

Clinical Practice Guideline for Venous Leg Ulcers: Assessment

WOUND

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Disclaimer:

This clinical practice guideline was developed by Hong Kong Enterostomal Therapists Association, New Zealand Wound Care Society, Wounds Australia and the Wound Healing Society of Singapore. It presents a comprehensive review of the best available evidence at the time of the literature search related to the assessment of people with or at risk of a venous leg ulcer. The clinical practice in this guideline is a general guide to appropriate care, to be implemented by qualified health professionals subject to their clinical judgment of each individual case and in consideration of the individual's personal preferences and available resources. The guideline should be implemented in a culturally safe and respectful manner in accordance with the principles of protection, participation and partnership.

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Abbreviations

ABI	Ankle brachial index (also called ankle brachial pressure index)
ASTP	Absolute systolic toe pressure (also called absolute toe pressure)
BMI	Body mass index
BWAT	Bates-Jensen Wound Assessment Tool
CCVUQ	Charing Cross Venous Ulcer Questionnaire
CEAP	Disease classification based on clinical, aetiological, anatomical and
	pathophysiological features
CIVIQ	Chronic Venous Insufficiency Questionnaire (CIVIQ-14/20)
CNPI	Checklist for Non-Verbal Pain Indicators
CVI	Chronic venous insufficiency
CWIS	Cardiff Wound Impact Schedule
DN4	Douleur Neuropathique 4 Questions
DVT	Deep vein thrombosis

EQ-5D™	European Quality of Life-5 Dimensions (EuroQol-5)
IWII-WIC	Wound Infection Institute's Wound Infection Continuum
HRQOL	Health related quality of life
NHP	Nottingham Health Profile
S-LANSS	Leeds Assessment of Neuropathic Symptoms and Signs Pain Scale
MNA/MNA-SF	Mini Nutrition Assessment/ MNA-Short Form
MPQ	McGill's Pain Questionnaire
MUST	Malnutrition Universal Screening Tool
NPQ-SF	Short version Neuropathic Pain Questionnaire
NRS	Numeric Rating Scale
NZWCS	The New Zealand Wound Care Society
PACSLAC/ PACSLAC-2	Pain Assessment Checklist for Seniors with Limited Ability to Communicate
PAD	Peripheral arterial disease
PDQ	Pain Detect Questionnaire
PROM	Patient reported outcome measure
PTS	Post thrombotic syndrome
PUSH	Pressure Ulcer Scale for Healing
PWAT	Photographic Wound Assessment Tool
QOL	Quality of life
SF-12/36	Short Form-12/36
SGA	Subjective Global Assessment
SNAQ	Simplified Nutritional Appetite Questionnaire
TBI	Toe brachial index (also called toe brachial pressure index)
TIME	Tissue, infection/inflammation, moisture, edge of wound
VAS	Visual analogue scale
VCSS	Venous Clinical Severity Score
VDS	Venous Disability Score
VDS/VRS	Verbal Descriptor Scale/Verbal Rating Scale
VEINES-QoL	Venous Insufficiency Epidemiological and Economic Study: Quality of Life
VEINES-QoL-Sym	VEINES-QOL Symptom sub-scale
VLU	Venous leg ulcer
VLU-QoL	Venous Leg Ulcer Quality of Life
VSDS	Venous Segmental Disease Score
WHO	World Health Organisation
WUWHS	World Union of Wound Healing Societies

Foreword

Assessment of the lower leg to determine and evaluate venous disease and venous leg ulcer (VLU) diagnosis is important to ensure timely and best practice management. This Clinical Practice Guideline presents clinical guidance and implementation considerations for assessment of people with or at risk of VLUs.

This Guideline updates the 2011 Australian and New Zealand Practice Clinical Practice Guideline for Prevention and Management of Venous Leg Ulcers. The Guideline was developed by the Venous Leg Ulcer Guideline Development Committee, which is a collaboration consisting of representatives of the Hong Kong Enterostomal Therapists Association, New Zealand Wound Care Society, Wounds Australia and the Wound Healing Society of Singapore. The Guideline, which focuses on assessment, is the first instalment in a series of guidelines that will also address prevention and treatment of VLUs.

The methodology used to develop this Guideline is included in the appendices. The project team consisted of 19 academic and clinical experts in the VLU field, one consumer and a methodologist. This edition of the guideline was underpinned by an on-line stakeholder survey to collect perspectives from health professionals, industry representatives, people with or at risk of VLUs and their family/whānau/informal carers on topics of priority. This survey was conducted in 2022 and has been previously published. An updated literature search identified research published up to December 2023 that was critically appraised and analysed. New research has been combined with research from the previous edition and project work conducted in 2016. A draft version of this Guideline was made available for public consultation via an on-line survey in mid-2024. A total of 66 people responded with feedback, and these responses were critically evaluated by the project team and informed the final version of the document.

This project was driven by volunteers who have been dedicated in producing this new clinical guidance for health professionals and people with chronic venous insufficiency in the Pan Pacific region. The team has been steadfast and driven by their passion to support the delivery of evidence based wound care for the betterment of lives of people with venous leg ulcers.

Mandy Pagan, Chair, VLU Guideline Committee Judith Barker, Immediate Past Chair, VLU Guideline Committee Emily Haesler, Methodologist, VLU Guideline Committee

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VLU Guideline Committee

Chair:

Mandy Pagan, MHSc, Post Grad Dip Wound Care

Hong Kong Enterostomal Therapists Association Representatives:

- Pang Yuk Kam, RN, MN, FHKANM(Surgery)
- Cecilia Sit, RN, DNurs, FHEA, FCHSM, FHKCHSE
- Pank Chak Hau, RN, BN, SCN, ET (retired Dec 2022)

Hong Kong Working Group Members:

- Chan Chiu Man Erica, RN, MN
- Cheung Chi Yeung, RN, MN

Wounds Australia Representatives:

- Judith Barker, RN, NP, STN, BHlthSci (Nurs), MN (NP), FWA (until 2024)
- Keryln Carville, RN, PhD, FWA
- Kathleen Finlayson, RN, PhD, FWA

Wounds Australia Working Group Members:

• Juliet Scott, RN, MN, NP

Consumer Representative:

Richard Greene, BSc (Hons), PhD

Methodologist and Editor-in-Chief:

Emily Haesler, PhD, BN, Post Grad Dip Adv Nurs (Gerontics), FWA

New Zealand Wound Care Society Representatives:

- Mandy Pagan, MHSc, Post Grad Dip Wound Care
- Maria Schollum, MHSc, NP
- Cathy Hammond, RN, MN (retired Dec 2022)

New Zealand Working Group Members:

- Rebecca Aburn, MHSc, NP (Vascular)
- Alice Cowie, MNS, BN
- Becky Dawson, Post Grad Dip Dip HSc

Wound Healing Society of Singapore Representatives:

- Sivagame D/O Maniya, RN, MN, DNP, APN, Adv Dip (Med-Surg), Grad Cert Clin Nurs (WOC), Cert IIWCC
- Luke Tay Hsien Ts'ung, FRCS, MMed (Surg), MRCS, MSc (Bioinformatics), MBBS

Singapore Working Group Members:

- Tan Wei Xian, RN, MSci (ClinNurs), RN, BN, Dip Adv Nurs (Crit Care), Grad Dip Clin Nurs (WOCN)
- Wang Chunmei, B Health Science (Nurs), MN
- Nanthakumahrie D/O Gunasegaran, RN, BHSc (Nursing), MSc (Clinical Leadership), Adv Dip (Med-Surg), Grad Cert Clin Nurs (WOC), Grad Cert Domiciliary Nurs
- Goh Wee Ting, RN

Summary of Good Practice Statements

- 1 It is good practice to conduct initial and ongoing comprehensive assessments of people who present with a lower leg ulcer to confirm the ulcer aetiology, inform the development of a management plan, inform referrals and to evaluate outcomes over time.
- 2 It is good practice to assess health related quality of life as a part of a comprehensive assessment of a person with a venous leg ulcer.
- **3** It is good practice to facilitate the assessment of health related quality of life with a personappropriate tool that has been designed for assessing health related quality of life and has been tested for validity and reliability.
- 4 It is good practice to conduct nutrition screening and assessment to identify people with or at risk of suboptimal nutrition and hydration status.
- 5 It is good practice to perform a comprehensive initial vascular assessment of all individuals presenting with a lower leg ulcer to inform the management plan, including referrals. The assessment should include a vascular history and physical examination of the lower leg.
- **6** It is good practice to screen for peripheral arterial disease in people with risk factors, a non-healing lower leg ulcer or a suggestive wound appearance and/or health history.

Screening for peripheral arterial disease should include pulse assessment and performing ankle brachial index and/or toe brachial index and/or absolute systolic toe pressure at a minimum (in the absence of contraindications).

Consider also performing transcutaneous oxygen pressure and/or evaluating Doppler waveforms, as indicted by the physical examination findings.

