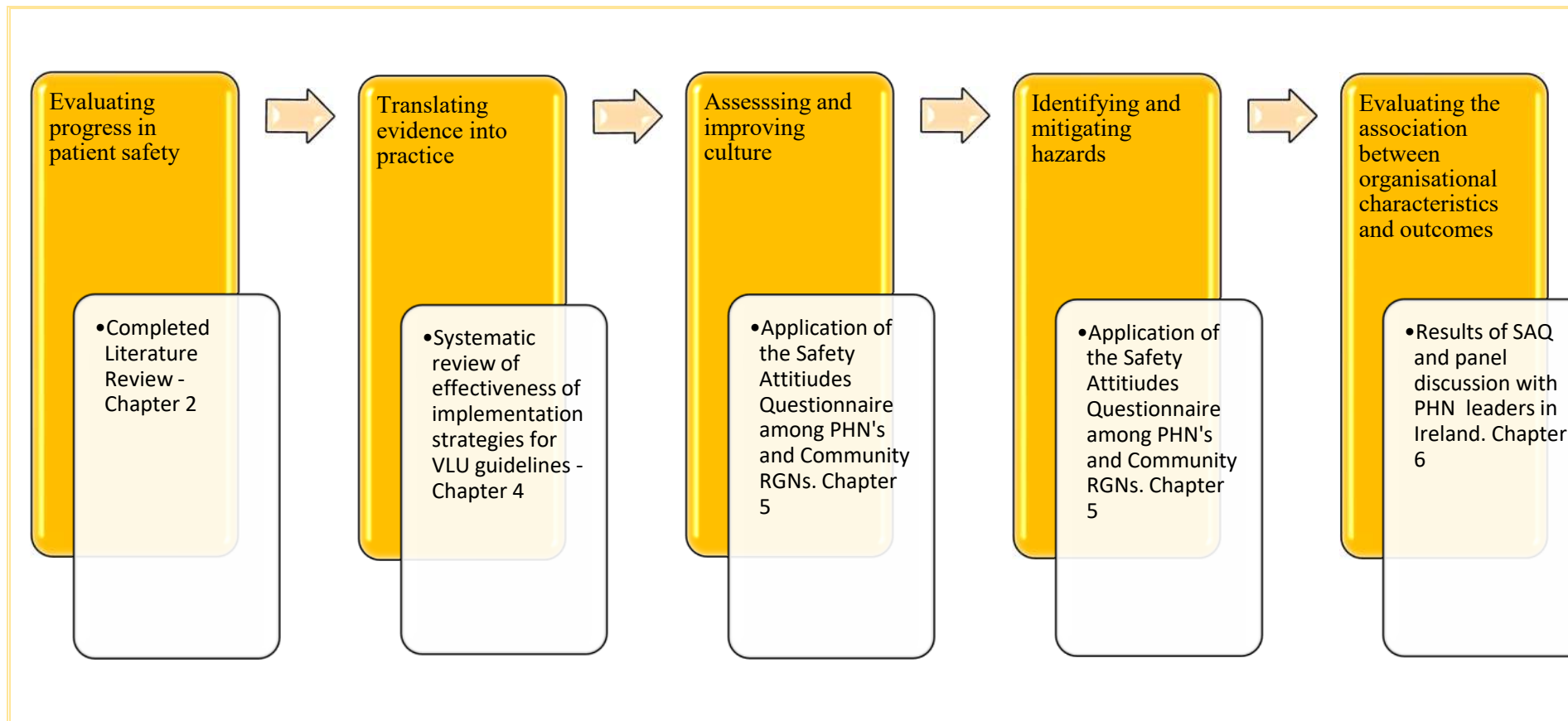


Figure 3-1 Relationship of the framework for patient safety and research to this thesis

3.3.2 Domain 1: Evaluating progress in patient safety.

The author completed a comprehensive literature review (Chapter 2) which included a specific review of patient safety. Although patient safety research is challenging advances have been made in reporting harm and addressing specific measures such as reducing healthcare associated infection e.g. central line infection (Yokoe & Classen, 2008); however it is equally important to identify compliance with evidence-based practice as patients may experience preventable harm in the omission of evidence-based practice interventions (Pronovost et al., 2009). For this thesis, preventable harm in the omission of evidence-based practice interventions includes the omission of adherence to evidence-based guidelines in the care of patients with VLU. As part of the process in evaluating progress in patient safety, it is important to consider what structures are in place to mitigate against the risk of non-adherence to evidence-based practice; Pronovost & Sexton (2005) state that to reduce the risk of non-adherence to evidence-based practice three things must be assessed (1) was a new policy, guideline or procedure created, (2) do staff know about the policy, guideline or procedure and (3) do staff use the policy, guideline or procedure as intended, the latter requiring an audit of the behaviour of staff, This will be explored further in the discussion and conclusion chapter, considering the results.

3.3.3 Domain 2: Translating evidence into practice.

It is challenging to translate evidence into practice, particularly in the form of clinical guidelines (Grol & Grimshaw, 2003) In order for evidence-based clinical practice guidelines to be effective, they must be disseminated appropriately. Once disseminated, they must be implemented; Rauh et al. (2018) argue that the highest quality evidence-based guidelines are essentially deemed useless if not used in daily practice. The evidence-based management of VLUs is well documented in clinical practice guidelines, for example with the Australian Wound Management Association (2011), Franks et al (2016), HSE 2018. The evidence for the management and treatment of VLUs is detailed in chapter 2 section 2.5 However, it is reported that despite the existence of evidence-based clinical practice guidelines for the treatment and management of VLUs that a gap remains in translating the evidence into practice resulting in patients not receiving the best possible care (Weller et

al., 2020). Interventions that increase the extent to which patients receive evidence-based care is presented in Chapter 2. In applying this domain of the framework, i.e., translating evidence into practice to this thesis, the author undertook a systematic review to assess the effectiveness of implementation strategies for VLU guidelines to evaluate interventions that increase the extent to which patients with VLUs receive evidenced-based care thus successfully translating evidence into practice. The preparation work for the systematic review and the full systematic review is presented in Chapter 4.

3.3.4 Domain 3: Assessing and improving culture.

Patient safety culture is comprehensively described and defined in this thesis in the literature review (Chapter 2). It is important to assess patient safety culture to understand the attitude of nurses towards patient safety. Safety culture is often measured using psychometric questionnaires; Chapter 5 describes this in greater detail. In applying this domain of the framework, i.e., assessing and improving culture, the author undertook primary research using a valid and reliable questionnaire (Chapter 5) to evaluate the safety attitudes of PHNs and CRGNs in the Republic of Ireland. The questionnaire and results are presented in Chapter 5.

3.3.5 Domain 4: Identifying and mitigating hazards

Although 90% of healthcare is delivered in the community setting, most patient safety research and the measuring and monitoring of patient safety have primarily focused on the acute hospital sector. This may be due to the primary or ambulatory setting being considered a lower risk intervention, and therefore harm is less impactful (Cooper & Chuter, 2015). Although individual hazards at a unit level will not be evaluated as part of this study, the author will capture contributory factors to patient safety through the questionnaire, e.g., staffing levels, the role of management, staff morale. Identifying contributory factors associated with hazards/adverse events allows organisations to plan strategies to mitigate against hazards recurring (Pronovost et al., 2009).

3.3.6 Domain 5: Evaluating the Association between organisational characteristics and outcomes

In evaluating the association between organisational characteristics and outcomes at the unit (health centre) level, Pronovost et al. (2009) point us to social and structural features of the workplace, including culture, policies, the dedication of leaders and it is recognised that measures of patient safety are difficult to obtain. The elements of culture, policies, and leadership will be an important element for the discussion panel to consider in the context of the findings from the questionnaire. This is presented in Chapter 6.

3.4 Chapter summary

This chapter provided the reader with an introduction to research in the context of this thesis. The methodological approach taken was presented, and the Framework for Patient Safety Research and Improvement was introduced, and the author described how this framework will be presented in the following three chapters. The Framework for Patient Safety Research and Improvement contained five domains: 1) evaluating progress in patient safety, 2) translating evidence into practice, 3) assessing and improving culture, 4) identifying and mitigating hazards, and 5) evaluating the association between organisational characteristics and outcomes. Each domain was aligned to a research method and is presented accordingly at the beginning of each chapter as relevant.

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Chapter 4 Systematic review

4.1 Introduction

This chapter is presented in three distinct sections.

Section (A) provides an introduction, overview, and rationale for undertaking a systematic review.

Section (B) presents preparation for the systematic review that were not included in the final published manuscript

Section (C) consists of the final published manuscript (Kerr, Devane, Ivory, Weller, & Gethin, 2020)

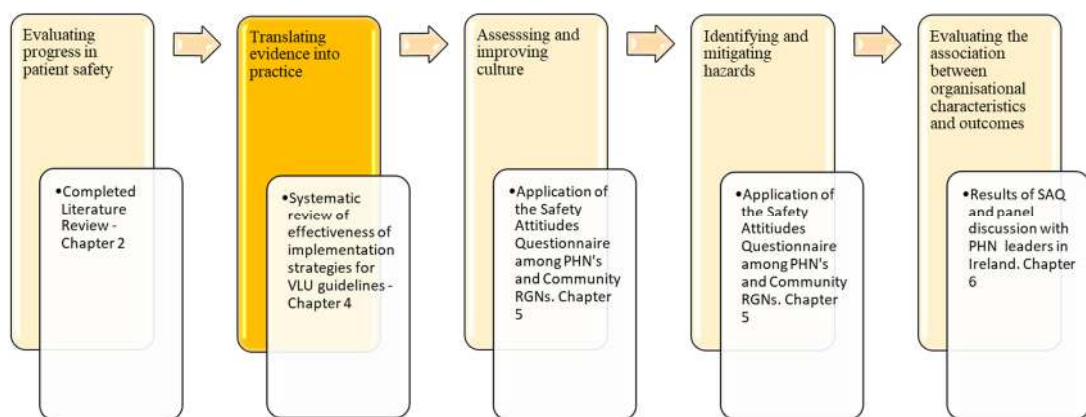


Figure 4-1 Domain 2: Translating evidence into practice in the context of this thesis

As described in the previous chapter, the Framework for Patient Safety and Research and the application to this thesis will be presented at the beginning of each chapter Figure 4-1; in this case, the reference is in relation to Domain 2: Translating evidence into practice, and this is examined by undertaking a systematic review.

4.2 Section A - Systematic review

Having undertaken the literature review (Chapter 2) and noting the barriers and facilitators regarding the uptake of evidence-based clinical practice guidelines, it was important to identify the evidence regarding

Chapter 4 Systematic Review

implementation strategies for evidence-based clinical practice guidelines for VLUs. A systematic review is the most appropriate methodological approach to answer the question in terms of reviewing the evidence.

James Lind is credited with undertaking a systematic review in the 1700s; it was not until the 1970s and 1980s however, momentum began to gather regarding the synthesis of evidence in medicine (Pericic & Tanveer, 2019). In 1971 Dr Archibald (Archie) Cochrane, a Scottish epidemiologist, wrote the monograph *'Effectiveness and Efficiency: Random Reflections on Health Services'* whereby he encouraged the use of Randomised Control Trials in order to improve the effectiveness, efficiency and equity of medicine, ultimately leading to the creation of The Cochrane Collaboration and evidence-based practice (Shah & Chung, 2009). Systematic reviews initially focused on the field of medicine, comparing one form of treatment to an alternative; it is acknowledged that the methodology now has much broader application and relevance and has reached into other disciplines other than medicine (Perry & Hammond, 2002).

There are many definitions in the literature for systematic reviews. Cochrane is the most cited organisation in the variety of definitions available. It is suggested that the Cochrane definition could be used as the most acceptable definition. The Cochrane handbook states that:

“Systematic reviews seek to collate evidence that fits pre-specified eligibility criteria in order to answer a specific research question. They aim to minimize bias by using explicit, systematic methods documented in advance with a protocol” (Chandler, Cumpston, Thomas, Higgins, & Deeks, 2020).

It is suggested that to reduce ambiguity and to be more succinct that at a minimum, a systematic review is a review that reports or includes the following:

- i) a research question
- ii) sources that were searched, with a reproducible search strategy (naming of databases, naming of search platforms/engines, search date and complete search strategy)

Chapter 4 Systematic Review

- iii) inclusion and exclusion criteria
- iv) selection (screening) methods
- v) critically appraises and reports the quality/risk of bias of the included studies
- vi) information about data analysis and synthesis that allows the reproducibility of the results (Krnjic Martinic, Pieper, Glatt, & Puljak, 2019).

4.2.1 The rationale for undertaking a Systematic Review

Research papers published in peer-reviewed journals may be one of the most significant influencers in driving evidence-based health care (Cullum, Ciliska, Haynes, & Marks, 2013). It is important to gather findings from published papers on the same topic and compare and contrast the findings (Polgar & Thomas, 2020). Systematic reviews are considered a central focus to evidence-based health care and are widely used to develop clinical practice guidelines (Munn et al., 2018). The author undertook a systematic review to identify the effective strategies to implement Clinical Practice Guidelines for the management of VLUs by health care professionals in the hospital, outpatient, home, and community settings. This is an important starting point, having identified barriers and enablers in using evidence-based practice guidelines from the literature review (Chapter 2). The preparation for the systematic review is presented in section 4.3 in this chapter.

4.3 Section B – Preparation for the systematic review

The purpose of this preparation for the systematic review is to provide an overview of recommendations in relation to the implementation of clinical guidelines; Implementation guidelines for VLUs will be considered as they are cross-discipline and international approaches to the management of VLUs can be examined. A significant amount of evidence is available about standardising practice concerning the management of VLUs; however, the quality of services for this patient group remains inconsistent as a barrier to implementation is created when guidelines contradict each other (Scott & Glasziou, 2012).

4.3.1 Background

In 1993 NHS Scotland formed the Scottish Intercollegiate Guideline Network (SIGN). The purpose and function of the network are to improve standardisation in the availability and quality of care for patients in Scotland. It is to achieve this by distributing evidence-based clinical practice guidelines (Scottish Intercollegiate Guideline Network, 2016). Similarly, The National Institute for Clinical Excellence was established in England in 1999. It was rebranded in 2005 to become the National Institute for Health and Clinical Excellence (NICE). In 2013 it was designated under legislation to include social care and became known as the National Institute for Health and Care Excellence (NICE, 2016). The function and purpose of the institute are to develop national guidance and standards to improve high-quality health and social care. The NICE guidelines is the system that is accessed in Wales to support clinical practice. In Ireland, the National Clinical Effectiveness Committee was established in 2010 by the Minister of Health and Children. The terms of reference are to publish standards for clinical practice guidelines and to publish guidance for National Clinical Guidelines and National Clinical Audit (National Clinical Effectiveness Committee).

It is well recognised that evidence-based guidelines play a pivotal role in patient safety and the quality of care they receive (Madden, 2008). This is reinforced through the presence of guidance bodies described above.

4.3.2 Description of the issue

Guidelines are written with the intention to standardise approaches to patient care and to aid decision making for the clinician. This applies to the entire multidisciplinary team; practice guidelines exist for medicine, nursing, physiotherapy, occupational therapy, speech and language therapy, etc. The National Guideline Clearing House part of the Agency for Healthcare Research and Quality use the definition for Clinical Practice Guidelines (CPG's) from the IOM as "statements that include recommendations intended to optimise patient care. They are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options" (Graham et al., 2011). It is well recognised that while clinical practice guidelines exist to improve patient care, there remain inconsistencies

between recommended practice and what actually happens in clinical practice (Flodgren, Eccles, Grimshaw, Leng, & Sheppard, 2013).

4.3.3 Description of the intervention

In the UK, the National Institute of Health and Care Excellence offer support in implementing NICE guidance in the form of:

- Return on Investment tools
- Education and learning
- Audit and service improvement
- Resource impact assessments

It is suggested that there is insufficient evidence regarding the most appropriate method of implementation strategy and that further research is required in order to develop and validate a framework that will result in better adherence to clinical practice guidelines (Grimshaw, Thomas, MacLennan, Fraser, & Ramsay, 2004)

4.3.4 How the intervention might work

The factors associated with non-adherence, non-compliance or the lack of implementation of new guidelines or new approaches to practice are considered in a systematic review undertaken by Baker et al. (2015). They suggest that unless the determinants of practice are considered, then it is not possible to plan interventions that will remedy the behaviours associated with the identified determinants of practice; these include barriers, enablers, obstacles and facilitators (Baker et al., 2015). Occasionally new practices are implemented with minimal obstacles; however, when the change requires better multidisciplinary teamwork, changes in clinical scheduling/routine, or how care delivery is organised, changes in practice are not easily achieved (Grol, Bosch Marije, Hulscher Marlies, Eccles Martin, & Michel., 2007). It is acknowledged in the literature that any change in health care is extremely difficult to achieve and by its very nature healthcare is a complex and complicated (Braithwaite, 2018).

Michie, Van Stralen, & West (2011) refers to intervention effectiveness concerning the implementation of clinical practice guidelines and references NICE and Cochrane Reviews as areas of evidence to be introduced; It is noted

Chapter 4 Systematic Review

that implementation is not always effective and recommends that we need to understand the science and technology of behaviour change and make it readily available to policy makers and those that develop interventions. Having evaluated 19 frameworks for change; they developed a behaviour change wheel that recommends that three conditions for change are met, namely: cognitive, opportunity and motivation for implementation of intervention to influence evidence-based practice and care. They go on to state nine interventions that support the conditions, namely: education, persuasion, incentivisation, coercion, training, enablement, modelling, environmental restructuring and restrictions (Michie et al., 2011)

4.3.5 Why it is important to do this review

The use of clinical practice guidelines results in a more cost-effective service with better patient outcomes through a reduction of inappropriate care (Prior, Guerin, & Grimmer-Somers, 2008). In 2003 it was considered that about 30–40% of patients did not receive care according to the available evidence, and about 20–25% of care provided was not needed or was potentially harmful to patients (Grol & Grimshaw, 2003). There is no current evidence in the literature to suggest that the situation since 2003 has improved. The systematic review is timely as the costs of healthcare is increasing, the environments in which care is being delivered is changing, and healthcare professionals have an obligation to deliver care that will not result in unnecessary use of resources nor deliver care that may potentially harm patients. One of the key drivers for undertaking this thesis is that the HSE have published new and updated guidelines so understanding effective implementation strategies is important and can inform the HSE on how to move forward.

4.3.6 Aim

The aim of the systematic review is to identify the most effective strategies to implement CPGs for the management of VLU by health care professionals in the hospital, outpatient, home, and community settings.

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4.4 Section C - Systematic Review

4.4.1 Section Overview

This Section presents the final submitted manuscript published in the Journal of Tissue Viability. The journal has an impact factor of 2.932

4.4.2 Journal Author Rights

Please note that, as confirmed by Elsevier that as the author of this article, the author retains the right to include it in a thesis or dissertation, provided it is not published commercially. Permission is not required from the publisher, but the publication must be referenced as the original source.

The citation for this publication is:

Kerr, J., Devane, D., Ivory, J., Weller, C. and Gethin, G., 2020. Effectiveness of implementation strategies for VLU guidelines: A systematic review. *Journal of tissue viability*, 29(3), pp.161-168.

A formatted version of the manuscript is presented below. The published manuscript is in

4.5 Title

Effectiveness of implementation strategies for VLU guidelines: a systematic review

4.6 Background:

The aim of clinical practice guidelines is to improve patient care; however, inconsistencies between recommended practice and what actually happens in clinical practice continues. VLUs have a significant negative impact on patients' quality of life, and it is acknowledged that managing people with VLUs is protracted and costly. The aim of this review is to identify the most effective strategies to implement clinical practice guidelines (CPGs) for the management of VLUs by health care professionals in the hospital, outpatient, home, and community setting.

4.7 Methods:

A systematic review guided by methods from the Cochrane EPOC group was undertaken to identify implementation strategies for VLU clinical practice guidelines. Eligible studies were identified via systematic electronic searches of Medline, Embase, CINHAL and the Cochrane Library.

4.8 Results:

We identified 142 potential studies, of which one randomised controlled trial met the inclusion criteria. Following an analysis of the included study, it is not possible to recommend one implementation strategy over another when implementing practice guidelines for people with VLUs.

4.9 Conclusion:

We identified a limited evidence base for the effectiveness of implementation strategies for VLU CPGs. No one implementation strategy is better than another to facilitate VLU CPG implementation by health care professionals in hospital, outpatient, home, or community settings.

4.10 Keywords:

Implementation, VLU, clinical practice guidelines

4.11 Funding:

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

4.12 Declaration of Interest:

None

4.13 Introduction

VLUs (VLUs) are considered complex wounds(Christie, Gray, Dumville, & Cullum, 2018) and are defined “as an open lesion between the knee and the ankle joint that remains unhealed for at least four weeks and occurs in the presence of venous disease” (Scottish Intercollegiate Guidelines Network, 2010, p. 1)^{p.1}. The estimated prevalence of venous leg ulceration is 1% in the adult population and 3% in those aged over 80 years (Franks et al., 2016). Due to the natural history of recurrence of VLUs, sustained healing after initial ulceration is a major challenge that has a considerable impact on health and quality of life. Patients’ health and healing needs are lacking due to poor implementation of evidence-based practices (Pacella, 2018), lack of clinician awareness of VLU diagnosis, inadequate clinician training and communication between health care providers, and lack of reliable data with the absence of a national VLU clinical registry (Weller & Evans, 2014).

Managing VLUs is costly (Guest, Fuller, & Vowden, 2018; Norman et al., 2016; Phillips et al., 2016). The annual costs associated with VLUs in the United Kingdom (UK) range from £596.6 to £921.9 million, allowing for adjusted comorbidities (Guest, Vowden, & Vowden, 2017). In Ireland, there are no specific studies available regarding the costs of VLUs however, the total annual healthcare cost of wound care was estimated at €629,064,198, accounting for 5% of total public health expenditure, which included the treatment of VLUs (Gillespie et al., 2019). In Australia, it has been estimated that the overall healthcare costs relating to chronic wound management, where the greater proportion of wounds are VLU, exceed AUD3 billion per year (Weller, Ademi, Makarounas-Kirchmann, & Stoelwinder, 2012; Weller & Evans, 2014),. Much of the direct cost of treatment is associated with dressings, compression bandages and community nurse visits (Norman et al., 2016). The burden and cost of VLUs is expected to rise dramatically due to

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the ageing population (Australian Bureau of Statistics, 2013), an increasing incidence of diabetes (Schofield et al., 2017), chronic cardiovascular disease and obesity (Haby, Markwick, Peeters, Shaw, & Vos, 2012). The cost savings related to reducing health service utilisation as a result of timelier healing has been calculated at AUD1.2 billion in recent economic modelling estimates (Cheng, Gibb, Graves, Finlayson, & Pacella, 2018).

It is projected that in the years 2014 to 2050, the percentage of adults aged 65 and over will increase from 18.9% to 28.5% of the general population and, more significantly, if life expectancy projections continue for the same timeframe, the general population aged 80 years and older will rise from 5.3% to 11.1% (Kluge, Goldstein, & Vogt, 2019). Reported prevalence data would suggest that 2.2% of those over 65 years (Mervis, Kirsner, & Lev-Tov, 2019) and 4% - 5% of those over 80 years (Neumann, 2017) then will experience a VLU during their lifetime.

Clinical practice guidelines aim to reduce variations in practice and support risk management processes in relation to adverse events and preventable errors, thus contributing to improving patient safety and improvement in the quality of patient care (Kredo et al., 2016). Despite this, the European Wound Management Association (EWMA) have identified variations in VLU guideline recommendations and the level of evidence to support them (Franks et al., 2016). These guidelines include a series of evidence-based recommendations for the detection, diagnosis, and management of people with VLU; however, the level of evidence of the included guidelines remains low.

The IOM (2011) United States of America states that ‘Clinical guidelines are statements that include recommendations intended to optimize patient care that is informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options’(IOM, 2011). In 2003, it was considered that about 30–40% of patients across the healthcare spectrum did not receive care according to the available evidence, and about 20–25% of care provided was not needed or was potentially harmful to patients (Grol & Grimshaw, 2003) . While clinical practice guidelines exist to improve patient

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care, inconsistencies remain between what is recommended in clinical practice and what actually happens in clinical practice (Flodgren et al., 2016).

Internationally, and particularly in the United States, Australia and the UK, there is a move towards aligning evidence-based practice (EBP) and quality and outcome frameworks to create a more accountable, cost-effective and quality-driven agenda through continuous learning (Scott & Glasziou, 2012). This is supported by other authors (Prior et al., 2008), and they state that the use of clinical practice guidelines results in a more cost-effective service with better patient outcomes through a reduction of inappropriate care. With this in mind, and despite the growing evidence base in the treatment of VLUs, there remains a call for improvements in leg ulcer management (Franks et al., 2016). Francke et al. (2008) concluded that a variety of strategies were required for CPG implementation and the need for evidence for the various implementation strategies.

It is recognised that there are significant challenges in implementing EBP including clinicians time and the knowledge base and skills of the practitioner (Woolf, 2008). Implementation science has emerged in an attempt to address some of those challenges (Bauer, Damschroder, Hagedorn, Smith, & Kilbourne, 2015). Eccles and Mittman define implementation science as *“the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services”* (Eccles & Mittman, 2006).

The aim of this review is to identify the most effective strategies to implement CPGs for the management of VLUs by health care professionals in the hospital, outpatient, home and community settings.

4.14 Methods

The PICO framework was used to develop a well-formulated answerable clinical question and is presented in Table 1. The interventions examined address the implementation of clinical practice guidelines where the purpose is to influence the clinician in practice. Any single strategy or combination of strategies will be considered.

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The EPOC Taxonomy of health systems – topics list (Cochrane, 2015) guided this systematic review, in particular, domain four of the topic list as it focuses on Implementation strategies and specifies – “*Professional interventions where interventions are designed to bring about changes in healthcare organisations, the behaviour of healthcare professionals or the use of health services by healthcare recipients*”(Cochrane, 2015, p. 9). The interventions are detailed in Table 4-1

Table 4-1 PICO Framework

PICO	Criteria
<p>Population</p>	<p>Health Care workers:</p> <p>Participants will be health care professionals and clinical and non-clinical administration staff either organising or delivering care to patients with VLUs (VLUs) in any healthcare setting or in the patient’s own home. We will include all members of the multidisciplinary team involved in the care of patients with VLU, this may include but is not limited to: geriatricians, dermatologists; nurses, physiotherapists, dieticians, nutritionists and clinical support staff. We will also include students in training.</p> <p>Patients: We will include studies in which patients have a diagnosis of a VLU.</p>
<p>Intervention</p>	<p>The intervention under consideration will be directly linked to CPG implementation and will utilise one or more of the strategies listed below. The sub category strategies listed in the EPOC Guidelines professional interventions that will be considered are:</p> <ul style="list-style-type: none"> • Distribution of educational materials - Distribution of published or printed recommendations for clinical care, including clinical practice guidelines/policies, audio-visual materials and electronic publications. • Educational meetings - Health care providers who have participated in conferences, lectures, workshops or traineeships.

- Local consensus processes - Inclusion of participating providers in discussion to ensure that they agreed that the chosen clinical problem was important and the approach to managing the problem was appropriate.
- Educational outreach visits - Use of a trained person who met with providers in their practice settings to give information with the intent of changing the provider's practice. The information given may have included feedback on the performance of the provider(s).
- Local opinion leaders - Use of providers nominated by their colleagues as 'educationally influential'. The investigators must have explicitly stated that their colleagues identified the opinion leaders.
- Audit and feedback - Any summary of clinical performance of health care over a specified period of time. The summary may also have included recommendations for clinical action.
- Reminders - Patient or encounter specific information, provided verbally, on paper or on a computer screen, which is designed or intended to prompt a health professional to recall information. This would usually be encountered through their general education; in the medical records or through interactions with peers, and so remind them to perform or avoid some action to aid individual patient care.
- Marketing - Use of personal interviewing, group discussion ('focus groups') or a survey of targeted providers to identify barriers to change and subsequent design of an intervention that addresses identified barriers.
- Mass media (i) varied use of communication that reached great numbers of people including television, radio, newspapers, posters, leaflets, and booklets, alone or in conjunction with other interventions; (ii) targeted at the population level.

Comparison	Any two of the above compared with each other; other strategies not listed above compared with any of the above or any strategy compared with no strategy.
Outcome	<p>Primary Outcome:</p> <p>The primary outcome is implementation of clinical practice guidelines for the management of venous leg ulceration in whole or in part.</p> <p>Secondary Outcome:</p> <p>Patient outcomes:</p> <ul style="list-style-type: none">i. Changes in Health-related quality of life as reported by study authorsii. Healing rates at times as reported by study authorsiii. Recurrence rates as reported by study authors <p>Service Outcomes:</p> <ul style="list-style-type: none">i. Costs<ul style="list-style-type: none">a. Direct medical costsb. Non direct medical costs – patient associated costsc. Cost utilisation, cost effectiveness other resource factors as reported by study authorsii. Reported measurements on staff behaviour

4.14.1 Search strategy

The electronic databases MEDLINE Ovid (1946 to May 2019), EMBASE Ovid (1974 to May 2019) CINAHL 1937 to May 2019) and the Cochrane Library (searched May 2019) were systematically searched. The search was developed in four distinct sections: (1) types of healthcare staff, (2) VLU (3) approach to implementation (4) environments in which care was delivered. The initial search was performed in Medline using a combination of MeSH Terms and keywords. The search terms were subsequently adjusted for EMBASE, CINAHL and the Cochrane Library. The language limits applied were English, Spanish, German and Dutch based on the language expertise of the author group and all databases were searched from inception to May 2019. The full search strategy is available in Appendix 2

4.14.2 Inclusion Criteria

The following types of studies were included(Cochrane Effective Practice and Organisation of Care (EPOC), 2017):

- Randomised Controlled Trials
- Non-Randomised Controlled Trials
- Interrupted Time Series – Interrupted time series studies are required to have a clearly defined intervention point and at least three data points before and after the intervention
- Controlled before-after study

4.14.3 Data Extraction and Analysis

Data extraction was conducted using a standardised Cochrane Collaboration Data Collection Form for Intervention review – Randomised trials and non-randomised trials(Cochrane Effective Practice and Organisation of Care (EPOC), 2017). Data extraction was undertaken by one author (JK) and verified by a second author (JI).

The search yielded 142 citations. The search results were imported into Covidence(Covidence Systematic Review software) and 11 duplicates removed. Two reviewers (JK, JI) independently screened the title and abstracts of the remaining 131 articles and 37 articles for full text review were selected. Any discrepancies were resolved following discussion. The PRISMA flow chart (Figure 1) summarises the results of the search strategy. The reasons for inclusion and exclusion were documented for every record at full text screening. As only one

RCT, Brown et al met the inclusion criteria, a meta-analysis was not conducted. The included study was evaluated by one review author initially (JK) and verified by a second author independently (JI). A third author (DD) was available to resolve any disagreements. The Cochrane Collaboration’s criteria for assessing risk of bias namely the “suggested risk of bias criteria for EPOC reviews”(Cochrane, 2015) was used to assess the risk of bias in the included study, this risk of bias assessment particularly focuses on studies with a separate control group.

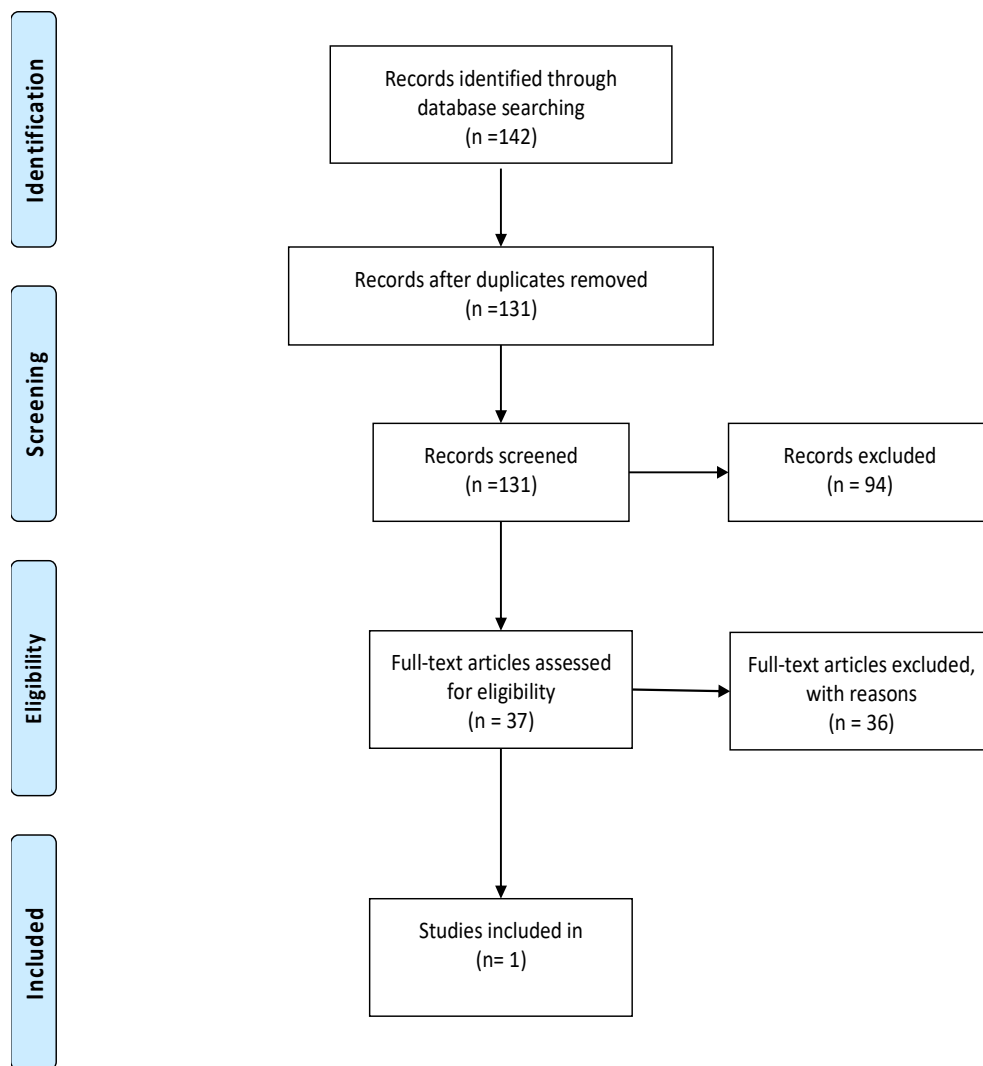


Figure 4-2 PRISMA Flow Chart

4.15 Results

4.15.1 Methodological Quality

The methodological quality of the included study was assessed using the EPOC group Risk of Bias criteria (Table 4-2). The study was assessed using the terms high, unclear, or low risk of bias for: random sequence generation (selection bias); allocation concealment (selection bias); baseline outcome measurements similar (blinding of participants); baseline characteristics similar; incomplete outcome data (attrition bias); follow-up; knowledge of the allocated interventions adequately prevented during the study; protection against contamination; selective outcome reporting (reporting bias); and other bias.

Table 4-2 Risk of Bias

Table Brown, A et al (2002)		
Cluster Randomised Control Trial	Judgement	Support for Judgement
Random Sequence generation	Low risk	Quote: “a multi-level modelling approach was used to undertake cluster randomisation”
Allocation concealment	Low Risk	Quote: “Allocation of localities to intervention or was based upon a method of minimisation which ensured approximate balance”
Baseline outcome measurements similar (blinding of participants)	Unclear risk	Insufficient information
Baseline characteristics similar	Low risk	Quote: “the intervention and control groups were well balanced in terms of age, sex, and the distribution between urban and rural populations”
Incomplete outcome data (attrition bias)	Low risk	Quote: “all subsequent response rates after telephone reminders, achieved 100%”
Knowledge of the allocated interventions adequately prevented during the study	Unclear risk	Insufficient information upon which to make a judgement
Protection against contamination	Low risk	Quote: “localities... geographically distinct and separate in terms of nursing administration hierarchy”
Selective outcome reporting (reporting bias)	Unclear risk	The study protocol is not available, but the expected outcomes do seem to have been reported on.
Other risks of bias	Low risk	The study appears to be free of other sources of bias

4.16 Included study

Brown et al (2002) reported a cluster randomised trial. The participants of the trial were patients receiving care in the home by community nurses from ten Health Board areas (15 Community Healthcare Trusts and the Western Isles Health Board, healthcare Division) covering a geographical spread of 2.65 million people. The study authors do not report the number of clusters nor the number of participants per cluster, however they do state that “allocation of localities to intervention or control was based upon a method of minimisation which ensured approximate balance with respect to the size of the leg ulcer populations” (Brown, 2002, p. 50). The study authors report that there were 50 localities with populations ranging from 4,600 – 203,000 with an average of 53,000 and a distribution of urban and rural communities. Following analysis of baseline data; a multi-level modelling approach was used to undertake cluster randomisation. The localities were randomised to receive no intervention (control group) or a nurse training programme (intervention group). The nurses in the intervention group received training comprising of attendance at core theory days of lectures and a three-day workshop to include training on leg ulcer assessment, Doppler techniques, indications for specialist referral, dressings, skin care, and bandaging techniques with pressure monitoring. The study was undertaken at the time the Scottish Intercollegiate Guideline Network introduced a new national guideline on leg ulcer care in 1998, the guideline formed the basis of the intervention programme. The study reported on the healing rates of 3,949 patients under the care of approximately 1,700 community nurses. A summary is provided in Table 4-3.

The study authors report on patient and ulcerated leg characteristics. The author reports a balanced distribution of control and intervention groups by, mean age, sex, rural and urban population spread.

Table 4-3 Patient and ulcerated leg characteristics (Brown, 2002) p50

	Control	Intervention
Age, mean (SD) years	76.8 (11.1)	77.0 (10.9)
Female patients (%)	75.3	74.6
Ulceration on other leg (%)	24.0	26.7
Duration of ulceration (%)		
3 months	59.2	56.4
4-11 months	20.4	21.8
12-35 months	11.7	12.8
>36 months	8.7	9.0

The response rates from participants in the study was 99.4% at the first round of data collection in which registration forms were sent to 649 Case Load Managers (CLMs), and subsequently 100% response rate for the data collection schedules that followed.

Table 4-4 Summary of Brown et al 2002

First Author, Year	Area of Care Delivery	Country	Study Design	Type of Policy Document	Type of Intervention (Implementation Strategy)	Comparator	Outcomes related to service	Outcomes related to the patient
Brown, A et al (2002)	Patients own home	Scotland	Cluster Randomised Control Trial (3,949 patients under the care of approximately 1,700 community nurses in 15 Community Healthcare Trusts and one Health Board Healthcare Division within 10 Health Boards in a population of 2.65m)	National guideline	Nurse Training Programme to coincide with new guideline dissemination.	No additional training provided	Not reported	No significant difference between the intervention and the control group in healing rates. (27% and 28% respectively). The odds ratio for an ulcer being healed after 3 months was 0.95 (95%CI 0.82 – 1.10, P=0.05) in the intervention areas compared with control areas.

4.16.1 Primary outcome

The primary outcome for this review is implementation of clinical practice guidelines for the management of venous leg ulceration in whole or in part. The authors of the included study Brown et al (Brown, 2002) report the outcome of healing rates and note that healing rates were not improved by a structured programme of guideline based nurse training when compared to no training.

4.16.2 Secondary outcomes:

Patient outcomes:

Changes in Health-related quality of life as reported by study authors.

- This was not reported by the authors.

Healing rates at times as reported by study authors

The baseline healing rate was 28% in both groups and following guideline implementation and training; the healing rate was 27% in the intervention group. There was no difference between the control group and the intervention group over the 21-month period of the study which remained at 27% throughout. The authors' report the odds ratio for a leg being healed after 3 months as 0.95 (95% confidence interval 0.82 to 1.10, $p=0.50$) in the intervention areas compared with the control areas. Patients who had an ulcer for three or more years at presentation had a 50% chance of it being healed in 27 months of ongoing treatment; those patients with an ulcer 3 months or less were healed after 21 months in 90% of cases in the intervention group. The study authors do not report the same data for the control group.

Recurrence rates as reported by study authors.

- Recurrence rates were not reported.

Service Outcomes:

Direct medical costs:

- The direct medical costs were not reported.

Non-direct medical costs – patient associated costs

- The non-direct medical costs were not reported.

Cost utilisation, cost effectiveness other resource factors as reported by study authors

- This was not reported.

Reported measurements on staff behaviour

In the intervention group the use of Doppler for assessment rose from 30% to 96% within the link nurses group (education leaders) and from 27% to 82% within the community nurse group.

4.17 Discussion

The objective of this systematic review was to summarise and present the findings from evidence of the effects of interventions to implement practice guidelines for VLUs. The systematic approach guided by EPOC group systematic review methodology directed the study types for inclusion in order to garner the highest level of evidence. It has been recommended (Kredo et al., 2016) previously that research is necessary to understand how clinical practice guidelines can be effectively and efficiently implemented in practice, resulting in improvements in clinical outcomes for patients as well as the process in which care is delivered. In this systematic review only one study met the inclusion criteria and reported an absence of effectiveness with regard to the type of intervention described within the study i.e., that healing rates did not improve with the implementation of a clinical practice guideline following a structured education programme.

This systematic review is timely as the costs of healthcare is increasing, the environment in which care is being delivered is changing and healthcare professionals have an obligation to deliver care that will not result in unnecessary use of resources nor deliver care which may potentially harm patients.

Franks et al (Franks et al., 2016) note there are a variety of guidelines available and it is of concern that given an ageing demographic, the increase in healthcare costs and the plethora of practice guidelines that exist regarding the treatment and management of VLUs, there is no standardisation in the

care and treatment in this patient group. Implementation of clinical practice guidelines may respond to the need to decrease costs for providers whilst improving the quality of care however the economic considerations were not reported in the RCT included in this systematic review.

Brown et al (Brown, 2002) conclude that there was no significant difference between the control group and the intervention group for healing outcomes at three months. They note that their findings are contrary to conventional thinking that educational programmes are required to improve adherence to guidelines and in response to their findings they did consider the effectiveness and appropriateness of the training programme provided to the health care professional. Brown et al report that although there were improvements in the use of doppler for patient assessment; healing rates did not improve using a single intervention approach i.e., education and training.

Local implementation of national clinical practice guidelines may be improved if there is stronger guidance regarding implementation. It is noteworthy from the excluded studies in this systematic review that in planning to improve approaches to care for patients with VLUs local pathways were often developed in responses to a local audit (Gardner, 2013; Rybak, Franks, Krasowski, Kalembe, & Glinka, 2012). The Commission on Patient Safety and Quality Assurance states that clinical audit is essential for good clinical governance and notes that it: *'...constitutes the single most important method which any healthcare organisation can use to understand and ensure the quality of the service that it provides'* (Madden D, 2008, p. 12).

The EPOC group (Cochrane, 2017) recommends that when reporting on results from excluded studies, a secondary objective could be specified to include strategies that have not been rigorously evaluated. As a secondary objective was not specified for this systematic review, detailed results from excluded studies are not presented. Indications from excluded studies do suggest however that further research which includes descriptive studies, audits and service evaluation may provide additional information. The aim of implementation science is to improve the quality of health care, although comparisons can be drawn with other quality improvement (QI)

methodologies, implementation science begins with acknowledging gaps in the delivery of EBP at various levels within organisations (Bauer et al., 2015). The authors suggest that it may be timely to examine the methods and principles offered through implementation science as a means for healthcare systems to respond more effectively in implementing EBP as we have found that a single approach does not produce the change required and a concentrated multifaceted implementation strategies are required (Bauer et al., 2015)

Tinkler et al (Tinkler, Hotchkiss, Nelson, & Edwards, 1999) reports that patients receiving VLU treatment need a clear association between improved practice and patient outcomes following the implementation of an evidenced based practice guideline; but the authors also note that it was not possible to ascertain which implementation strategy contributed to the improved study outcomes. The primary outcome of this study was implementation of clinical practice guidelines for the management of people with VLU. Based on our systematic review it is not possible to recommend one strategy over another.

Significant challenges for clinicians in the delivery of EBP care to patients with VLUs still exist. We found no definitive evidence of the most effective strategies to implement clinical practice guidelines in VLU management. It is recommended that in order to implement a guideline successfully in a specific setting or with a single professional group, it should have stakeholder involvement and a program that is well designed, prepared and tested prior to implementation (Grol, 2001). Given the findings of this systematic review, it is reasonable to consider the professional group as community nurses delivering care in the patient's own home; therefore, it should be possible for guideline developers to design, prepare and make recommendations for testing appropriate strategies prior to guideline implementation with community nurses as the healthcare professionals.

The implementation strategies examined were measured against the implementation strategies stated by the EPOC Taxonomy for implementation strategies (Cochrane, 2015). During the full text review, it became apparent that a number of studies were presenting the position of changing practice in

the form of establishing specialised leg ulcer clinics as a means to improve outcomes for patients with VLUs. These studies were excluded from this review, as they did not meet our pre specified inclusion criteria. Additional useful data may have been garnered if the process of delivering care i.e., the creation of leg ulcer clinics had been included as an intervention strategy. Given the significant costs associated with the treatment of VLUs and the pain and suffering reported by patients, it is noteworthy that this systematic review identified only one randomised trial for inclusion.

Based on this systematic review we have found that the evidence base for implementation strategies for practice guidelines for VLUs is extremely poor. The one RCT that met the inclusion criteria did not report any significant change in healing rate following national guidelines and targeted educational sessions.

4.18 Study Limitations

The inclusion criterion was restricted to RCT, Non RCT, and Interrupted Time Series Controlled before-after study only and therefore other study designs were excluded.

4.19 Conclusions

Based on this systematic review there is insufficient evidence to recommend one implementation strategy over another for implementing clinical practice guidelines for VLUs.

Variation in clinical practice in management of people with VLUs remain despite the plethora of information available. Research needs to be undertaken to assess the impact of the implementation of guidelines at the point of care. If not, there will be little change in the spiralling costs associated with the treatment of VLUs nor an improvement in the patient's quality of life with this debilitating condition. There is a notable absence of robust mechanisms or recommendations from guideline developers as to how to implement clinical practice guidelines. The excluded studies in this systematic review reported improvements in outcomes, future researchers in this space may wish to examine other study designs that include other implementation strategies.

4.20 Chapter Summary

This chapter provided an introduction to systematic reviews, and the rationale to include a systematic review as part of this study was evidenced. The preparatory work for the systematic review was provided, and the entire manuscript of the published systemic review was included. The PICO framework was used to develop the clinical question, and the details of this approach were presented.

The section that applies to the Framework for Patient Safety and Research was clearly identified at the beginning of the chapter.

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Chapter 5 Survey research

5.1 Introduction

This chapter will introduce the importance of survey research, outline the rationale for this methodology and present results.

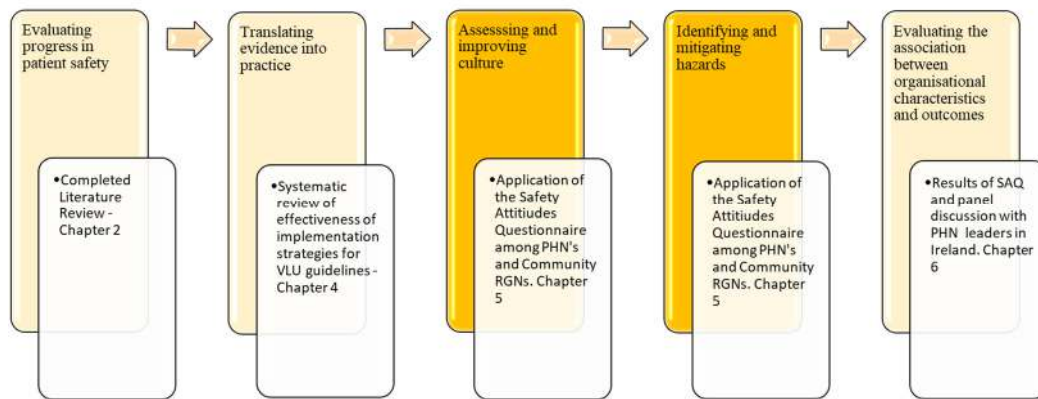


Figure 5-1 Translating evidence into practice – Assessing and improving culture and identifying and mitigating hazards in the context of this thesis.

The elements of the framework for patient safety research as related to this chapter is highlighted in Figure 5-1. This chapter is divided into two distinct sections.

Section (A) - presents an introduction to survey research, and a rationale for this methodology is offered. The objectives for this part of the study are listed. An in-depth exploration of suitable instruments of inquiry are presented, and a rationale for the final questionnaire is given. The issues of ethical approval, consent, validity, and reliability are discussed. Additional questions and the procedures in administering the survey are presented. The details on data collection presentation and data analysis are provided. The population surveyed was PHNs and CRGNs in the Republic of Ireland.

Section (B) - presents the results in terms of response rates, respondent characteristics and demographics. As the data collected is in the format of multiple-choice responses, the data will be presented in bar charts.

This will be followed by the responses from the items within the domain analysis. A data table presents the results under each domain in the aggregate.

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Tables are appropriate for providing exact values (Robbins & Heiberger, 2011). Results will then be presented from questions (Q)13, (Q)20, (Q)28, (Q)36, (Q)46, (Q)48 and (Q)78 as they specifically refer to patient safety and questions specifically related to clinical practice guidelines, i.e. (Q)51, (Q)55, (Q)78 and (Q)79. Diverging stacked bar charts are used to summarise responses to the patient safety questions and the practice guidelines questions. Question 78 is presented in both as it refers directly to clinical practice guidelines and patient safety. Diverging stacked bar charts are the recommended method to present results of surveys with rating scales (Robbins & Heiberger, 2011).

The subsequent results presented are from the one open-ended question at the end of the questionnaire. The six domain climate categories will be used to elicit themes from the response and presented using directed content analysis.

Table 5-1 The six climate domains and corresponding questions in the questionnaire.

Climate domain	Associated Question
Teamwork climate	Nurse input is well received in this office.
	In this office, it is difficult to speak up if I perceive a problem with patient care.
	Disagreements in this office are resolved appropriately (i.e., not who is right but what is best for the patient).
	I have the support I need from other personnel to care for patients.
	It is easy for personnel in this office to ask questions when there is something that they do not understand.
	The physicians and nurses here work together as a well-coordinated team.
Safety climate	I would feel safe being treated here as a patient.
	Medical errors are handled appropriately in this office.
	I receive appropriate feedback about my performance.
	In this office, it is difficult to discuss errors.
	I am encouraged by my colleagues to report any patient safety concerns I may have.
	The culture in this office makes it easy to learn from the errors of others.
Working conditions	I know the proper channels to direct questions regarding patient safety in this office.
	This office does a good job of training new personnel.
	All the necessary information for diagnostic and therapeutic decisions is routinely available to me.
	This office deals constructively with problem personnel.
Job satisfaction	Trainees in my discipline are adequately supervised.
	I like my job.
	Working in this office is like being part of a large family.
	This office is a good place to work.
Perceptions of management	I am proud to work at this office.
	Morale in this office is high.
	The management of this office supports my daily efforts.
	Office management does not knowingly compromise the safety of patients.
Stress recognition	The levels of staffing in this office are sufficient to handle the number of patients.
	I am provided with adequate, timely information about events in the office that might affect my work.
	When my workload becomes excessive, my performance is impaired.
	I am less effective at work when fatigued.
	I am more likely to make errors in tense or hostile situations.
	Fatigue impairs my performance during emergency situations (e.g., code or cardiac arrest).

5.2 Section A - Survey research

Survey research is a non-experimental design approach that is consistent with the positivist paradigm and quantitative research methodology. Survey research can be defined as a

“non-experimental research approach that is used to gather information about the incidence and distribution of, and the relationships that exist between, variables in a predetermined population” (Coughlan, Cronin, & Ryan, 2009, p. 1).

Questionnaires are considered the mainstay for survey research (Welford, Murphy, & Casey, 2012). The use of questionnaires has many advantages, they are cost-effective and can reach a wide sample size, they provide a sense of anonymity for the participant, and the researcher can reaffirm this, they can be time-specific and using a survey instrument that is deemed to be valid and reliable increases the strength in the design of the research work (Boswell & Cannon, 2014). Limitations of questionnaires include the risk of respondents not completing the questionnaire, it may not be apparent if respondents understand the questions, respondents may get bored or feel they cannot provide the correct information (Rowley, 2014), and a further limitation is that one cannot understand the reasons for a chosen response. A well-constructed survey can mitigate against the limitations (Rowley, 2014).

5.3 The rationale for survey research

In understanding the strengths and limitations of survey research, the author considered that survey research was the most appropriate methodology to use at this stage of the thesis and was the most appropriate means to capture the required information. The use of the Safety Attitudes Questionnaire is advocated by the creators of the framework for patient safety research and improvement (Pronovost et al., 2009). Noting the findings from the systematic review coupled with the understanding that the use of clinical practice guidelines contribute to translating evidence into practice (Pronovost et al., 2009) and taking cognisance of the outcomes of the literature review regarding contributory factors to patients safety, it was important to ascertain if published evidence-based clinical practice guidelines are actually used in practice; and if so, do those using them feel there is a connection between

clinical practice guidelines and patient safety, and whether the other factors to be considered are recognised amongst practitioners

The objective of this part of the study therefore is:

- i) To examine safety attitudes of PHNs / CRGNs.
- ii) To analyse the alignment of current practice in the management of VLUs against a national guideline amongst PHNs / CRGNs
- iii) To examine whether PHNs / CRGNs consider that clinical practice guidelines influence patient safety.

5.4 Measuring safety attitudes

Safety climate assessment is the most common approach to assessing safety in the primary care setting, although there is no recommendation that one safety climate instrument performs better than another (Curran et al., 2018). In order to measure safety climate effectively, it is important to ensure that the instrument measures what it sets out to measure and can reproduce similar results if the measurement is undertaken again (Pronovost & Sexton, 2005). Measuring safety climate helps to understand the culture within a unit, which can influence patient outcomes (Flin, Burns, Mearns, Yule, & Robertson, 2006).

A wide variety of surveys to measure patient safety climate are available and vary in accordance with their general characteristics, the dimensions covered, the psychometric properties therein and how they are applied in practice (Colla et al., 2005; Curran et al., 2018). It is recommended that in choosing a questionnaire for use, one must choose a reliable questionnaire with sound psychometric testing. The chosen questionnaire should be selected for a particular purpose, and that it has been used in a similar setting previously. There must also be consideration of a correlation between climate and patient safety outcomes (Colla et al., 2005). If a questionnaire is reported to have good psychometric properties, the scale is both reliable and valid. It must be evaluated extensively, where psychometric properties denote the validity and reliability of the instrument (Asunta, Viholainen, Ahonen, & Rintala, 2019). Measurement tools must have robust psychometric properties to support the validity and reliability of safety climate scores (Alsalem et al., 2018). A

concern raised by Curran et al. (2018) is that using a survey created for one health care environment such as The Hospital Survey on Patient Safety Culture (HSOPSC) may not be considered valid or reliable to be used in a new domain such as primary care. It is essential that when choosing a safety climate questionnaire, it must be valid and reliable for the area of healthcare practice in which it will be applied.

5.5 The difference between Safety culture and safety climate

In selecting an appropriate measurement tool to assess safety attitudes, it is important to understand the nuances between safety culture and safety climate. This is presented in detail in the literature review – chapter 2, sections 2.3.17 and section 2.3.18, noting that a safety culture is considered a mainstay of overall patient safety and safety climate is described as the measurable subset elements of safety culture (Colla et al., 2005).

5.6 Evolution of the Safety Attitudes Questionnaire

The Safety Attitudes Questionnaire (SAQ) was created from foundations in the aviation industry, building particularly from the Flight Management Attitudes Questionnaire (FMAQ), which contributed to the development of the Intensive Care Unit Management Attitudes Questionnaire. Following extensive pilot testing and dialogue with experts in the field and healthcare providers, researchers refined the questionnaire further and created the Safety Attitudes Questionnaire (Sexton et al., 2006).

Using exploratory factor analysis, Sexton et al. (2006) concluded 6 factor attitudinal domains using 30 items from the questionnaire. Further work with a more rigorous multi-level confirmatory factor analysis, the fit for the final model was deemed to be satisfactory and is presented in **Error! Reference source not found.** Appendix 5, The SAQ covers six distinct domains: teamwork climate, safety climate, working conditions, job satisfaction, perceptions of management and stress recognition.

5.7 Adaptation of the SAQ

The SAQ has been adapted and implemented in many clinical settings and at various levels of an organisation, including Neo-natal Intensive Care Units (Profit et al., 2012), Acute medical Units (Relihan, Glynn, Daly, Silke, &

Ryder, 2009), Operating Theatres (Sevdalis, Hull, & Birnbach, 2012) and long term care facilities (Buljac-Samardzic, Van Wijngaarden, & Dekker–Van Doorn, 2016). However, the SAQ has been developed further for the ambulatory setting, notably the outpatient setting emerging as the SAQ - ambulatory version (SAQ-AV) (Modak, Sexton, Lux, Helmreich, & Thomas, 2007). This is important for this thesis as traditionally, patient safety research has been focused in hospital settings despite 90% of healthcare being delivered in the primary care/community care settings (Cooper & Chuter, 2015). The work of Bondevik et al. (2014) provides a valid and reliable tool that builds on the original work of Modak et al. (2007) that was also deemed to have valid and reliable psychometric properties.

5.8 The Safety Attitudes Questionnaire – Ambulatory Version (SAQ AV)

The SAQ AV is (Appendix 5) where the respondents note their agreement to each question using a 5-point Likert scale (Likert, 1932): 1 = strongly disagree, 2 = disagree slightly, 3 = neutral, 4 = slightly agree, 5 = strongly agree, “Not applicable” is also included as a response category. Scores of negatively worded items are reversed so that higher scores in the data set always indicate a more positive evaluation of the patient safety culture (Bondevik, Hofoss, Husebø, & Deilkås, 2019). When assessing the perceptions of groups through the use of this questionnaire, it is recommended that the term “*safety climate*” or “*teamwork climate*” is used as this is a more measurable term with regards to the safety culture of the group (Sexton et al., 2006)

The content of this questionnaire is informed by two conceptual frameworks, i.e. Charles Vincent’s framework for analysing risk and safety in clinical medicine (Vincent, Taylor-Adams, & Stanhope, 1998) and Donabedian’s framework of structure, process and outcome (Donabedian, 1988) (Sexton et al., 2006). The work of Charles Vincent and the work of Donabedian have been described in the literature review section 2.3 and contribute to the theoretical underpinning for this thesis.

The questionnaire offers insight into how frontline clinical staff perceive the patient safety culture within their own unit/department, or it can be applied to

the broader organisation. In the context of this thesis, the attitudes at a primary care/community care setting team level are sought.

The questionnaire has been identified in previous studies (Alsalem et al., 2018; Colla et al., 2005) as a measurement tool that had a good rating with regards to validity and reliability and linked safety climate scores and patient outcomes.

5.9 Validity and Reliability of the Safety Attitude Questionnaire

Modak et al. (2007) made minor amendments to the wording of the SAQ to make it more applicable to the outpatient setting and noted that their version, the SAQ-A scales have

“good internal reliability and can be used in future efforts to measure the safety climate or safety “culture” of ambulatory practices”. (Modak et al., 2007, p. 3)

They report a confirmatory factor analysis tested the validity of the SAQ-AV and a comparative fit index (CFI) of 0.973, a Tucker-Lewis Index (TLI) of 0.977 and the root mean square error of approximation (RMSEA) of 0.067, all within recommended cut off values; a Cronbach alpha of greater than 0.7 was reported in all factors except in the ‘working conditions’ factor which reported a Cronbach alpha of 0.68. (Modak et al., 2007).

Importantly the questionnaire is considered to be valid and reliable when adapted as each questionnaire has the same content with minor variations to reflect the individualised clinical setting, and the questions used to measure climate scale remain consistent (Sexton et al., 2006).

5.10 Validity & Reliability

Validity and reliability are essential elements in evaluating a measurement tool such as survey questionnaires. A measurement tool such as a survey or questionnaire cannot be valid unless it is reliable (Tavakol & Dennick, 2011).

5.10.1 Validity

Validity focuses on the accuracy of the test procedure and ensures the adequacy of reproducibility in order to ensure that results are accurate and valid (Polgar & Thomas, 2020); essentially, it is about the confidence that the

measurement tool measures what it intends to measure (Tavakol & Dennick, 2011). Validity is defined as “*a test that can truthfully measure what it purports to measure*” (Boswell & Cannon, 2014, p. 321). Validity can be further demarcated as content-related validity, criterion-related validity, and construct validity; these terms are described further in Table 5-2. Curran et al. (2018) presented their approach in measuring the validity of safety attitude questionnaires.

5.10.2 Reliability

Reliability is concerned with the reproducibility of the results and assesses if the measurement tool measure instrument is consistent (Polgar & Thomas, 2020). Reliability and accuracy are inextricably linked; the more robust the reliability, the more accurate the results (Boswell & Cannon, 2014). The most widely used objective statistical measure of the reliability of a scale is Cronbach’s alpha (Tavakol & Dennick, 2011).

5.11 Face Validity

The SAQ AV is appropriate for the primary care setting (Smits et al., 2017). Having adjusted the wording in the questionnaire to an Irish context the author undertook to assess the SAQ for face validity. Face validity has been defined as:

“the degree that respondents or users judge that the items of an instrument are appropriate to the targeted construct and assessment objectives”
(Hardesty & Bearden, 2004, p. 99).

Face validity is confirmed when an expert in the field concludes that an instrument measures the area of interest being examined (Sangoseni, Hellman, & Hill, 2013). It examines the appearance of a questionnaire in terms of feasibility, readability, style, layout and clarity of wording (Taherdoost, 2016).

To achieve face validity, the questionnaire was sent to four senior practitioners in the Public Health Nursing sector. Namely:

- an academic leader who also practices as a PHN on a part-time basis

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- a Director of Public Health Nursing with direct responsibility for service delivery
- a Director of Public Health Nursing with Regularity governance responsibilities
- a Nurse Practice Development Coordinator (Assistant Director of Nursing) with national public health nursing responsibility.

The adjusted Safety Attitudes Questionnaire was issued to the four individuals above, and they were then asked the following questions:

- i) Is the wording used in the questionnaire clear and appropriate to the public health nursing sector?
- ii) Is the layout of the questions easy to follow?
- iii) Is the style of the questions easy to follow?
- iv) Is it likely that the target audience, i.e., those working in public health nursing, would be able to answer the questions?

The feedback from the four experts was consistent, and they made just a few recommendations:

- Rather than using the word ‘office’, it should be changed to ‘centre’ as public health nursing staff are based within a health centre or a primary care centre.
- Adjust any reference from a multidisciplinary team to nursing specific.
- Questions regarding management structure to be adjusted as managers may not necessarily work within the centre.
- Adjust reference to emergency practice; this is not usual in public health nursing.

All reported that the layout and style of questions were easy to follow and that the target audience should have no problem answering any questions. To apply the SAQ-AV to an Irish context and the following feedback from the practice experts, some wording has been adjusted to reflect the community nursing setting. The original SAQ-AV and the change of wording to reflect

an Irish context and is presented in Appendix 5; some examples of changes are highlighted below:

Original	Amended
I know the proper channels to direct questions regarding patient safety in this office	I know the proper channels to direct questions regarding patient safety in this centre
Disruptions in the continuity of care (e.g., shift changes, patient transfers, etc.) can be detrimental to patient safety	Disruptions in the continuity of care can be detrimental to patient safety

It is argued in the literature that face validity is the weakest form of validity (Taherdoost, 2016); however it can provide information that is useful when examining an entire assessment instrument and the degree to which it is meeting the measures it purports to measure (Colton & Covert, 2007).

5.11.1 Cronbach’s Alpha

Cronbach’s alpha is a coefficient measure of the internal consistency of a test or a scale, that is, how closely related a set of items are as a group and is expressed as a number between 0 and 1, acceptable values of alpha range between 0.70 and 0.95 (Tavakol & Dennick, 2011) a maximum value of alpha at 0.90 has been suggested as a more desirable level of internal consistency; Cronbach’s alpha is directly affected by the length of the test, where an alpha score is greater than 0.90 it is suggested that the measurement tool should be shortened (Streiner, 2003). The relationship between the Cronbach Alpha measurement and the six-factor domains of the safety attitude questionnaire is presented in section 3.8.11. and in Table 5-2.

5.11.2 Validity and Reliability of Safety Climate Surveys

In order to provide evidence of the validity and reliability of safety climate surveys, an assessment must be undertaken with regards to the methodological quality of studies that have used them, with a particular focus on the psychometric properties in each study (Alsalem et al., 2018).

A 2005 systematic review of surveys used to measure patient safety climate in healthcare identified nine surveys used in different healthcare settings, all of which used a 5 point Likert scale to measure respondents’ attitudes about patient safety. They also identified that only one of the nine surveys - the

Safety Attitudes Questionnaire (SAQ) – explored the relationship between safety climate scores and patient outcomes (Colla et al., 2005). They recommend that when selecting a survey instrument that researcher should select surveys that have demonstrated reliable psychometric testing and can be recommended for a particular purpose; this influenced the authors decision making in choosing the questionnaire for this thesis.

A 2018 systematic review identified and critically reviewed the adequacy of the psychometric properties of safety culture measurement tools (Alsalem et al., 2018). They analysed the psychometric properties of five studies which met their inclusion criteria. The methodological quality of the included studies were measured against seven indicators developed by Flin et al., (2006). Of the five studies included in their review three were rated as good (the highest rating); that is that they fulfilled six indicators related to study aims, study methodology, design, data collection, study population, response rate, data analysis method and results (Alsalem et al., 2018). The tools rated as good were (i) The Hospital Survey on Patient Safety Culture (HSOPSC), (ii) the Canadian Patient Safety Climate Scale (Can-PSC) and (iii) the Safety Attitudes Questionnaire (SAQ). It must be noted that the tools were applied in a hospital setting. However, the focus of their systematic review was to examine the psychometric properties of the measurement tools for their intended purpose and not merely the environment in which there were administered. The psychometric properties of the included studies were examined for validity in terms of content validity, criterion-validity, construct validity, and reliability. Alsalem et al. (2018) note however that limitations on reporting psychometric properties have been found by other authors (Colla et al., 2005; Flin et al., 2006) with the exception of the Hospital Survey on Patient Safety Culture (HSOPC) and the Safety Attitudes Questionnaire (SAQ) and that both tools repeatedly come through as recommended tools. Again, as the Safety Attitudes Questionnaire has been adopted to a primary care setting it is the most appropriate choice for this thesis.

A 2018 systematic review undertaken by Curran et al. included 23 studies; and 17 survey instruments were identified. The characteristics of the 17 instruments were assessed under the heading (i) Country and Author, (ii) No.

of items in the survey, (iii) No. of domains in the survey, (iv) QATSDD¹ Score, (v) Clinical setting, (vi) No of reported studies and (vii) mean response rate. They undertook a comprehensive assessment of all 17 survey instruments. The psychometric properties assessment included content validity, construct validity, criterion-related validity and reliability and is comprehensively presented in Table 5-2. Of the survey instruments examined only four studies stated all four parameters of content validity, construct validity and reliability; criterion-related validity had been reported previously. de Wet et al., (2010) used the survey instrument ‘PC SafeQuest’; Hoffman et al. (2011) used ‘FraSiK’; Zwart et al. (2011) used ‘SCOPE’ and Bondevik et al. (2014) used the Safety Attitudes Questionnaire-AV. This finding further informed the authors decision making with regards to the assessment tool selected for this thesis.

Table 5-2 Psychometric Criteria – assessing validity (Curran et al., 2018)

(Reproduced with permission from Wiley)	
<p>Content validity The degree to which the survey items are representative of a defined factor, which they are intended to measure. It can usually be determined from several sources (e.g., literature review and relevant theory, expert review).</p>	<p>No: 1. No evidence of content validity assessment within instrument 2. No evidence of content validity assessment within instrument, but reference made to previous validation</p> <p>Yes: Evidence of content validity assessment within the survey instrument. Content validity was further categorized under the following codes: A. Expert panel review with documented interrater agreement. B. Expert panel review with no documented interrater agreement C. Literature review to inform the survey development. D. Pilot test of survey or pre-test panel where survey was reviewed by a focus group of experts before being further revised or retested</p>
<p>Construct validity The extent to which the survey measures what it is intended to measure. The</p>	<p>No: No evidence of factor analysis or interdimensional correlations</p> <p>Yes:</p>

¹ Quality Assessment Tool for Studies with Diverse Designs (QATSDD). This tool allows standardized evaluation of studies with varying research designs (Curran et al., 2018)

<p>identification of a reliable factor structure within the survey that is consistent with theory supporting assumptions of adequate construct validity.</p>	<p>Evidence of factor analysis or correlations. Where construct validity assessment was present, it was further categorized under the following headings: A. Evidence of exploratory factor analysis. B. Evidence of confirmatory factor analysis C. Evidence of both exploratory and confirmatory factor analysis. D. Evidence of interdimensional correlation assessment</p>
<p>Criterion-related validity Assessed by correlating the SC scores with another outcome or criterion variable.⁸ It can also include correlating SC scores to assess the impact of an intervention.</p>	<p>No: No evidence of criterion-related validity.</p> <p>Yes: Evidence of criterion-related validity was further categorized under the following: A. The number of reported patient safety incidents or incident reports per practice B. Correlations with other quality and safety indicators (e.g., patient safety as agenda for practice meeting, chronic disease score or prevention score, patient safety culture indicator error management, practice demographics in terms of practice size, patient population, deprivation score) C. Stages of healthcare information technology implementation (e.g., evaluation after introduction of electronic medical record system)</p>
<p>Reliability This is a measure of consistency of the internal factor structure or the extent to which the survey elicits the same scores each time it is used under the same conditions. A Cronbach α score of >0.7 is usually regarded as indicative of acceptable internal reliability.</p>	<p>No: 1. No evidence of reliability measurement within the instrument 2. No evidence of reliability measurement within the instrument but reference made before consideration or assessment</p> <p>Yes: Evidence of reliability measurement within the instrument and the range of Cronbach α was reported A. Acceptable Cronbach $\alpha >0.69$ throughout all SC domains B. Cronbach $\alpha >0.7$ for most SC domains, but not all domains C. Overall reliability of survey provided >0.7 D. Raykov coefficient also reported in conjunction with Cronbach α</p>

5.12 Rationale for the selection of the SAQ-AV for this thesis

The author has selected the SAQ-AV as described by Modak et al. (2007) and later Bondevik et al. (2014) as the SAQ-AV:

- i) is one of the most commonly used and rigorously validated instruments for measuring the safety climate in healthcare (Gabrani, Hoxha, Simaku, & Gabrani, 2015).
- ii) has been modified for an ambulatory setting and primary care/community care settings (Modak et al., 2007)
- iii) has been reported to have good construct validity and internal consistency, and it is recommended that the complete questionnaire is used (Pronovost & Sexton, 2005)
- iv) is underpinned by the work of Charles Vincent and Donabedian's framework, and therefore it is congruent with the framework for this study.
- v) is the only safety climate survey which asks a question on the use of policies, procedures and guidelines.
- vi) will allow for an audit of behaviours regarding the awareness of existing policy documents and offer an understanding of whether staff use the policy document

Although the questionnaire has been used in primary care settings in other European countries, namely Norway (Tschudi Bondevik, Dag Hofoss, Holm Hansen, & Tvetter Deilkås, 2014), the Netherlands (Smits et al., 2017) and in an Irish hospital setting (Relihan et al., 2009) the author was not able to identify previous studies where it has been used in primary care services in Ireland.