- 7 It is good practice to include skin assessment and assessment of neurosensory status, oedema and functional mobility when performing a physical examination of the lower leg and foot.
- 8 It is good practice to assess, classify and monitor venous signs and symptoms. Venous signs and symptoms should be described and classified using Clinical severity aEtiology, Anatomy Pathophysiology (CEAP). Consider using venous disease severity tools/scales to assess and monitor venous signs and symptoms.
- **9** It is good clinical practice to assess and document lower limb pain as a part of a comprehensive assessment of a person with venous disease and to assess and document wound-related pain when the individual has an active venous leg ulcer.
- **10** It is good clinical practice to use a pain assessment tool that has been tested for validity and reliability.

- **11** It is good clinical practice to conduct and document a comprehensive initial wound assessment and a re-assessment at each wound procedure. Assessment includes (but is not limited to):
 - wound history,
 - wound healing (phases),
 - wound measurements,
 - wound bed,
 - wound edge,
 - peri-wound skin,
 - exudate, and
 - signs and symptoms of infection.
- 12 It is good clinical practice to review the diagnosis of venous leg ulcers that do not exhibit 25— 40% healing within 2—4 weeks of commencing a best practice management plan.
- **13** It is good practice to refer to a vascular expert for further assessment and appropriate interventions:
 - Individuals with venous symptoms and/or with active ulcer/s who have not had an initial review by a vascular expert,
 - Individuals with screening results indicating significant peripheral artery disease, and
 - In contexts where clinical investigations to screen for peripheral artery disease cannot be conducted.
- 14 It is good practice to involve the multidisciplinary team in assessment, diagnosis and care of individuals with or at risk of a VLU.

Culturally safe practice



Throughout the guideline, this symbol is used to identify culturally safe practice¹⁻⁴ and health information specific to Aboriginal and Torres Strait Islander people, Māori and Pacific people.

It is important to consider the needs of the diverse multicultural communities throughout the Pan Pacific when undertaking assessment of people with and at risk or VLUs. Information on delivering VLU-related care in multicultural communities is included throughout this guideline in the implementation considerations.

1. Background

Aetiology of venous leg ulcers

<u>Venous leg ulcers</u> (VLUs) are one of the most common types of lower leg ulcer, accounting for around 50% of all hard-to-heal wounds,⁵ and around 42% of all leg ulcers being treated in a typical Australian wound service.⁶ Venous leg ulceration is a debilitating, chronic condition that affects people of all ages, but occurs at a higher rate in older people.

Figure 2.1 illustrates an overview of the complex pathophysiology leading to VLUs. <u>Venous ulceration</u> occurs in the most severe stages of <u>chronic venous insufficiency</u> (CVI). Chronic venous insufficiency occurs across a spectrum from <u>telangiectasias</u>, <u>reticular veins</u> and <u>varicose veins</u>, to <u>oedema</u>, <u>lipodermatosclerosis</u>, skin changes such as <u>atrophie blanche</u>, and alterations to the skin integrity in the form of ulceration.^{7, 8} These changes occur due to sustained high venous pressure (<u>venous hypertension</u>) resulting from either venous obstruction (e.g., due to thrombosis) or from venous valve dysfunction causing reflux, or arising from a combination of the two.^{7, 9} Primary chronic venous disease arises from sustained venous hypertension that causes ischaemic and inflammatory changes in the venous walls, chronic lymphatic overload and increasing extracellular fluid in the leg,¹⁰ manifesting in oedema and skin symptomology.^{7,11} Chronic venous disease can also arise from secondary causes, such following deep vein thrombosis (DVT), which occurs in up to 50% of DVT events, and is referred to as <u>post thrombotic syndrome (PTS)</u>.¹²



Figure 2.1: Pathophysiology of venous leg ulcers (adapted from Jindal et. al. (2018)⁸)

As noted above, CVI can lead onto lymphatic insufficiency and is termed <u>phlebolymphoedema</u>, phleboedema or venous lymphoedema.¹³ The excessive accumulation of fluid within the venous system leads to valve damage and fluid leakage into interstitial space that can eventually overload the lymphatic system, causing oedema. This is also exacerbated by inflammatory processes. Over time, this protein-rich fluid causes additional disease processes that further impede the function of both the vascular and lymphatic systems.¹⁴

Factors such as calf muscle weakness, reduced ambulation and declining ankle range of motion can also contribute to <u>venous disease</u> progression by reducing the <u>calf muscle pump function</u> that assists in venous return.^{8, 15} Venous disease progressively worsens over time if not managed. This means VLUs frequently recur.^{8, 16}

Venous ulceration is strongly related to risk factors, including but not limited to genetic profile, previous surgery for varicose veins, venous disease, phlebitis, deep vein thrombosis (DVT), congestive cardiac failure, obesity, immobility¹⁷ and previous leg injury/trauma.¹⁸

Extent of the problem

Venous leg ulcer management is a significant burden on people with wounds, their families/<u>whānau</u> and the health care system. Estimates of <u>prevalence</u> of CVI are high. The prevalence of symptomatic venous disease in countries of ethnic diversity similar to New Zealand and Australia is reported to range from 6.8—39%.¹⁹ Some studies suggest that only 10%—35% of the general population have no clinical indicators of CVI.²⁰ General prevalence increases with age, with nearly 80% over people over 70 exhibiting some signs and symptoms of CVI.¹¹ Although CVI is a slowly developing disease that can be addressed with early surgical or procedural interventions, recurrence is high. For example, varicose veins recur in up to 62% of people after surgical repair.¹¹ Prevalence in other south-east Asian countries is unreported.^{21, 22} The global rising significance of adjustable risk factors for CVI, including obesity and immobility in an ageing population, place many people across the Pan-Pacific region at future risk.

Leg ulceration is observed in more severe and progressed CVI. The global prevalence of VLUs is similar across different countries and is under 1%,^{6, 8, 23, 24} with estimates varying depending on the nature of the population being reported and the diagnostic criteria used.²⁵ A recent meta-analysis that pooled results from 13 international prevalence studies reported a pooled VLU prevalence of 0.32% (95% confidence interval 0.1295 to 0.595%).²⁵ Most studies in the pooled analysis reported prevalence in populations receiving formal wound care. A recent Australian study identified VLUs account for approximately 17% of all wounds being managed in health services,⁶ and an audit conducted in a Chinese wound healing department reported prevalence of VLUs as 9.4%.²⁶

Additionally, it is acknowledged that once a VLU occurs, recurrence is a significant concern and ongoing prevention is required. Although recurrence rates are difficult to accurately determine it is evident that they are high, with studies reporting recurrence of up to 45–70% within 3 months of, and up to years after, healing.^{16, 27, 28} This significantly increases the ongoing burden of VLUs.

However, incidence is higher in some specific cohorts. For people diagnosed with CVI, incidence of VLUs is up to 3.3% over five years, and up to 7.3% over 20 years.²⁹ It is well established that VLUs occur more often in older adults. Australian data indicates that approximately 99% of individuals with a VLU are aged 60 years or over.^{30, 31} Prevalence has been reported at 4% in adults aged over 65 years.³² In long term aged care settings, estimates of VLU incidence have ranged from 1-2.2%.²⁹ Viewed in the context of ageing populations across the Pan-Pacific region, financial, health and personal burden of VLUs is significant. The proportion of the population aged over 65 years is projected to increase in Australia (21 to 23% by 2066³³), Hong Kong (36% by 2046³⁴), New Zealand (24% by 2053³⁵) and Singapore (at least 14% by 2024³⁶).



Aboriginal and Torres Strait Islander people, Māori and Pacific people have much higher rates of comorbidities associated with chronic venous insufficiency.³⁷

In Australia and New Zealand, the health of Indigenous populations differs from that of the general population, including medical conditions closely associated with VLUs.³⁸⁻⁴¹ In New Zealand, a 1986 prevalence survey found symptomatic CVI in 36.3-47.4% of Māori, compared to 21.5-40.4% of Caucasian people.⁴² A survey of people presenting for wound-related care in one New Zealand district nursing service found that over 5 years, Pasifika people were up to 20 times more likely than non-Indigenous people to have symptomatic CVI, while Māori were up to 6.6 times more likely.⁴³ People from New Zealand Indigenous backgrounds had a lower average age of presentation with a VLU,⁴³ which reflects the higher rates of chronic disease and health disparity that is directly related to poor socioeconomic status in these populations.^{38, 40, 44, 45} In Australia, there is a higher prevalence of many chronic health conditions in Aboriginal and Torres Strait Islander people compared with non-Indigenous populations.^{39, 41, 46} The most recent data indicate an average difference of 26 percentage points between Indigenous and non-Indigenous adults for good health rating, with VLU risk factors such as hypertension, overweight/obesity and decreased physical exercise making a significant contribution to poorer health ratings.^{26, 47} In a study reporting the incidence of hard-to-heal wounds from a nationwide database in Singapore, the minority Indians had a higher incidence rate of venous-origin wounds compared to the Chinese majority, especially among those aged 50 years and above.⁴⁸ In Indigenous populations in Pan Pacific regions, rates of obesity are higher than non-Indigenous populations,^{40, 41} suggesting another potential higher risk for CVI and VLUs.

Management of VLUs accounts for a significant amount of time spent managing wounds in community health services,^{6, 49-51} which represents an economic burden to health systems in the Pan Pacific. In addition, the financial cost of other resources associated with the prevention and treatment of VLUs, including but not limited to secondary or tertiary admissions, infection management, wound dressings and compression therapies is substantial.⁵²⁻⁵⁴ The weekly cost of providing optimal care for a lower leg ulcer was reported to be approximately \$AUD 300 in 2019–2022.^{28, 54, 55} Additional societal costs include but are not limited to loss of time worked, travel, decreased population health related quality of life (HRQOL) and informal carer burden.⁵⁴

The need for clinical guidance

Region-specific clinical guidelines provide guidance for <u>health professionals</u> that addresses the needs of the populations in the region, with consideration to the health care systems in which care is delivered. The last regional clinical guideline for managing VLUs, *Australian and New Zealand Clinical Practice Guideline for Prevention and Management of Venous Leg Ulcers*, was published in 2011.⁵⁶ Since that time, a substantial body of research on the prevention and management of VLUs has been published, and wound care has advanced. Additionally, there has been a global shift, mirrored in the Pan-Pacific, from diagnosis and management primarily occurring in the tertiary health care sector to community-based identification and treatment.⁵⁷⁻⁵⁹

The following points indicate there is a high degree of urgency for an updated guideline on management of VLUs:

• There is a high incidence of VLUs, and their recurrence within Pan Pacific communities,^{6, 28, 48, 53} and an ageing Pan Pacific population³³⁻³⁶ suggests incidence will rise.

- The significant impacts of wounds on the person, their family/whānau/other informal carers, the community and health systems indicate there is an urgent need to improve clinical outcomes for people with wounds.⁶⁰
 - There is a wide variability in professional knowledge, clinical skills and implementation of best practice in the management of VLUs.⁶¹⁻⁶⁴
 - There is a lack of community awareness and public education about venous disease⁶⁵ and the assessment, prevention and management of VLUs (including for those with a VLU).^{61, 66, 67}
 - The current Pan Pacific clinical guidance related to VLUs⁵⁶ was last published in 2011.

Scope of this series of clinical guidelines

The focus of this series of clinical guidelines is leg ulcers of venous origin. The guideline series does not seek to provide comprehensive resources for managing other types of wound, including leg ulcers arising from other aetiologies.

Accurate identification of wound aetiology before implementing good practice statements and recommendations designed to manage VLUs is an imperative.

This is the first document in a series of Pan Pacific guidelines addressing venous leg ulcer prevention and treatment. The focus of this document, *Pan Pacific Clinical Practice Guideline for Venous Leg Ulcers: Assessment* is assessment of people with and at risk of VLUs. The guideline takes a holistic approach to assessment, and includes good practice guidance on assessing the person, their quality of life, nutrition, pain, their lower leg and assessment of the VLU.

The primary underlying condition associated with developing a VLU is CVI. However, the focus of this guideline series is on assessment, diagnosis, prevention and management of VLUs rather than management of underlying pathologies. Co-morbidities, including lymphoedema, arterial disease and atypical leg ulcers, are associated with leg ulceration in many people, and these conditions require co-management. While some of the guideline series content is appropriate for assessing and treating co-morbidities and mixed-aetiology wounds, these are not the primary focus.

The guideline includes resources intended for use by:

- Health professionals and health workers formally engaged in VLU care,
- People with/at risk of VLUs or at risk of VLU recurrence,
- Carers and organisations representing healthcare consumers, and
- People working in health administration and policy, industry, academia and education settings.

The resources are for routine people requiring VLU-related care and their carers in Australia, Hong Kong, New Zealand and Singapore, and other regions within the Pan Pacific. Particular consideration has been given to people who are overweight or obese, older people, people with darker skin tones and Indigenous populations.

2. Introduction to Assessment

Chronic venous insufficiency (CVI) and venous leg ulcers (VLUs) require a comprehensive assessment and diagnostic process due to the complex nature of differential diagnosis and the clinical skills required to accurately perform examination. This chapter discusses the broad requirements for an assessment of the person with or at risk of VLUs and considerations in ensuring assessment, prevention and management of VLUs is conducted in accordance with the person's needs and preferences.

Clinical question

What should be included in an assessment of people with or at risk of VLUs?

Overview of assessment

The optimal outcome for a person with a VLU is facilitated by a continuous process of assessment of the individual, the wound and the wound healing environment. A comprehensive assessment underpins an accurate diagnosis of wound aetiology, informs the development of an appropriate individualised prevention and treatment plan, and provides a theoretical framework to evaluate the efficacy of management.⁹ A comprehensive assessment of people presenting with or at risk of a VLU includes assessment of:^{9, 68-72}

- Health history,
- Additional investigations to support assessment and diagnosis,
- Nutrition,
- Health related quality of life (HRQOL) and psychosocial wellbeing,
- Vascular profile, including examination of the legs, and
- The wound (for people with an active ulcer).

Assessment should be conducted and documented by a health professional with education and experience in the management of VLUs⁹ and with communication skills that facilitate information exchange.^{71, 73}

1. It is good practice to conduct initial and ongoing comprehensive assessments of people who present with a lower leg ulcer to confirm the ulcer aetiology, inform the development of a management plan, inform referrals and to evaluate outcomes over time.

Implementation considerations

Assessment goals

- A holistic assessment requires a comprehensive history, physical examination and diagnostic reasoning.
- Conducting an assessment to identify the aetiology of the ulcer is an imperative before commencing compression therapy. This is because damage can occur if compression is applied to a limb with critical ischaemia.^{9, 68} Applying compression to ulcers arising from other aetiologies (e.g. pyoderma gangrenosum) can exacerbate signs and symptoms.

Preparing for the assessment



In consultation with the person receiving wound care, invite an advocate/whānau/family carer to support the person during the assessment.

Assess the person's language, comprehension skills and health literacy.^{9, 74} When required, access translation services and/or cultural health teams.

Assessment process

- Use culturally-appropriate models of care to underpin holistic assessment and to promote culturally safe, person-centred care.⁷⁵
- Consider using a structured framework to conduct and document a comprehensive assessment. Examples include the generic HEIDIE approach (see *Box 3.1*) and the New Zealand Wound Care Society's Venous Leg Ulcer Assessment Form.⁷⁶

Summary of evidence supporting the consensus good practice statement

Wound-related clinical practice guidelines⁶⁸ indicate that a comprehensive assessment is required to differentiate the aetiology of lower leg wounds. A comprehensive assessment designed to establish the aetiology can inform decisions about the interventions that are appropriate for the individual. General clinical guidance suggests using a systematic process improves clinical skills and clinical reasoning.⁷⁷

Essential in comprehensive assessment is the identification of the aetiology of the lower leg ulcer.^{9, 68-71} There is substantial risk to the individual from an incorrect vascular aetiology diagnosis and inappropriate commencement of compression therapy. Health professionals who undertake wound and lower leg assessment require appropriate education in clinical reasoning, theory-driven assessment and clinical skills in to reduce this risk.^{9, 60, 69, 78}

Facilitating the assessment process

Establishing a therapeutic relationship is fundamental in facilitating assessment, prevention, and management and establishing goals of wound care. Connecting with the individual and their carer in positive ways promotes respect, interpersonal understanding, collaborative care and agreement on the goals of care.⁷³

To facilitate engagement of the individual and their whānau/family carers in the assessment process, understanding factors that can influence <u>health literacy</u> and engagement in the assessment process is important. Include assessment of the following factors in the initial consultation:^{9, 73-75, 79-81}

- Culture, religion and social practice that influences ways of understanding health and health expectations,
- Preference for engagement in their health assessment and management,
- Cognition and capacity to make informed decisions,
- Relevant health knowledge and literacy (specifically related to venous disease and VLUs),
- Language and need for interpreter services, and
- Disability that might influence involvement in the assessment process.

Outcomes from this assessment will provide guidance on considerations in performing the rest of the individual's assessment and development of an individualise prevention and management plan.^{73, 82} This will include appropriate communication strategies and selection of assessment tools.