5.13 Survey Procedures

Having identified the Safety Attitudes Questionnaire as the appropriate survey instrument, additional questions were explicitly included focusing on demographic data and VLU guidelines.

5.14 Additional questions related to the respondents

Additional questions were included at the beginning of the survey to capture the demographic factors of the respondents. Demographics refers to particular characteristics of the population being studied (Salkind, 2010). This essentially will offer the author an insight into the professional composition

of those completing the survey. The additional demographic questions are available in Appendix 6

5.15 Additional questions related to HSE guidelines

The literature review presented in Chapter 2 includes current evidence in the management of VLUs. The HSE in Ireland published direct patient care guidelines, in relation to wound management (HSE, 2018). The guidelines detail the assessment & management of VLUs, and the post-healing management of VLUs. The guidelines also provide an evidence statement and graded recommendations for practice.

The objectives included in this survey are already identified in section 5.3. To analyse the alignment of current practice in the management of VLUs against the national HSE guideline, the specific recommendations from the assessment section of the national HSE guideline were converted into questions and inserted at the beginning to the safety attitudes questionnaire. The particular questions related to the assessment of leg ulcers are presented in Appendix 7

It is important to note that the purpose of the survey is regarding the safety attitudes of PHN's and CRGNs and the broader implementation of the HSE guidelines. The author was purposeful in that the questionnaire should not be read as an assessment of an individual's practice. Therefore, the section from the national guidelines on the management of VLUs was captured in two generic questions in the questionnaire – (1) Are you aware of the HSE National Wound Management Guidelines 2018? and (2) Do you refer to the section on VLUs when caring for this group of patients?

5.16 Additional open-ended question

One additional open-ended question was included at the end of the questionnaire – *“Please add anything at this point which you would like to bring to the attention of the researcher”*. This question was included to allow participants to include further information on the subject and may offer the researcher an opportunity to collect further detail on how the respondents think.

5.17 Creating the questionnaire

The questionnaire was created using the software package Question Pro. The additional questions above were front-loaded so as not to interfere with the validity and reliability assessment previously confirmed except for the final open-ended question.

An introduction note from the author to the participants outlined the purpose of the study and detailed additional demographic questions that also included specific questions regarding the HSE National Wound Management Guidelines (2018).

Depending on individual responses from those completing the survey, participants were redirected to the next appropriate question based on the answer from the previous question for the section using the bridging function within the software package.

5.18 Ethical Approval

Ethical approval was sought from and granted by the Saolta University Health Care Group prior to distribution of the survey. Ref Number: CA2498 (Appendix 8)

The author was sensitive to the audience to whom the safety attitude questionnaire was being issued and was aware that some of the questions contained therein may be a little uncomfortable for the participant to answer truthfully. It was essential to make this explicit in the ethics application form when seeking ethical approval. The author aimed to reassure the participant that the researcher had no way of identifying them as individual participants nor could the questionnaire be linked back to them at any stage. The author advised the participant of this from the outset and stated at the very beginning of the questionnaire that -

“I appreciate that some of the questions are a little direct, but please rest assured that I will have absolutely no way of identifying you, your region or the service you are working in. The response is COMPLETELY ANONYMOUS. However, if you feel uncomfortable answering any questions, you can withdraw from the survey at any point. Your survey responses will be strictly confidential and data from this research will be

reported only in the aggregate and again please note I have absolutely no way of tracking a result to you”

5.19 Consent

The process of obtaining consent was sought at the beginning of the questionnaire. The candidates are asked to confirm that they understand the purpose and nature of this study and that they are participating voluntarily. It is also made clear that they can withdraw from the study at any time, without any penalty or consequences. It is explained that their responses will be anonymous and that no professional information or organisation or business name can be identified. Consent as to how the data can be used is also sought. Specific permission is requested for the researcher to use the responses in aggregate or anonymous statements. They understand the researcher cannot identify them, and any comments presented cannot be individually attributed.

If an individual opens the email link and subsequently decides not to partake in the survey, they can simply close out of the application; or select ‘no’ at the consent question where they will be brought to a termination screen, at which point they are thanked for their consideration, and the questionnaire is terminated.

All respondents consented to take part in the survey, and all respondents granted their permission to use responses in the aggregate and have individual comments anonymously presented.

5.20 Sample and sample size

The targeted population was PHNs and CRGNs registered in the Republic of Ireland, and a purposive sample from that population was drawn. A homogeneous purposive sample is appropriate as it recognises the topic being researched and participants with similar traits, such as professional roles (Etikan, 2016). The author deliberately chose the purposive sample techniques as the literature review identified that patients with VLU primarily take place in the community. It was important to survey participants (PHNs, CRGNs) who actively deliver care to patients with the condition being studied. This purposive sample facilitated a broad reach across the Republic of Ireland.

The most recent data available stated the number of PHNs whole Time Equivalents (WTE) employed within the HSE is n=1548 (Health Service Executive, 2020). All PHNs are targeted therefore the population size for this element of the study is n=1548. There is no differentiation made between PHNs and CRGN's in the HSE reporting of staff WTE's. No sampling was undertaken. To maximise the response rate and given this was an online survey it was reasonable to invite all to participate.

5.21 Response rate

The response rate needed to be representative of the public health nursing sector with a 95% confidence interval with a margin of error of 5% is n=306 (Krejcie & Morgan, 1970)

5.22 Dissemination of the survey

The questionnaire was disseminated via a Director of Public Health Nursing with a lead national role in public health nursing who had email addresses for all Directors of Public Health Nursing in the Republic of Ireland. The questionnaire was issued via email on December 3rd, 2020 and closed on January 3rd, 2021. An introduction letter was included (Appendix 9). A reminder email was issued via the same route on day seven and again on day 14, and this again cascaded through the email system. The researcher did not have direct access to the email directory of potential recipients. There was an active campaign on Twitter and Linked In whereby direct links to the questionnaire were included in tweets and messaging on the related platform.

Upon receipt of the email containing a link to the questionnaire, The Directors of Public Health Nursing then cascaded this to the Assistant Directors of Nursing, PHNs and CRGNs.

Upon opening the email link contained within the invitation to participate email, potential participants would be greeted with an introduction that detailed the purpose of the study and a link to further reading regarding the Safety Attitudes Questionnaire, and the entire questionnaire can be seen in Appendix 10

Having offered reassurance regarding the anonymity and confidentiality regarding data collection, potential participants were invited to proceed by

clicking a 'next step' button and the process of gaining informed consent commenced.

5.23 Data collection

The questionnaires were issued through the software package Question Pro as this is available to the author under licence through the National University of Ireland Galway. When a survey is completed, the information is readily available for analysis. The advantages of using Question Pro include:

- Data entry is done automatically
- The data can be easily downloaded
- Branching is available to redirect participants to questions based on previous answers

5.24 Results of questions related to demographics and national guidelines.

Results from section one (demographics and national guidelines) of the questionnaire will be presented using bar graphs. Each figure is labelled with a declarative title; this style of figure labelling supports the reader in understanding the main take-home message. This is then complemented in reading more of the text and allowing for ease of reading and understanding when large amounts of data are presented (International Science Editing, 2020). The demographic and national guideline related questions are as numbered in the survey:

- Q. 64 Please state your current role
- Q. 65 How long have you been working in public health nursing?
- Q. 67 Do you provide care for patients with VLU's as part of your role (directly or in a supervisory capacity)?
- Q. 68 Do you have formal training/education in wound management?
- Q69. Please specify wound management qualification.
- Q. 70 Are you aware of the HSE National Wound Management Guidelines 2018?
- Q. 72 Do you refer to the section on VLU's when caring for this group of patients?

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- Q73. In your area of practice does a nurse with post basic education and training in the assessment and management of leg ulcers conduct a comprehensive assessment of all patients presenting with a leg ulcer
- Q74. What pertinent medical/family history do you consider when assessing a patient with a leg ulcer? (Choose all that apply)
- Q75. Do you routinely undertake a bilateral limb assessment?
- Q76. Please choose the investigations that you use or refer onward to confirm presence of vascular disease and document its severity.
- Q77. When you identify abnormalities at your assessment do you refer onward for specialist investigation and opinion.
- Q78. If you have a query regarding the aetiology of an ulcer do you refer to a colleague trained and competent in the assessment and management of leg ulceration if required.
- Q79. Do you refer patients with a non-healing or atypical leg ulcer for further investigations, including consideration of biopsy.
- Q82. If you refer onwards, are you made aware of the investigations undertaken?

5.25 Domain Analysis

The six climate factor domains used to assess the safety climate in organisations with the associated questions are presented in Appendix 5 under the headings:

- Teamwork Climate
- Safety Climate
- Perceptions of Management
- Job Satisfaction
- Working Conditions
- Stress Recognition

The questions marked with an Asterix (*) listed in Appendix 5 are reversed scored.

The results will be presented in the aggregate using a summary statistics table. This is in keeping with other authors' data presentation, such as Sexton et al. (2006).

5.26 Exploratory data analysis

Exploratory data analysis often consists of visualising the data to explore its main patterns and characteristics (Tukey, 1977). Exploratory data analysis of the safety attitudes survey responses is presented using diverging stacked bar charts that display the balance of Likert responses per question. Likert scale data can be examined using diverging stacked bar charts. The recommended default orientation is to present the bars horizontally as the data is easier to read when displayed horizontally on the y axis (Heiberger & Robbins, 2014). Heiberger & Robbins (2014) comprehensively explain the construction of stacked bar charts using Likert data:

“Each row of the table is mapped to a stacked bar in a bar chart. Usually, the bars are horizontal. The counts (or percentages) of respondents on each row who agree with the statement are shown to the right of the zero line in one colour; the counts (or percentages) who disagree are shown to the left in a different colour. Agreement levels are coded from light (for closer to neutral) to dark (for more distant from neutral). The counts (or percentages) for respondents who neither agree nor disagree are split down the middle and are shown in a neutral colour. The neutral category is omitted when the scale has an even number of choices” (Heiberger & Robbins, 2014, p. 6)

The results are presented in this format for questions explicitly referring to *patient safety* and for questions explicitly referring to *guidelines* as these are the two main areas of interest and it was important to get an understanding of patient safety and practice guidelines are viewed in practice.

5.27 Confirmatory data analysis

5.27.1 Question pair interrelationships

Questionnaire data can be used to explore how related the responses to one question are with another question. A set of a priori selected question pairs were chosen (column one Table 5-4) to explore inter-question relationships (e.g., are those who answered positively to question X more likely than

chance to answer positively to question Y). These question pairs were chosen as they relate to the broader parameters of safety, and it was important to get an appreciation if there was a correlation between one or another.

To test if the responses to selected pairs of questions were related, contingency tables (also called cross-tabulations) of the responses were prepared and analysed. Contingency tables display the number of respondents responding in each level of the first question for each level in the second question. For example, 44 people responded "Agree" to both Q48 and Q51. The counts for all combinations of responses to both questions form the contingency table. It is possible to inspect the counts in the contingency tables to see if there appears to be a relationship between the responses to the two questions (e.g., are those responding "strongly agree" to question X also responding "strongly agree" to question Y or are they more random).

The contingency tables for each pair of questions was visualised using spine plots, which are two variable bar plots where the width of the horizontal bar is proportional to the count in a given level of the question displayed on the x-axis. Each plot shows the proportion of respondents in each Likert level for the bottom question by width and the proportion of respondents to the question on the left by colour. Data are cross-tabulations of the response counts.

To assess the statistical significance of the relationship between the responses to the question pairs, an ordinal chi-square test was run. Ordinal data have an order (e.g., strongly disagree, slightly disagree, neutral). A regular chi-square test ignores this; therefore, an ordinal chi-square test was selected for inference. Formally, we test a linear-by-linear association in two-way tables (Agresti, 2003); this tests independence of two-way ordinal data. The significance level for the test was set at 0.05 and Bonferroni corrected for multiple pairs tested to maintain the nominal significance value.

5.27.2 Question and climate relationships

Each respondent was given a score for each climate according to the 100-point scale from Modak et al. (2007). The relationship between responses to an a priori selected set of questions and climates (e.g. Q46 - All the staff in

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this centre take responsibility for patient safety and its relationship to the safety climate found a highly **significant** positive relationship between these two variables respondents were more likely to strongly agree if safety climate is high and more likely to strongly disagree if safety climate is low.

Table 5-5) was then visualised as a scatterplot. To test if the relationship was significant, an ordinal regression (ordered logistic regression) was performed with the response to a given question as to the response variable and the climate as the explanatory variable (Agresti, 2003). Note that none of the selected-response questions were used to calculate the climates. The significance of the relationship was tested using a likelihood ratio test between an intercept-only model and an alternative model including the climate as an explanatory variable. The significance level was again set at 0.05, and Bonferroni corrected for multiple comparisons. Where a significant relationship was found, the results are visualised in a predicted proportion plot that shows how the proportion in a given level (e.g., strongly agree) changes over the climate score. This provides evidence of a relationship between the climate and responses to selected questions.

5.28 Responses from the open-ended question

The responses from the open-ended question at the end of the survey – *“Please add anything at this point which you would like to bring to the attention of the researcher”* will be analysed using content analysis. Content analysis is defined as:

“a research method for the subjective interpretation of the content of text data through the systematic classification process of coding and identifying themes or patterns” (Hsieh & Shannon, 2005, p. 1278)

Content analysis is considered a suitable method for analysing text data (Cavanagh, 1997). Hsieh and Shannon (2005) identify three approaches of content analysis, namely conventional, directed and summative approaches to analyse text. Although content analysis is situated within a naturalistic paradigm, historically, it was used as a quantitative research method whereby the text data was coded into different categories (Hsieh & Shannon, 2005).

The aim of directed content analysis is to use existing theory or research to determine the initial coding structure or relationship between coding (Hsieh & Shannon, 2005). Directed content analysis is structured in that it uses existing theory or prior research. Key themes previously identified can be used as the initial coding categories, and any text that could not be categorized

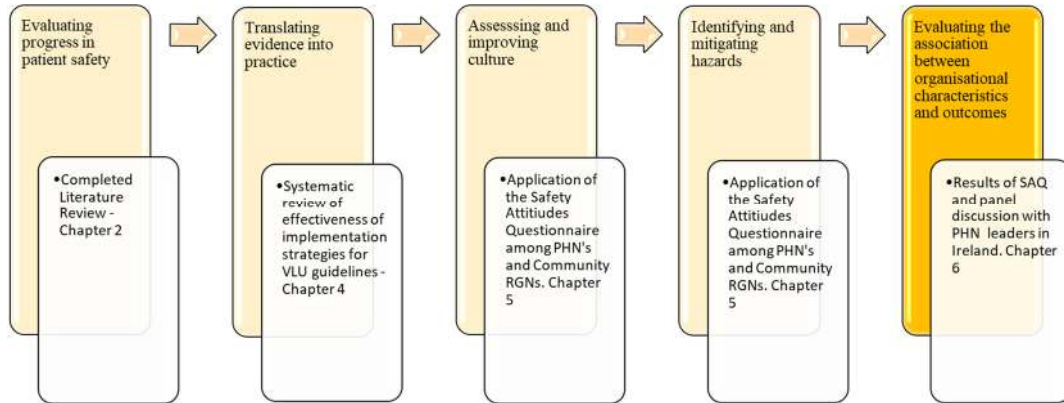
from within the predetermined coding structure can be aligned to a new code or subcategory (Hsieh & Shannon, 2005). The author is satisfied that the climate factors already identified can be used as the predetermined categories, and any new categories will be created from the phenomena being examined without biasing the text offered by the respondents. The evidence will be presented using direct quotations from the respondents, where appropriate, under each of climate domains i.e., teamwork, safety, perceptions of management, job satisfaction, working conditions and stress recognition and will include five additional categories previously identified from the results: COVID-19, clinical practice guidelines, VLU/wound management, documentation, and the questionnaire itself.

Coding data is a way of making sense of the text data collected as part of the research process that supports the researcher to map the data (in this study, it is the free text comments from survey participants) in relation to the research question (Elliott, 2018). Coding aims to support the researcher in identifying phrases, and themes and patterns from responses. Coding is a common step in the analysis process of qualitative data analysis irrespective of the researcher's philosophical, ontological, and epistemological position (Neale, 2016).

Capturing free-text responses will enrich the information made available and provide an insight into the participants' views.

5.29 Section B – results from the questionnaire

This section will provide a comprehensive overview of the survey results, which will be discussed in chapter 6.



5.29.1 Response rates

The questionnaire was issued via the Directors of Public Health Nursing with a potential reach to circa N=1548 nurses. The target was to receive responses from 360 PHNs. Responses were received from 161 respondents (percentage of the target response rate 44.7%), with a total of n=113 (31.3%) respondents completing the full survey. It is important to note here that inferences are restricted to those who responded rather than the whole population due to the response rate achieved.

Forty-eight dropped out at various points after starting the survey, and the average time to complete the survey was 12 minutes.

5.29.2 Respondents characteristics and demographics

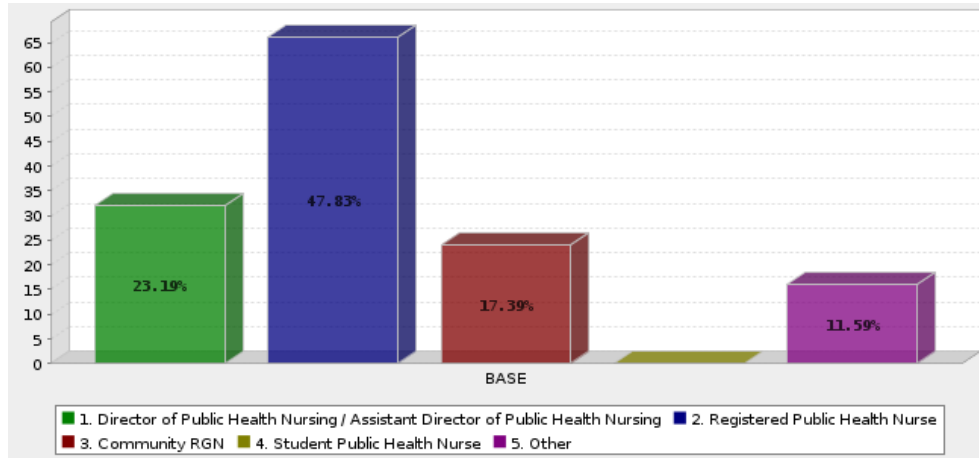


Figure 5-2 The highest number of respondents were registered, PHNs.

Where respondents selected other, they identified themselves into the following area, Director of Operations, General Practice Nurse, Tissue Viability Nurse, Advanced Nurse Practitioner, Liaison CNM2, CNM2, Lecturer and there were 6 omissions noted.

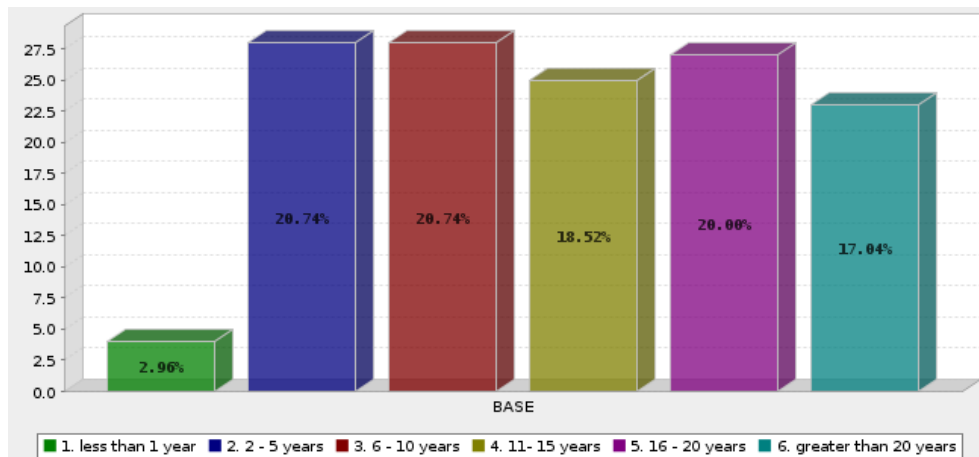


Figure 5-3 The duration of time working in public health nursing was reasonably evenly spread across the time frames, except in those less than one year practicing

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A very high proportion of respondents provide care for patients with VLUs almost 84%, and 77% reported having formal training/education in wound management.

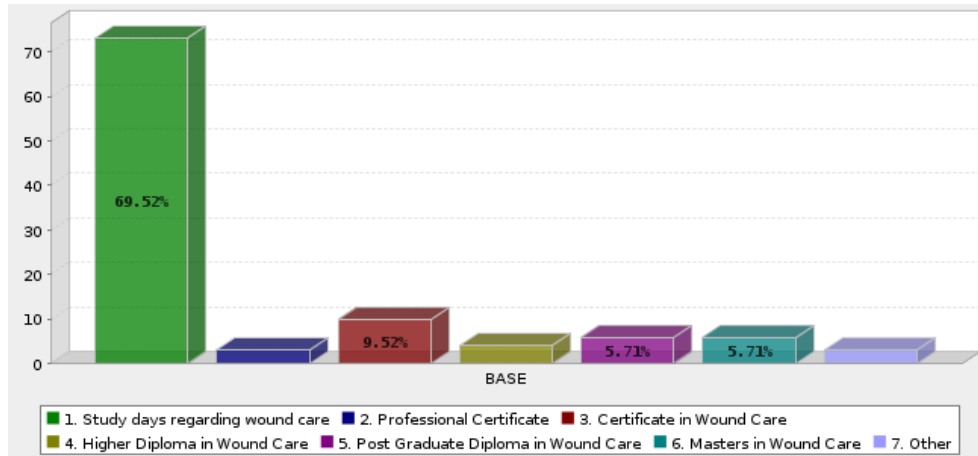


Figure 5-4 A significant majority of respondents reported attending study days regarding wound care as formal training/education in wound management

Those that responded in the other category are presented in Table 5-3

Table 5-3 Responses from those that responded with other

	Answer	Count	Percent
1.	Study days regarding wound care	73	69.52%
2.	Professional Certificate	3	2.86%
3.	Certificate in Wound Care	10	9.52%
4.	Higher Diploma in Wound Care	4	3.81%
5.	Post Graduate Diploma in Wound Care	6	5.71%
6.	Masters in Wound Care	6	5.71%
7.	Other	3	2.86%
	Total	105	100%

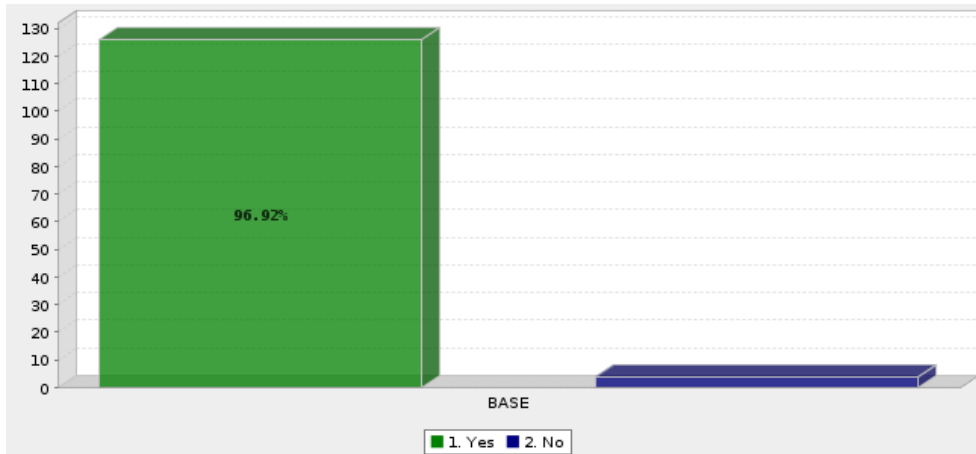


Figure 5-5 Almost 97% of respondents stated that they were aware of the HSE National Wound Management guidelines 2018

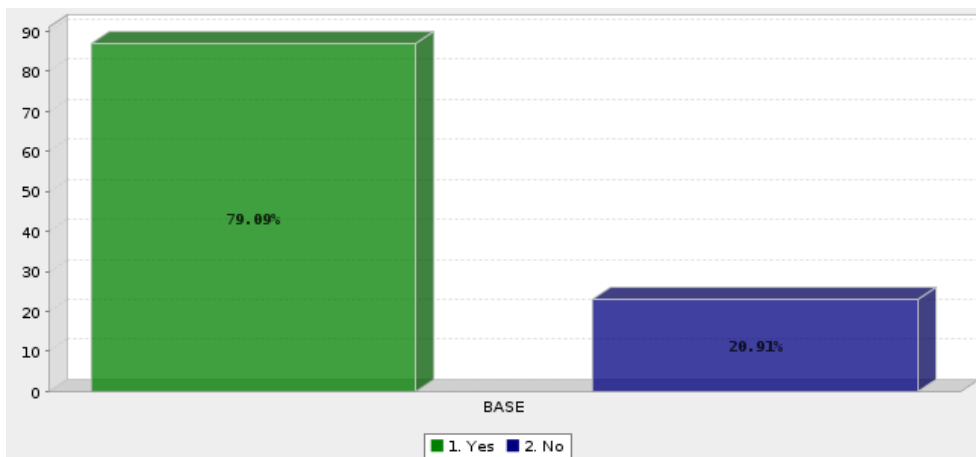


Figure 5-6 Almost 80% of respondents stated that they referred to the section on VLU's when caring for this group of patients.

5.29.3 Patient Assessment

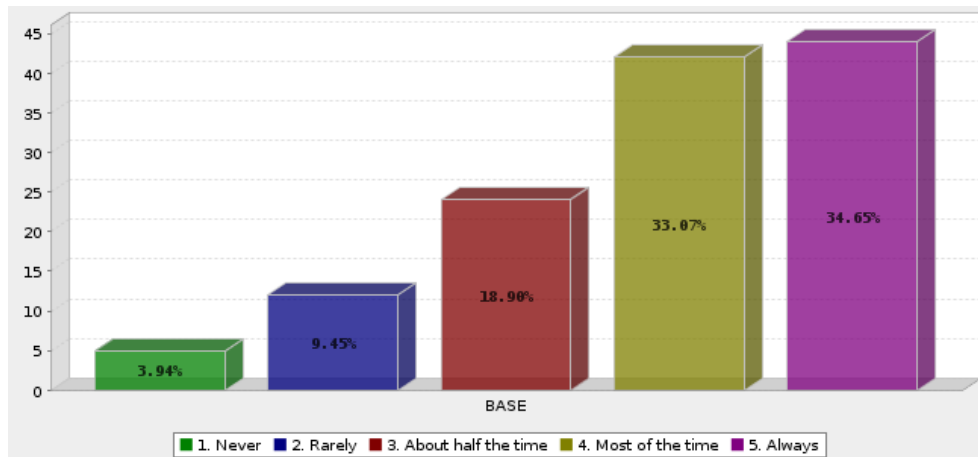


Figure 5-7 Combining the result from respondents report about half the time, most of the time and always amounted to Almost 87% of respondents reporting that a nurse with post-basic education conducts a comprehensive assessment of all patients presenting with a leg ulcer

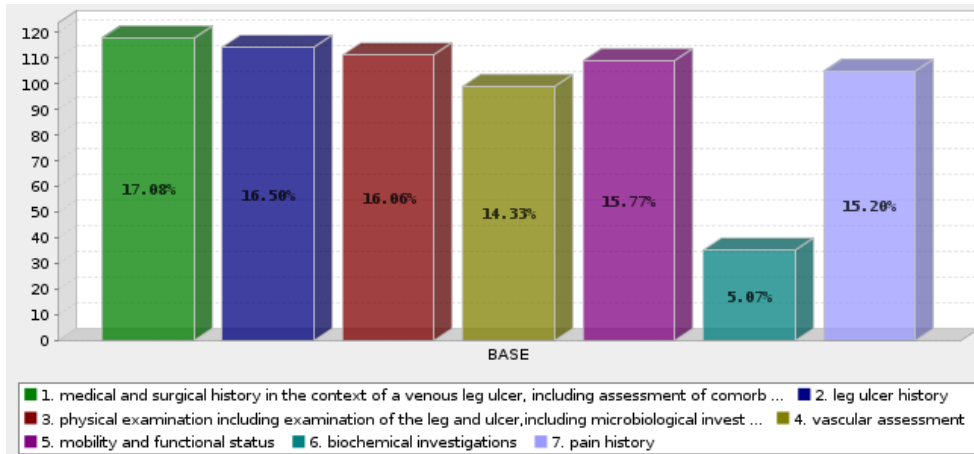


Figure 5-8 What pertinent medical/family history do you consider when assessing a patient with a leg ulcer? (Choose all that apply)

	Answer	Count	Percent
1.	medical and surgical history in the context of a VLU, including assessment of comorbidities	118	17.08%
2.	leg ulcer history	114	16.50%
3.	physical examination including examination of the leg and ulcer, including microbiological investigation when applicable	111	16.06%
4.	vascular assessment	99	14.33%
5.	mobility and functional status	109	15.77%
6.	biochemical investigations	35	5.07%
7.	pain history	105	15.20%
	Total	691	100%

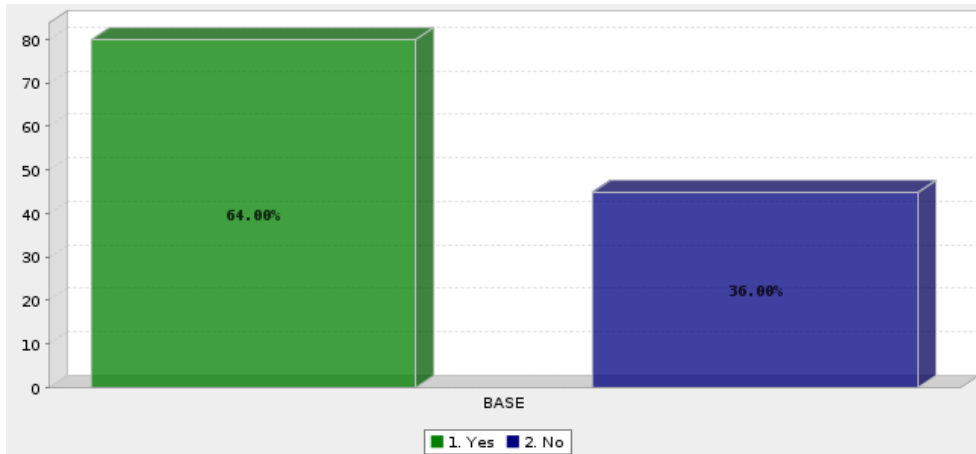


Figure 5-9 the majority of respondents undertake a bilateral limb assessment.

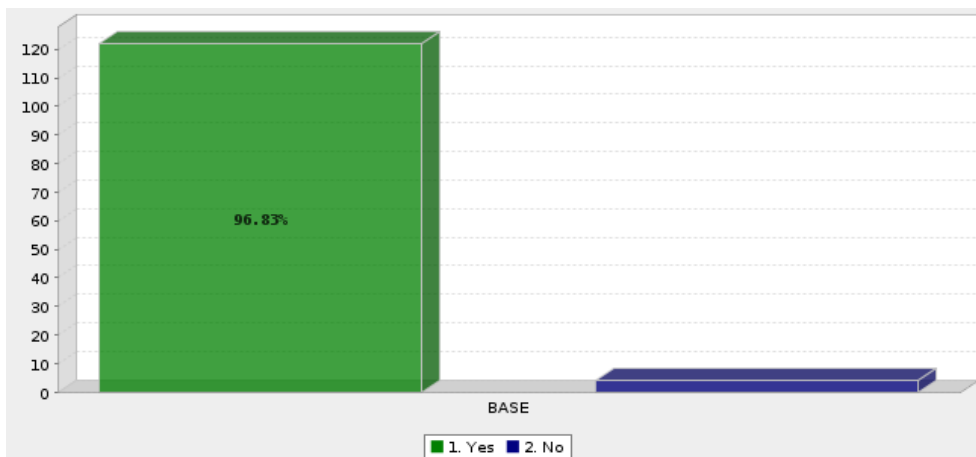


Figure 5-10 Almost 97% of respondents reported that they refer onward for specialist investigation and opinion when they identify abnormalities at assessment.

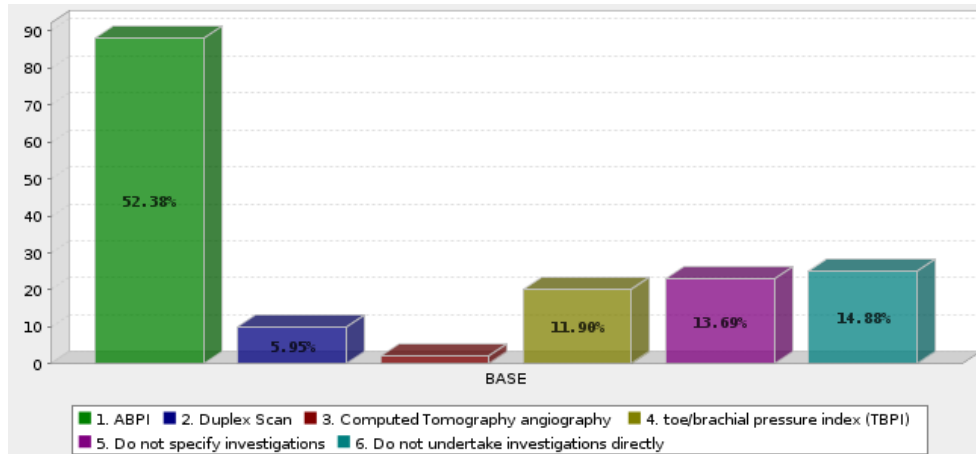


Figure 5-11 Please choose the investigations that you use or refer onward to confirm presence of vascular disease and document its severity.