Aboriginal and Torres Strait Islander people and Māori experience the consequences of colonialism and systemic racism, including lower employment and income, and higher rates of socioeconomic disadvantage that can negatively impact health literacy.^{44, 73, 75, 83}



Models of Care

A model of care describes the way in which health care is delivered and elements that underpin the health service delivery. Person-centred models of care are often based on theoretical, philosophical, social and cultural understanding of health, and might be driven by the health professional's understanding, the local community or the beliefs of the person and their family/whānau/informal carers.^{37, 84}

Being knowledgeable of and adopting local models of health of Aboriginal, Torres Strait Islander, Māori and Pacific Island communities is important to promote the feeling of cultural safety for Indigenous people receiving care.^{75, 85} Māori models of care (e.g. the Te Whare Tapa Whā model by Mason Durie) are often built around a framework of four interdependent cornerstones of health: Wairua (spiritual wellbeing), Hinengaro (emotional and intellectual wellbeing), Tinana (physical wellbeing) and Whānau (community/family wellbeing).^{75, 86} Indigenous people from the Pacific islands including Tonga, Samoa, and Cook Islands have country-specific health models that reflect their diversity and include health care models based on metaphor, or natural and social realities⁸⁷ (e.g. the Fonofale model by Fuimaono Karl Pulotu-Endemann⁸⁸). Similarly, Aboriginal and Torres Strait Islander health embraces a holistic perspective in which health and wellbeing involves the whole community across the entire life course. The concept of health of Australian Indigenous people includes social, environmental and cultural wellbeing; justice, equity and rights; traditional knowledge and health; and connection to country.^{89, 90}



Partnering with Aboriginal and Torres Strait Islander people and Māori and Pacific people to deliver health care using traditional models of care of the local Indigenous community is fundamental to promoting trust, cultural safety, health equity and engagement.^{37, 75, 85}

Assessment frameworks and care pathways

Using a formal assessment process to undertake an assessment of the person can simplify both the initial assessment and ongoing monitoring of the person and the ulcer.^{69, 77, 91} Formalising the assessment process assists the health professional's clinical reasoning and development of an individualised plan to meet the person's needs and preferences.⁷⁷ Using reflective reasoning, formalised assessment frameworks (for an example see Box 3.1), algorithms, protocols and clinical pathways may improve clinical assessment skills and reduce diagnostic error.⁷⁷

While many assessment frameworks are generic, the New Zealand Wound Care Society (NZWCS) Leg Ulcer Assessment Form,⁷⁶ provides a comprehensive assessment specifically for people presenting with a lower leg ulcer. The tool outlines all areas to consider when assessing the person and the wound, and provides



a template for consistent, relevant and comprehensive documentation of the assessment. In addition, a

companion document to the NZWCS Leg Ulcer Assessment Form,⁷⁶ the NZWCS Leg Ulcer Pathway,⁹² details a clinical pathway for optimal progression of the management of a person with a VLU, based on national/international analysis of VLU management, complications, outcomes and resources.

Taking a health history

The <u>health history</u> includes an overview of the person's medical history (including cognitive and psychological), surgical history, congenital abnormalities, medication regimen (prescribed, over-the-counter and topical creams/lotions/etc), and allergies and sensitivities (including medications, topical preparations, foods and others).^{9, 71, 72, 76} History-taking seeks to clarify the aetiology of vascular morbidity and to identify co-morbidities that may require further investigation and/or concurrent management, and that might influence wound treatment selection and VLU healing.

The assessment process should consider factors that can impact wound healing, including but not limited to smoking/vaping, glycaemic control, nutritional status, alcohol and drug use, prescription and non-prescription medication regimen. Co-morbidities of significance to consider include but are not limited to:^{9, 68-71}

- Surgical and trauma history, particularly vascular surgery and lower limb surgery,
- Cardiac history,
- Liver and kidney disease,
- Arterial disease (e.g., peripheral arterial disease, hypertension, arteriovenous fistula),
- Venous disease (e.g., varicose veins, deep vein thrombosis),
- Lymphoedema or lipoedema,
- Skin cancers/lesions,
- Blood disorders (e.g., sickle cell anaemia, thalassemia),
- Metabolic disorders (e.g., diabetes mellitus),
- Neuropathic disorders (peripheral or central neuropathy),
- Skin disorders (e.g., psoriasis, bullous skin disease),
- Inflammatory/autoimmune disorders (e.g., pyoderma gangrenosum, <u>vasculitis</u>, rheumatoid arthritis, systemic lupus erythematosus),
- Congenital abnormalities,
- Exogenous causes of a wound (e.g., heat, cold, pressure, chemical, trauma), and
- Self-harm, including injectable substance use.

Further discussion of vascular history is discussed under Vascular Assessment.

Additional investigations to support assessment and diagnosis

Appropriate biochemical analysis should be guided by the findings of the person's history, vascular assessment and examinations, nutrition and hydration deficits and potential differential diagnoses relevant to the individual. Potential investigations may include, but are not limited to:^{9, 68, 69, 93}

- <u>glycated haemoglobin</u> (HbA1c) and fasting blood glucose level,
- haemoglobin,
- urea and electrolytes,
- serum albumin and prealbumin,
- lipids,
- rheumatoid factor,
- auto antibodies,
- white blood cell count,
- erythrocyte sedimentation rate (ESR),

- <u>C-reactive protein</u> (CRP),
- liver function tests,
- thyroid function tests,
- B-type natriuretic peptide (BNP),
- Vitamin/mineral/trace element levels.

3. Health Related Quality of Life and Wellbeing

Chronic venous insufficiency (CVI) and venous leg ulcers (VLUs) negatively affects health related quality of life (HRQOL). However, the HRQOL of people living with CVI with and without an active VLU often receives inadequate attention in clinical practice, where the focus is primarily on wound care and promoting physical healing. This chapter discusses HRQOL of people with or at risk of VLUs and considerations in its assessment.

Clinical questions

- What is the experience of people who have a VLU?
- How should HRQOL be assessed in people with or at risk of VLUs?

The experience of people living with or at risk of venous leg ulcers

Chronic disease is reported to have a negative psychosocial impact. The literature reported that people with or at risk of VLUs may be at an increased risk of negative psychosocial outcomes, including depression, low self-esteem, social isolation, fear and anger. Contributing factors to HRQOL include pain, functional limitations, impacts of compression therapy (e.g. finding shoes/clothes to cover bandaging), worry about the wound and its healing, and the financial burden of ongoing care. These factors may also reduce the individual's concordance with therapy in the long term.⁹⁴⁻⁹⁷

Having a long standing VLU impacts negatively upon all areas of daily living.^{96, 98} Having limited HRQOL was a significant theme in both quantitative and qualitative research, with limitations identified across all domains of functioning (physical, social and psychological). Quantitative research that used validated assessment tools (e.g., SF-36 and SF-12) shows that reduced HRQOL across all domains is associated with having a VLU.⁹⁹⁻¹⁰³

Pain has been identified as a dominant factor that impacts on activities of daily living, and is consistently identified as having a significant and negative impact on the HRQOL of people living with VLUs.^{96, 99, 103-113} Pain is often described as unceasing and as dominating lives by disrupting the individual's sleep^{96, 105, 109, 112} and limiting their daily activities.^{96, 99, 109} Venous leg ulcer treatment, for example compression therapy and wound dressing changes, often adds to the pain a person with a VLU experiences^{16, 105} However, some interventions, for example compression therapy, may also reduce leg and VLU pain and improve HRQOL.^{94, 114-116}

Coping with <u>wound exudate</u>, malodour, limited mobility and lack of sleep (often due to pain) poses major challenges for <u>individuals/people</u> with VLUs.^{96, 99}, ^{100, 111} These physical limitations may lead to psychosocial difficulties. For example, sleep disturbance and fatigue are both associated with decreased HRQOL.¹¹³ Embarrassment, distress and shame are common experiences that often arise from wound and leg appearance, wound malodour and difficulty maintaining personal hygiene in the presence of an active VLU. Self-imposed social isolation is a common response.^{94, 96, 113} Having a VLU has also been associated with decline in social, family and work participation, which has both HRQOL impacts (e.g. increased feelings of burden and shame) and economic impact.⁹⁹ Social isolation and work restrictions may be further exacerbated by treatment for venous disease and active VLUs, including the time taken to attend appointment, costs and inconvenience (e.g. elevation of the legs).^{94, 98, 99, 111, 112, 117} Limited mobility has also been associated with reduced HRQOL.^{99, 103, 117} Although little research addresses the topic, it is likely that VLU risk negatively impacts cultural and spiritual practice, as it does other aspects of psychological and social well-being.

Other aspects of care also impact on the HRQOL of people living with venous disease and VLUs.^{96, 106, 112} (see *Figure 4.1*). Limitations of physical functioning and associated psychosocial difficulties have been described in relation to compression therapy. For example, compression bandaging can be bulky and restrict movement, often necessitating clothing adjustments, thereby leading to further erosion of self-identity.^{96, 117, 118} Low self-esteem is described in relation to wound-related symptoms,^{96, 98} while better self-esteem improvement is linked to healing of the wound.¹¹⁶ Low levels of social support and self-efficacy are notably associated with increased risk of a VLU recurrence.¹¹⁹

Depression and low mood were common in both people living with CVI and those with an active VLU. ^{99, 120, 121} Feelings of hopelessness, burden, shame, anger, anxiety, sadness and powerlessness (lack of control) are described.^{98, 99, 106, 109, 111, 112, 117, 122, 123} Hopelessness and powerlessness appear to be more common in people with non-healing/recurrent ulcers—the seemingly endless cycles of treatment and failure are discouraging,^{108, 112} as are frequent wound dressing changes, wound malodour and exudate.¹²² Despite this, many people with CVI and active VLUs remain hopeful⁹⁶ and report improvements in HRQOL over time, particularly if they have fewer comorbidities, less pain, less restriction to functional mobility, or undergo surgical intervention to manage their venous disease.¹²³⁻¹²⁵

Access to both formal and informal care can impact all aspects of mental, physical and social wellbeing. Availability wound care services, care coordination and continuity, and collaborative interaction with health providers influence quality of care and the experience of people with wounds.¹²⁶ Informal carers (e.g. family/whānau) play pivotal roles in supporting the person with a wound across the biopsychosocial domains through wound care delivery; other care delivery; mental, social and emotional support; advocacy; and care planning. There is evidence that people with wounds who live alone have poorer wound outcomes.¹²⁷



Figure 4.1: Venous disease HRQOL conceptual framework (adapted from Ruseckaite et. al. 2020¹¹¹)

It should not be overlooked that caring for a person with a VLU can also negatively impact the quality of life of that person's spouse or other whānau/family carers. Time involved in delivering direct wound care and associated care (e.g. travel), distress arising from the person with a VLU's pain, and characteristics of the wound including its visual appearance and odour and relationships strains impact on family/whānau quality of life,^{110, 128} and intimate and sexual relationships.

Correlation of chronic venous insufficiency with quality of life

Reduced HRQOL has been associated with numerous disease-specific factors including:

- greater disease severity, including having an active ulcer (<u>CEAP classification</u> of C5 and C6),^{99, 129-135}
- longer duration of VLU,^{103, 133, 136}
- larger ulcer size,^{103, 136}
- anatomical location of the wound (e.g. ability to maintain a wound dressing in-situ),¹³⁶
- more comorbidities,¹²³
- presence of exudate and/or clinical infection, ^{136, 137} and
- experiencing more venous signs and symptoms.¹³⁸

A relationship has also been described between specific venous symptoms and QOL domains. Symptoms including cramp, restless legs, leg swelling and leg heaviness are associated with poorer physical and mental health functioning, while tingling is associated with reduced mental health scores.¹³⁸ Oedema and <u>hyperpigmentation</u> have also been shown to be associated with lower HRQOL scores.¹²⁵ Reduction in venous signs and symptoms are associated with improved HRQOL scores.^{123, 139}



Issues such as lower income and education have been associated with poorer HRQOL outcomes¹⁴⁰ suggesting Aboriginal and Torres Strait Islander people, Māori and Pacific people with CVI or an active VLU may experience poorer HRQOL. More research on the HRQOL impact on Indigenous people is required.

Assessing health related quality of life

Best practice dictates that every consultation should address issues of importance to the person living with a VLU, including HRQOL, pain, and wound-related symptoms.^{9, 71, 96, 141}

2. It is good practice to assess health related quality of life as a part of a comprehensive assessment of a person with a venous leg ulcer.

Implementation considerations

- Performing a HRQOL assessment facilitates identification of issues for which the person with a VLU might require additional support and contributes to development of a holistic management plan.
- Ongoing assessments of HRQOL contribute to development and evaluation of the management plan and response to treatment.
- Consider evaluating the following HRQOL items when performing a comprehensive assessment:
 - cultural and spiritual impact on the person and their family/whānau,
 - life satisfaction,
 - coping skills,
 - optimism and hope for the future,

- pain and anxiety,
- social isolation,
- self-efficacy.
- Particularly for individuals with cognitive limitations, observe for non-verbal cues that provide insight into HRQOL. Consider involving the individual's family/whānau in the assessment process.

Summary of evidence supporting the good practice statement

Assessing HRQOL is considered a priority topic by people with and at risk of VLUs and their formal and informal carers.^{142, 143} It is considered best clinical practice and a part of holistic care to perform an assessment of the individual's HRQOL and wellbeing.^{9, 71}

Health related quality of life is an important <u>patient-reported outcome</u> that is routinely used to evaluate health interventions.¹⁴⁴⁻¹⁴⁶ It is expected to use valid and reliable patient-reported outcome measures (PROMs) as standard practice to evaluate the impact of interventions on the person's experience (e.g. psychosocial outcomes). This is in part a response to the recognition that while advances in medical science have enabled us to increase our longevity, this often comes at a cost to both the individual, society and the health care system.^{146, 147} For example, VLUs are sometimes associated with other long term conditions such as diabetes or obesity, as well as being a corollary of an aging population. Some treatments may be aggressive, causing as much pain and distress as the ulcer itself. Furthermore, despite medical advancement it is not always possible to cure the CVI that causes VLUs. Additionally, people with wounds may have expectations that are different from health professionals (and possibly different from their family/whānau); it is important that outcomes are meaningful to the recipients of care.¹⁴⁷ Thus, HRQOL is often not just an outcome, but an endpoint measure in itself, particularly in palliative care settings.^{146, 148}

In many clinical situations, individual choice becomes a vital part of the clinical decision-making process. Venous leg ulcers have variable, and often protracted healing rates,¹⁴⁹ which can lead to a wound becoming long standing and hard-to-heal, even when optimum care is provided. Health professionals, the person living with an ulcer and their informal carers may need to acknowledge early in the care process that, whilst healing may be the main intended long term outcome, it may not always be the priority of care. Understanding the individual's expectations and incorporating a measure of HRQOL within a care pathway shifts the focus from the wound and physical outcomes, to the whole person.¹⁴⁶⁻¹⁴⁸ Outcome measures can highlight that the goal of care for many people with or at risk of VLUs is maximising HRQOL while living with a chronic disease and/or a hard-to-heal wound.

Quality of life assessment and measurement has been considered a challenge.¹⁵⁰ This is in part due to the subjective nature of HRQOL, which means that it cannot be measured by objective observation and can only be assessed by self-report from the individual. Furthermore, individual reports cannot be verified by others, or by observation alone.¹⁵⁰

Various strategies are used to assess HRQOL, including qualitative or quantitative tools; however in most clinical settings fixed-response quantitative measures such as questionnaires are the most feasible assessment strategy.¹⁴⁸ While such tools are recommended as providing a feasible assessment strategy that aids longitudinal evaluation, their use may not always be relevant to the individual. For example, such tools may not be appropriate for people with cognitive impairment, low health literacy, learning disabilities, or the tool may not be available in an appropriate language. Observing for non-verbal cues or involving the individual's family/whānau in the assessment process may assist in eliciting more information about the impact of CVI and/or having a VLU on the individual's QOL.

3. It is good practice to facilitate the assessment of health related quality of life with a personappropriate tool that has been designed for assessing health related quality of life and has been tested for validity and reliability.

Implementation considerations

- Consider the following factors when selecting a HRQOL assessment tool:
 - health literacy,
 - cognitive impairment,
 - preferences of the individual,
 - purpose of the assessment,
 - relevance of the domains covered,
 - similarity of the population and setting in which the measure was developed to the population and setting in which the assessment will occur,
 - reliability and validity of the measure,
 - length of time taken to complete,
 - self-administered versus requiring assistance from a health professional,
 - cultural appropriateness and availability of the tool in the individual's language, and
 - ease of use.
 - For people with an active VLU, the following assessment tools have all been translated and tested in different cultures:¹⁵¹⁻¹⁵⁵
 - Charing Cross Venous Ulcer Questionnaire (CCVUQ),
 - Venous Insufficiency Epidemiological and Economic Study (VEINES-QoL),
 - Cardiff Wound Impact Schedule (CWIS), and
 - Wound-QoL and Short Form 36 (SF-36).



For people with CVI and at risk of a VLU, the following assessment tools have all been translated and tested in different cultures: ^{153, 156}

- Chronic Lower Limb Venous Insufficiency Questionnaire (CIVIQ-20 and CIVIQ-14),
- Venous Insufficiency Epidemiological and Economic Study: Quality of life/Symptom sub-scale (VEINES-QoL-Sym), and
- Short Form-36 (SF-36).
- The CIVIQ-14 is short, fast to complete and has high response and completion rates.^{153, 157}
- The developers of CIVIQ-20 and CIVIQ-14, suggest that re-assessments using these tools should be conducted at least 4 weeks apart.¹⁵⁸ Frequency of reassessment using other tools was not reported.

Summary of evidence supporting the good practice statement

The research on assessing HRQOL of people with or at risk of a VLU focuses on reports of psychometric testing of HRQOL assessment tools. The research indicates that using a HRQOL tool that has been tested for reliability and validity is feasible and acceptable and generally achieves a high response rate,^{151, 152, 156, 157, 159-161} with most people being able to complete HRQOL tools without assistance. Many of the reported tools have been psychometrically tested in languages other than English.