	Answer	Count	Percent
1.	ABPI	88	52.38%
2.	Duplex Scan	10	5.95%
3.	Computed Tomography angiography	2	1.19%
4.	toe/brachial pressure index (TBPI)	20	11.90%
5.	Do not specify investigations	23	13.69%
6.	Do not undertake investigations directly	25	14.88%
	Total	168	100%

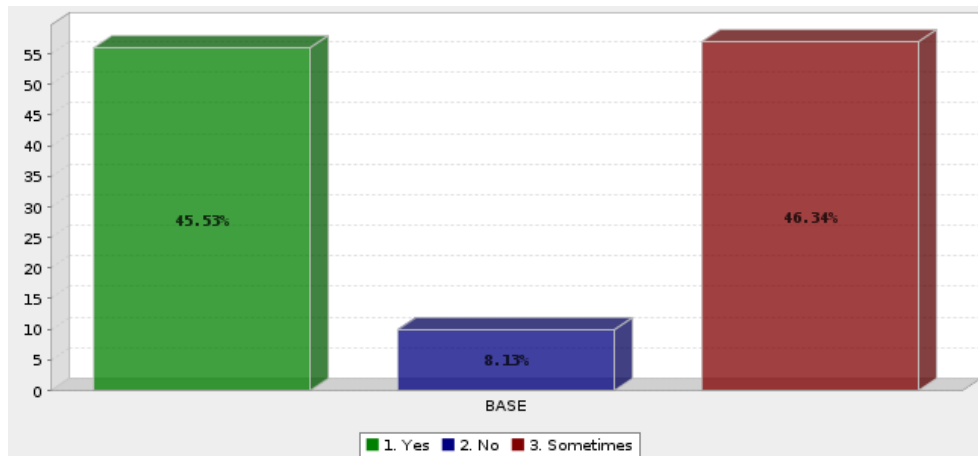


Figure 5-12 If you refer onwards, are you made aware of the investigations undertaken?

	Answer	Count	Percent
1.	Yes	56	45.53%
2.	No	10	8.13%
3.	Sometimes	57	46.34%
	Total	123	100%

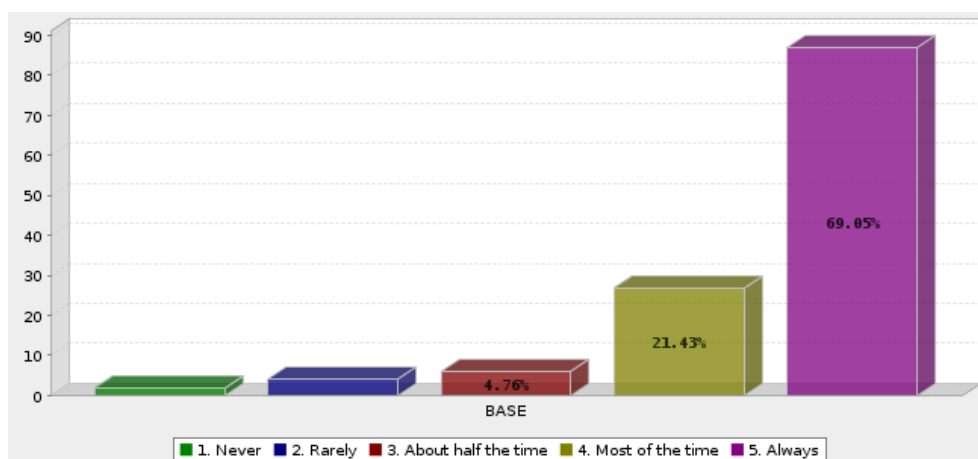


Figure 5-13 90% of respondents reported that where they have a query regarding the aetiology of an ulcer, they refer to a colleague trained and competent in the assessment and management of leg ulceration if required?

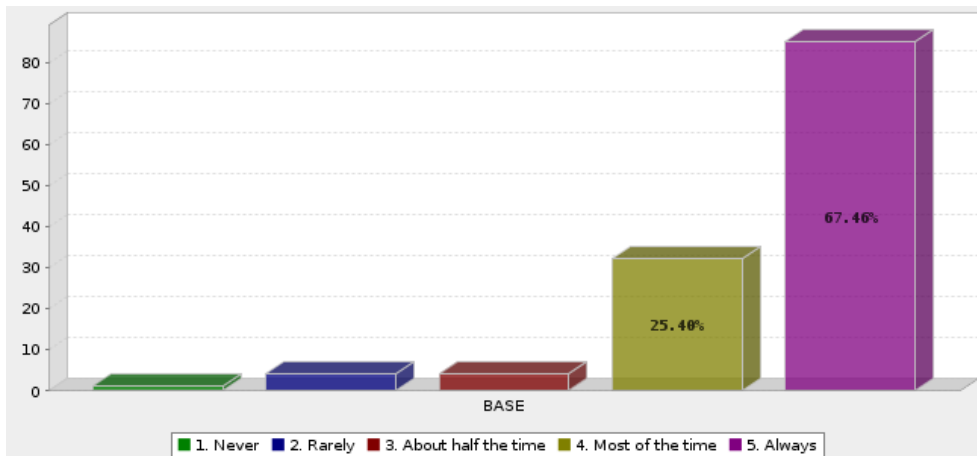


Figure 5-14 Almost 93% of respondents refer patients with a non-healing or atypical leg ulcer for further investigations, including consideration of biopsy either most or all of the time.

5.30 Question pair interrelationships

Results of the question pair interrelationships (column one Table 5-4) are visualised in Figure 5.15. Commentary in relation to the significance of the relationship between the two questions are presented in column two Table 5-4. e.g., the question pair Patient safety is constantly reinforced as the priority in this centre (Q48) and there is widespread adherence to clinical guidelines & evidence-based criteria in this centre (Q51) found that there was a Highly significant positive relationship between the responses to these questions.

Table 5-4 Question pair interrelationships. Significance is tested via ordinal chi-squared tests and Bonferroni correct *p*-values.

a priori selected question pairs	Significantly related?
Do you have formal training in wound management (Q68) and specify wound management qualification (Q69)?	All respondents that responded "no" to Q68 had no response to Q69 so no need for analysis.
Are you aware of the HSE National Wound Management Guidelines 2018 (Q70) and do you refer to the section on VLU's when caring for this group of patients (Q72)?	Only 4 respondents responded "no" to Q70 and these did not answer Q72, therefore analysis was not possible here as all valid pairs responded "yes" on Q70.
Do you have formal training in wound management (Q68) and please choose the investigations that you use or refer onward to confirm presence of vascular disease and document it severity (Q77)	No significant relationship - only four respondents of 126 don't refer onwards and 2 of them have and 2 of them don't have formal training. Test statistic: $X^2 = 0.46$, $df = 1$, p -value = 0.49). Note X^2 test used here as outcomes are both binary.
Morale in this centre is high (Q41) and the culture in this centre makes it easy to learn from the errors of others (Q21)	Highly significant positive relationship between the responses to these questions. This means respondents that rate Q41 low also rate Q21 low whereas those that rate Q41 high also rate Q21 high. Test statistic: $Z = 4.69$, p -value < 0.0001.
Patient safety is constantly reinforced as the priority in this centre (Q48) and there is widespread adherence to clinical guidelines & evidence-based criteria in this centre (Q51)	Highly significant positive relationship between the responses to these questions. Test statistic: $Z = 4.12$, p -value < 0.0001.
How long have you been working in public health nursing (Q65) and Clinical Practice guidelines are important for patient safety (Q78)	No significant relationship. Most respondents answered 4 or 5 on Q78 and of those the proportion did not vary according to length of service. Test statistic: $Z = 1.97$, p -value = 0.057.
How long have you been working in public health nursing (Q65), and I routinely refer to clinical practice guidelines to support my day-to-day practice (Q79)	No significant relationship. Most respondents responded 3, 4 or 5 to Q79 with no significant differences in the proportions according to the length of service. Test statistic: $Z = 0.42$, p -value = 0.73.
Personnel frequently disregard rules or guidelines that are applicable in this centre (Q55) and other team members in this centre are doing a good job (Q45)	Highly significant relationship with most responding 1 or 2 to question 55 but the proportions responding to either differing between those who answered 4 or 5 on Q45. Test statistic: $Z = -3.86$, p -value = 0.0002.
The team here work together that is well coordinated (Q38) and all the staff in this centre take responsibility for patient safety (Q46)	Highly significant positive relationship between the responses to these questions. Test statistic: $Z = 5.28$, p -value < 0.0001.

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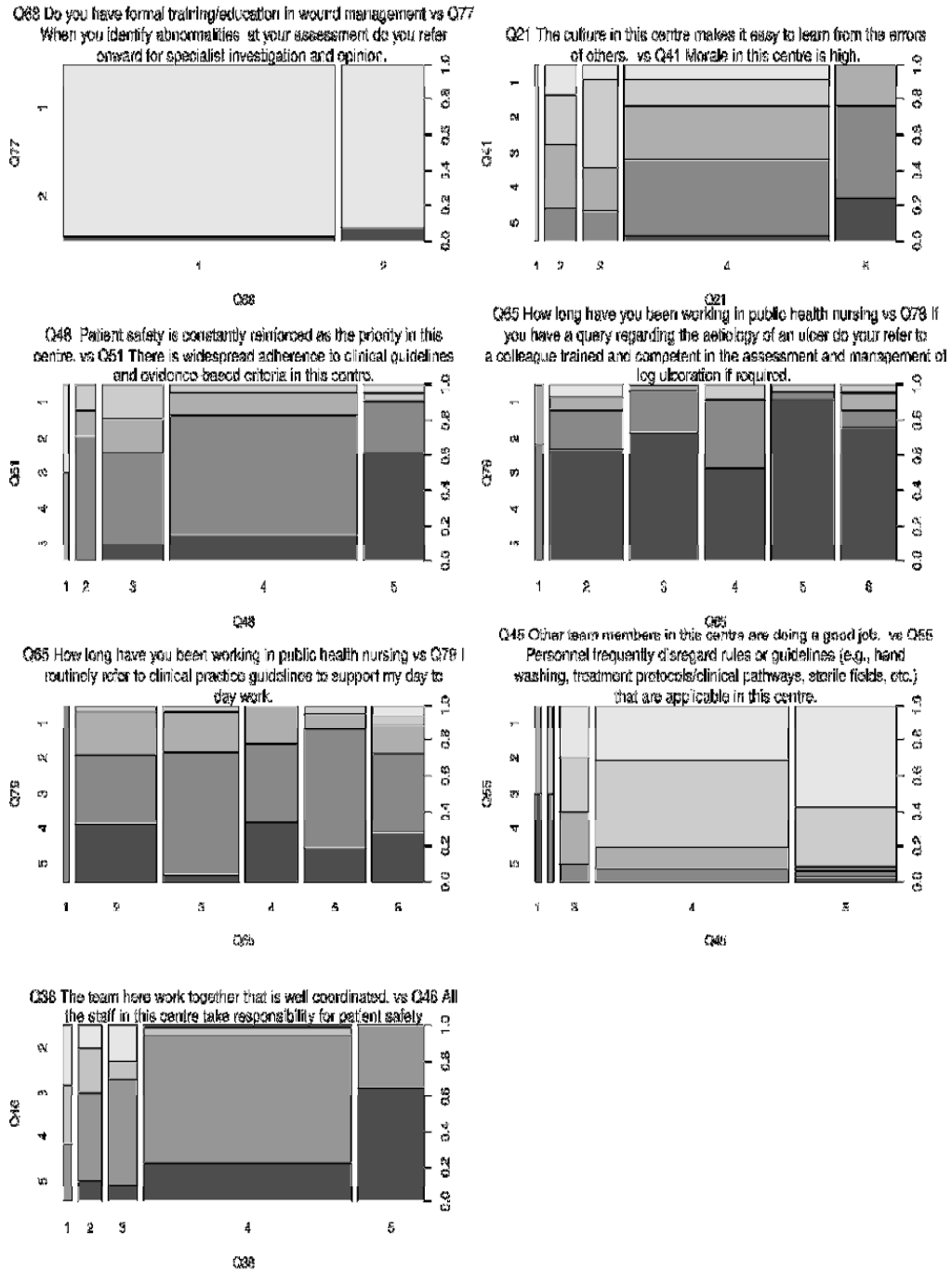


Figure 5-15 Spine plots of the two-contingency tables to display the relationship between the responses to selected questions (a priori selected).

Numbers on the x-axis correspond to responses to that question: 1 = strongly disagree, 2 = disagree slightly, 3 = neutral, 4 = slightly agree, 5 = strongly agree. Colours correspond to responses to the question on the y-axis going from 1 (strongly disagree) to dark grey (strongly agree).

5.31 Question and climate relationships

Significant relationships between a given climate and question responses were found in 3 of the 6 a priori climate-question relationships (Figure 5-16). For those significant relationships, the predicted proportions plot shows how the proportion in a given level (e.g., strongly agree) changes over the climate score (Figure 5-16). Scatterplots of individual climate scores and relationship to a priori selected questions are presented in Figure 5-16 (**significant**) & Figure 5-17 (**Non Significant**) e.g. Q46 - All the staff in this centre take responsibility for patient safety and its relationship to the safety climate found a highly **significant** positive relationship between these two variables respondents were more likely to strongly agree if safety climate is high and more likely to strongly disagree if safety climate is low.

Table 5-5 Question and climate relationships. Significance is tested via ordinal regression and Bonferroni correct p -values.

Question	Climate	Significantly related?
Information obtained through incident reports is used to make patient care safer in this centre (Q54)	Teamwork	Highly significant positive relationship between these two variables. More likely to strongly agree if teamwork climate is high and more likely to strongly disagree if teamwork climate is low. Test statistic: $D = 28.79$, $df = 1$, p -value < 0.0001 .
All the staff in this centre take responsibility for patient safety (Q46)	Safety climate	Highly significant positive relationship between these two variables. More likely to strongly agree if safety climate is high and more likely to strongly disagree if safety climate is low. Test statistic: $D = 19.69$, $df = 1$, p -value < 0.0001 .
Other team members in this centre are doing a good job. (Q45).	Perception of Management	Significant positive relationship between these two variables. More likely to strongly agree if perception of management climate is high and more likely to strongly disagree if perception of management is low. Most of this is driven however by the neutral, agree and disagree however. Test statistic: $D = 11.22$, $df = 1$, p -value = 0.00081.
I feel that I am working too hard in my role (Q53)	Job Satisfaction	Almost significant relationship. The p -value is 0.00389 whereas the cut-off is 0.00385 so strictly is does not meet the significance criteria. It would however be remiss not to note this result and classify it as almost significant. This is an example of where the p -value is not low enough to reject the null hypothesis of independence given the number of tests we are running but it is very close. The direction is for increased proportions responding 1 and 2 to Q53 who rated job satisfaction highly. Test statistic: $D = 8.34$, $df = 1$, p -value = 0.00389.
Management does not knowingly compromise the safety of patients (Q17)	Working conditions	No significant relationship between these two variables. Test statistic: $D = 3.51$, $df = 1$, p -value = 0.061.
high levels of workload are common in this centre* (reversed scored) Q1)	Stress recognition	No significant relationship between these two variables. Most responded 4 or 5 to Q1 but these were spread out across the Stress recognition climate with no pattern. Test statistic: $D = 0.04$, $df = 1$, p -value = 0.85.

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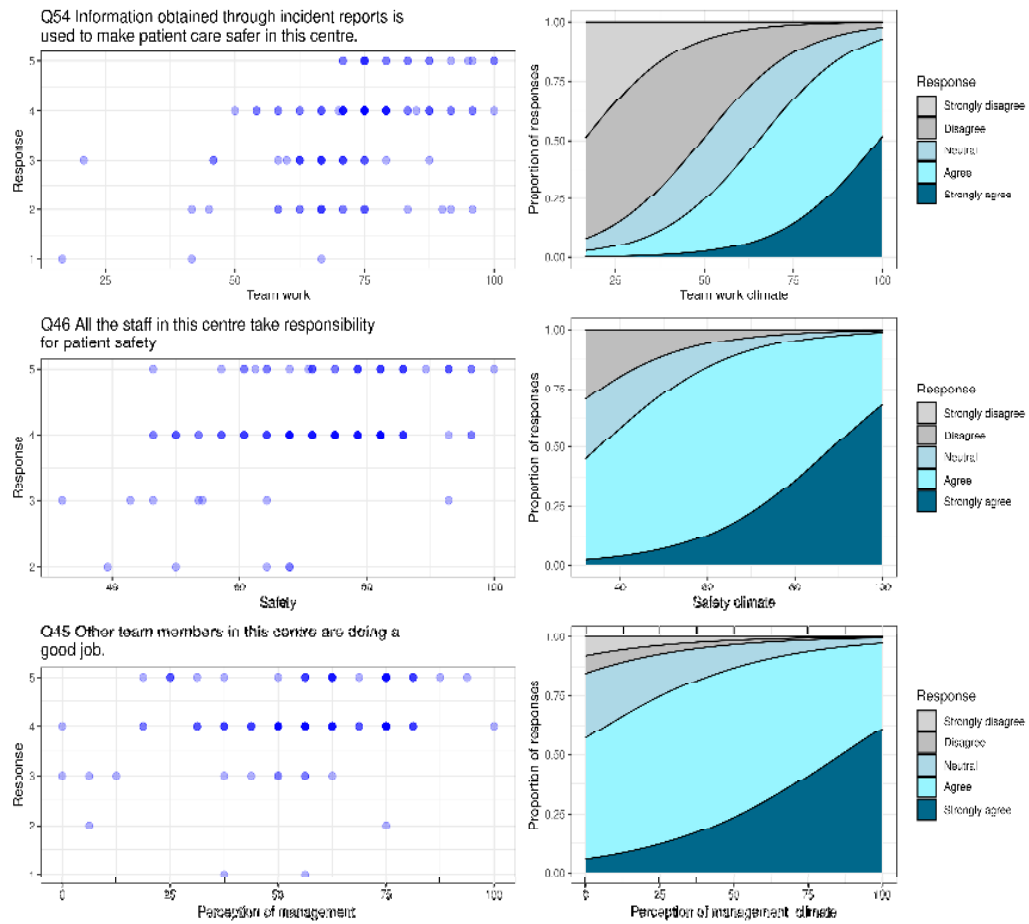


Figure 5-16 Plot of individual climate score versus question response on left; and predicted proportion in each level from the fitted ordinal regression on the right. All relationships in this panel were significant.

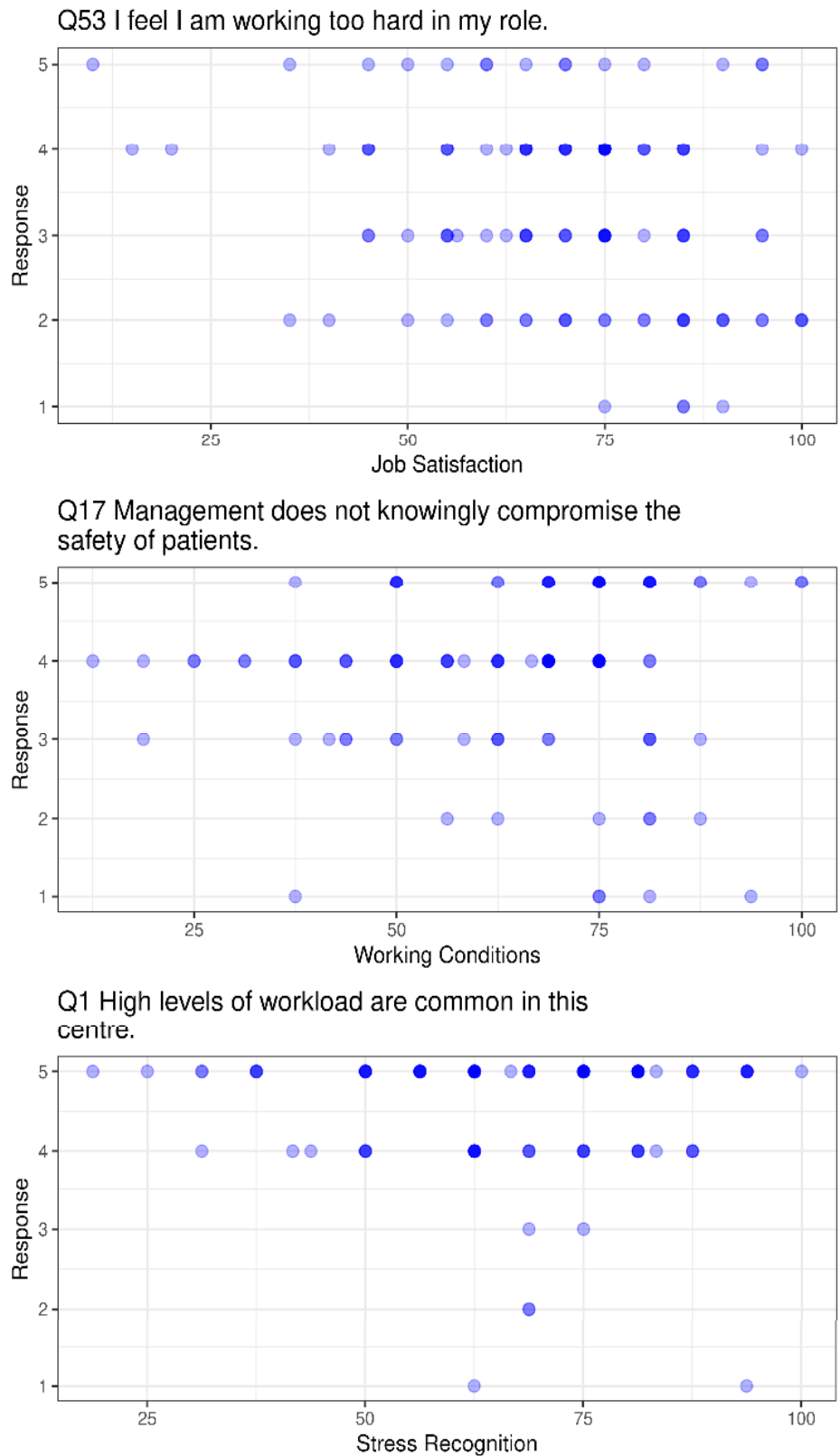


Figure 5-17 Plot of individual climate score versus question response. All relationships here are non-significant.

5.32 Domain Analysis

The SAQ AV is presented in six distinct domains; the aggregated results are presented in Table 5-6. The domains reflect the correlation of each of the individual questions within that domain and therefore reflect the thematic association that is consistent with the purpose of the questionnaire (Bondevik et al., 2019). The analysis includes the percentage agreement and neutral responses in the aggregate. Items with an asterisk (*) are reversed scored. Items with "agree" or "agree strongly"; are presented in the positive and items with "disagree" or "disagree strongly" are presented in the negative. When individual attitudes are aggregated, the SAQ provides an insight at a point in time into the safety climate of the service (Sexton et al., 2006).

Table 5-6 Characteristics of responses according to the climate domain.

Q. #	Original (SAQ-A)	Mean	% Neutral	% Disagree	% Agree
Teamwork climate scale (6 items, alpha=0.82)					
Q24	In this centre, it is difficult to speak up if I perceive a problem with patient care*	2.276	12.07	72.41	15.52
Q38	The nurses here work together as a well-coordinated team	3.888	8.62	9.49	81.9
Q30	Disagreements in this centre are appropriately resolved (i.e., not who is right but what is best for patient)	3.746	12.28	9.65	78.07
Q3	Nursing input is well received in this centre	4.096	8.65	5.77	85.58
Q34	I have the support I need from other personnel to care for patients	3.871	16.38	5.17	78.45
Q35	It is easy for staff in this centre to ask questions when there is something that they do not understand.	4.095	6.9	4.31	88.79

Safety climate scale (7 items, alpha=0.76)					
Q20	I am encouraged by my colleagues to report any patient safety concerns I may have	4.171	5.98	3.41	90.6
Q21	The culture in this centre makes it easy to learn from errors of others	3.861	10.43	10.44	79.13
Q5	Clinical errors are handled appropriately in this centre	4.289	9.65	2.63	87.72
Q28	I know the proper channels to direct questions regarding patient safety in this centre	4.103	5.98	3.41	90.06
Q11	I receive appropriate feedback about my performance	2.974	37.93	24.14	37.93
Q4	I would feel safe being treated here as a patient	4.296	2.61	6.09	91.31
Q12	In this centre, it is difficult to discuss errors*	2.5	18.42	61.4	20.17
Perception of management scale (4 items, alpha=0.72)					
Q9	Management supporting this centre is doing a good job	3.474	23.68	18.42	57.9
Q10	Management in this centre supports my daily efforts	3.443	27.83	16.52	55.65
Q26	I am provided with adequate, timely information about events in the centre that might affect my work	3.422	23.28	17.24	59.48
Q18	The levels of staffing in this centre are sufficient to handle the number of patients	2.862	14.66	43.96	41.38
Job satisfaction scale (5 items, alpha=0.86)					

Q15	This centre is a good place to work	3.949	13.68	5.13	81.19
Q29	I am proud to work in this centre	4.017	15.65	3.48	80.87
Q8	Working in this centre is like being part of a large family	3.655	19.47	15.04	65.48
Q41	Morale in this centre is high	3.181	29.31	25	45.69
Q45	I like my job	4.2	10.34	3.44	86.24
Working conditions scale (4 items, alpha=0.68)					
Q6	This centre offers a good local induction programme.	3.574	14.78	19.13	66.08
Q22	This centre deals constructively with challenging staff.	2.877	33.33	35.09	41.58
Q7	All the necessary information for clinical decisions is routinely available to me.	3.765	13.04	13.04	73.91
Q42	Students are adequately supervised.	4.018	9.73	4.42	85.84
Stress recognition scale (4 items, alpha=0.72)					
Q25	When my workload becomes excessive, my performance is impaired	3.931	6.03	14.66	79.31
Q32	I am more likely to make errors in tense or hostile situations	3.828	13.79	11.2	74.93
Q57	Fatigue impairs my performance during routine care.	2.835	15.65	48.7	36.65
Q31	I am less effective at work when I am fatigued	4.154	5.98	3.42	91.6

*Items are reversed scored

5.33 Questions explicitly related to patient safety

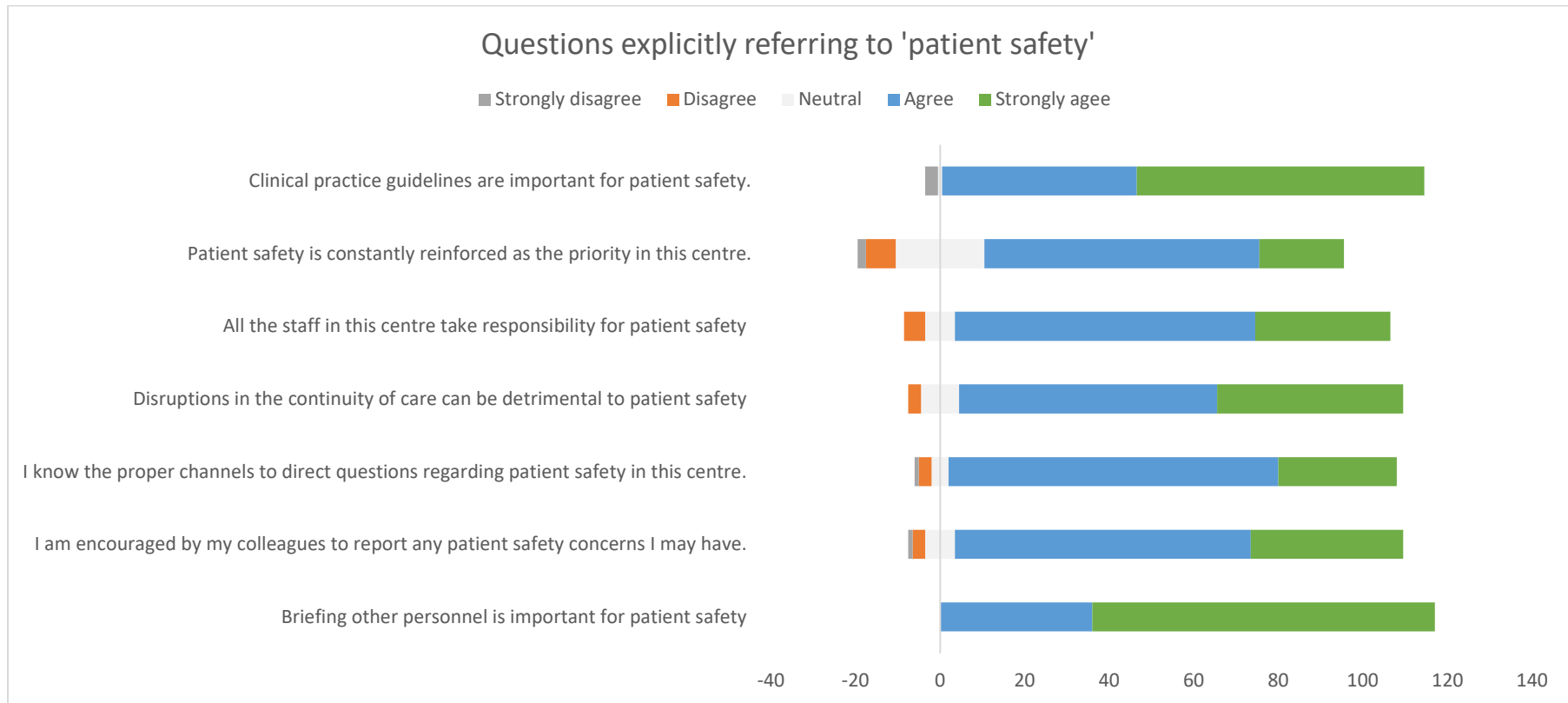
The six questions explicitly stating the term 'patient safety' are detailed with the results in a diverging stacked bar chart in Figure 5-18. The results

demonstrated there was an overwhelming response in the positive across all of the questions specifically relating to patient safety (Figure 5-18). All but one question achieved over 75% when combining the agree or strongly agree categories. The only question that marginally did not achieve a 75% threshold was the question "*Patient safety is constantly reinforced as a priority in this centre*", which achieved 73.91% of agreement. Interestingly this question was also the question that scored the highest in the neutral category with a score of 18.26% (Figure 5-18)

5.34 Questions explicitly related to guidelines

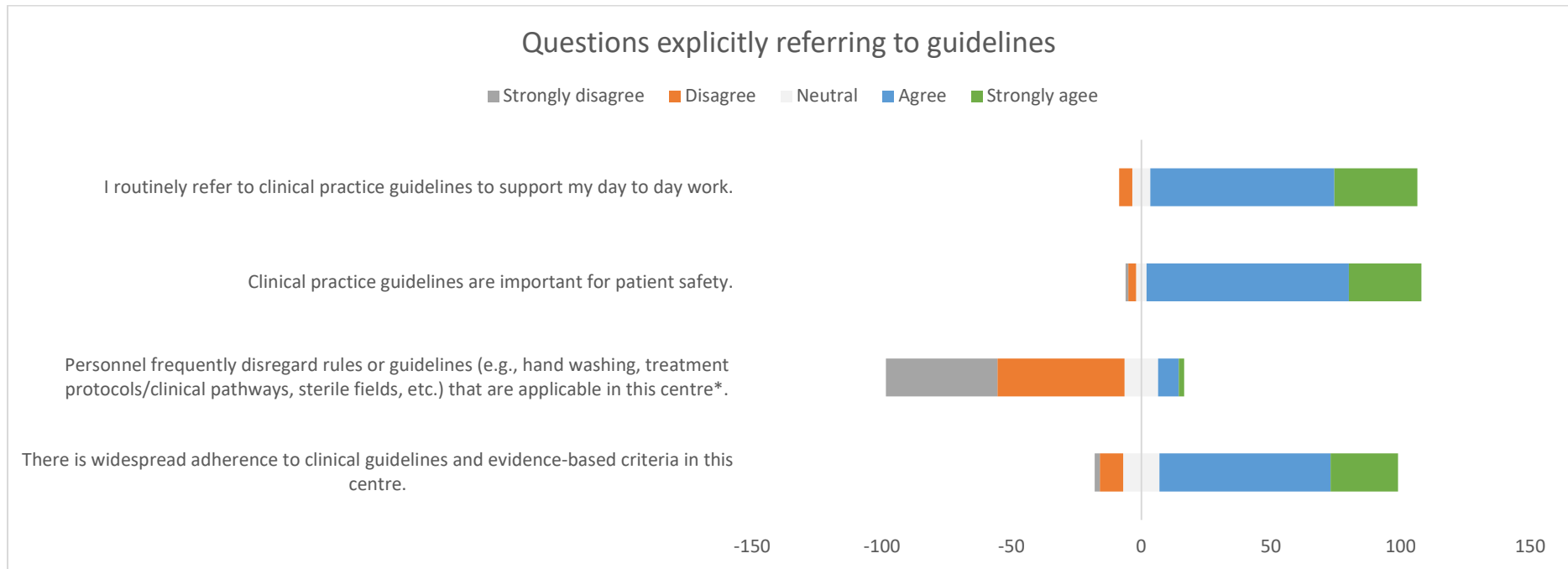
The four questions that explicitly referred to clinical guidelines are presented in Figure 5-19. All four questions received positive responses, i.e., aggregate responses greater than 75% when combining the agree or strongly agree categories, in this case Question 55 - "*Personnel frequently disregard rules or guidelines (e.g., hand washing, treatment protocols/clinical pathways, sterile fields, etc.) that are applicable in this centre*" was negatively scored and therefore the results were reversed. The response to question 78 which specifically stated "Clinical practice guidelines are important for patient safety" received a positive response of 96.6%.

Two questions, question 70 and question 71, asked – "Are you aware of the HSE National Wound Management Guidelines 2018?" and "Do you refer to the section on VLU's when caring for this group of patients?". The responses received 96.92% and 79.09% positive responses, respectively Figure 5-18 and Figure 5-19



* Reversed scored item

Figure 5-18 Questions explicitly referring to patient safety



* Reversed scored item – this refers to negatively phrased questions, therefore the responses are recorded in the positive for analysis purposes

Figure 5-19 Questions explicitly related to guidelines.

5.35 Open ended question

Twenty-nine qualitative responses were received in total from the respondents (n=161). The author closely examined the data for common themes using directed content analysis as described in section 5.27. For ease of reference, the domain climate categories will be used to elicit themes from the qualitative data, and a means to present the qualitative findings. Where a response is not appropriate to be aligned to the domain, the author will create separate subheadings that will support the alignment of the remaining responses. As the volume of qualitative data returned is not from a large dataset, there is no need for a software package to code the information returned. The author systematically reviewed the data guided by the domains categories and the questions therein. All the results are presented according to their theme and will be explored in the discussion chapter,

5.35.1 Teamwork climate

"We work well as a team, there is poor management support, they are too far removed from the ground"

"There is a great primary care team where I work, with excellent working relationships between disciplines." "...it's a great team but we are struggling."

"While I agree all referrals are done in a timely fashion, it is then waiting for the third party i.e. OT, Physio, SAGE or otherwise to review the client as they always have long waiting lists."

"Staff work well together"

"Level of effective communication between professionals within community and hospital and community is not optimal."

"Professionals can be responsible for many areas of patient care with large client base limiting potential for effective client care and professional work satisfaction."