Approaches to health related quality of life assessment

Measurement of HRQOL usually takes one of two possible approaches, generic or condition-specific assessment. Generic questionnaires measure broad aspects of HRQOL and provide a general sense of the effect of health status on wellbeing and function.¹⁵⁰ Questions cover general issues of health, such as whether an individual has experienced any pain, and what impact that has had on their HRQOL. The questions are applicable to the general population, and measures can be applied to any disease group or healthy individuals. This approach allows a comparison to be made between the HRQOL of people with a specific condition and the general population.^{150, 154}

The second approach uses measures specific to a condition or population. Questions relate to issues specifically relevant to a particular illness and its treatment.¹⁶² Because they are specific to the individual's condition, disease-specific instruments are likely to be more powerful at detecting intervention effects than generic HRQOL instruments.^{150, 162, 163} This is not to say that disease–specific instruments provide superior assessments of HRQOL, rather the choice of using a generic or disease-specific instrument depends on the purpose of the assessment. Thus, generic measures are appropriate when making comparisons of HRQOL between people with a VLU and those without a VLU.^{150, 163} Disease-specific measures are more useful when making comparisons within a medical condition or population (e.g., when considering the relative benefits and costs of different treatment regimens for individuals with CVI or a VLU) while a condition-specific measure covers issues pertaining to a specific disease or population and, as such, can only be applied to the disease or population for which they were developed.

While the questions on generic and disease-specific measures have a different focus, both types of tool share a multidimensional construct that integrates physical, social and psychological functioning. In practice, many measures are consistent with the World Health Organisation (WHO) statement that health is "a state of complete physical, mental, and social well-being; not merely the absence of disease."¹⁶⁴ The conceptual foundation and the focus of both types of tool is specifically on the impact of illness and its treatment on aspects of daily life. The core components of physical, mental and social functioning are sometimes supplemented with additional dimensions, such as satisfaction and spirituality. Thus, whilst both generic and wound-specific tools cover the minimum domains of physical, social and emotional functioning, the wound-specific measures also include other domains such as vitality, cosmesis, pain and odour.¹⁵⁴



Although many generic and disease-specific measurement tools have been tested for their reliability and validity for evaluating HRQOL in different cultural groups, most have not been tested for use evaluating HRQOL of Aboriginal and Torres Strait Islander people or Māori or Pacific Island people.

Condition-specific health related quality of life assessment tools

Condition-specific HRQOL assessment tools focus on issues specific to that condition. Thus, a measure designed to assess HRQOL of a person with venous disease who is at risk of developing a VLU may focus on well-established signs and symptoms of CVI (e.g., leg swelling, sensations of heaviness, night cramping and lower leg pain).¹⁶⁵ Similarly, a measure designed to assess HRQOL of a person with an active VLU would ask about the impact of ulcer-related symptoms, such as wound pain and exudate.^{9, 70, 72, 166} Questions are also likely to address issues such as the effect of wound dressing changes, compression bandaging or other wound treatments. Examples of valid condition-specific measures commonly used for people with CVI with or without an active VLU are provided in *Table 4.2*.

For people with an active VLU, the research reports testing of both VLU-specific tools^{55, 153, 160, 167} wound-specific^{152, 155, 161, 168-171} or tools designed for the broader population of individuals with hard-to-heal wounds.^{152, 161, 168-170}

There is moderate quality evidence that the VLU-specific tool, Venous Leg Ulcer Quality of Life (VLU-QoL), is responsive to change in a VLU over time and has low discriminant validity based on ulcer size.^{55, 153} There is moderate quality evidence that the CCVUQ^{55, 153} and the VEINES-QoL are responsive to change in the VLU over time.⁵⁵ Low quality evidence showed the Leg Ulcer and Foot Questionnaire (often called the Highland Instrument) has ambiguous responsiveness to healing versus non-healing ulcers. The CWIS, a tool specific for hard-to-heal wounds, is supported by moderate quality evidence indicating it is responsive to change over time.⁵⁵ There is low quality evidence that the Well-being in Wounds Inventory (WOWI), developed for assessing people with wounds, discriminates HRQOL between people with poor, moderate and good health status, and is responsive to change in wellbeing over time.¹⁷¹

The research on assessing HRQOL of people at risk of a VLU includes studies conducted in people with CVI, varicose veins and PTS,^{153, 156, 157, 172} and also cohorts who underwent procedural interventions to treat venous disease.^{159, 168, 173} There is moderate quality evidence that the venous-disease specific tool, the CIVIQ-20/CIVIQ-14 and the VEINES-QoL/Sym are valid and reliable for assessing HRQOL.¹⁵³ Low quality evidence suggests that the CIVIQ-14/CIVIQ-20 are responsive to clinical change in lower limbs with venous symptoms and able to differentiate disease severity, suggesting the tools can be used to track change over time. ¹⁵³ The VEINES-QoL/Sym is reported as having lower ability to differentiate disease severity in people with CVI,¹⁵³ although a small study provided moderate evidence that the tool differentiates disease severity in people with PTS.¹⁵⁶

Generic health related quality of life assessment tools

For people with an active VLU, the research reports testing of generic HRQOL tools in populations of people specifically with VLUs.^{55, 160, 167} These include the generic SF-36, or abridged versions of the tool,^{154, 156} the European Quality of Life-5 Dimensions (EQ-5D[™]) and the Nottingham Health Profile (NHP). Evidence indicates that while these tools might provide a generic assessment and provide a comparison against the general population, they are not responsive to change in HRQOL in people with or at risk of VLU so are not appropriate to measure response to treatment.

Many other generic HRQOL assessment tools are available, but there was no evidence on their performance as an assessment tool in people with VLUs or CVI.

	HRQOL tool	Tool description	Psychometric testing	Uses for the tool
	Charing Cross Venous Ulcer Questionnaire (CCVUQ) <u>Available in a</u> <u>published article</u>	21 items distributed in four domains: social interaction; domestic activities; emotional state; aesthetics	 Strong <u>internal consistency</u> for overall tool and each domain Good <u>test-retest reliability</u> Moderate <u>construct</u> <u>validity</u> 	 Assess HRQOL Track response to clinical changes in a VLU, based on low quality evidence
-SPECIFIC HRQOL TOOLS	Hyland Instrument (Leg Ulcer and Foot Questionnaire) <u>Available online</u>	34 items distributed in three sections: condition of hospitalisation and ulcer; pain, sleep, time thinking about/treating the ulcer; functional limitation and mood	 Good internal consistency for each factor Questionable <u>structural</u> <u>validity</u> 	 Potentially use to assess HRQOL Might be used to differentiate between a healing or non- healing VLU, based on low quality evidence
ארח	Venous Leg Ulcer Quality of Life (VLU-QoL) <u>Available in a</u> published article	34 items distributed in three domains: activity limitation; psychological effects; symptom distress	 Good internal consistency for each factor Good reliability for each factor Moderate to good construct validity Low <u>discriminant validity</u> 	 Assess HRQOL Track response to VLU changes, based on moderate quality evidence
OL TOOLS	Cardiff Wound Impact Schedule (CWIS) <u>Available online</u>	Developed for assessing HRQOL in people with lower leg ulcers as a 47- item tool with three domains: physical symptoms and daily living; social life; wellbeing.	 Good to strong internal consistency Strong reliability Moderate construct validity 	 Assess HRQOL Track response to clinical changes in a VLU, based on moderate quality evidence
OUND-SPECIFIC HRQC	Well-being in Wounds Inventory (WOWI) <u>Available in a</u> published article	Includes two domains: personal resources and wound worries	 Good to strong internal consistency Good reliability Strong discriminant ability 	 Assess HRQOL Track changes to HRQOL based on low quality evidence
2	Wound-QoL <u>Available in a</u> published article	Developed for assessing HRQOL in people with lower leg ulcers as a 17- item tool.	 Good internal consistency Moderate construct validity 	• Assess HRQOL

Table 4.2: Summary of tools to assess health related quality of life^{55, 151, 152, 154-157, 168, 173, 174}

	HRQOL tool	Tool description	Psychometric testing	Uses for the tool
	CIVIQ-20 • <u>Available</u> <u>online in</u> <u>multiple</u> <u>languages</u> • <u>Scoring also</u> <u>available</u>	 A 20-item instrument developed with consideration to patient preferences. Organised in 4 dimensions: pain, physical, psychological and social. 	 Strong internal consistency Strong reliability Moderate to good construct validity Ability to differentiate severity rated on CEAP 0-4. 	 Assess HRQOL, based on moderate quality evidence. Track response to clinical changes people with CVI, based on low quality evidence
CIFIC HRQOL TOOLS	CIVIQ-14 • <u>Available</u> <u>online in</u> <u>multiple</u> <u>languages</u> • <u>Scoring also</u> <u>available</u>	 A 14-item version of the CIVIQ-20. developed with consideration to patient preferences. Organised in 3 dimensions: pain, physical and psychological. 	 Strong internal consistency Strong reliability Ability to differentiate severity rated on CEAP 0-6 Reported to be more stable that the original 20-item tool 	 Assessing HRQOL, based on moderate quality evidence. Track response to clinical changes in people with CVI, based on low quality evidence.
VENOUS DISEASE SP	 VEINES- QoL/Sym Published in a study Available in a published article 	 VEINES-QoL has 26 items distributed in three factors: usual activities, VEINES-Sym, feelings The VEINES-QoL/Sym sub-scale is often used as a stand-alone tool 	 Strong internal consistency Strong reliability moderate construct validity Moderate ability to differentiate PTS severity. Weak ability to differentiate CVI severity. 	 Assessing HRQOL, based on moderate quality evidence. Track response to changes in a VLU, based on moderate quality evidence Might be used to differentiate VLU severity (size), based on moderate quality evidence Potential to track response to venous changes in people with some forms of venous disease/risk, based on low quality evidence.
GENERIC HRQoL TOOLS	Short Form-36 (SF-36) <u>Available online</u> <u>Scoring also</u> <u>available</u>	 Developed for assessing HRQOL in any person. 36 items including physical, role, emotional and social functioning; wellbeing; pain; general health and change 	Low discriminant validity for people with PTS.	 Assess HRQOL. Compare HRQOL in people with VLUs to that of the general population.

Table 4.2: Summary of tools to assess health related quality of life^{55, 151, 152, 154-157, 168, 173, 174}

4. Nutrition Assessment

Healthy nutrition and hydration are essential for people with chronic disease. The disease process through which nutrients are lost due to fluid leakage from tissues, together with demographic characteristics such as older age, place people with chronic venous insufficiency (CVI) and venous leg ulcers (VLUs) at higher risk of malnutrition. Nutritional deficits can be managed with appropriate interventions as a part of comprehensive care. This chapter discusses the assessment process to identify people at nutritional risk.

Clinical questions

• How should nutritional status be assessed in people with or at risk of VLUs?

Nutrition and healing of venous leg ulcers

A healthy diet and nutritional status promote general health, health related quality of life (HRQOL), physiological functioning and wound healing. An inadequate nutritional intake can exacerbate disease, negatively impact phases of wound healing that require increased energy (particularly protein) and nutrients.^{175, 176} Adequate nutritional intake is necessary for wound healing processes such as collagen synthesis and maturation and attaining tensile strength.¹⁷⁵ For example, vitamin C is associated with collagen synthesis and angiogenesis.¹⁷⁷ Vitamin D has a role in stimulating phagocytosis.¹⁷⁷ Additionally, a less than adequate dietary intake might negatively impact the immune system, increasing the risk of wound infection.¹⁷⁵ However, nutritional intake is complex and requires holistic consideration of the person's needs. For example, people with chronic kidney disease may need a lower protein intake to manage their symptoms and co-morbidities.

Malnutrition is of significance to people with or at risk of VLUs. It occurs frequently in both older people in general, and in people with wounds.¹⁷⁸ People with VLUs often have inadequate diets, deficient in calories and protein, high lipid intake and low intake of vitamin A, C and zinc.¹⁷⁹ One study reported around 35% of people over 68 years with a wound also had malnutrition.¹⁸⁰ Worsening status of a VLU, including delayed healing, increasing size, complications and recurrence, might be related to malnutrition or <u>body mass index</u> (BMI) less than 20.^{24, 181} There is mixed research on whether overweight and obesity is a risk factor for delayed VLU healing, or whether it has no effect.¹⁸¹

Consistent with what is known regarding the role of dietary components in wound healing, protein deficiency, and low serum albumin levels and serum vitamin C levels have all been reported as risk factors for worsened VLU outcomes.¹⁸¹ Noting the pathophysiology of CVI, which is characterised by chronic inflammation, the role of reactive oxygen species and its imbalance has been explored as a factor contributing to delayed wound healing.¹⁸²

The research on specific dietary management for people with CVI and with VLUs is limited, and recommendations for VLUs are largely based on evidence for other wound types and expert opinion, and generally focus on correcting malnutrition and identified deficiencies.^{181, 183, 184} Therefore, identifying people who have, or are at risk of, malnutrition is important so that interventions to correct nutritional deficits can be implemented to promote optimal wound healing.¹⁸¹



Nutrition status in Indigenous populations

Prior to the European colonisation of Australia, the diet of Aboriginal and Torres Strait Islander people was rich in nutrient-dense foods that helped to protect against chronic diseases.¹⁸⁵ Evidence suggests that

introduction of foods with high levels of sugar and salt, and refined cereals, are associated with a reduction in the quality of diets now consumed by Indigenous Australians, which is also associated with high rates of chronic disease.^{185, 186} Additional factors associated with colonisation and systemic racism, including higher likelihood that an Aboriginal and Torres Strait Islander person will live in poverty and with other socioeconomic disadvantages, are associated with poorer nutritional status in Indigenous Australians.¹⁸⁵⁻¹⁸⁷

In the same way, Māori harvested nutrient-dense traditional food prior to colonisation. Elements of the Māori philosophies and knowledge systems emphasise the role of food in the social and cultural lives and wellbeing of the Māori community, and traditionally food was associated with spiritual practice.¹⁸⁸⁻¹⁹⁰ Pacific Islander people also consider food as inter-dependent across the five dimensions of the Fonua model.¹⁸⁸ Colonisation has contributed to poorer availability of traditional foods,¹⁸⁸ contributing to malnutrition in Māori and Pacific Island people.¹⁸⁹

Nutrition assessment

Although the significance of identifying people who have or are at risk of malnutrition is evident, there is limited evidence on the best assessment methods for people with VLUs.

4. It is good practice to conduct nutrition screening and assessment to identify people with or at risk of suboptimal nutrition and hydration status.

Implementation considerations

- Nutrition screening should be conducted on admission to a health service and be included as part of regular assessment of people with and at risk of VLUs.
- Any member of the <u>interdisciplinary team</u> can screen nutrition and hydration status using appropriate screening tools that are reliable and valid for conducting nutrition screening.
- People identified with or at risk of malnutrition or who are suspected to have other nutritional issues should be referred to an accredited practicing dietitian for nutrition assessment, intervention and monitoring.¹⁹¹
- If reporting BMI, calculate as:¹⁹²

• Consider nutritional laboratory assessments (e.g. albumin, prealbumin, transferrin, vitamins and minerals, glucose, lipids etc.) to identify specific deficits.^{9, 69-71, 93}

Summary of evidence supporting the good practice statement

There is no recent research on how to assess the nutritional status of people with or at risk of a VLU. The consensus statement is based on recommended practice for the general community and people with other types of wound. Screening for malnutrition using a tool tested for reliability and validity, and referring people identified as having nutrition concerns is considered best practice.⁹ Nutrition assessment is considered to be a priority area for clinical guidance.^{73, 142}

 $[\]frac{\text{weight } (kg)}{[\text{height } (m)]^2}$

Nutrition screening

Nutrition screening is considered the first stage of identifying people who might have malnutrition. Malnutrition screening tools are designed to be easy to use by both health professionals and the general population, to recognise presence of a higher risk of malnutrition. Expert opinion recommends that nutrition screening be conducted using a tool that has been tested for validity and reliability because such a tool is most likely to identify people with a risk for malnutrition.⁹



Nutrition screening and assessment is of particular significance for Aboriginal and Torres Strait Islander people, Māori and Pacific Islander people, who are at high risk for malnutrition.¹⁸⁵

In Australia, the most used nutrition screening tools when assessing people with leg ulcers appear to be the Mini Nutrition Assessment (MNA), MNA-Short form (MNA-SF) and the Subjective Global Assessment (SGA),¹⁹³ all of which have been tested in older people receiving care in aged care settings and acute care settings.^{193, 194} *Table 5.1* provides an overview of common nutrition screening tools.

Nutrition screening tools ^{193, 194}				
Acute care settings	Mini Nutritional Assessment-Short Form (MNA)(for older adults)			
	Malnutrition Universal Screening Tool (MUST)			
	Simplified Nutritional Appetite Questionnaire (SNAQ)			
	Malnutrition Screening Tool			
	Nutritional Risk Screening			
	Subjective Global Assessment (SGA)			
Residential care	MNA-SF (for older adults)			
	MUST			
	SNAQ			
	Simple Nutrition Screening Tool			
	SGA			
Rehabilitation settings	MNA-SF			
	Rapid Screen			
Community settings	MNA-SF (for older adults)			
	MUST			
	SNAQ			
	Seniors in the Community: Risk Evaluation for Eating and Nutrition			
	Short Nutritional Appetite Questionnaire			
Nutrition assessment tools ¹⁹⁴				
Acute care settings	MNA (for older adults)			
	Subjective Global Assessment (SGA)			
	Patient-Generated Subjective Global Assessment			
Residential care	SGA			
Rehabilitation settings	MNA			
Community settings				

Table 5.1: Nutrition screening and assessment tools that have been tested for reliability and valid	able 5.1: Nutrition screening and assessment tools that have be	een tested for reliability	and validity
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The value of BMI in identifying malnutrition has been questioned, particularly because of the issues associated with accurate weight and height measurements of many people in health care settings, variance in body composition and diversity based on racial background.¹⁹³ Body mass index has been shown in several studies to have no significant relationship to nutrition status in people with wounds.¹⁹⁵ However, some nutrition screening tools and consensus guides include BMI as a screening item.^{72, 193}

Nutrition assessment

A full nutrition assessment should be conducted for people who are identified as being at risk of suboptimal nutrition.¹⁷⁸ A nutrition assessment should be conducted using a population-specific nutrition assessment tool by an accredited practicing dietitian.⁹

The MNA-SF and the MUST tool are reported to be helpful tools to assess nutritional status in people with VLUs or other lower leg wounds;²⁴ however, evidence of the reliability an validity of these tools in these population has not been formally investigated. *Table 5.1* provides an overview of common nutrition assessment tools.