"Long waiting list for expert assessment and timely intervention unsatisfactory for clients and professional."

"I work as a PHN in a rural health centre. I work mostly on my own except for 1 day per week when a CRGN works in my area also. I do not generally receive input from other PHN's/management unless I directly seek it... Isolation from being a

lone worker is a significant issue particularly in public health and never more so now with restrictions with COVID-19. Teamwork, positive learning environments, discussions with regards incident management, even having a discussion over lunch over a work-related concern is the ideal but not something readily available to us all!"

"teamwork amongst nursing and ot (sic) really good"

"GP slow to forward test results have to constantly chase"

5.35.2 Safety climate

"Patient safety is paramount".

"The documentation is now, in one way, a risk factor to patient care, though vital for continuity of care etc, it is now burdensome. It is very stressful and very demanding trying to balance documentation with clinical calls, patient care and definitely impacts on time to learn. It is even harder when there is only one computer and printer in a health centre between 3 or 4 staff."

"You always put patient safety first sometimes at our own personal cost."

5.35.3 Perception of management climate

"Top level management understanding of the staff who deliver care is abysmal"

"high workloads and staff sick leave are a consistent issue it makes it difficult to undertake further training..."

"I have not seen poor behaviour or practice tackled by management which is very disappointing"

"My job is frustrating due to lack of staff. Its impossible to deliver service excellence due to poor staffing. A basic safe service is delivered at the 'expense'/ wellbeing of the existing staff. Main reason for staff leaving the role is burn out."

"Our organisation has a very high of health and safety and feels a very safe place to work where I am protected as an employee from doing something unsafe (e.g. in the home and community settings situations are often very chaotic and unregulated. The patient/client is protected too due to the standard of care I am expected to provide."

"Too big a caseload for PHNs...needs to be reviewed"

"Staffing levels are lower due to people shielding, maternity leaves not being covered and of course COVID. I am actually ready to leave at this stage and I love the community."

"We need more nurses in the Community due to volume of complex cases and extensive paperwork."

5.35.4 Job satisfaction climate

"Working in a covid environment since last March has effected staff morale. Due to redeployment we have less staff, but we are trying to maintain a pre covid level of service to the public. all patient care takes longer as a risk assessment has to be completed."

"People are doing their best, but culture could be better. I find the role of the CRGN very frustrating as there are no set processes day to day and every health centre is different."

5.35.5 Working conditions climate

"Public health is very frustrating, often don't feel listened too. Referrals received often lack any info and hospital are no help."

"The building we work in is wholly inadequate- prefabs etc, this centre has been waiting for a new primary care building for years."

"Lack of IT systems is a major barrier to the productive, smooth flow of work in this PCC. Paper based documentation means that as a PHN I feel I am constantly writing, often the same information. An appropriate IT system linking all disciplines of the MDT would ensure a safer, more efficient service for our clients."

5.35.6 Stress recognition climate

"Risk assessments etc seem to be a paper exercise, extra staff approved then withdrawn so caseloads very heavy, huge backlog of child health appts with no real plan to catch up, nothing changes, and staff are fatigued from heavy workload"

"In regards stress, fatigue etc I am basing this on a busy time at work which usually involves being short staffed. Currently due to covid we have gained more CRGNs which has led to a better system of working"

5.35.7 COVID-19

"...COVID-19 has made this (management understanding) much worse as we don't meet face to face anymore and as a management team we have become more fractured and distanced in every way..."

"Covid has highlighted the overcrowding problems, inadequate access and egress and ability to safely see clients in clinics (sic)"

"This year in particular and the COVID-19 Pandemic has proved very stressful for staff and management. The uncertainty, ongoing restrictions and change in work practices have all contributed to this stress. PHNs and CRGN's have worked through it all with resilience and professionalism, which should be acknowledged."

"At the minute people are burnt out with COVID. I have been redeployed to eight different settings and am so tired."

5.35.8 Clinical Practice Guidelines

"Staffing issues and a high volume (sic) of work do not allow time to refer to the clinical guidance and pathways that are always being updated this can lead to a fatigue / burn out feeling".

"Sometimes there is so much house calls and documentation, you don't have time to look at emails with incident report findings or look into clinical practice guidelines/policies"

5.35.9 VLUs/Wound Management

"The one big obstacle to care of clients with leg ulcers is lack of proper leg washing facilities such as shower and leg washing sink. The alternative is bucket lined with plastic bag. This breaches Manual Handling and Infection Control guidelines."

"Phns have a responsibility to oversee clinical care of all patients delegated to CRGNs and review all wounds especially chronic wounds at defined intervals. It is essential that they have evidence based wound care training and the time to cover their caseload properly. Very often cross covering and staff shortages results in essential care only and reactive rather than proactive care"

"I'm the Leg Ulcer Clinic lead so based on Doppler and comprehensive assessment I know the wound aetiology. I refer to Vascular Consultant as necessary based on

criteria for onward referral. I have attended several study days on leg ulcers. We have input when needed from our TVN in wound care."

5.35.10 Documentation

"the level of required documentation and repetitive documentation is mind boggling and enormously time wasteful"

"in my present working job as a phn I have not adequate time to always complete my paperwork in a timely fashion."

"Phns workload is always added to frustrating having to write a name address and details on 60 pages of a chart, we get referrals from every source, families now expect immediate responses"

5.35.11 The Questionnaire

"The centre does not reflect the environment we work in. Most of our work is in people's homes in the community."

"questionnaire too long"

"Them questions covered a lot"

5.36 Chapter Summary

This chapter opened by presenting the two sections that apply to the Framework for Patient Safety and Research.

The author provided a very detailed overview of survey research, and a rationale for this methodology was included in section (A). A clear rationale for the questionnaire of choice was given and explained further. The areas of validity, reliability and ethical approval were presented. The author provided detail as to how the questionnaire results would be presented.

Section (B) included the questionnaire results, and this was presented in several ways as appropriate to the question type. The key findings from the survey will be discussed in the next chapter, chapter six and some findings are particularly significant if considered in the context of clinical practice guidelines, such as almost 70% of respondents stated that the extent of their formal education and training amounted to study days and less than six percent reporting that they have completed either a Higher Diploma, Post Graduate Diploma or Master in wound care.

Interestingly there was an even spread in terms of respondents profile and years of experience albeit just 3% of respondents had less than 1 years' experience. Encouragingly almost 97% of respondents were aware that the HSE National Wound guidelines existed with almost 80% referring to the section on VLUs when caring for this group of patients. Responses directly related to patient safety were overwhelmingly positive as were responses related to practice guidelines.

Particular questions of interest were cross tabulated and included a highly significant positive relationship between high morale and learning from the errors of others and; prioritising patient safety and adherence to clinical guidelines

The domain analysis was presented in the aggregate, followed by cross-tabulation between a domain and relevant questions. A highly significant positive relationship between the teamwork domain and the use of incident reports was noted as was the highly significant positive relationship between the safety climate domain and individual staff taking responsibility for patient safety. These findings and the other domain cross tabulations are discussed further in the next chapter.

The chapter closed with a verbatim narrative presentation of the open-ended questions' responses. These were presented in their totality and aligned to the appropriate domain.

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Chapter 6 Discussion Panel

6.1 Introduction

This chapter presents the results from the panel discussion. This includes an overview of the approach taken. Some of the feedback and discussion elements of verbatim responses are included; an analysis of the discussion panel responses is presented in Chapter 7- Discussion and Conclusion, where the panel discussion responses are considered in the context of the literature review, the systematic review, and the results from the questionnaire.

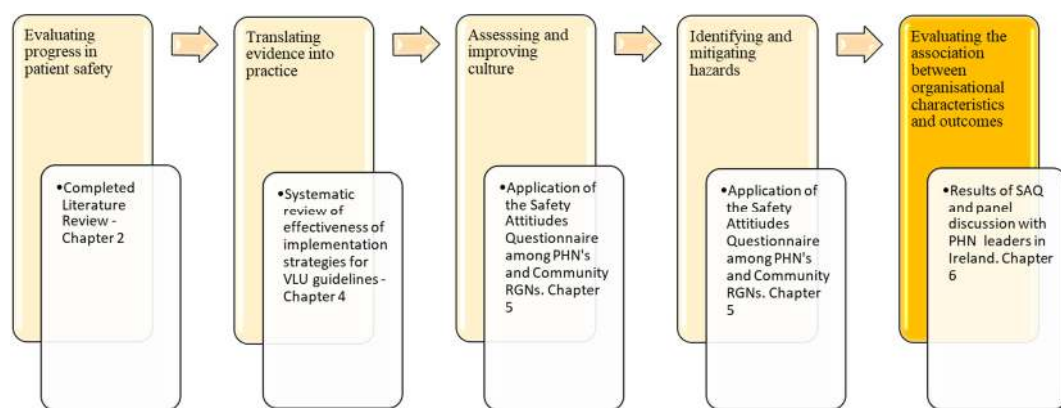


Figure 6-1 Evaluating the association between organisational characteristics and outcomes.

6.2 Feedback from the discussion panel

The author purposefully selected the panel to engage with those in various aspects of practice. It is important to give feedback on the results to those who participated in undertaking the questionnaire's face validity (Bloor, Frankland, Thomas, & Robson, 2001). Three Registered Nurses in the Republic of Ireland took part in the discussion panel. The first participant is a Community Registered General Nurse currently in practice. The second is a Registered Nurse working mainly in academia, however, she works as a Public Health Nurse every other weekend, and the third is a Registered Nurse who previously held the position of a public health nurse for over 20 years and now holds a corporate role in nursing. To maintain anonymity, the panel members will be referred to as Panel Member (PM) PM1, PM2, and PM3, particularly where direct quotes are attributed to a panel member.

To maximise the time with the discussion panel, maintain consistency, and keep the short time we had together focussed, the author took the approach to present the results from the SAQ and asked the panel for feedback on the findings. For consistency the author used the six climate factors from the questionnaire namely: Teamwork Climate, Safety Climate, Perceptions of Management, Job Satisfaction, Working Conditions & Stress Recognition and incorporated the additional five categories identified through directed content analysis as detailed in section 5.27.1; COVID-19, clinical practice guidelines, VLU/wound management, documentation and then the questionnaire itself to guide the structure of the discussion. The author moderated the panel by being mindful of guiding the discussion without participation (Gill, Stewart, Treasure, & Chadwick, 2008).

Accessing the discussion panel was necessary for this research as it completed the framework for patient safety in ‘evaluating the association between the organisational characteristics and outcomes’ and offered the researcher an opportunity to examine the responses and gain insight into the broader reactions of the participants. A discussion panel is appropriate as the author wishes to drill down into the information for further clarity, explore data collected through other methods, and feedback results to participants in the research (Gill et al., 2008). The focus of the discussion panel was to create a dialogue regarding the questionnaire results contextualised to the experiences of the panel members.

6.3 Summary of Panel Discussion

The discussion was guided by the findings of the safety attitude questionnaire. The panel was asked about their views about each question's findings and then the findings from each domain.

The panel meeting took place on Wednesday, July 28th, 2021, via Microsoft Teams© and was recorded using the recording function on Microsoft Teams©. Conducting focus group discussions online is an increasingly common approach for qualitative data collection, particularly as the availability of technology is more accessible (Woodyatt, Finneran, & Stephenson, 2016). This was vital for the author as the response to the COVID-19 pandemic demanded a reduction in groups of people coming together and curtailments in the distances one was permitted to travel. Consent was sought from each participant before the commencement of recording.

The questions asked of the discussion panel were open-ended, and the salient information is presented (verbatim in some instances) in this section. The full transcript has been documented verbatim and was issued to the panel participants to confirm accuracy. No corrections were required. For the purposes of this chapter the authors has summarised the discussion as it is not possible to present a full transcript due to the volume of dialogue available.

The panel discussion opened with the author presenting the results of the demographic data, namely:

- Please State your current role
- How long have you been working in public health nursing?
- Do you participate in wound management as part of your role? (either in a direct or supervisory capacity)
- Do you have formal training/education in wound management?
- If yes to question 5, please specify wound management qualification.
- Are you aware of the HSE National Wound Management Guidelines 2018?
- Do you refer to the section on VLU's when caring for this group of patients?
- Do you provide direct care for patients with VLU's as part of your role?

The author then opened the discussion and referred to each question individually; as the panel discussion progressed, some toing and froing between questions added to the richness of the discussion. The key comments, findings/points of agreement are presented below.

6.3.1 Awareness and use of HSE guidelines

The author's first question sought a response from the panel members: **Are you aware of the HSE National Wound Management Guidelines 2018?** The response to this question in the survey was that 97% of respondents were aware of the HSE National Wound Management Guidelines 2018. The panel members were not surprised by the high positive response to this question. They were more surprised that four respondents stated that they did not know about the national HSE Wound Management Guidelines. They went on to say that the guidelines were widely distributed through the health centres via the assistant directors of public health nursing, that they were readily available, and that they felt that there was an

excellent uptake and awareness regarding the wound management guidelines. This is of note as there was agreement that these guidelines were so relevant to practice and were very comprehensive, easy to use, and accessible that it would be unusual for this level of uptake for regular policies and guidelines. This will be discussed further in the next chapter as it relates explicitly to the dissemination of CPGs in practice. The observations of the panel members are essential on this point as it relates directly to the nub of this research thesis.

When asked about the responses to the question: **When caring for this group of patients, do you refer to the section on VLU's;** The panel members felt that the responses were justified in the context of the grades of staff returning the questionnaire and perhaps the interpretation of the question. For example, PM1 noted:

"From my practice point of view, I would have if I got a new patient in or when I looked at the wound and thought gosh I am not sure about that then I would consult the book, but then if a second patient came in with the same presentation I would just go on the knowledge of the file, I might not go and consult it on every patient but I would have become familiar with it, but definitely if it was something new or different that I hadn't seen before, so maybe its not always that I would refer back to the guidelines'

The majority of respondents to the questionnaire came from registered PHNs at 48%, followed by Assistant Directors of Nursing at 23% and CRGN's at 17%. It was important to share the demographic data with the panel members and the panel advised that they would not expect Directors or Assistant Directors of Public Health Nursing to reference the guidelines regularly but still felt that a positive response rate of 79% of respondents referred to this section of the guidelines was good as you do become familiar with the guideline content.

6.3.2 Education regarding wound care & initial assessment

The next area discussed was professional education regarding wound care, which dovetailed with patient assessment. The panel members noted that almost 87% of respondents reported that a nurse with post-basic education conducts a comprehensive assessment of all patients presenting with a leg ulcer; and that 70% of respondents stated that they had attended study days regarding wound care and

a further 77% of respondents reported that they have formal training/education in wound management. However, contrary to the fact that most respondents reported that they had post-basic education in wound care, almost 97% of respondents reported that they refer onward for specialist investigation and opinion when they identify abnormalities at assessment. Of these, 53% referred onwards for ABPI measurement. A particular focus on onward referral centred around ABPI measurement. The panel members noted that not all wound management courses offer ABPI measurement as part of the curriculum and specific doppler assessment programmes. So, while nurses complete a good 'leg ulcer history,' doppler assessment would generally be undertaken by a clinical nurse specialist or in the 'bigger health centres.' The panel members were encouraged that if a nurse had a query regarding the aetiology of an ulcer that over 95% were referred onward to a clinical nurses specialist or a GP for onward management to a consultant. The panel members felt that this did reflect current practice. This is significant and will be explored further in the next chapter as this is an important observation by the discussion panel in the context of the findings from the systematic review undertaken by the author and the notion of delayed delivery of care and the impact on patient safety.

The domain responses from the questionnaire was then presented to the panel members. The results were presented in the aggregate, the individual responses that have been thematically aligned to the domains have been included to ensure consistency.

6.3.3 Domain responses

Teamwork Climate Scale

The first domain explored with the panel members is the **Teamwork Climate Scale**. The panel members felt that the results were generally very good. They reflected on personal experience, PM2 specifically remarked

"my experience of working in the community would validate that there is a real sense of experience sharing and building relationships; even though you work sometimes on your own, you can pick up the phone and speak to a colleague and say I am worried about this person what do you think."

The other panel members strongly supported this.

The free text responses from the questionnaire reflected the good teamwork ethos with staff working well together. However, they did note that they did not engage routinely with management unless they sought it and the impact of COVID-19 further compromised team working, particularly for isolated or lone workers. The dispersed nature of the role and long waiting list in other professions in the team were also reported from a small number of respondents. The panel members were in agreement with the responses.

Safety Climate Scale

The following area discussed were about the **Safety Climate Scale**. There was significant agreement that staff would feel safe being treated as a patient of the service. One panel member particularly referred to the finding of question 11: I receive appropriate feedback about my performance and felt that the responses from this survey correlated with the HSE national staff survey and that the responses were consistent. The responses to the finding from the survey in these areas focused mainly on expectations of staff regarding the role of feedback on performance, and the panel members agreed that while the *'younger generation expected formative feedback where it is constructive and learning orientated'* it is not always the case in practice, yet it was acknowledged that the managers give feedback about work done well.

Regarding discussing errors, the panel members stated that this might have more to do with confidence in discussing an error or disclosing than the reporting process. They were not surprised that over 90% of respondents were encouraged to report any patient safety concerns and that almost 80% felt that the culture in the centre made it easy to learn from the errors of others.

The free text responses stated that *'patient safety is paramount'* and *'You always put patient safety first sometimes at our own personal cost'*.

Another respondent noted

'The documentation is now, in one way, a risk factor to patient care, though vital for continuity of care, etc, it is now burdensome. It is very stressful and very demanding trying to balance documentation with clinical calls, patient

care and definitely impacts on time to learn. It is even harder when there is only one computer and printer in a health centre between 3 or 4 staff.'

The panel members strongly identified with the comments offered by respondents and agreed that this is a true reflection of the working environment. The frustrations felt with the working environment, working with paper-based antiquated filing systems, and the risks to patient safety that these structures pose were shared amongst the panel.

Perception of Management scale

The following domain explored was the **perception of management scale**. While it was acknowledged that the responses were in the main still positive, they were not quite as positive as other domains. It was noted that almost 44% of respondents disagreed with the question regarding staffing levels. However, there was a recognition that more nurses in the community were required and that caseloads were currently too high. There was an acknowledgement of the impact of COVID-19 on the PHN service also.

The panel members felt that the results presented were consistent with their experience and referred to the role of CRGN in the Public Health Nursing Service; the panel members were shocked that there was no differentiation between the PHN and the CRGN in national reporting figures. One respondent noted

'Our organisation has a very high (sic) of health and safety and feels a very safe place to work where I am protected as an employee from doing something unsafe e.g., in the home and community settings situations are often very chaotic and unregulated. The patient/client is protected too due to the standard of care I am expected to provide.'

Furthermore, PM1 noted this particularly and referenced the role of the CRGN and their lack of exposure to ongoing education for CRGNs and that PHNs were more prepared for the chaotic nature of Public Health Nursing. Exploring the role of the CRGN and the PHN is significant as it is referred to several times throughout the panel discussion under several domains. The relationship and role of the PHN and the CRGN has emerged as significant and will be explored in further detail in the discussion chapter – Chapter 7 Discussion and Conclusion.

Job satisfaction scale

The next domain that the author presented to the panel was **the job satisfaction domain**. The panel members felt that this was well aligned to the HSE staff satisfaction survey and that overall, staff were satisfied in their roles. However, they acknowledged that while staff morale was good it could be improved; they noted that much cynicism exists and 'when you have got cynicism, it reduces *'morale in general.'*

The role of the PHN and how it interfaced with the role of the RGN garnered much discussion; it was felt that there was an imbalance and lack of recognition of the role of the CRGN, noting that it was almost like the PHN was in charge, which is not the case in reality. There was frustration noted that there were no set processes across health centres, and CRGNs could move between health centres in the same week. The language used to describe the CRGN who may not be personally assigned to a health centre caused concern PM3 noted witnessing language such as *'she was promised to me.'*

Working Conditions scale

The next domain explored is the **working condition domain**, and the author took the panel members through the results. One panel member responded to each of the sections and was surprised by the high number of respondents offered an induction programme and by the high number of respondents who felt challenging staff were constructively dealt with as this would not have been their experience working across many health centres. The other panel members agreed with this position. The environments staff are working in focused this part of the discussion, again noting the lack of IT infrastructure to support multidisciplinary team working was an important consideration. It was acknowledged that while there have been significant strides with new primary care centres, some facilities remained wholly inadequate.

Stress recognition scale

The next scale was the **stress recognition scale**, and the panel members were asked for their views on the responses. The panel members found the results from this domain interesting, particularly that fatigue was not considered a factor in impairing performance. The panel members felt it reflected a level of pride in the work they

do, the value they bring to their role, and the impact they have on their patients' comments were made in the free text regarding heavy workload and backlogs of work.

That concluded the feedback on the domains from the safety attitude questionnaire. The author's next area with the panel members was concerning the questions specifically addressing patient safety. The author presented the results to the panel members using a stacked bar chart (presented on pages 143 and 144) and presented each question and the result associated with each question. The author asked the panel members for comments or observations. Overall, the response from the questionnaire demonstrated that the respondents agreed or strongly agreed with the questions that explicitly referred to patient safety. The panel members stated that they would expect that result as there is an ongoing expectation that patient safety is a priority for all of who work in the community and PM2 *'our duty of care is to do no harm.'*

The panel members discussed that they were surprised that there were responses reported as to disagree at all and that *'Perhaps that was from a few respondents that may have interpreted the question, and all staff may have included cleaning and admin staff and may not have considered their role in patient safety or indeed you may have one colleague that particularly does not focus on patient safety, and that may have biased the response'*. Interestingly none of the free text comments from the respondents referred directly to patient safety.

The next set of results discussed with the panel members was explicitly related to guidelines. The author presented the panel with the stacked bar chart as presented on page 143. The discussion in this regard was short as the panel members felt that this had been addressed throughout the discussion thus far. Two respondents particularly referred to clinical practice guidelines in the free text section of the questionnaire. Both noted it was difficult to refer to clinical practice guidelines due to the high workload, home visits, and documentation. Interestingly, the questions in this section presented overwhelming positive responses, and PM1 *stated 'the results match other questions you have asked and the responses you have received, so I think it indicates consistency of evidence. It does not surprise me'*.

The panel members then discussed the findings presented in the free text about VLU's and wound management. One comment raised a difference of opinion:

"PHNs have a responsibility to oversee clinical care of all patients delegated to CRGNs and review all wounds, especially chronic wounds, at defined intervals. It is essential that they have evidence-based wound care training and the time to cover their caseload properly. Very often cross covering and staff shortages results in essential care only and reactive rather than proactive care."

The panel members discussed the roles and responsibilities in this comment at length. However, they understood its essence concerning the fluid nature of visits of CRGNs and the consistency of care. It was felt that continuing education for CRGNs was important.

The final question to the panel was open to them to add any additional observations. It was noted that although the questionnaire was very positive that the majority of the response in the free text section was negative. They felt that there was a level of frustration in those that commented. It was noted that PHNS and CRGNs are bombarded with new evidence, and the IT infrastructure does not support them in this regard.

The impact of COVID-19 was discussed and noted that most of the PHNs had been redeployed to vaccination centres and contact tracing. The respondents noted in relation to COVID-19 that there had been a significant impact on the service one respondent reported: *'At the minute, people are burnt out with COVID. I have been redeployed to eight different settings and I am so tired.'*

It has been challenging for managers also, and one respondent noted that:

"...COVID-19 has made this (management understanding) much worse as we don't meet face to face anymore and as a management team we have become more fractured and distanced in every way...."

Furthermore, finally, to support one respondent and acknowledge the work PHNs and CRGNs are doing, they said:

'This year in particular and the COVID-19 Pandemic has proved very stressful for staff and management. The uncertainty, ongoing restrictions, and change in work practices have all contributed to this stress. PHNs and CRGNs have worked through it all with resilience and professionalism, which should be acknowledged.'

6.3.4 Key messages from panel discussion

- The use of local leaders and accessibility to CPGs was considered key to raising awareness and use of CPGs.
- While a high proportion of respondents claimed to have further education in wound care, it was considered the norm that a nurse would make an onward referral for further investigation, including assessing ABPI measurements.
- There was a strong sense of teamwork reflected in the results, and whilst the PHN service can often be an isolated role support was available from other team members and management.
- The working environment has a significant role in the overall safety climate and contributes to dialogue regarding patient safety. However, feedback with regards to performance remains underutilised within the service.
- The physical environment outside of the new primary care centres remains inadequate.
- Nursing staffing levels within the community is an area of concern for respondents.
- A lack of clarity remains between the role of the PHN and the CRGN.
- Fatigue and stress do have a role in potential errors.

6.4 Chapter Summary

This chapter provided an overview of the panel discussion. The feedback from the panel members was summarised in the order of the discussion on each of the SAQ domains. Overall, the panel members were not surprised by the questionnaire's findings, which was encouraging given the positive results. The panel members are at the coalface working alongside the respondents to the questionnaire. It was important to understand their position, and understanding their views was critical in advancing this research as they could offer a context to the findings. The discussion with the panel members brought together elements from the literature

review, the systematic review, and the questionnaire. They also offered rationale from their experience. The next chapter will explore their responses in much more detail and in the context of the findings for the other elements of this research study, with a particular focus on patient safety.

Chapter 7 Discussion and Conclusion

7.1 Introduction

This discussion chapter will focus on bringing together all of the findings in relation to the literature. The author will discuss the finding from this research study in the context of the literature review. Implications for clinical practice and further research will be considered, and a conclusion of the thesis will be presented.

A systematic review was undertaken to ascertain the effectiveness of implementation strategies for clinical practice guidelines for VLUs. This systematic review was timely as healthcare costs continue to increase due to an ageing population with an associated increased prevalence of chronic conditions (Haynes, 2020) and the environment in which care is being delivered is changing (Robbins & Davidhizar, 2020), it is also very timely to undertake this study given the new HSE wound management guidelines and understanding how they can be implemented. The outcome of the systematic review notes that evidence regarding implementation strategies for VLUs is extremely poor. Interestingly, however, the included study (Brown, 2002) does not support the traditional view that new guidelines require an educational component to support implementation. The EPOC sub-category strategies of interventions listed in table 4.1 identify the distribution of educational materials, educational meetings, and educational outreach visits as appropriate interventions. The panel members were more convinced from their experience of the role of key personell and in this instance the Assistant Director of Nursing in raising awareness of the local policy document acknowledging that this promotes dissemination and encourages implementation. Again, the EPOC sub-category strategies of interventions note that local opinion leaders are considered an intervention when identified by their colleagues.

The application of the safety attitudes questionnaire provided insight into the attitudes of PHNs and CRGNs regarding the broader facets of patient safety and will be discussed in further detail later in this chapter. The respondents were very positive throughout the questions and the questionnaire domains. The discussion panel members supported this positive disposition during the discussion. It is clear that patient safety is very much at the heart of nursing practice and central to the registered nurse's activities in delivering patient care. It is also clear from the

literature review and the panel discussion that the concept of patient safety is a complex phenomenon and that patient safety remains firmly rooted in incident reporting or errors or active harm. This research thesis has provided data on patient safety attitudes in public health nursing in Ireland and to the authors knowledge is the first report of this nature undertaken with this professional group.

7.1.1 Awareness and availability of clinical practice guidelines

As identified in the methods chapter Pronovost & Sexton (2005) state that to reduce the risk of non-adherence to evidence-based practice, three things must be assessed (1) was a new policy, guideline or procedure created, (2) do staff know about the policy, guideline or procedure and (3) do staff use the policy, guideline or procedure as intended, the latter requiring an audit of the behaviour of staff. The evidence from this thesis notes that 97% of respondents stated that they were aware of the HSE National Wound Management Guidelines 2018 and that all of those responding to that question stated that they referred to the section on VLU when caring for this group of patients. The panel members were not at all surprised by this and specifically said:

Panel Member (PM) 1 *'... those guidelines were widely distributed amongst the health centres, and they are based as well on European wound care guidelines, it surprises me more, of the four that didn't know about them.'*

PM 2 *'I think it is an excellent uptake on awareness around wound management guidelines when you compare it to other kinds of policies and guidelines that go out, you would not get this kind of an uptake at all, but it just goes to show you how pertinent guidelines are for clinical practice for this group of nurses'*

It may be concluded that not only were the respondents aware of the existence of the national HSE guidelines, but they were adhering to elements of them in practice and that there was not an overreliance on experience to inform practice. This is contrary to Weller et al. (2020) who found that among primary care practitioners in Australia, VLU guidelines are not routinely used in primary care. They reported that most of the participants in their study did not know that clinical practice guidelines on the management of VLUs in primary care existed.

The panel members recalled how the wound management guidelines were made available and identified that they were disseminated by the Assistant Directors of Public Health Nursing; that the documents were made available in hard copy format in the health centre. They commented further that the guidelines were clear and well laid out and that the pictures and illustrations were '*very good*' in the guidelines. It is interesting that the panel members made such observations as it is commonly cited in the literature that a significant barrier to guideline use is the clinical practice guideline itself, in that it is not user friendly, including the format and content and that the guideline is not easily accessible (Jun et al., 2016).

7.2 Full application of guidelines in practice

VLU guidelines reviewed by the author recommend or suggest the need to rule out arterial insufficiency before commencing with compression therapy. This is achieved in part, through the measurement of the Ankle Brachial Pressure Index (described in detail in chapter 2 section 2.5.12). The results from the questionnaire noted that 53% of respondents referred onwards for ABPI assessment and the panel members confirmed that Doppler² assessment would be carried out by tissue viability nurses or clinical nurse specialists upon referral. It is unclear from the findings however if the remaining 47% undertook ABPI measurement themselves or if they proceeded with compression therapy in the absence of confirmation of arterial disease. Whilst the HSE guidelines do not make a recommendation in that an ABPI is required prior to compression but locally this is often the case. There is ambiguity across guidelines on this issue and compression can be started without an ABPI being performed and the HSE guidelines note that assessment should be undertaken by someone with the appropriate education and training. It could be concluded that 47% of respondents did not consider themselves competent to undertake the full assessment. Therefore in considering this through the lens of patient safety a delay in full assessment and therefore commencement in appropriate evidence based treatment results in delayed care. Vowden & Vowden (2016) note that The Burden of Wounds study (Guest et al., 2015) reported that despite published guidelines, that only 16% of cases with leg or foot ulceration

² The term Doppler and ABPI measurement are interchangeable terms.

included in their study had a Doppler ankle-brachial pressure index (ABPI) recorded.

In a cross-sectional survey, Gray et al. (2018) found that there was a general underuse of ABPI and underuse of compression therapy in community health care settings in the north of England. The discussion panel, whilst noting that almost 70% of respondents had attended a study day regarding wound care they advised that undertaking ABPI measurement would not have been included in the content of the study day, and the recording of ABPI measurement would typically only be delivered during more comprehensive study programmes and even then it was not consistent that vascular assessment would be taught as part of the course and that Doppler assessment does require specific training. The panel members stated that the vascular assessment would be undertaken by clinical nurse specialists or tissue viability nurses and that some PHNS and CRGNs would not routinely undertake this role but refer onwards to specialist nurses; they also confirmed that the equipment required to undertake the assessment would not be readily available and then only in the bigger health centres. Doppler assessment would only be undertaken by nurses who have completed a doppler assessment programme or a more significant course other than a study day. The panel members' responses in the discussion to this issue as an acceptable norm; however, this is of concern as Gerrard (2021) reports a culture of passivity developing amongst clinicians in the community resulting in delays of APBI measurements and, therefore a reduction in timely therapeutic interventions.

7.2.1 Delays in care delivery

Having to refer the patient onwards for appropriate vascular assessment may delay the correct diagnosis, which may delay the correct intervention, e.g., compression therapy therefore directly impacting on patient safety through delayed care. It is noted that any delay in the implementation of compression therapy increases the time that patients require care (Bernatchez, Peterson, & Fife, 2017). Given that 53% of respondents refer onwards for ABPI measurement, it is reasonable to conclude that there is a delay in commencing compression therapy where it is appropriate to do so. This research supports findings from other authors (Vowden & Vowden, 2013) in acknowledging that despite the plethora of readily available clinical

practice guidelines for the treatment and management of VLUs stating that compression therapy is the gold standard of treatment, many patients may not receive appropriate compression in a timely manner and that this is a very significant problem for patients and the management of their VLU (Bernatchez et al., 2017). Bernatchez et al. (2017) have recommended that clinicians in outpatient settings be trained and equipped to measure ABPI, which should be considered a minimum competency. The test does not require expensive equipment or access to specialised centres, and when performed correctly, compression therapy will commence at the first visit and avoid unnecessary delays. The literature is clear with regards to the management of patients with VLUs in the community in that if there is any delay in measuring ABPI there is a detrimental effect to the patient (Gerrard, 2021) If we are to reconsider patient safety beyond active harm and incidents, we must accept, therefore, that patient safety is affected as a result of delayed care.

7.2.2 Use of the Safety Attitudes Questionnaire as an appropriate survey tool

The Safety Attitudes Questionnaire was entirely appropriate to use as a measurement tool to assess the safety climate (culture) at the front line. It was particularly appropriate in reflecting the findings from the literature review and the work of Charles Vincent and Donabedian as the development of the SAQ relied on these two conceptual frameworks in informing the questions (Sexton et al., 2006). In administering the safety attitudes questionnaire and exploring the results through the panel discussion, it is apparent that patient safety is very much a part of the working lives of front-line nursing staff. Interestingly, the questionnaire demographics data indicated that the duration of time working in public health nursing was relatively evenly spread across the time frames, except for those less than one-year practising. A very high proportion of respondents provide care for patients with VLUs.

7.2.3 Patient safety culture

As referred to in the literature review, in 2008, the Government of Ireland published a report entitled Building a culture of patient safety which was the report of the Commission on patient safety and quality assurance (Madden, 2008) - the Madden Report. The Commission was established following many high profile adverse

events resulting in inquiries and reports bringing patient safety to the forefront of the Irish healthcare policy agenda.

The importance of a safety culture is well documented within the Madden Report, and given that it was published in 2008, it very much focuses on a safety-I perspective - in terms of incident reporting and follow up. However, it does recognise the important role of CPGs in ensuring that patients get the best possible outcomes from their care but notes that there are no quality assurance standards for evidence-based guidelines, nor are systems in place to monitor the implementation of guidelines. The report went on to say that the implementation of guidelines is critical and must be linked to service priorities.

The analysis from the safety attitude questionnaire for this thesis and the panel discussion supports the theory that organisations need to create a positive patient safety culture. This is encompassed by the work of organisation leaders, staff interactions, their attitudes and routine practice (Smits et al., 2017). Almost 80% of respondents agreed that the culture in the health centre supported the notion of learning from others; however one CRGN felt very frustrated with the role, and while they felt people were doing their best, the culture could be better. A safety culture comprises of values, attitudes, beliefs and norms as well as the behaviours expected for patient safety (Lawati, Dennis, Short, & Abdulhadi, 2018); the safety attitudes questionnaire provided an understanding of the values, attitudes and beliefs and the panel discussion allowed for this to be considered in the context of behavioural norms. Interestingly, whilst the majority of patient safety research has taken place in the acute hospital environment, Gallego et al. (2012) used a hierarchical two-level regression model to compare the patient safety cultures of types of services across a health system and found that the most favourable safety attitudes were found in primary and community care & screening services, this is consistent with the finding in this thesis.

7.2.4 SAQ Domains

It is recognised in the literature that a patient safety culture has many facets with a focus on establishing a systems approach to reducing and preventing harm to patients. To achieve this, there must be effective and open communication, maintained staffing levels, adherence to procedures, a safe and secure place to work,

good leadership and in the absence of such things, patient safety is compromised (Ammouri et al., 2015). The author will now present a discussion of the finding using the headings from the six domains from the SAQ which encompasses the elements that contribute to patient safety as recognised by Ammouri et al, (2015).

7.2.5 Teamwork domain

It is established that effective teamwork can positively impact patient safety (Baker, Gustafson, Beaubien, Salas, & Barach, 2005; Vincent, 2010). The domain analysis of the teamwork climate demonstrated an overwhelmingly positive response from the participants, and this is consistent with other studies (Modak et al., 2007). There was strong evidence from the results of working well together as a team. The respondents felt the voice of nurses were heard within the team and that they were well supported and felt comfortable speaking up if there felt that there was a problem (72% of respondents disagreed with the statements that it is difficult to speak up if I perceive a problem with patient care). The respondents felt they could ask questions if there was something they did not understand. The findings were supported by the discussion panel members and they acknowledged that while as a PHN, one would often work in isolation that there was a sense that support was only a phone call away. However, it is essential to recognise that a finding from this research is that there does appear to be a two-tier system in terms of roles within the Public Health Nursing Service. There is the role of the PHN and the role of the CRGN, feedback from the survey and the discussion panel suggested that the CRGNs do not always feel valued by the PHN. This is also evident in the Perception of Management domain. Whilst the Teamwork domain is in the positive, it would be important to understand that the elements in this domain need to be actively managed to ensure the culture remains strong in this regard and attention is given to supporting the role of the CRGN.

The questions specifically relating to patient safety incorporating teamwork such as; *All the staff in this centre take responsibility for patient safety* and *I am encouraged by my colleagues to report any patient safety concerns I may have received* overwhelming positive responses. Although the questionnaire found the respondents to be positive to the questions asked and the free-text responses were also positive in the main for this climate, some respondents did feel that some

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practices such as following up on results and working in isolation were challenging elements of the role. They also report that while communication between nurses is good, there are challenges regarding communication with other team members or between the hospital and community.

The author ran a cross-tabulation of question 38 – *The team here works well together and is well coordinated* and question 46 – *The staff in this centre take responsibility for patient safety*. The data suggest a highly significant positive relationship between both responses. Therefore if staff are taking individual responsibility for patient safety, their experience is that the team is well coordinated.

The WHO recognises the important role of teamwork for patient safety. It includes a dedicated chapter on being an effective team player in their Patient Safety Curriculum Guide: multi-professional edition (World Health Organisation, 2011a). The WHO recognises that healthcare care teams work right across the spectrum in health care delivery and range from operating room teams in complex surgery's to being a single doctor and nurse in primary care settings. De Vasconcelos et al. (2019) note that individual practitioners who engage with teamwork are more likely to engage in actions to promote patient safety.

7.2.6 Safety climate domain

The safety climate scale has the most questions of all the domains and is particularly focused on patient safety; there is a dearth of studies exploring safety climate among PHNs or CRGNs . The focus on safety climate regarding nursing practice is within the acute hospital sector, particularly in areas such as the operating room or in areas of specialist practice such as stroke care. The results in this domain were overwhelmingly positive across all seven questions. Three questions, question 20 - *I am encouraged by my colleagues to report any patient safety concerns I may have*, question 28 - *I know the proper channels to direct questions regarding patient safety in this centre* and question 4 – *I would feel safe being treated here as a patient* all receiving over 90% in the positive. Two respondents also stated that:

"patient safety is paramount" and that "you always put patient safety first sometimes at our own personal cost."

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In undertaking an analysis of this domain and question 46 – *All the staff in this centre take responsibility for patient safety*; the author found that there was a highly significant relationship with the responses in that the respondents were more likely to strongly agree if safety climate is high and more likely to strongly disagree if safety climate is low. The panel members agreed with the responses as reflective of the clinical environment. They noted that patient safety is often discussed in the health centre and that while the role of the PHN or CRGN is often isolated, there is a sense that support is just a phone call away.

A significant finding when running a cross tabulation between two questions ie Q 48 - *Patient safety is constantly reinforced as the priority in this centre* and Q51 - *There is widespread adherence to clinical guidelines & evidence-based criteria in this centre* found a highly significant positive relationship between the responses. It can be concluded that when there is a focus on patient safety in the workplace then adherence to CPGs and evidence-based care will follow. The author explores the impact of dissemination and implementation of CPGs later in this chapter.

7.2.7 Perception of management domain

Although the perception of management is reported as a separate domain, it is evident from this study that the perception of management does influence other domains, including safety climate, teamwork climate, working conditions and job satisfaction; this is supported by other authors (Lee, Zeng, Huang, & Wu, 2018; Sexton et al., 2006; Weng, Kim, & Wu, 2016).

The analysis for this domain was very interesting in that while the respondents agreed that management supporting the centre was doing a good job, and that their daily efforts were supported, and they had access to timely information to support them in doing their work; the respondents were split almost 50/50 regarding the levels of staffing being sufficient to handle the number of patients. Weng et al. (2016) note that this domain reflects the extent of staff approval of management decisions. This is particularly evident in the free text question of the questionnaire. The responses included several comments regarding high workloads/caseloads, lack of staff and the impact of COVID-19. One respondent noted that *"top-level management understanding of the staff who deliver care is abysmal"*.

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The panel members agreed with the finding from this domain and talked again about the role of the CRGN and the role of the PHN. It was evident from the discussion that it felt that there was little value placed on the role of the CRGN and that this was evidenced further in that the national statistics on staffing did not capture the nursing workforce in the community accurately and did not report on the numbers of PHNs and the numbers of CRGNs separately.

The findings in this domain would be consistent with the finding from the Health Service Executives 2018 staff survey, Your Opinion Counts, where 6 in 10 respondents were positive about the support received from their manager (Ipsos MRBI, 2018).

The author undertook a cross-tabulation of this domain, and question 45 – Other team members are doing a good job and found a significant positive relationship between the two variables that is respondents are more likely to strongly agree if the perception of management climate is high and more likely to disagree if perception of management is low strongly. Leadership is recognised as a key element of good teamwork and involves coordination and planning of the service, as well as creating an atmosphere of motivation in an environment that is supportive (Weller, Boyd, & Cumin, 2014). It is interesting however at this point that one respondent to the questionnaire did note that:

"we work well as a team, there is poor management support, they are far too removed from the ground."

The author ran a cross-tabulation of question 38 – The team here works well together and is well coordinated and question 46 – The staff in this centre take responsibility for patient safety. The data suggest a highly significant positive relationship between both responses. Therefore if staff consider that the team is well coordinated it contributes to them taking individual responsibility for patient safety.

7.2.8 Job satisfaction domain

The perception of management domain and the job satisfaction domain are inextricably linked. It is well established that effective leadership contributes to

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improvements in patient safety and plays a key role in job satisfaction (Boamah, Laschinger, Wong, & Clarke, 2018).

The results for the questionnaire in this domain were in the positive, with most respondents identifying that the centre they worked in was a good place to work, they were proud to work there, it was like being part of a large family and with a high majority of over 86% liking their jobs. However, the panel did feel that there was still room for improvement in terms of staff morale, and this was reflected in question 41 – Morale is high in this centre, with just over 45% of respondents stating that morale was high.

One respondent noted that the impact of COVID-19 has affected staff morale, redeployment resulted in less staff whilst trying to continue to deliver a pre-covid level of service and that the added burden of doing additional risk assessments was a factor.

Another respondent referred to the role of the CRGN and expressly stated the culture could be better and that there were no set processes. The panel members discussed this at length. The lack of understanding or acknowledgement in the role of the CRGN caused a lot of frustration amongst CRGN's and may contribute to poor job satisfaction.

In a cross-tabulation of the results with question 41- Morale in this centre is high, and question – 21 the culture in this centre makes it easy to learn from the errors of others found that there was a highly significant positive relationship meaning that respondents that rate Q41 low also rate Q21 low whereas those that rate Q41 high also rate Q21 high. The author undertook further cross-tabulation in this entire domain and question 53 – I feel I am working too hard in my role, the finding was that it was almost significant; therefore, it was not the case that job satisfaction was linked to hard work. This is a significant finding and while it is recognised that good staff morale contributes to a positive learning environment when errors are made there is no room for complacency; particularly when there is a clear demarcation in the role of the PHN and the CRGN

It was interesting to note from the observations of the panel members that the finding in this domain again reflected the findings of the national staff survey in

that 64% of respondents in the HSE's national staff survey were satisfied with their job and that 68% felt that their job gives them a personal sense of fulfilment (Ipsos MRBI, 2018).

7.2.9 Working conditions domain

The responses to the working conditions domain were somewhat divided. There was an overwhelmingly positive response to question 7 - All the necessary information for clinical decisions is routinely available to me, and question 42 students are adequately supervised with scores of 74% and 86%, respectively, and 66% of respondents felt that they had a good local induction programme. Whilst only 42% agreed that challenging staff were dealt with constructively, 35% disagreed, and 33% were neutral, this was the highest neutral score of the questionnaire; therefore, it may be reasonable to conclude that exposure to challenging staff is not routine in terms of working conditions. Although one of the panel members commented that they were surprised by the high number of responses that felt challenging staff were dealt with effectively. While the majority of respondents did feel that they had the necessary information to do their job, one respondent did note that: *"Public health is very frustrating, often don't feel listened to. Referrals received often lack any info, and hospitals are no help."*

Respondents to the questionnaire expressed frustration with the building they had to work in and the lack of IT infrastructure. The panel members also discussed this and felt that the lack of IT infrastructure added to the frustrations and increased workload. A paper-based system did not support a patient safety agenda.

The author undertook a cross-tabulation of this domain, and Q17 - *management does not knowingly compromise the safety of patients* and identified that there was no significant relationship between these two variables, indicating while there was a frustration in the working conditions, the respondents did not feel that management was compromising on patient safety. The working conditions domain can not be underestimated in regards to its impact on patient safety. Donabedian (2005) recognised that the structures in which care is delivered, including the fabric of the building, is significant in relation to the model of structure, process and outcome, with the assumption being that given the proper setting, good care will follow.

7.2.10 Stress recognition domain

The stress recognition scale is an interesting scale to interpret, the majority of respondents to the questionnaire agreed that when their workload becomes excessive, their performance is impaired, that they are more likely to make mistakes in tense or hostile situations and that they are less effective at work when they are fatigued. However, only 36% agreed that fatigue impairs their performance during routine care. Gallego et al. (2012) conclude that in this domain when respondents agree what they are stating is that they are acknowledging how stressors impact their personal performance and not necessarily their work environment and that this domain differs from other domains in the SAQ in that they measure the individuals self-behaviour whilst the other domains focus on the behaviours of others within the workplace. This is supported by Taylor & Pandian (2013); they consider that the stress recognition domain measures the respondents stress at a point in time, i.e. at the time they are completing the questionnaire; this is an interesting position to take regarding this domain, particularly given the responses below.

One respondent noted that:

"In regards stress, fatigue etc, I am basing this on a busy time at work which usually involves being short staffed. Currently due to covid we have gained more CRGNs which has led to a better system of working"

Although another comment did report that

"staff were fatigued from heavy workloads."

The panel members felt that the responses reflected an element of pride in the work that nurses do and the direct impact on their patients and further reflected the understanding of the role of the CRGN. While the cross-tabulation of this domain and that 'high levels of work are common', there was no significant relationship found.

7.3 Putting patients first

Patient safety and patient welfare are considered to be at the heart of what it means to be a health care professional. Health professionals report that they often put patient needs before their own, resulting in staff missing meal breaks, working late, and working in unsafe situations (Sinnott, Eley, & Winch, 2014). It is important to

note that this observation was reflected in the feedback from the panel discussion when they considered the results of the SAQ.

7.3.1 Dissemination

There needs to be a clear understanding of the difference between the term implementation and dissemination. Dissemination can be defined as:

"the targeted distribution of information and intervention materials to a specific public health or clinical practice audience. The intent is to spread knowledge and the associated evidence-based interventions" (McCormack et al., 2013)

In order for clinical practice guidelines to make a difference in practice and to impact patient safety, those responsible for adhering to guideline-based care must know that the guidelines exist in the first place.

Grimshaw et al. (2001) examined 41 systematic reviews to understand how to translate research findings into practice using active dissemination and implementation strategies; they concluded that various dissemination and implementation strategies are effective under certain conditions and that educational outreach and reminder are broadly effective. Passive dissemination is generally ineffective (Grimshaw et al., 2001), although there may be variable effectiveness when coupled with local opinion leaders. This is supported in the experience of members from the panel discussion, where they confirmed that it was clear that the assistant directors of nursing that they worked with had influenced the uptake in the use of the HSE National Wound Management Guideline's 2018. They stated unequivocally that one of the key strengths of raising awareness of the HSE National Wound Management Guidelines (2018) document was that the guidelines were readily available in the practice setting. However, it is recognised that simply creating guidelines and making them available does not guarantee their use in practice (Grimshaw, Eccles, Lavis, Hill, & Squires, 2012).

Following a systematic review undertaken by Tomasone, Kauffeldt, Chaudhary, & Brouwers (2020), they state insufficient evidence to recommend a 'universal' dissemination strategy for clinical practice guidelines. It is acknowledged that their systematic review was limited to cancer care however no evidence can be sourced that recommends one dissemination strategy over another. Based on the findings

from this thesis recommendations regarding the dissemination of clinical practice guidelines are presented later in this chapter.

7.3.2 Implementation

The HSE National Wound Management Guidelines acknowledge that:

"The implementation of clinical guidelines requires a multi-faceted approach combining several methods that include education, organisational systems and a quality agenda that promotes efficacy and professional accountability and encourages continuous improvement" (HSE, 2018, p. 238) and that

"The CEO, General Manager, Clinical Director and the Director of Nursing and/or Midwifery of health service providers have corporate responsibility for the implementation of the recommendations in this guideline. Each member of the multidisciplinary team is clinically and professionally accountable for implementing the recommendations relevant to their discipline." (HSE, 2018, p. 248)

Section five of the HSE National Wound Management Guidelines 2018 entitled Implementation, has subsections specified as:

- Barriers and facilitators to implementation
- Education, responsibility for implementation
- Organisational responsibility
- Roles and responsibilities

The roles and responsibilities are detailed further to senior managers, Heads of departments and all clinical staff. The Institute of Healthcare Improvement (IHI) recognises that to improve and advance safety, leadership within organisations are required to develop robust safety cultures, it was important therefore that this thesis explored the safety culture of the PHN service to include an exploration of leadership within the service. The role of the ADPHN was particularly significant regarding dissemination. Based on the findings from this thesis recommendations regarding the dissemination of clinical practice guidelines are presented later in this chapter.

Chapter 7 Discussion and Conclusion

A systematic review undertaken by Tan, Luo, Onida, Maccatrozzo, & Davies (2019) included fourteen clinical practice guidelines for the management of VLU. They identified that most of the CPGs they reviewed failed to address the implementation of the guideline. Gagliardi & Alhabib (2015) found from their systematic scoping review, which evaluated the implementation of guidelines on arthritis, diabetes, colorectal cancer and heart failure, that although a variety of strategies have been used to implement guidelines, their impact is inconsistent. However, specifically related to compression therapy for VLUs Andriessen et al. (2017) state that from their literature review of EBP guidelines, none of the guideline included an implementation strategy and they recommend that this is an important step and should be included. Whilst acknowledging this recommendation there is no reliable way to recommend one implementation strategy over another, particularly when addressing practice in different contexts. Gagliardi & Alhabib (2015) acknowledge that the evidence is sparse and it is not possible to identify trends in guideline implementation. They recognise from their review that most studies they examined employed education of staff or patients combined with other strategies. This is interesting as the findings from the systematic review (SR) undertaken by the author are consistent with the findings from Gagliardi & Alhabib (2015) i.e. the author cannot recommend one implementation strategy over another for the implementation of VLU guidelines.

Whilst Gagliardi & Alhabib (2015) recognise that education combined with another strategy was employed in many of the studies included in their review, the study included in the SR undertaken by the author found that education specific to a new guideline did not impact patient outcomes. This finding was surprising and significant to the original study authors, so much so that Brown (2002) (the authors of the study included in the SR) undertook further analysis to explore the findings from their research and questioned elements of their methodology and asked of themselves:

- (i) Was the trial of too short a duration?
- (ii) Were the SIGN guidelines incorrect?
- (iii) Was the nurse training programme inappropriate or ineffective?

- (iv) Did the working environment in the community impede the effective application of acquired skills?
- (v) Were the VLUs intractable?
- (vi) Was there a lack of specialist support for community care?

They found that all possible contributory factors were satisfied.

Gagliardi & Alhabib (2015) recommend that further research is required to ascertain the barriers to guideline implementation and identify the appropriate implementation strategy to address those barriers. Other authors have explored this (Pacella, 2018; Weller et al., 2020) and note that the implementation of evidence-based practice guidelines remains poor. As a result of the SR undertaken by the author, it is evident that more work is required to ascertain appropriate mechanisms or interventions to implement clinical practice guidelines within a defined cohort of practitioners and the author cannot recommend one implementation strategy over another.

7.3.3 Partial Implementation

The literature recognises that guidelines are poorly implemented in practice; however, the author cannot source any papers recognising the partial implication of guidelines. Therefore, one must be mindful of broad statements regarding the adherence to or implementation of clinical practice guidelines in practice. This is particularly important when the guidelines are multi-faceted and comprehensive, including patient assessment and management within the same guideline, which is often the case in relation to VLU guidelines. Guidelines may be partially implemented, or there may be pockets of adherence to certain practices contained within the guidelines, e.g. adherence to best practice in compression bandaging whilst non-adherence to measuring ABPI at the point of assessment.

Wang, Norris, & Bero (2018) do recognise that interventions in evidence-based guidelines may be impossible to implement if the local context of care delivery is not considered. Therefore failure of implementation is essentially a waste of resources both in terms of the time involved from the team and the fiscal elements in developing the guideline in the first place.

Whilst it is not the intention of CPGs to completely replace clinical judgement or experience, nor to completely prescribe decision making (Tetreault et al., 2019), it is interesting when cross tabulating Q65 and Q78 that the duration of service was not a significant factor when considering the role of CPGs and patient safety.

Considering the positive comments from the discussion panel members, it is reasonable to conclude that the implementation strategy detailed in the National guidelines was effective, particularly in light of contradictory findings from other studies (Weller et al., 2020). However, the author can find no evidence of ongoing monitoring, audit and evaluation, although this is not to say that such evaluation is not being undertaken at a local practice level.

7.4 Patient safety

It is evident from the literature review that patient safety is a complex phenomenon that continues to receive a significant amount of interest across all facets of healthcare. However, the majority of patient safety research has mainly reflected the work in the acute hospital setting (Smits et al., 2017). Therefore when considering the concept of patient safety for the purposes of this research, it was essential to find a definition that would reflect the essence of this work. The definition cited by the author in chapter 2:

"The avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare" (Vincent, 2006, p. 31)

acted as an important anchor in focusing this thesis and the author's work. Having undertaken this research, the author reflects on the definition offered by Vincent (2006) and notes there is a need to recognise the suffering of patients who do not experience evidence-based care from readily available clinical practice guidelines and that a paradigm shift is required in understanding patient safety in this regard, this moves us beyond adverse events, errors and active harm. An adverse outcome for a patient with a VLU is delayed healing. It is noted that patient safety incidents in primary healthcare tend to be less harmful when considered against incident reports for hospitals and that collaboration and communication in primary care were key issues related to patient safety in primary care. (Verbakel, Langelaan, Verheij, Wagner, & Zwart, 2016)

The responses to the questions in the SAQ were overwhelmingly positive, where respondents either agreed or strongly agreed in the main. This is very encouraging and was acknowledged in the panel discussion.

7.4.1 The complexity of the working environment

The lack of appreciation as to the complexity of the setting in which care is delivered may contribute to the current response to improving patient safety. The environments in which care is delivered is complex and chaotic, somewhat disjointed, intricate socio-cultural environments with an abundance of interdependencies (Mannion & Braithwaite, 2017). The insight offered from the results of the questionnaire and by the panel discussion, particularly addressing the complexities above, was profound. For example, a response to the open-ended question at the end of the safety attitudes questionnaire included "*...feels a very safe place to work where I am protected as an employee from doing something unsafe (e.g. in the home and community settings situations are often very chaotic and unregulated...*" the panel members responded to this, and in particular one-panel member acknowledged the chaotic state both from the perspective of the environments care is being delivered and the system in which care is being delivered

Safety in health care is considered a constantly moving target. What was previously considered normal consequences of or side effects of healthcare, such as catheter-associated infections, are now considered preventable harm (Vincent & Amalberti, 2015). Acknowledging that the lens in which patient safety is viewed is expanding as discussed in the literature review creates conceptual challenges regarding patient safety. It raises the question of whether we need to reconsider measuring adverse events as an indicator of patient safety (Vincent & Amalberti, 2015). Patient safety now needs to be viewed from the perspective of the patient (Vincent & Amalberti, 2016), and given the expansion of our thinking concerning patient safety, we must also consider the types of harm, including the harm that results from a failure to treat appropriately whereby causation of harm may not be so clearly defined as it is noted that many patients fail to receive standard evidenced-based care (Vincent & Amalberti, 2016)

Whilst recognising that much has changed much has remained the same regarding patient safety. While evidence-based best practice related to a reduction in harm is available, they are seldom implemented effectively and that the focus on preventable harm has too often focused on specific harms rather than focussing a more system-wide approach, which includes safety culture, teams and patient engagement (National Steering Committee for Patient Safety, 2020).

It is evident from the literature that CPGs are critical for clinical practice in reducing variation, improving consistency among treatment protocols, and if used correctly, may improve the quality and effectiveness of patient care (Kotzeva et al., 2014; O'Donnell & Balk, 2011). However, it is noted by the Guideline International Network Implementation Working group that limited use of guidelines does result in preventable harm and suboptimal patient care (Gagliardi & Alhabib, 2015). This is consistent with the findings from this thesis. It is clearly articulated within national guidelines the expected standards of care concerning assessing and managing patients with VLUs in the Republic of Ireland. However, the survey results and feedback from the panel discussion demonstrated that there is an unmet need for appropriate education with the current approach to continuing education for registered nurses.

7.4.2 Ulcer aetiology

Compression therapy is contraindicated in the presence of significant arterial disease, and in wounds where there is mixed aetiology, nurses may err on the side of caution and avoid compression therapy (Bernatchez et al., 2017).

Interestingly, almost 90 % of respondents referred their patients to a colleague trained and competent in assessing and managing leg ulceration if they were concerned about the aetiology of an ulcer, irrespective of the duration of time working in public health nursing. The Scottish Intercollegiate Guideline on VLUs (Scottish Intercollegiate Guideline Network, 2010) recommends such action and this is also an explicit recommendation in the HSE National Wound Management Guidelines. Almost 93% of respondents refer patients with a non-healing or atypical leg ulcer for further investigations, including consideration of biopsy either most or all of the time. This is an important finding as it would appear that across the sector it is recognised by PHNs and CRGNs that further intervention is required in cases

when a wound is not healing or is atypical. This is an important finding from a patient safety perspective as the literature review identified the psychological impact of VLU and delayed healing would directly impact on this situation for patients; onward referral is extremely important for effective patient management and is directly in keeping with the national guidelines.

7.5 Strengths and limitations of this thesis

The methodological approach taken for this thesis is a distinct strength. It was important to collect quantitative data (in the main) to consider the impact of clinical practice guidelines on patient safety. The author cannot identify any other studies that have examined the role of clinical practice guidelines in this way, particularly with this professional group and patient group; this rigorous approach was necessary given the complexity of patient safety.

The SAQ was an appropriate valid, and reliable tool to use, and the statistical analysis in examining the data was robust. It is noteworthy that similarities were found in the HSE national staff satisfaction survey 2018.

Although the systematic review yielded one result from the criteria applied, the search strategy applied was comprehensive and complete—the review adhered to the EPOC taxonomy of health system interventions. The threshold for the systematic review in restricting the studies to Randomised Controlled Trials, Non-Randomised Controlled Trials, Interrupted Time Series, Controlled before-after studies may have been too limiting; and may have excluded other study methodologies that may have provided additional information for consideration.

The author acknowledges that the response rates from the survey did not reach the expected numbers, which could be related to the timing of survey distribution during the pandemic. The lower-than-expected response rates may have implications on the generalisability of the results; therefore, the survey should be repeated at a point in time when normal service delivery resumes. This does not have to be at a national level as it is suitable to apply the survey at a local level.

7.6 Implication for practice

The concept of patient safety is complex, the diagnosis and management of VLUs are complex and implementing clinical practice guidelines in practice is also

complex. There is no clear evidence from the literature and this study that one implementation strategy for implementing clinical practice guidelines is superior to another. However, what has been identified in this study is that the dissemination of guidelines and their focus on clinical practice does seem to influence the use of guidelines in practice. The panel discussion members recalled at length as to how the national HSE wound care guidelines were disseminated, i.e. that they were issued in a hard copy format in a distinctive folder through the Assistant Directors of Public Health Nursing, resulting in the guidelines being directly available and easily accessible in the practice setting. As discussed earlier in this chapter, the panel members were not surprised by the high levels of awareness or the high levels of uptake of these guidelines in the practice setting.

This study should reassure Directors of Public Health Nursing regarding evidence-based care. There was overwhelming positive responses regarding the use of guidelines in practice, irrespective of the length of service. However, it is important to recognise that although patient safety was at the forefront of PHNs and CRGNs practice, the findings from this research thesis suggests an acceptance or lack of recognition that a PHN or CRGN may not be in a position to undertake a full assessment at the point of initial contact; and that this may be interpreted as an acceptable norm and that the existing system drives delays in commencing appropriate evidence-based care.

The role of the PHN and how this role is complemented by the role of the CRGN needs to be explored. There is clear evidence from the findings of this study that clarity regarding the role, role and value of the CRGN warrants further examination.

This study is valuable to health care funders and providers, particularly as the default position is to provide education when new policy documents are issued; however, there has been no evidence found to support this position. Interestingly, some studies report that education and training is a requirement in order to optimise the application of clinical guidelines to practice (Weller et al., 2020); however, this study found that the most significant influence appears to be the voice of local opinion leaders, and the availability and useability of guidelines in practice. This may influence the requirements for nurses to attend study days or education

sessions for new policy documents, which further reduces the availability of staff to their patients and is a very costly approach.

7.6.1 Recommendation: Education and Training

As already identified, compression bandaging is the gold standard for managing VLU's. Any delay in commencing appropriate evidence-based treatment will lead to longer treatment times, delayed healing and potentially result in patient harm. This study has identified that not all registered nurses, PHNs, or CRGNs have the necessary training or equipment to undertake a full assessment, particularly measuring ABPI on the day of the initial assessment. It is recommended that a national review of educational offerings for wound management is undertaken to ascertain the types of programmes that a) focus on VLUs and b) support ABPI measurement training. An education programme should be developed to allow for the education of all PHNs and CRGNs to undertake ABPI measurements on the day of the initial assessment in order to allow appropriate and evidence-based treatment to commence on the day of the initial assessment. The economic outlay for appropriate equipment can be undertaken using an appropriate economic evaluation.

7.6.2 Recommendation: Clinical Practice Guideline Dissemination

It is recognised that VLU's carry significant costs to healthcare systems globally (O'Donnell & Balk, 2011), and there is a significant economic impact of inappropriate care (Vowden & Vowden, 2016). The findings from this study clearly reflected a national document that was disseminated well throughout the system. It is recommended that future clinical practice guidelines include a dissemination plan with an identified local opinion leader as a champion for the dissemination.

7.6.3 Recommendation: Clinical Practice Guideline Implementation

The findings from this study suggest that the implementation strategy detailed in the HSE National Wound Management Guidelines 2018 was effective. However, this is not reflected in the literature and would not appear to be the norm. The barriers and facilitators for implementation were not listed in detail whilst referred to in the document. It is recommended that future clinical practice guidelines are pragmatic in nature, easily accessible and have a detailed implementation plan and

that the outcomes from monitoring and audit are also published to promote awareness and adherence.

7.6.4 Recommendation: Local application of SAQ

It is recognised that there are high levels of variability within any organisation. While the results of this study are encouraging, it is recommended that the SAQ be repeated at a local level. The front line staff have been under enormous pressure due to the COVID-19 global pandemic. It is recommended that the short version of SAQ is repeated at a point in time in the future when structures return to a more normal model of care delivery. Analysis tools are freely available for the short version of the SAQ.

7.7 Implications for research

The author undertook a systematic review to identify the most effective strategies to implement clinical practice guidelines for the management of VLU by health care professionals in the hospital, outpatient, home and community settings. Despite having a well-formulated clinical question, the results from the systematic review were surprising in that only one study met the inclusion criteria (Brown, 2002). - Effect of a National Community Intervention Programme on Healing Rates of Chronic Leg Ulcer: Randomised Control Trial. Nevertheless, the study included in the systematic review was comprehensive in terms of the research methodology and number of participants. The results of the systematic review are detailed in Chapter 4. A copy of the published manuscript is presented in Appendix 4. As only one study met the inclusion criteria, there clearly is a gap in the available evidence.

However, on reflection and given that only one study was identified for inclusion (albeit comprehensive), the threshold for included studies may have been too high. The author identified a number of other studies (Bently 2001, Macdougall et al. 2014, Marshall et al. 2001) that may have offered additional information. A Cochrane review undertaken by Ivers et al. (2012) to assess the effects of audit and feedback on the practice of healthcare professionals found that audit and feedback may lead to minor improvements in professional practice. Therefore, including audit and feedback studies may have presented the author with additional relevant information. The Cochrane EPOC group specify the interventions to be examined, and they are listed as part of the PICO framework; while audit and feedback are

Chapter 7 Discussion and Conclusion

recognised as an intervention but were not included in the inclusion criteria for study types. Future research work should look to analyse the results from audit and feedback as a comparison.

VLU's represent a significant burden to healthcare providers and to the patient, and the prevalence is only set to increase due to a growing older population (Lal, 2015). Given the significant economic impact on the health service provider and the personal impact that VLU's have on patients, further research is required to explore how to optimise the implementation of clinical practice guidelines as it remains the case from this study and others that there is no generally accepted framework or theory for choosing one strategy over another to implement a practice change (Smith & Williams, 2021). Clinical practice guidelines that are multi-faceted in nature require a coordinated approach regarding their implementation. Further, studies should explore the use of audit and feedback as inclusion criteria as types of studies.

7.8 Contribution to knowledge

This study has proved important in contributing to new knowledge; there is clearly a deficit in the literature regarding the impact of clinical practice guidelines on patient safety.

Findings from the systematic review in Chapter 4 highlights the deficit of knowledge regarding the most effective approaches to implementing clinical practice guidelines within a defined cohort of practitioners. While there are an overwhelming amount of clinical practice guidelines being made available, there is a dearth of evidence of their impact on patient safety. The patient safety agenda remains focussed on acute care and high-risk events at a population level, whilst acknowledging there is a paradigm shift with Safety-II, more work is required to move from a reactive position to a proactive position for patient safety. This study moves the agenda a step forward in that regard.

This is the first study to use the SAQ in a PHN setting in Ireland. Using the SAQ in a PHN setting nationally opens the door for a more focused organisational level assessment at individual health centres or clusters of similar services. While this study demonstrated a strong focus on patient safety and an awareness of national practice guidelines, it is clear that the required standards expected in the guidelines

cannot be met due to the current models of CPD and continuing formal education provided to PNHS and CRGNs. This knowledge is essential as it is necessary to understand the application of clinical practice guidelines in practice, ensuring that the evidence-based care is delivered appropriately and on time.

The economic cost of staff education and training is immense, and this study suggests that the dissemination and implementation of guidelines should be carefully considered. The role of local opinion leaders should not be underestimated. Supporting audit of behaviours with tangible outcomes regarding the use of any new guideline should be established before the default position of education is offered. This will promote robust engagement with the evidence-based practice, support local ownership, improve the quality of care, improve patient outcomes and reduce the cost of care.

7.9 Conclusion

To the authors knowledge, this thesis is the first to consider the impact of clinical practice guidelines on patients with VLUs from a patient safety perspective. Patient safety is a term used throughout the literature; the complexity of the science of patient safety and the culture in which it is considered a central focus of this study.

This thesis approached the concept of patient safety from a less explored perspective. It did not examine patient safety from the perspective of actual harm linked to an error in practice but from the perspective of potential harm related to the non-application of recommended practice. The detailed literature review undertaken by the author examined the three main elements of patient safety, clinical practice guidelines and VLUs. The dearth of information collectively reinforced the need for this study.

The sequential methodological approach taken by the author was appropriate. It allowed the author to explore the existing evidence for implementing clinical practice guidelines, understand their role in practice, and contextualise that to VLUs and patient safety. Although sequential, one element of the study did not inform the next element as it was important to have patient safety as the central focus throughout. The framework for patient safety and research (Pronovost et al., 2009) allowed each element of the thesis to be considered in the sum of its parts.

Chapter 7 Discussion and Conclusion

It is the case that nurses do not practice with the intention to harm their patients and that patient safety remains at the core of the work that nurses do; the findings from the questionnaire and the panel discussion reflected this while recognising the challenging environments in which they practice.

The finding of this thesis should inform the approach taken by health care management and policymakers regarding the dissemination and implementation of clinical practice guidelines. This thesis does not support the notion that an educational programme must support clinical practice guidelines. It would appear that the most significant influence in the utilisation of clinical practice guidelines is that the staff expected to use the guidelines know that they exist in the first instance; that their existence has been communicated in a manner that is familiar to them, and that the guidelines are readily accessible in their immediate work environment. It is evident that a local opinion leader influences their uptake.

The application of the Safety Attitudes Questionnaire in this context offered rich data at a national level, but the shorter version of the questionnaire lends itself to the application at a health centre level and could be utilised by front line managers in assessing the safety attitudes of staff on a more routine basis.

Nicolaides & Labropoulos (2019) recognise that with an increased ageing population and the growing obesity epidemic, CVD will continue to be a significant burden on the health care system, with estimates of 2% of healthcare expenditure in this area set to rise. It is also noted that evidence-based patient management and the adherence to evidence-based practice is vital if we are to reduce the burden on the health system and the suffering of patients; Nicolaides & Labropoulos (2019) urge clinicians to understand the consequences of inadequate treatment whilst appreciating that patient safety requires a combination of evidence-based care, clinical competence and expertise and patient preferences.

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Chapter 8 Unexpected Events

8.1 Introduction

This chapter outlines some significant unexpected events during the research process, namely the impact of COVID-19 and two cyber-attacks directly related to the author's area of research and study environment.

8.2 COVID-19

The WHO officially declared a pandemic on March 11th, 2020, and the Taoiseach (Prime Minister of Ireland) announced the closure of schools, colleges, and childcare facilities until March 29th. The COVID-19 situation continued to worsen, and the Taoiseach issued a 'Stay at Home' order on March 27th, 2020, and on April 10th, 2020, the nation was advised that the measures introduced to interrupt the transmission of the virus would remain in place until at least May 5th, 2020, this was then extended to May 18th, 2020.

Initially, the study methodology was to explore the main aim of the research using focus groups with PHNs and CRGNs. The approach was discussed and presented at the author's Group Research Committee (GRC) meeting in Spring 2020. It became apparent that accessing PHNs for a focus group was becoming less and less of a possibility due to COVID-19 and the extreme pace of change that emerged within the HSE to respond to the pandemic. It was agreed at the end of April 2020 that to be in a position to collect primary data, the author would need to change to a more accessible means of data collection and that the survey methodology was appropriate within the target group of PHNs.

Following an extensive literature review, the Safety Attitudes Questionnaire (SAQ) was identified as a suitable instrument for data collection. The author augmented the SAQ with additional national guidelines on VLU's with additional questions. The detail is presented in Chapter 5.

(The pandemic then remained relatively stable, and the country remained within level 2 precautions until October 5th, 2020; however, there were pockets of level 5 restrictions during this time.)

The questionnaire was formatted and then issued to several key experts for face validity. The necessary changes were made, and the application for ethical approval was made and received through the HSE on November 7th, 2020.

There was an easing of restrictions due to the pandemic from December 1st; by December 17th, there was a notable increase in covid cases nationally. The national public health emergency team advised on further lockdown from Christmas eve. It was clear that there was a significant additional strain on our public health system, and a third wave of the pandemic was declared a short time after having identified a variant in the strain of COVID-19—the most significant wave of the pandemic.

The questionnaire was disseminated via a Director of Public Health Nursing. The questionnaire was issued via email on December 3rd, 2020, and closed on January 3rd 2021. A reminder email was issued on day seven and again on day 14; this again cascaded through the email system. The author did not have direct access to the email directory of potential recipients. There was an active campaign on Twitter and Linked In whereby direct links to the questionnaire were included in tweets and messaging on the related platform.

Upon receiving the email containing a link to the questionnaire, The Directors of Public Health Nursing then cascaded this to the Assistant Directors of Nursing, Registered PHNs and CRGNs. To put into context, it is of note that this communication and activity was now right in the middle of this third and most significant wave of the pandemic

8.2.1 Impact of the pandemic

Given the HSE's position regarding the cessation of all 'non-essential clinical work', the national press has now reported that this has impacted the work of PHN's and there has been a high level of redeployment from the service. It is not possible to source evidence of redeployment or sick leave from this cohort of staff; anecdotally however, the author had been advised that there was significant redeployment to other services, including new structures such as patient assessment hubs, contact tracing hubs and covid testing centres. The author has also been advised that there was significant sick leave as covid positive cases or recommendation of isolation as close contact or isolation due to being identified as a high-risk category; in some areas, this is as much as 20% of staff.

Following a conversation with a PHN national lead regarding extending the questionnaire further, the author was strongly advised against it, stating that "*PHN's are exhausted*". The qualitative feedback from the questionnaire corroborates this as one respondent states, "*I have been moved to 8 different services in a matter of weeks*". The impact was stated further by the members of the panel discussion.

8.3 Panel Discussion

Following data analysis of the questionnaire in Spring 2021, it was planned to hold focus groups with small teams of PHN's and CRGN's to complete the research cycle related to the thesis.

8.4 Cyber-attack – HSE

However, in May 2021, the HSE was subjected to a significant criminal cyber-attack, causing a complete shutdown of its IT systems and infrastructure. An independent report to establish the facts and learn from the incident was published on December 3rd, 2021. The background summary of the report notes:

Having invoked a critical incident management plan, the HSE switched off all HSE IT systems and disconnected the National Healthcare Network from the internet. This action immediately impacted all healthcare professionals as all access to all IT systems was gone. This included email and all networked phone lines (Price Waterhouse Coopers, 2021). It is noted that:

"The Incident had a far greater and more protracted impact on the HSE than initially expected, with recovery efforts continuing for over four months" (Price Waterhouse Coopers, 2021, p. 1)

The Irish Times reported it as the most significant cybercrime attack on an Irish state agency and the largest attack on a health service IT system (Lally, 2021).

It proved impossible for the author to communicate at a national level with PHN's and CRGN's. The author reached out to national leaders in PHN and recruited a small number of staff to participate in a panel discussion. Significant resumption of IT services (including staff email) did not happen until September 2021.

It must be noted that redeployment vaccination centres and other pandemic related responses were ongoing at this time also.

8.5 Cyber-attack – National University of Ireland Galway

The National University of Ireland Galway (NUIG) was the target of an attempted cyber-attack on September 30th 2021. All internet traffic to and from the university was blocked immediately, thus affecting the authors' ability to engage with online material, particularly the university library. The author sourced other library access options from other providers in the intervening time. This remained the case till Mid November 2021.

Appendices

Appendix 1 List of preferred terms and definitions for key concepts.

List of Preferred Terms and Definitions for Key Concepts.	
1. Classification	An arrangement of concepts into classes and their subdivisions to express the semantic relationships between them.
2. Concept	A bearer or embodiment of meaning.
3. Class	A group or set of like things.
4. Semantic relationship	The way in which things (such as classes or concepts) are associated with each other on the basis of their meaning.
5. Patient	A person who is a recipient of healthcare.
6. Healthcare	Services received by individuals or communities to promote, maintain, monitor or restore health.
7. Health	A state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity.
8. Safety	Freedom from hazard.
9. Hazard	A circumstance, agent or action that can lead to or increase risk.
10. Circumstance	Any factor connected with or influencing an event, agent or person(s).
11. Event	Something that happens to or involves a patient.
12. Agent	A substance, object or system which acts to produce change.
13. Patient Safety	Freedom, for a patient, from unnecessary harm or potential harm associated with healthcare.
14. Healthcare-associated harm	Harm arising from or associated with plans or actions taken during the provision of healthcare rather than an underlying disease or injury.
15. Patient safety incident	An event or circumstance which could have resulted, or did result, in unnecessary harm to a patient.
16. Error	Failure to carry out a planned action as intended or application of an incorrect plan.
17. Violation	Deliberate deviation from an operating procedure, standard or rules.
18. Risk	The probability that an incident will occur.
19. Adverse event	An incident which results in harm to a patient.
20. Harm	Impairment of structure or function of the body and/or any deleterious effect arising there from.
21. Disease	A physiological or psychological dysfunction.
22. Injury	Damage to tissues caused by an agent or circumstance.

23. Suffering	The experience of anything subjectively unpleasant.
24. Disability	Any type of impairment of body structure or function, activity limitation and/or restriction of participation in society, associated with past or present harm.
25. Near Miss	An incident that did not cause harm.
26. Contributing Factor	A circumstance, action or influence which is thought to have played a part in the origin or development of an incident or to increase the risk of an incident.
27. Incident type	A descriptive term for a category made up of incidents of a common nature grouped because of shared, agreed features.
28. Patient characteristics	Selected attributes of a patient.
29. Attributes	Qualities, properties or features of someone or something.
30. Incident characteristics	Selected attributes of an incident.
31. Adverse reaction	Unexpected harm resulting from a justified action where the correct process was followed for the context in which the event occurred.
32. Side effect	A known effect, other than that primarily intended, related to the pharmacological properties of a medication.
33. Preventable	Accepted by the community as avoidable in the particular set of circumstances.
34. Detection	An action or circumstance that results in the discovery of an incident.
35. Mitigating factor	Mitigating factor: an action or circumstance which prevents or moderates the progression of an incident towards harming a patient.
36. Patient outcome	The impact upon a patient which is wholly or partially attributable to an incident.
37. Degree of harm	The severity and duration of harm, and the treatment implications, that result from an incident.
38. Organizational Outcome	The impact upon an organization which is wholly or partially attributable to an incident.
39. Ameliorating action	An action taken or circumstances altered to make better or compensate any harm after an incident.
40. Actions taken to reduce risk	Actions taken to reduce, manage or control the harm, or probability of harm associated with an incident.
41. Resilience	The degree to which a system continuously prevents, detects, mitigates or ameliorates hazards or incidents.
42. Accountable	Being held responsible
43. Quality	The degree to which health services for individuals and populations increase the

	likelihood of desired health outcomes and are consistent with current professional knowledge.
44. System failure	A fault, breakdown or dysfunction within an organization's operational methods, processes or infrastructure.
45. System improvement	The result or outcome of the culture, processes, and structures that are directed toward the prevention of system failure and the improvement of safety and quality.
46. Root cause analysis	A systematic iterative process whereby the factors which contribute to an incident are identified by reconstructing the sequence of events and repeatedly asking why? Until the underlying root causes have been elucidated.

Appendix 2 Systematic Review Search Strategy in Medline

1. nurses/ or nurse administrators/ or nurse practitioners/ or family nurse practitioners/ or nurse specialists/ or nurse clinicians/ or nurses, community health/ or nurses, international/ or exp nursing staff/ or Geriatric Nursing/ or Infection Control/ or case managers/ or nurse administrators/ or Licensed Practical Nurses/ or Nurses, Male/ or Nursing, Practical/ or Nursing Staff, Hospital/ or Public Health Nursing/ or community health nursing/ or home health nursing/ or home care services/ or home care services, hospital-based/ or home health nursing/ or home nursing/ or respite care/ or primary care nursing/ or Ambulatory Care/ or specialties, nursing/ or emergency nursing/ or family nursing/ or rural nursing/ or nurses improving care for health system elders/ or students, nursing/ or nursing care/ or home nursing/
2. ((administrat* or practition* or family or specialist* or clinic* or community or district or "home care" or "wound care" or "Public health" or international or adult or "acute care" or gerontolog* or geriatric or "infection control" or foreign or licensed or practical or male or consult* or registered or staff or admin* or emergency or rural or visiting or community or "community health" or "home care" or hospital or respite or "primary care" or "primary care" or ambulatory or specialt* or student*) adj2 Nurs*).tw.
3. "Case manag*".tw.
4. (health personnel/ or caregivers/ or medical staff/ or medical staff, hospital/ or hospitalists/ or personnel, hospital/ or physicians/ or dermatologists/ or general practitioners/ or geriatricians/ or physicians, family/ or physicians, primary care/ or physicians, women/ or students, medical/ or Internal Medicine/ or Internship.mp.) and Residency/ [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
5. (doctor* or GP* or "family doctor*" or "family physician*" or "general practice physician*" or "general practitioner*" or "primary care practitioner*" or "general physician" or "general practice physician*" or "general practitioner*" or "primary

care practitioner*" or "medical practitioner*" or "medical doctor*" or "physician* associate*" or practitioner* or "private physician").tw.

6. ("Internal medicine" adj2 (specialist* or physician*)).tw.

7. allied health personnel/ or community health workers/ or home health aides/ or nursing assistants/ or physical therapist assistants/ or nutritionists/ or physical therapists/

8. ("allied health professional*" or "allied health personnel" or physiotherapist* or "physiotherapist* assistant*" or physical therapist* or "physical therapist* assistant*" or nutritionist* or dietician*).tw.

9. Aftercare/ or Day Care, Medical/ or hospitalization/ or nursing homes/ or intermediate care facilities/ or skilled nursing facilities/ or "Delivery of Health Care, Integrated"/ or Long-Term Care/ or Community Health Services/ or Primary Health Care/ or secondary care/ or tertiary healthcare/ or residential facilities/ or homes for the aged/

10. ((delivery or after or "age specific" or day or hospital or community or home or institutional or integrated or "long term" or nursing or primary or secondary or tertiary or residential) adj4 care).tw.

11. ("length of stay" or "home for the aged" or "integrated health care system*" or "integrated healthcare system*").tw.

12. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11

13. varicose Ulcer/

14. leg Ulcer/

15. ((venous or leg or varicose or "venous leg" or stasis or "venous stasis" or hypertension or "venous hypertension") adj3 (ulcer* or wound*)).tw.

16. "ulcus cruris".tw.

17. 13 or 14 or 15 or 16

18. 12 and 17

19. exp Inservice Training/ or medical audit/ or nursing audit/

20. ((medical or clinic* or nursing) adj3 audit).tw.
21. "inservice training".tw.
22. implementation science/
23. ((Strateg* or barrier* or enabl* or facilitat*) adj2 implement*).tw.
24. ((material* or meeting*) adj2 education*).tw.
25. 19 or 20 or 21 or 22 or 23 or 24
26. guidelines as topic/ or practice guidelines as topic/
27. practice guideline/
28. evidence-based medicine/ or evidence-based nursing/
29. ((evidence-base* or "Evidence base*") adj4 (medicine or Nurs*)).tw.
30. ("clinical practice guideline*" or CPG or "Practice guideline*").tw.
31. consensus/
32. Patient Care Planning/
33. "quality of health care"/ or guideline adherence/ or "outcome and process assessment (health care)"/ or "outcome assessment (health care)"/ or patient reported outcome measures/
34. Nursing Evaluation Research/
35. "Delivery of Health Care"/
36. Professional Practice Gaps/
37. treatment outcome/
38. ("evaluation research" or implementation or guideline* or "process analysis" or multigent* or pragmatic or "evidence-based practice" or "clinical practice guideline*" or CPG).tw.
39. 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38
40. 18 and 25 and 3

Appendix 3 Data Collection Form



Data collection form

Intervention review —
Randomised trials and non-randomised trials

This form can be used as a guide for developing your own data extraction form. Sections can be expanded and added, and irrelevant sections can be removed. It is difficult to design a single form that meets the needs of all reviews, so it is important to consider carefully the information you need to collect, and design your form accordingly. Information included on this form should be comprehensive, and may be used in the text of your review, ‘Characteristics of included studies’ table, risk of bias assessment, and statistical analysis.

Notes on using a data extraction form:

- Be consistent in the order and style you use to describe the information for each included study.
- Record any missing information as unclear or not described, to make it clear that the information was not found in the study report(s), not that you forgot to extract it.
- Include any instructions and decision rules on the data collection form, or in an accompanying document. It is important to practice using the form and give training to any other authors using the form.
- You will need to protect the document in order to use the form fields (Tools / Protect document)

Review title or ID

Study ID (surname of first author and year first full report of study was published)

Report IDs of other reports of this study (e.g. duplicate publications, follow-

Notes:

General Information

Date form completed (<i>dd/mm/yyyy</i>)	
Name/ID of person extracting data	
Report title (title of paper/ abstract/ report that data are extracted from)	
Report ID (if there are multiple reports of this study)	
Reference details	
Report author contact details	
Publication type (e.g. full report, abstract, letter)	
Study funding source (including role of funders)	

Possible conflicts of interest (for study authors)	
Notes:	

Eligibility

Study Characteristics	Review Inclusion Criteria (Insert inclusion criteria for each characteristic as defined in the Protocol)	Yes/ No / Unclear	Location in text (pg & ¶/fig/table)
Type of study	Randomised trial	...	
	Non-randomised trial	...	
	Controlled before-after study <ul style="list-style-type: none"> • Contemporaneous data collection • At least 2 intervention and 2 control clusters 	...	
	Interrupted time series OR Repeated measures study <ul style="list-style-type: none"> • At least 3 timepoints before and 3 after the intervention • Clearly defined intervention point 	
	Other design (specify):	...	
Participants		...	
Types of intervention		...	

Study Characteristics	Review Inclusion Criteria (Insert inclusion criteria for each characteristic as defined in the Protocol)	Yes/ No / Unclear	Location in text (pg & ¶/fig/table)
Types of outcome measures		...	
Decision: ...			
Reason for exclusion			
Notes:			

DO NOT PROCEED IF STUDY EXCLUDED FROM REVIEW

Population and setting

	Description	Location in text (pg & ¶/fig/table)
	Include comparative information for each group (i.e. intervention and controls) if available	
Population description (from which study participants are drawn)		
Setting (including location and social context)		
Inclusion criteria		
Exclusion criteria		
Method/s of recruitment of participants		
Notes:		

Methods

	Descriptions as stated in report/paper	Location in text (pg & ¶/fig/table)
Aim of study		

Design (e.g. parallel, crossover, non- RCT)		
Unit of allocation (by individuals, cluster/ groups or body parts)		
Start date		
End date		
Duration of participation (from recruitment to last follow-up)		
Notes:		

Risk of Bias assessment

See [Chapter 8](#) of the *Cochrane Handbook*. Additional domains may be required for non-randomised studies.

Domain	Risk of bias Low/ High/Unclear	Support for judgement	Location in text (pg & ¶/fig/table)
Random sequence generation (selection bias)	...		
Allocation concealment (selection bias)	...		

Domain	Risk of bias Low/ High/Unclear	Support for judgement	Location in text (pg & ¶/fig/table)
Blinding of participants and personnel (performance bias)	...	Outcome group: All/	
(if required)	...	Outcome group:	
Blinding of outcome assessment (detection bias)	...	Outcome group: All/	
(if required)	...	Outcome group:	
Incomplete outcome data (attrition bias)	...		
Selective outcome reporting? (reporting bias)	...		
Other bias	...		
Notes:			

Participants

Provide overall data and, if available, comparative data for each intervention or comparison group.

	Description as stated in report/paper	Location in text (pg & ¶/fig/table)
Total no. randomised (or total pop. at start of study for NRCTs)		
Clusters (if applicable, no., type, no. people per cluster)		
Baseline imbalances		
Withdrawals and exclusions (if not provided below by outcome)		
Age		
Sex		
Race/Ethnicity		
Severity of illness		
Co-morbidities		
Other treatment received (additional to study intervention)		

	Description as stated in report/paper	Location in text (pg & ¶/fig/table)
Other relevant sociodemographics		
Subgroups measured		
Subgroups reported		
Notes:		

Intervention groups

Copy and paste table for each intervention and comparison group

Intervention Group 1

	Description as stated in report/paper	Location in text (pg & ¶/fig/table)
Group name		
No. randomised to group (specify whether no. people or clusters)		

	Description as stated in report/paper	Location in text (pg & ¶/fig/table)
Description (include sufficient detail for replication, e.g. content, dose, components; if it is a natural experiment, describe the pre-intervention)		
Duration of treatment period		
Timing (e.g. frequency, duration of each episode)		
Delivery (e.g. mechanism, medium, intensity, fidelity)		
Providers (e.g. no., profession, training, ethnicity etc. if relevant)		
Co-interventions		

	Description as stated in report/paper	Location in text (pg & ¶/fig/table)
Economic variables (i.e. intervention cost, changes in other costs as result of intervention)		
Resource requirements to replicate intervention (e.g. staff numbers, cold chain, equipment)		
Notes:		

Outcomes

Copy and paste table for each outcome.

Outcome 1

	Description as stated in report/paper	Location in text (pg & ¶/fig/table)
Outcome name		

	Description as stated in report/paper	Location in text (pg & ¶/fig/table)
Time points measured (specify whether from start or end of intervention)		
Time points reported		
Outcome definition (with diagnostic criteria if relevant and note whether the outcome is desirable or undesirable if this is not obvious)		
Person measuring/reporting		
Unit of measurement (if relevant)		
Scales: upper and lower limits (indicate whether high or low score is good)		
Is outcome/tool validated?	... <i>Yes/No/Unclear</i>	

	Description as stated in report/paper	Location in text (pg & ¶/fig/table)
Imputation of missing data (e.g. assumptions made for ITT analysis)		
Assumed risk estimate (e.g. baseline or population risk noted in Background)		
Notes:		

Results

Copy and paste the appropriate table for each outcome, including additional tables for each time point and subgroup as required.

For randomised or non-randomised trial - Dichotomous outcome

	Description as stated in report/paper	Location in text (pg & ¶/fig/table)
Comparison		
Outcome		
Subgroup		

	Description as stated in report/paper				Location in text (pg & ¶/fig/table)
Time point (specify whether from start or end of intervention)					
Results Note whether: ... post-intervention OR ... change from baseline And whether ... <i>Adjusted</i> OR ... <i>Unadjusted</i>	Intervention		Comparison		
	No. events	No. participants	No. events	No. participants	
Baseline data	Intervention		Comparison		
	No. events	No. participants	No. events	No. participants	
No. missing participants and reasons					
No. participants moved from other group and reasons					
Any other results reported					

	Description as stated in report/paper		Location in text (pg & ¶/fig/table)
Unit of analysis (e.g. by individuals, health professional, practice, hospital, community)			
Statistical methods used and appropriateness of these methods (e.g. adjustment for correlation)			
Reanalysis required? (if yes, specify why, e.g. correlation adjustment)	... <i>Yes/No/Unclear</i>		
Reanalysis possible?	... <i>Yes/No/Unclear</i>		
Reanalysed results			
Notes:			

For randomised or non-randomised trial - Continuous outcome

	Description as stated in report/paper						Location in text (pg & ¶/fig/table)
Comparison							
Outcome							
Subgroup							
Time point (specify whether from start or end of intervention)							
Post-intervention or change from baseline?							
Results Note whether:	Intervention			Comparison			
	Mean	SD (or other variance)	No. participants	Mean	SD (or other variance)	No. participants	

		Description as stated in report/paper					Location in text (pg & ¶/fig/table)
... post-intervention OR ... change from baseline And whether ... <i>Adjusted</i> <i>OR</i> ... <i>Unadjusted</i>							
Baseline data	Intervention			Comparison			
	Mean	SD (or other variance)	No. participants	Mean	SD (or other variance)	No. participants	
No. missing participants and reasons							

	Description as stated in report/paper		Location in text (pg & ¶/fig/table)
No. participants moved from other group and reasons			
Any other results reported			
Unit of analysis (e.g. by individuals, health professional, practice, hospital, community)			
Statistical methods used and appropriateness of these methods (e.g. adjustment for correlation)			
Reanalysis required? (if yes, specify why)	... <i>Yes/No/Unclear</i>		
Reanalysis possible?	... <i>Yes/No/Unclear</i>		
Reanalysed results			

	Description as stated in report/paper	Location in text (pg & ¶/fig/table)
Notes:		

For randomised or non-randomised trial - Other outcome

	Description as stated in report/paper				Location in text (pg & ¶/fig/table)
Comparison					
Outcome					
Subgroup					
Time point (specify whether from start or end of intervention)					
Type of outcome					
Results	Intervention result	SD (or other variance)	Control result	SD (or other variance)	
	Overall results		SE (or other variance)		

	Description as stated in report/paper		Location in text (pg & ¶/fig/table)
No. participant	Intervention	Control	
No. missing participants and reasons			
No. participants moved from other group and reasons			
Any other results reported			
Unit of analysis (e.g. by individuals, health professional, practice, hospital, community)			
Statistical methods used and appropriateness of these methods			
Reanalysis required? (if yes, specify why)	...		
Reanalysis possible?	...		
Reanalysed results			
Notes:			

For controlled before-after study

	Description as stated in report/paper				Location in text (pg & ¶/fig/table)
Comparison					
Outcome					
Subgroup					
Timepoint (specify whether from start or end of intervention)					
Post-intervention or change from baseline?					
Results	Intervention result	SD (or other variance)	Control result	SD (or other variance)	
	Overall results		SE (or other variance)		
No. participants	Intervention		Control		
No. missing participants and reasons					
No. participants moved from other group and reasons					

	Description as stated in report/paper	Location in text (pg & ¶/fig/table)
Any other results reported		
Unit of analysis (individuals, cluster/ groups or body parts)		
Statistical methods used and appropriateness of these methods		
Reanalysis required? (specify)	... <i>Yes/No/Unclear</i>	
Reanalysis possible?	... <i>Yes/No/Unclear</i>	
Reanalysed results		
Notes:		

For interrupted time series or repeated measures study

	Description as stated in report/paper	Location in text (pg & ¶/fig/table)
Comparison		
Outcome		
Subgroup		

	Description as stated in report/paper	Location in text (pg & ¶/fig/table)
Length of timepoints measured (e.g. days, months)		
Total period measured		
No. participants measured		
No. missing participants and reasons		
No. timepoints measured	Pre-intervention	Post-intervention
Mean value (with variance measure)		
Difference in means (post – pre)		
Percent relative change		
Result reported by authors (with variance measure)		
Unit of analysis (individuals or cluster/ groups)		

	Description as stated in report/paper				Location in text (pg & ¶/fig/table)
Statistical methods used and appropriateness of these methods					
Reanalysis required? (specify)	...				
	<i>Yes/No/Unclear</i>				
Reanalysis possible?	...				
	<i>Yes/No/Unclear</i>				
Individual timepoint results					
Read from figure?	...				
	<i>Yes/No/Unclear</i>				
Reanalysed results	Change in level	in SE	Change in slope	in SE	
Notes:					

Applicability

Have important populations been excluded from the study? (consider disadvantaged populations, and possible differences in the intervention effect)	...	
	<i>Yes/No/Unclear</i>	

<p>Is the intervention likely to be aimed at disadvantaged groups? (e.g. lower socioeconomic groups)</p>	<p>... <i>Yes/No/Unclear</i></p>	
<p>Does the study directly address the review question? (any issues of partial or indirect applicability)</p>	<p>... <i>Yes/No/Unclear</i></p>	
<p>Notes:</p>		

Other information

	Description as stated in report/paper	Location in text (pg & ¶/fig/table)
<p>Key conclusions of study authors</p>		
<p>References to other relevant studies</p>		
<p>Correspondence required for further study information (what and from whom)</p>		
<p>Further study information requested (from whom, what and when)</p>		
<p>Correspondence received (from whom, what and when)</p>		

Notes:



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Effectiveness of implementation strategies for venous leg ulcer guidelines: A systematic review

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ABSTRACT

Background: The aim of clinical practice guidelines (CPGs) is to improve patient care; however inconsistencies between recommended practice and what actually happens in clinical practice continues. Venous Leg Ulcers (VLUs) have a significant negative impact on patients' quality of life and it is acknowledged that managing people with venous leg ulcers is protracted and costly. The aim of this review is to identify the most effective strategies to implement clinical practice guidelines for the management of VLUs by health care professionals in the hospital, outpatient, home and community setting.

Methods: A systematic review guided by methods from the Cochrane Effective Practice and Organisation of Care (EPOC) group was undertaken to identify implementation strategies for VLU clinical practice guidelines. Eligible studies were identified via systematic electronic searches of Medline, Embase, CINAHL and the Cochrane Library.

Results: We identified 142 potential studies of which one randomised controlled trial met the inclusion criteria. Following an analysis of the included study, it is not possible to recommend one implementation strategy over another when implementing practice guidelines for people with VLUs.

Conclusion: We identified a limited evidence base for the effectiveness of implementation strategies for VLU CPGs. No one implementation strategy is better than another to facilitate VLU CPG implementation by health care professionals in hospital, outpatient, home or community settings.

1. Introduction

Venous leg ulcers (VLUs) are considered complex wounds [1] and are defined "as an open lesion between the knee and the ankle joint that remains unhealed for at least four weeks and occurs in the presence of venous disease" [2]. The estimated prevalence of venous leg ulceration is 1% in the adult population and 3% in those aged over 80 years [3]. Due to the natural history of recurrence of venous leg ulcers, sustained healing after initial ulceration is a major challenge that has a considerable impact on health and quality of life. Patients' health and healing needs are lacking due to poor implementation of evidence-based practices [4], lack of clinician awareness of VLU diagnosis, inadequate clinician training and communication between health care providers, and lack of reliable data with the absence of a national VLU clinical registry [5].

Managing venous leg ulcers is costly [6–8]. The annual costs associated with VLUs in the United Kingdom (UK) range from £590.6 to £921.9 million allowing for adjusted comorbidities [9]. In Ireland, there are no specific studies available regarding the costs of VLUs however the total annual health-care cost of wound care was estimated at €629,064,198, accounting for 5% of total public health expenditure which included the treatment of VLUs [10]. In Australia, it has been estimated that the overall healthcare costs relating to chronic wound management, where the greater proportion of wounds are VLU, exceed AUD3 billion per year [7,11]. Much of the direct cost of treatment is associated with dressings, compression bandages and community nurse visits [7]. The burden and cost of VLUs is expected to rise dramatically due to the ageing population [12], an increasing incidence of diabetes [13], chronic cardiovascular disease and obesity [14]. The cost savings related to reducing health service utilisation as a result of timelier

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healing has been calculated at AUD1.2 billion in recent economic modelling estimates [15].

It is projected that in the years 2014–2050, the percentage of adults aged 65 and over will increase from 18.9% to 28.5% of the general population and, more significantly, if life expectancy projections continue for the same timeframe, the general population aged 80 years and older will rise from 5.3% to 11.1% [16]. Reported prevalence data would suggest that 2.2% of those over 65 years [17] and 4%–5% of those over 80 years [18] then will experience a VLU during their lifetime.

Clinical practice guidelines aim to reduce variations in practice and support risk management processes in relation to adverse events and preventable errors thus contributing to improving patient safety and improvement in the quality of patient care [19]. Despite this, the European Wound Management Association (EWMA) have identified variations in VLU guideline recommendations and the level of evidence to support them [3]. These guidelines include a series of evidence-based recommendations for the detection, diagnosis and management of people with VLU, however the level of evidence of the included guidelines remains low.

The Institute of Medicine (2011) United States of America states that ‘clinical guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options’ [20]. In 2003, it was considered that about 30–40% of patients across the healthcare spectrum did not receive care according to the available evidence, and about 20–25% of care provided was not needed or was potentially harmful to patients [21]. While clinical practice guidelines exist to improve patient care, inconsistencies remain between what is recommended clinical practice and what actually happens in clinical practice [22].

Internationally, and particularly in the United States, Australia and the UK, there is a move towards aligning evidence based practice (EBP) and quality and outcome frameworks to create a more accountable, cost effective and quality driven agenda through continuous learning [23]. This is supported by other authors [24] and they state that the use of clinical practice guidelines results in a more cost effective service with better patient outcomes through a reduction of inappropriate care. With this in mind and despite the growing evidence base in the treatment of VLUs there remains a call for improvements in leg ulcer management [3]. Francke et al. [25] concluded that a variety of strategies were required for CPG implementation and the need for evidence for the various implementation strategies.

It is recognised that there are significant challenges in implementing EBP including clinicians time and the knowledge base and skills of the practitioner [26]. Implementation science has emerged in an attempt to address some of those challenges [27]. Eccles and Mittman define implementation science as ‘the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services’ [28].

The aim of this review is to identify the most effective strategies to implement CPGs for the management of VLUs by health care professionals in the hospital, outpatient, home and community settings.

2. Methods

The PICO framework was used to develop a well-formulated answerable clinical question and is presented in Table 1. The interventions examined address the implementation of clinical practice guidelines where the purpose is to influence the clinician in practice. Any single strategy or combination of strategies will be considered.

The EPOC Taxonomy of health systems – topics list [29] guided this systematic review, in particular, domain four of the topic list as it focuses on implementation strategies and species – ‘Professional

interventions where interventions are designed to bring about changes in healthcare organisations, the behaviour of healthcare professionals or the use of health services by healthcare recipients’ [29 p9]. The interventions are detailed in Table 1.

3. Search strategy

The electronic databases MEDLINE Ovid (1946 to May 2019), EMBASE Ovid (1974 to May 2019) CINAHL 1937 to May 2019) and the Cochrane Library (searched May 2019) were systematically searched. The search was developed in four distinct sections: (1) types of healthcare staff, (2) VLU (3) approach to implementation (4) environments in which care was delivered. The initial search was performed in Medline using a combination of MeSH Terms and keywords. The search terms were subsequently adjusted for EMBASE, CINAHL and the Cochrane Library. The language limits applied were English, Spanish, German and Dutch based on the language expertise of the author group and all databases were searched from inception to May 2019. The full search strategy is available in Appendix A.

3.1. Inclusion criteria

The following types of studies were included [30]:

- Randomised Controlled Trials
- Non Randomised Controlled Trials
- Interrupted Time Series – Interrupted time series studies are required to have a clearly defined intervention point and at least three data points before and after the intervention
- Controlled before-after study

3.2. Data extraction and analysis

Data extraction was conducted using a standardised Cochrane Collaboration Data Collection Form for Intervention review – Randomised trials and non-randomised trials [30]. Data extraction was undertaken by one author (JK) and verified by a second author (JI).

The search yielded 142 citations. The search results were imported into Covidence [31] and 11 duplicates removed. Two reviewers (JK, JI) independently screened the title and abstracts of the remaining 131 articles and 37 articles for full text review were selected. Any discrepancies were resolved following discussion. The PRISMA flow chart (Fig. 1) summarises the results of the search strategy. The reasons for inclusion and exclusion were documented for every record at full text screening. As only one RCT, Brown et al. met the inclusion criteria, a meta-analysis was not conducted. The included study was evaluated by one reviewer initially (JK) and verified by a second author independently (JI). A third author (DD) was available to resolve any disagreements. The Cochrane Collaboration’s criteria for assessing risk of bias namely the ‘suggested risk of bias criteria for EPOC reviews’ [29] was used to assess the risk of bias in the included study, this risk of bias assessment particularly focuses on studies with a separate control group.

4. Results

4.1. Methodological quality

The methodological quality of the included study was assessed using the EPOC group Risk of Bias criteria (Table 2). The study was assessed using the terms high, unclear or low risk of bias for: random sequence generation (selection bias); allocation concealment (selection bias); baseline outcome measurements similar (blinding of participants); baseline characteristics similar; incomplete outcome data (attrition bias); follow-up; knowledge of the allocated interventions adequately

Table 1
PICO framework.

PICO	Criteria
Population	<p>Health Care workers: Participants will be health care professionals and clinical and non-clinical administration staff either organising or delivering care to patients with Venous Leg Ulcers (VLU) in any healthcare setting or in the patient's own home. We will include all members of the multidisciplinary team involved in the care of patients with VLU, this may include but is not limited to: geriatricians, dermatologists; nurses, physiotherapists, dieticians, nutritionists and clinical support staff. We will also include students in training.</p> <p>Patients: We will include studies in which patients have a diagnosis of a VLU.</p>
Intervention	<p>The intervention under consideration will be directly linked to CPG implementation and will utilise one or more of the strategies listed below. The sub category strategies listed in the EPOC Guidelines professional interventions that will be considered are:</p> <ul style="list-style-type: none"> ● Distribution of educational materials - Distribution of published or printed recommendations for clinical care, including clinical practice guidelines/policies, audio-visual materials and electronic publications. ● Educational meetings - Health care providers who have participated in conferences, lectures, workshops or traineeships. ● Local consensus processes - Inclusion of participating providers in discussion to ensure that they agreed that the chosen clinical problem was important and the approach to managing the problem was appropriate. ● Educational outreach visits - Use of a trained person who met with providers in their practice settings to give information with the intent of changing the provider's practice. The information given may have included feedback on the performance of the provider(s). ● Local opinion leaders - Use of providers nominated by their colleagues as 'educationally influential'. The investigators must have explicitly stated that their colleagues identified the opinion leaders. ● Audit and feedback - Any summary of clinical performance of health care over a specified period of time. The summary may also have included recommendations for clinical action. ● Reminders - Patient or encounter specific information, provided verbally, on paper or on a computer screen, which is designed or intended to prompt a health professional to recall information. This would usually be encountered through their general education; in the medical records or through interaction with peers, and so remind them to perform or avoid some action to aid individual patient care. ● Marketing - Use of personal interviewing, group discussion ('focus groups') or a survey of targeted providers to identify barriers to change and subsequent design of an intervention that addresses identified barriers. ● Mass media (i) varied use of communication that reached great numbers of people including television, radio, newspapers, posters, leaflets, and booklets, alone or in conjunction with other interventions; (ii) targeted at the population level.
Comparison	Any two of the above compared with each other; other strategies not listed above compared with any of the above or any strategy compared with no strategy.
Outcome	<p>Primary Outcome: The primary outcome is implementation of clinical practice guidelines for the management of venous leg ulceration in whole or in part.</p> <p>Secondary Outcome: Patient outcomes:</p> <ol style="list-style-type: none"> i. Changes in health-related quality of life as reported by study authors ii. Healing rates at times as reported by study authors iii. Recurrence rates as reported by study authors <p>Service Outcomes:</p> <ol style="list-style-type: none"> i. Costs <ol style="list-style-type: none"> a. Direct medical costs b. Non direct medical costs - patient associated costs c. Cost utilisation, cost effectiveness other resource factors as reported by study authors ii. Reported measurements on staff behaviour

prevented during the study; protection against contamination; selective outcome reporting (reporting bias); and other bias.

4.2. Included study

Brown et al. [32] reported a cluster randomised trial. The participants of the trial were patients receiving care in the home by community nurses from ten Health Board areas (15 Community Healthcare Trusts and the Western Isles Health Board, healthcare Division) covering a geographical spread of 2.65 million people. The study authors do not report the number of clusters nor the number of participants per cluster, however they do state that "allocation of localities to intervention or control was based upon a method of minimisation which ensured approximate balance with respect to the size of the leg ulcer populations" [32] p20. The study authors report that there were 50 localities with populations ranging from 4,600 to 203,000 with an average of 53,000 and a distribution of urban and rural communities. Following analysis of baseline data; a multi-level modelling approach was used to undertake cluster randomisation. The localities were randomised to receive no intervention (control group) or a nurse training programme (intervention group). The nurses in the intervention group received training comprising of attendance at core theory days of lectures and a three day workshop to include training on leg ulcer assessment, Doppler techniques, indications for specialist referral, dressings, skin care, and bandaging techniques with pressure monitoring. The study was undertaken at the time the Scottish Intercollegiate Guideline Network introduced a new national guideline on leg ulcer

care in 1998, the guideline formed the basis of the intervention programme. The study reported on the healing rates of 3,949 patients under the care of approximately 1,700 community nurses. A summary is provided in Tables 3 and 4.

The study authors report on patient and ulcerated leg characteristics (Table 3). The author reports a balanced distribution of control and intervention groups by, mean age, sex, rural and urban population spread.

The response rates from participants in the study was 99.4% at the first round of data collection in which registration forms were sent to 649 Case Load Managers (CLMs), and subsequently 100% response rate for the data collection schedules that followed.

4.3. Primary outcome

The primary outcome for this review is implementation of clinical practice guidelines for the management of venous leg ulceration in whole or in part. The authors of the included study Brown et al. [32] report the outcome of healing rates and note that healing rates were not improved by a structured programme of guideline based nurse training when compared to no training.

4.3.1. Secondary outcomes

4.3.1.1. Patient outcomes

4.3.1.1.1. Changes in health-related quality of life as reported by study authors

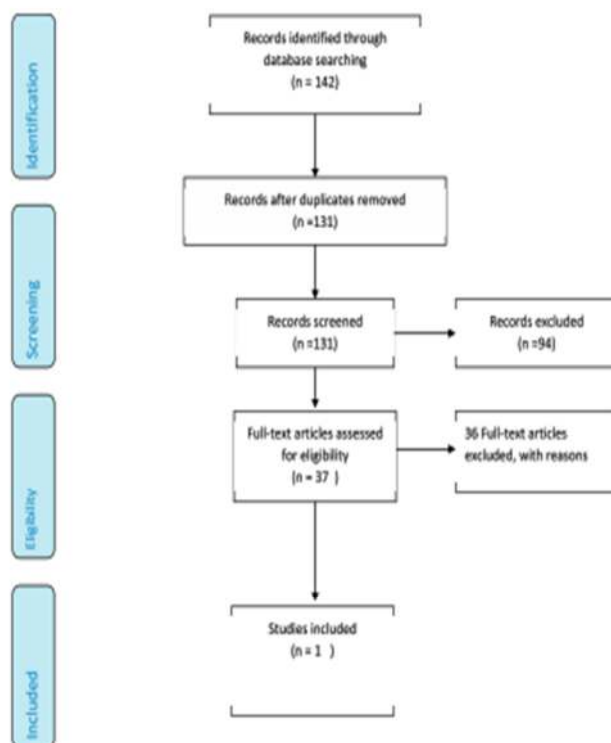


Fig. 1. Prisma flow chart.

Table 2
Risk of Bias Table Brown, A et al (2002).

Cluster Randomised Control Trial	Judgement	Support for Judgement
Random Sequence generation	Low risk	Quote: "a multi-level modelling approach was used to undertake cluster randomisation"
Allocation concealment	Low Risk	Quote: "Allocation of localities to intervention or was based upon a method of minimisation which ensured approximate balance"
Baseline outcome measurements similar (blinding of participants)	Unclear risk	Insufficient information
Baseline characteristics similar	Low risk	Quote: "the intervention and control groups were well balanced in terms of age, sex, and the distribution between urban and rural populations"
Incomplete outcome data (attrition bias)	Low risk	Quote: "all subsequent response rates after telephone reminders, achieved 100%"
Knowledge of the allocated interventions adequately prevented during the study	Unclear risk	Insufficient information upon which to make a judgement
Protection against contamination	Low risk	Quote: "localities... geographically distinct and separate in terms of nursing administration hierarchy"
Selective outcome reporting (reporting bias)	Unclear risk	The study protocol is not available but the expected outcomes do seem to have been reported on.
Other risks of bias	Low risk	The study appears to be free of other sources of bias

Table 3
Patient and ulcerated leg characteristics^{59, 50}.

	Control	Intervention
Age, mean (SD) years	76.8 (11.1)	77.0 (10.9)
Female patients (%)	75.3	74.6
Ulceration on other leg (%)	24.0	26.7
Duration of ulceration (%)		
3 months	59.2	56.4
4–11 months	20.4	21.8
12–35 months	11.7	12.8
>36 months	8.7	9.0

• This was not reported by the authors.

4.3.1.1.2. *Healing rates at times as reported by study authors.* The baseline healing rate was 28% in both groups and following guideline implementation and training; the healing rate was 27% in the intervention group. There was no difference between the control group and the intervention group over the 21 month period of the study which remained at 27% throughout. The authors' report the odds ratio for a leg being healed after 3 months as 0.95 (95% confidence interval 0.82 to 1.10, $p = 0.5$) in the intervention areas compared with the control areas. Patients who had an ulcer for three or more years at presentation had a 50% chance of it being healed in 27 months of ongoing treatment; those patients with an ulcer 3 months or less were healed after 21 months in 90% of cases in the intervention group.

Table 4
Summary of Brown et al., 2002.

First Author, Year	Area of Care Delivery	Country	Study Design	Type of Policy Document	Type of Intervention (Implementation Strategy)	Comparator	Outcomes related to service	Outcomes related to the patient
Brown, A et al. (2002)	Phon to own home	Scotland	Cluster Randomised Control Trial of 949 patients under the care of approximately 1,700 community nurses in 15 Community Healthcare Trusts and one Health Board Healthcare Division within 10 Health Boards in a population of 2.6m	National guideline	Nurse Training Programme to coincide with new guideline dissemination.	No additional training provided	Not reported	No significant difference between the intervention and the control group in healing rates (27% and 28% respectively). The odds ratio for an ulcer being healed after 3 months was 0.95 (95%CI 0.82-1.10, P = 0.51) in the intervention areas compared with control areas

4.3.1.1.3. Recurrence rates as reported by study authors

- Recurrence rates were not reported.

4.3.2. Service outcomes

4.3.2.1. Direct medical costs

- The direct medical costs were not reported.

4.3.2.2. Non-direct medical costs – patient associated costs

- The non-direct medical costs were not reported.

4.3.2.3. Cost utilisation, cost effectiveness other resource factors as reported by study authors

- This was not reported.

4.3.2.3.1. Reported measurements on staff behaviour. In the intervention group the use of Doppler for assessment rose from 30% to 90% within the link nurses group (education leaders) and from 27% to 82% within the community nurse group.

5. Discussion

The objective of this systematic review was to summarise and present the findings from evidence of the effects of interventions to implement practice guidelines for VLUs. The systematic approach guided by EPOC group systematic review methodology directed the study types for inclusion in order to garner the highest level of evidence. It has been recommended [19] previously that research is necessary to understand how clinical practice guidelines can be effectively and efficiently implemented in practice, resulting in improvements in clinical outcomes for patients as well as the process in which care is delivered. In this systematic review only one study met the inclusion criteria and reported an absence of effectiveness with regard to the type of intervention described within the study i.e. that healing rates did not improve with the implementation of a clinical practice guideline following a structured education programme.

This systematic review is timely as the costs of healthcare is increasing, the environment in which care is being delivered is changing and healthcare professionals have an obligation to deliver care that will not result in unnecessary use of resources nor deliver care which may potentially harm patients.

Franks et al. [3] note there are a variety of guidelines available and it is of concern that given an ageing demographic, the increase in healthcare costs and the plethora of practice guidelines that exist regarding the treatment and management of VLUs, there is no standardisation in the care and treatment in this patient group. Implementation of clinical practice guidelines may respond to the need to decrease costs for providers whilst improving the quality of care however the economic considerations were not reported in the RCT included in this systematic review.

Brown et al. [32] conclude that there was no significant difference between the control group and the intervention group for healing outcomes at three months. They note that their findings are contrary to conventional thinking that educational programmes are required to improve adherence to guidelines and in response to their findings they did consider the effectiveness and appropriateness of the training programme provided to the health care professional. Brown et al. report that although there were improvements in the use of doppler for patient assessment; healing rates did not improve using a single intervention approach i.e. education and training.

Local implementation of national clinical practice guidelines may be improved if there is stronger guidance regarding implementation. It is noteworthy from the excluded studies in this systematic review that in planning to improve approaches to care for patients with venous leg

ulcers local pathways were often developed in responses to a local audit [33,34]. The Commission on Patient Safety and Quality Assurance states that clinical audit is essential for good clinical governance and notes that it: '... constitutes the single most important method which any healthcare organisation can use to understand and ensure the quality of the service that it provides' [35, p.12].

The EPOC group [36] recommends that when reporting on results from excluded studies, a secondary objective could be specified to include strategies that have not been rigorously evaluated. As a secondary objective was not specified for this systematic review, detailed results from excluded studies are not presented. Indications from excluded studies do suggest however that further research which includes descriptive studies, audits and service evaluation may provide additional information. The aim of implementation science is to improve the quality of health care, although comparisons can be drawn with other quality improvement (QI) methodologies, implementation science begins with acknowledging gaps in the delivery of EBP at various levels within organisations [27]. The authors suggest that it may be timely to examine the methods and principles offered through implementation science as a means for healthcare systems to respond more effectively in implementing EBP as we have found that a single approach does not produce the change required and concentrated multifaceted implementation strategies are required [27].

Tinkler et al. [37] reports that patients receiving VLU treatment need a clear association between improved practice and patient outcomes following the implementation of an evidenced based practice guideline; but the authors also note that it was not possible to ascertain which implementation strategy contributed to the improved study outcomes. The primary outcome of this study was implementation of clinical practice guidelines for the management of people with VLU. Based on our systematic review it is not possible to recommend one strategy over another.

Significant challenges for clinicians in the delivery of EBP care to patients with VLUs still exist. We found no definitive evidence of the most effective strategies to implement clinical practice guidelines in VLU management. It is recommended that in order to implement a guideline successfully in a specific setting or with a single professional group, it should have stakeholder involvement and a program that is well designed, prepared and tested prior to implementation [38]. Given the findings of this systematic review, it is reasonable to consider the professional group as community nurses delivering care in the patient's own home; therefore it should be possible for guideline developers to design, prepare and make recommendations for testing appropriate strategies prior to guideline implementation with community nurses as the healthcare professionals.

The implementation strategies examined were measured against the implementation strategies stated by the EPOC Taxonomy for implementation strategies [29]. This systematic review followed the development of a detailed protocol and searches of four relevant databases. During the full text review, it became apparent that a number of studies were presenting the position of changing practice in the form of establishing specialised leg ulcer clinics as a means to improve outcomes for patients with VLUs. These studies were excluded from this review, as they did not meet our pre specified inclusion criteria. Additional useful data may have been garnered if the process of delivering care i.e. the creation of leg ulcer clinics had been included as an intervention strategy. Given the significant costs associated with the treatment of VLUs and the pain and suffering reported by patients, it is noteworthy that this systematic review identified only one randomised trial for inclusion.

Based on this systematic review we have found that the evidence base for implementation strategies for practice guidelines for venous leg ulcers is extremely poor. The one RCT that met the inclusion criteria did not report any significant change in healing rate following national guidelines and targeted educational sessions.

6. Study limitations

The inclusion criterion was restricted to RCT, Non RCT, and Interrupted Time Series Controlled before-after study only and therefore other study designs were excluded.

7. Conclusions

Based on this systematic review there is insufficient evidence to recommend one implementation strategy over another for implementing clinical practice guidelines for VLUs.

Variation in clinical practice in management of people with VLUs remain [3] despite the plethora of information available. Research needs to be undertaken to assess the impact of the implementation of guidelines at the point of care. If not, there will be little change in the spiralling costs associated with the treatment of VLUs nor an improvement in the patient's quality of life with this debilitating condition. There is a notable absence of robust mechanisms or recommendations from guideline developers as to how to implement clinical practice guidelines. The excluded studies in this systematic review reported improvements in outcomes, future researchers in this space may wish to examine other study designs that include other implementation strategies.

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Declaration of competing interest

None.

Appendix A

Search Strategy in Medline

1. Nurses/or nurse administrators/or nurse practitioners/or family nurse practitioners/or nurse specialists/or nurse clinicians/or nurses, community health/or nurses, international/or exp nursing staff/or Geriatric Nursing/or Infection Control/or case managers/or nurse administrators/or Licensed Practical Nurses/or Nurses, Male/or Nursing, Practical/or Nursing Staff, Hospital/or Public Health Nursing/or community health nursing/or home health nursing/or home care services/or home care services, hospital-based/or home health nursing/or home nursing/or respite care/or primary care nursing/or Ambulatory Care/or specialties, nursing/or emergency nursing/or family nursing/or rural nursing/or nurses improving care for health system elders/or students, nursing/or nursing care/or home nursing/
2. ((administrat* or practition* or family or specialist* or clinic* or community or district or "home care" or "wound care" or "Public health" or international or adult or "acute care" or gerontology* or geriatric or "infection control" or foreign or licensed or practical or male or consult* or registered or staff or admin* or emergency or rural or visiting or community or "community health" or "home care" or hospital or respite* or "primary care" or "primary care" or ambulatory or special* or student*) adj2 Nurs*).tw
3. "Case manag*".tw
4. (health personnel/or caregivers/or medical staff/or medical staff, hospital/or hospitalists/or personnel, hospital/or physicians/or dermatologists/or general practitioners/or geriatricians/or physicians, family/or physicians, primary care/or physicians, women/or students, medical/or Internal Medicine/or Internship.mp.) and Residency/imp = title, abstract, original title, name of substance

- word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms)
5. (doctor* or GP* or "family doctor*" or "family physician*" or "general practice physician*" or "general practitioner*" or "primary care practitioner*" or "general physician*" or "general practice physician*" or "general practitioner*" or "primary care practitioner*" or "medical practitioner*" or "medical doctor*" or "physician* associate*" or practitioner* or "private physician").tw.
 6. ("Internal medicine" adj2 (specialist* or physician')).tw.
 7. Allied health personnel/ or community health workers/ or home health aides/ or nursing assistants/ or physical therapist assistants/ or nutritionists/ or physical therapists/
 8. ("allied health professional*" or "allied health personnel" or physiotherapist* or "physiotherapist assistant*" or physical therapist* or "physical therapist assistant*" or nutritionist* or dietician*).tw.
 9. Aftercare/ or Day Care, Medical/ or hospitalization/ or nursing homes/ or intermediate care facilities/ or skilled nursing facilities/ or "Delivery of Health Care, Integrated"/ or Long-Term Care/ or Community Health Services/ or Primary Health Care/ or secondary care/ or tertiary healthcare/ or residential facilities/ or homes for the aged/
 10. ((delivery or after or "age specific" or day or hospital or community or home or institutional or integrated or "long term" or nursing or primary or secondary or tertiary or residential) adj4 care).tw.
 11. ("length of stay" or "home for the aged" or "integrated health care system*" or "integrated healthcare system").tw.
 12. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11
 13. Varicose Ulcer/
 14. Leg Ulcer/
 15. ((venous or leg or varicose or "venous leg" or stasis or "venous stasis" or hypertension or "venous hypertension") adj3 (ulcer* or wound')).tw.
 16. "ulcus cruris".tw.
 17. 13 or 14 or 15 or 16
 18. 12 and 17
 19. Exp Inservice Training/ or medical audit/ or nursing audit/
 20. ((medical or clinic* or nursing) adj3 audit).tw.
 21. "inservice training".tw.
 22. Implementation science/
 23. ((Strateg* or barrier* or enabl* or facilitat*) adj2 implement*).tw.
 24. ((material* or meeting*) adj2 education*).tw.
 25. 19 or 20 or 21 or 22 or 23 or 24
 26. Guidelines as topic/ or practice guidelines as topic/
 27. Practice guideline/
 28. Evidence-based medicine/ or evidence-based nursing/
 29. ((evidence-base* or "Evidence base") adj4 (medicine or Nurs')).tw.
 30. ("clinical practice guideline*" or CPG or "Practice guideline").tw.
 31. Consensus/
 32. Patient Care Planning/
 33. "quality of health care"/ or guideline adherence/ or "outcome and process assessment (health care)"/ or "outcome assessment (health care)"/ or patient reported outcome measures/
 34. Nursing Evaluation Research/
 35. "Delivery of Health Care"/
 36. Professional Practice Gaps/
 37. Treatment outcome/
 38. ("evaluation research" or implementation or guideline* or "process analysis" or multicent* or pragmatic or "evidence-based practice" or "clinical practice guideline*" or CPG).tw.
 39. 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38
 40. 18 and 25 and 3

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Appendix 5 SAQ-AV and adjusted questions following assessment of face validity.

Original (SAQ-A)	Adjusted for Public Health Nursing in an Irish context.
Teamwork climate scale (6 items, alpha=0.82)	
In this office, it is difficult to speak up if I perceive a problem with patient care*	In this centre, it is difficult to speak up if I perceive a problem with patient care*
The physicians and nurses here work together as a well-coordinated team	The nurses here work together as a well-coordinated team
Disagreements in this office are appropriately resolved (i.e., not who is right but what is best for patient)	Disagreements in this centre are appropriately resolved (i.e., not who is right but what is best for patient)
Nurse input is well received in this office	Nursing input is well received in this centre
I have the support I need from other personnel to care for patients	No Change
It is easy for personnel in this office to ask questions when there is something that they do not understand	It is easy for staff in this centre to ask questions when there is something that they do not understand.
Safety climate scale (7 items, alpha=0.76)	
I am encouraged by my colleagues to report any patient safety concerns I may have	No Change
The culture in this office makes it easy to learn from errors of others	The culture in this centre makes it easy to learn from errors of others
Medical errors are handled appropriately in this office	Clinical errors are handled appropriately in this centre
I know the proper channels to direct questions regarding patient safety in this office	I know the proper channels to direct questions regarding patient safety in this centre
I receive appropriate feedback about my performance	I receive appropriate feedback about my performance
I would feel safe being treated here as a patient	I would feel safe being treated here as a patient
In this office, it is difficult to discuss errors*	In this centre, it is difficult to discuss errors*
Perception of management scale (4 items, alpha=0.72)	
Senior management of this office is doing a good job	Management supporting this centre is doing a good job
The management of this office supports my daily efforts	Management in this centre supports my daily efforts
I am provided with adequate, timely information about events in	I am provided with adequate, timely information about events in the centre that might affect my work

the hospital that might affect my work	
The levels of staffing in this office are sufficient to handle the number of patients	The levels of staffing in this centre are sufficient to handle the number of patients
Job satisfaction scale (5 items, alpha=0.86)	
This office is a good place to work	This centre is a good place to work
I am proud to work in this office	I am proud to work in this centre
Working in this office is like being part of a large family	Working in this centre is like being part of a large family
Morale in this office is high	Morale in this centre is high
I like my job	No Change
Working conditions scale (4 items, alpha=0.68)	
This office does a good job of training new personnel	This centre offers a good local induction programme.
This office constructively deals with problem physicians and employees	This centre deals constructively with challenging staff.
All the necessary information for diagnostic and therapeutic decisions is routinely available to me	All the necessary information for clinical decisions is routinely available to me.
Trainees in my discipline are adequately supervised	Students are adequately supervised.
Stress recognition scale (4 items, alpha=0.72)	
When my workload becomes excessive, my performance is impaired	No Change
I am more likely to make errors in tense or hostile situations	No Change
Fatigue impairs my performance during emergency situations (e.g., code or cardiac arrest)	Fatigue impairs my performance during routine care.
I am less effective at work when I am fatigued	No Change
Items not included in the scales (32 items) Ambulatory Process of Care Items (5 items)	
I am satisfied with the current referral process in this office	I am satisfied with the current referral process in this centre (Receiving referrals)
There is adequate and timely transfer of patient information between primary care physician and specialist	There is adequate and timely transfer of patient information between the team as appropriate.
Medications are refilled in a timely manner	Removed NA in an Irish context
Medications are filled correctly	Removed NA in an Irish context
Abnormal test results are frequently lost or overlooked*	No Change*

Others (27 items)	
High levels of workload are common in this office*	High levels of workload are common in this centre*
Briefing other personnel before a procedure (e.g., biopsy) is important for patient safety	Briefing other personnel is important for patient safety
Briefings are common in this office	Briefings are common in this centre
When I am interrupted, my patients' safety is not affected	Removed
The management of this office knowingly compromises the safety of patients*	Management does not knowingly compromise the safety of patients.
Decision-making in this office should include more input from other personnel than it does now	Decision making in this centre utilises input from relevant personnel.
This office encourages teamwork and cooperation amongst its personnel	Teamwork and cooperation is encouraged
The medical equipment in this office is adequate	The equipment in this centre is adequate for me to do my job.
I have seen others make errors that had the potential to harm patients	No Change
Stress from personal problems adversely affects my performance	No Change
Disruptions in the continuity of care (e.g., shift changes, patient transfers, etc.) can be detrimental to patient safety	Disruptions in the continuity of care can be detrimental to patient safety
During emergencies, I can predict what other office personnel are going to do next	Removed – Not an emergency service.
I am frequently unable to express disagreement with attending physicians/primary care providers in this office*	I am frequently unable to express disagreement with other staff in this centre.*
Very high levels of workload stimulate and improve my performance*	Very high levels of workload stimulate and improve my performance*
Truly professional personnel can leave personal problems behind when working*	No Change*
I know the first and last names of all the personnel I worked with during my last shift	I know the first and last names of all the staff I work with.
I have made errors that had the potential to harm patients	No Change
Attending physicians/primary care providers in this office are doing a good job	Other team members in this centre are doing a good job.
All the personnel in this office take responsibility for patient safety	All the staff in this centre take responsibility for patient safety

If necessary, I know how to report errors that happen in this office	If necessary, I know how to report errors that happen in this centre
Patient safety is constantly reinforced as the priority in this office	Patient safety is constantly reinforced as the priority in this centre.
Interactions in this office are collegial, rather than hierarchical	Removed
Important issues are well communicated at shift changes	Important issues are well communicated to the team.
There is widespread adherence to clinical guidelines and evidence-based criteria regarding patient safety here	There is widespread adherence to clinical guidelines and evidence-based criteria in this centre.
Personnel are not punished for errors reported through incident reports	Information obtained through incident reports is used to make patient care safer in this centre.
During emergency situations (e.g., emergency resuscitations), my performance is not affected by working with inexperienced or less capable personnel*	Removed*
Personnel frequently disregard rules or guidelines (e.g., handwashing, treatment protocols/clinical pathways, sterile field, etc.) that are established for this office* or cardiac arrest)	Personnel frequently disregard rules or guidelines (e.g., hand washing, treatment protocols/clinical pathways, sterile fields, etc.) that are applicable in this centre*

Appendix 6 Additional questions regarding respondents

- Please State your current role
- How long have you been working in public health nursing?
- Do you participate in wound management as part of your role? (either in a direct or supervisory capacity)
- Do you have formal training/education in wound management?
- If yes to question 5, please specify wound management qualification.
- Are you aware of the HSE National Wound Management Guidelines 2018?
- Do you refer to the section on VLUs when caring for this group of patients?
- Do you provide direct care for patients with VLUs as part of your role?

Appendix 7 Additional questions related to HSE guidelines

- In your area of practice does a clinician with post basic education and training in the assessment and management of leg ulcers conduct a comprehensive assessment of all patients presenting with a leg ulcer?
- What pertinent medical/family history do you consider when assessing a patient with a leg ulcer? (Choose all that apply)
- Do you routinely undertake a bilateral limb assessment?
- Please choose the investigations that you use or refer onward to confirm presence of vascular disease and document its severity.
- When you identify abnormalities at your assessment do you refer onward for specialist investigation and opinion.
- If you have a query regarding the aetiology of an ulcer do you refer to a colleague trained and competent in the assessment and management of leg ulceration is required.
- Do you refer patients with a non-healing or atypical leg ulcer for further investigations, including consideration of biopsy.

Appendix 8 Ethical Approval



Ospidéal na h-Ollscoile, Páirc Mheirlinne
Merlin Park University Hospital
GALWAY UNIVERSITY HOSPITALS

Clinical Research Ethics Committee
Room 59
1st Floor
HR Building
Merlin Park Hospital
Galway.

10th November, 2020.

Mr. Justin Kerr
School of Nursing & Midwifery
National University of Ireland
Newcastle Road
Galway.

Ref: C.A. 2498 *Do Evidence based clinical practice guidelines impact on patient safety*

Dear Mr. Kerr,

I have considered and reviewed the above submission, and I wish to confirm that I am happy to grant Chairman's approval to proceed.

This submission has been reviewed from an ethical perspective only. It is the responsibility of the PI/sponsor/data controller and relevant Data Protection Officer to ensure and monitor compliance with any relevant legislation in the country where the study is due to take place or any local policy in the site where the study is due to take place.

Chairman's approval is normally ratified at the next Clinical Research Ethics Committee meeting. If any issues with your application are identified at the meeting we will contact you again.

Yours sincerely,

B. Gerard Loftus FRCPI,MD
Emeritus Professor of Paediatrics, NUI, Galway
Adjunct Professor of Paediatrics, IMU, Kuala Lumpur
Chair, Galway Clinical Research Ethics Committee.

c.c. Dr. Georgina Gethin, Head of School, Senior Lecturer, School of Nursing and Midwifery, 3rd Floor, Aras Moyola, National University of Ireland, Galway.

Ospidéal na h-Ollscoile, Páirc Mheirlinne, MERLIN PARK UNIVERSITY HOSPITAL,
Galway, Ireland. Tel: 00 353 (0)91 757631

Appendix 9 Introduction Letter

Dear nursing colleague,

Patient safety is really important to us in nursing, and it is at the forefront of our decision making. I would be most grateful if you would participate in a survey that looks at attitudes towards patient safety. The public health nursing sector has been underrepresented in this space and given that the majority of patient care is delivered in the community I am really interested to hear your views. The survey that I am using is internationally recognised and is recommended for use in the community. Further information can be found on the link below if you wish to read more about the questionnaire.

This survey is part of a nursing PhD study into patient safety and practice guidelines with a particular focus on VLUs. It will take approximately 10 minutes to complete the questionnaire. Your participation in this study is completely voluntary and I appreciate that some of the questions are a little direct, but please rest assured that I will have absolutely no way of identifying you, your region or the service you are working in. The response is **COMPLETELY ANONYMOUS**. However, if you feel uncomfortable answering any questions, you can withdraw from the survey at any point. Your survey responses will be strictly confidential and data from this research will be reported only in the aggregate and again please note I have absolutely no way of tracking a result to you.

If you have questions at any time about the survey or the procedures, you may contact me using the details below.

Thank you very much for your time and support, I appreciate this is a very busy time for everyone. Please start with the survey now by clicking on the Next button below.

Kind regards

Justin Kerr

PhD Nursing Candidate

email: j.kerr4@nuigalway.ie

Telephone: 0863569387

Further

information:

<https://bmchealthservres.biomedcentral.com/track/pdf/10.1186/1472-6963-6-44>

Appendix 10 SAQ as presented to the participants

The researcher requests your consent for participation in a study. I agree to participate in the research study. I understand the purpose and nature of this study and I am participating voluntarily. I understand that I can withdraw from the study at any time, without any penalty or consequences.

1. Yes
2. No

I understand that my responses will be anonymous and will have no professional information or organization or business name identified.

1. Yes
2. No

I grant permission for the researcher to use my responses in aggregate or anonymous statements, and I understand the researcher has no way to identify me and any comments presented cannot be individually attributed.

1. Yes
2. No

Please state your current role

1. Director of Public Health Nursing / Assistant Director of Public Health Nursing
2. Registered Public Health Nurse
3. CRGN
4. Student Public Health Nurse
5. Other _____

How long have you been working in public health nursing

1. less than 1 year
2. 2 - 5 years
3. 6 - 10 years
4. 11- 15 years
5. 16 - 20 years
6. greater than 20 years

Do you provide care for patients with VLU's as part of your role (directly or in a supervisory capacity)

1. Yes
2. No

Do you have formal training/education in wound management?

1. Yes
2. No

Please specify wound management qualification.

1. Study days regarding wound care
2. Professional Certificate
3. Certificate in Wound Care
4. Higher Diploma in Wound Care
5. Post Graduate Diploma in Wound Care
6. Masters in Wound Care
7. Other _____

Are you aware of the HSE National Wound Management Guidelines 2018

1. Yes
2. No

Do you refer to the section on VLU's when caring for this group of patients

1. Yes
2. No
3. NA

In your area of practice does a nurse with post basic education and training in the assessment and management of leg ulcers conduct a comprehensive assessment of all patients presenting with a leg ulcer

1. Never
2. Rarely
3. About half the time
4. Most of the time
5. Always

What pertinent medical/family history do you consider when assessing a patient with a leg ulcer? (Choose all that apply)

1. medical and surgical history in the context of a VLU, including assessment of comorbidities
2. leg ulcer history
3. physical examination including examination of the leg and ulcer,
4. including microbiological investigation when applicable
5. vascular assessment
6. mobility and functional status
7. biochemical investigations
8. pain history

Do you routinely undertake a bilateral limb assessment?

1. Yes
2. No

When you identify abnormalities at your assessment do you refer onward for specialist investigation and opinion.

1. Yes
2. No

Please choose the investigations that you use or refer onward to confirm presence of vascular disease and document its severity.

1. ABPI
2. Duplex Scan
3. Computed Tomography angiography
4. toe/brachial pressure index (TBPI)
5. Do not specify investigations
6. Do not undertake investigations directly

If you refer onwards are you made aware of the investigations undertaken?

1. Yes
2. No
3. Sometimes
4. NA

If you have a query regarding the aetiology of an ulcer do you refer to a colleague trained and competent in the assessment and management of leg ulceration if required.

1. Never
2. Rarely
3. About half the time
4. Most of the time
- 5.
6. Always

Do you refer patients with a non-healing or atypical leg ulcer for further investigations, including consideration of biopsy.

1. Never
2. Rarely
3. About half the time
4. Most of the time
5. Always

The next section you will be brought to the safety questionnaire, please be assured that this is entirely confidential and the author has absolutely no way of identifying you as an individual.

1. Select and click next

I like my job

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

Nursing input is well received in this centre - (if not multi-disciplinary please select NA)

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

High levels of workload are common in this centre.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

I would feel safe being treated here as a patient

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

Clinical errors are handled appropriately in this centre.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree

6. NA

This centre offers a good local induction programme.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

All the necessary information for clinical decisions is routinely available to me.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

Working in this centre is like being part of a large family.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

Management supporting this centre is doing a good job.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

Management in this centre supports my daily efforts.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

I receive appropriate feedback about my performance.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

In this centre, it is difficult to discuss errors.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

Briefing other personnel is important for patient safety

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

Briefings are common in this centre.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

This centre is a good place to work.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

Communication breakdowns which lead to delays in delivery of care are common.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

Management does not knowingly compromise the safety of patients.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

The levels of staffing in this centre are sufficient to handle the number of patients.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

Decision making in this centre utilises input from relevant personnel.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

I am encouraged by my colleagues to report any patient safety concerns I may have.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

The culture in this centre makes it easy to learn from the errors of others.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

This centre deals constructively with challenging staff.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

The equipment in this centre is adequate for me to do my job.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

In this centre it is difficult to speak up if I perceive a problem with patient care.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree

5. Strongly agree
6. NA

When my workload becomes excessive, my performance is impaired.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

I am provided with adequate, timely information about events in the centre that might affect my work.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

I have seen others make errors that had the potential to harm patients.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

I know the proper channels to direct questions regarding patient safety in this centre.

1. Strongly disagree

2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

I am proud to work in this centre.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

Disagreements in this centre are resolved appropriately (i.e., not who is right but what is best for the patient).

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

I am less effective at work when fatigued.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

I am more likely to make errors in tense or hostile situations

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

Stress from personal problems adversely affects my performance.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

I have the support I need from other personnel to care for patients

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

It is easy for staff in this centre to ask questions when there is something that they do not understand.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

Disruptions in the continuity of care can be detrimental to patient safety

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

The team here work together that is well coordinated.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. N/A

I am frequently unable to express disagreement with other staff in this centre.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

Truly professional personnel can leave personal problems behind when working.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

Morale in this centre is high.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

Students are adequately supervised.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

I know the first and last names of all the staff I work with.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

I have made errors that had the potential to harm patients.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree

5. Strongly agree
6. NA

Other team members in this centre are doing a good job.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

All the staff in this centre take responsibility for patient safety

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

I feel fatigued when I have to get up in the morning and face another day on the job.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

Patient safety is constantly reinforced as the priority in this centre.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

I feel burned out from my work.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

Important issues are well communicated to the team.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

There is widespread adherence to clinical guidelines and evidence-based criteria in this centre.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

I feel frustrated by my job.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

I feel I am working too hard in my role.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

Information obtained through incident reports is used to make patient care safer in this centre.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

Personnel frequently disregard rules or guidelines (e.g., hand washing, treatment protocols/clinical pathways, sterile fields, etc.) that are applicable in this centre.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

Fatigue impairs my performance during routine care.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

I am satisfied with the current referral process in this centre (Receiving referrals)

1. Yes
2. No
3. neither satisfied nor dissatisfied

There is adequate and timely transfer of patient information between the team as appropriate.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

Abnormal test results are frequently lost or overlooked.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

Clinical practice guidelines are important for patient safety.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

I routinely refer to clinical practice guidelines to support my day to day work.

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
6. NA

Please add anything at this point which you would like to bring to the attention of the researcher.



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