5. Lower Leg Assessment

People who present with chronic venous insufficiency (CVI) with or without an active venous leg ulcer (VLU) require a comprehensive lower leg assessment. Point-of-care assessment of the lower leg includes history taking, physical examination and clinical investigations. This chapter discusses assessment of the lower limb, including venous and arterial status, skin and subcutaneous tissue and functional mobility. The assessment process provides insight into disease aetiology and severity of symptoms, that will guide selection of appropriate prevention and management strategies.

Clinical questions

• What should be included in a point-of-care assessment of the lower limb in people presenting with venous symptoms with or without a leg ulcer?

Clinical and vascular history

A holistic assessment of the lower limb requires a comprehensive history, physical examination, investigations and diagnostic reasoning.

The individual's lower leg history, including present or previous VLUs, helps develop a comprehensive picture of their overall health and identifies people who require referral for more advanced investigations and diagnosis.

History taking and clinical assessment seek to identify and/or confirm the likely aetiology of lower leg ulcers, identify individuals who may have concurrent conditions (e.g. peripheral artery disease [PAD] and/or lymphoedema) that could influence their management. History taking and clinical assessment should identify factors that could assist in differentiating vascular and lymphatic presentations, noting that many people will have mixed aetiology disease. *Table 6.2* summarises clinical and vascular history indicative of venous versus arterial disease.

For individuals with confirmed longer-standing CVI, clinical history assists to monitor disease severity and effectiveness of management strategies.



Comprehensive clinical assessment is imperative for people from Indigenous backgrounds. Aboriginal and Torres Strait Islander people, Māori and Pacific Islander people are at higher risk for peripheral artery disease due to higher prevalence of risk factors (e.g., smoking, hypertension and diabetes mellitus) and are more likely to develop and die prematurely from cardiovascular disease.¹⁹⁶ 5. It is good practice to perform a comprehensive initial vascular assessment of all individuals presenting with a lower leg ulcer to inform the management plan, including referrals. The assessment should include a vascular history and physical examination of the lower leg.

Implementation considerations

- Apply a structured approach to assessment (see Introduction to Assessment).
- When taking a clinical and vascular history and examining the lower limb, screen for factors indicative of potential arterial, venous and <u>mixed aetiology</u> (see *Table 6.2*).
- No single investigation should be interpreted in isolation, particularly in individuals with a high likelihood of calcified/non-compressible blood vessels (e.g. people with diabetes and/or advanced renal disease).¹⁹⁷

Summary of evidence supporting the good practice statement

Clinical guidelines^{165, 198-202} concur that all individuals presenting with a lower leg ulcer require a comprehensive clinical assessment conducted by a health professional with the required expertise. Relevant clinical guidelines identify important components of a vascular assessment to be taking a health history and examining the lower leg. While vascular assessment is considered a very high priority by stakeholders¹⁴² and is generally tolerable,¹⁶⁷ its routine conduct is influenced by time, access to appropriate equipment and the health professional's skill in performing tests and interpreting the results.^{60, 197-199, 201, 203, 204} Implementation of the recommendations could focus on supporting appropriate education and training, clinical assessment, procedural competency, interpretation of results and making referrals with documented care pathways.

Table 6.2: Differential diagnosis: venous versus arterial presentation 71, 72, 198, 201, 202, 205-209

Note: Do not base diagnosis on presence of any signs or symptoms in isolation.

-	Venous	Arterial
Clinical and vascular history	 Confirmed venous disease diagnosis Pulmonary embolism, deep vein thrombosis (DVT), varicose veins and/or phlebitis Surgical/procedural intervention for vascular conditions (e.g., varicose vein surgery) Obesity Familial history of varicose veins, venous insufficiency and/or venous ulcers Fracture/trauma or surgery to the leg Lifestyle factors (prolonged standing or sitting, injection drug use on lower limb) Multiple pregnancies 	 Confirmed arterial disease diagnosis Diabetes mellitus Chronic kidney disease Coronary artery or cerebrovascular disease Hypertension Vasculitis Rheumatoid arthritis Abdominal obesity Familial history of PAD, heart disease, blood vessel disease or stroke Lifestyle factors (e.g., smoking, sedentary) Preeclampsia or gestational diabetes

Note: Do not base diagnosis on presence of any signs or symptoms in isolation.				
	Venous	Arterial		
Pulses	 Normal leg pulses, although may be decreased or non-palpable in presence of oedema 	 Possible decreased or non-palpable pulses Vascular bruit 		
Lower limb examination findings	 Normal capillary refill (2 seconds) Firm/"brawny" oedema, often with rapid onset. Reddish brown pigmentation/hyperpigmentation (haemosiderin deposit). May present as darker brown or black pigmented skin changes in people with dark skin tones. Dilated and/or torturous superficial veins. Reticular veins and/or telangiectasias. May not be visible in people with dark skin tones. Atrophie blanche. May present as pale pink/ivory or loss of pigmentation in people with dark skin tones. Venous eczema/dermatitis (wet or dry) Induration and fibrosis (lipodermatosclerosis). Indurated areas may be darker than surrounding skin in people with dark skin tones. Altered leg shape (inverted "champagne bottle") Corona phlebectatica (ankle flare) Decreased calf muscle pump function or foot/ankle range of motion Signs and symptoms of oedema (<i>Table 6.7</i>) Evidence of healed ulcers 	 Delayed capillary refill (> 2 seconds) Pale, bluish or dark reddish skin. In dark skin-toned individuals skin is pale, dark blue or brownish. Lower limb coolness to touch Elevation pallor or dependent rubor of the foot (assessed using Buerger's test). May appear as an ashen hue in dark skin toned individuals. Dry lower limb skin Lower limb muscle atrophy Loss of hair on the feet and legs Dystrophic toenails Perceived impaired ambulation Calloused feet 		
Lower leg ulcer and surrounding area	 Lower third of leg (gaiter region) Anterior to medial malleolus Peri-wound maceration, pruritus and skin scale Irregular shaped wound edges, often shallow Often heavy exudate Ruddy granulation tissue or fibrinous tissue in ulcers of longer duration Often slough is present with other signs of local wound infection (see Table 8.2) Hyperkeratosis Chronic inflammation 	 Lower leg or foot (check for inter-digit wounds) More regular wound edges Punched out appearance Pale, poorly perfused wound and periwound area Often full thickness wounds that may show bone and/or tendon Necrotic tissue, slough or gangrene may be present Often dry wound bed with minimal or no exudate 		
Pain experience	Refer to Table 7.1	Refer to Table 7.1		

Table 6.2: Differential diagnosis: venous versus arterial presentation 71, 72, 198, 201, 202, 205-209

Lower leg vascular assessment

A comprehensive clinical examination should be undertaken, to fully evaluate the condition of the legs. Examination of the lower leg is undertaken to:

- determine the aetiology of vascular disease,
- screen and identify PAD,
- inform decisions on the use of compression therapy,
- assess and monitor the signs and symptoms of CVI, and to
- assess concurrent issues that require management, including skin conditions^{203, 210, 211} and phlebolymphoedema.

The most common presenting signs for CVI include hyperpigmentation, venous eczema/dermatitis, atrophie blanche and ulceration (see *Table 6.2: Lower limb examination findings*). However, these signs are not unique to CVI and venous ulceration. It is important not to base the diagnosis on the presence of any signs and/or symptoms in isolation.^{197, 199, 200, 207, 212}

The clinical examination should include examining the lower leg, palpating the lower limb pulses, and conducting point-of-care clinical investigations.^{200-202, 207, 208, 212} Grouping of signs and symptoms helps to determine aetiology and require clinical tests for confirmation. Be aware that many people with PAD are asymptomatic, so a clinical examination cannot exclude arterial disease.²¹³

In epidemiological studies conducted in the US, Europe and Africa, people with dark skin tones appear to have a higher prevalence of PAD than people with pale or Asian skin tones^{201, 207, 214} These studies also suggest that Asian people may have lower rates of PAD compared to people from Caucasian backgrounds. Variations in prevalence patterns appear to change with migration, suggesting these observed differences are influenced more by environmental factors than genetic background.²⁰¹ Within Singapore, there is a 22.8% prevalence of PAD among Malay populations versus 17.9% among Indian people and 12.5% in people from Chinese backgrounds.²¹⁵

6. It is good practice to screen for peripheral arterial disease in people with risk factors, a nonhealing lower leg ulcer or a suggestive wound appearance and/or health history.

Screening for peripheral arterial disease should include pulse assessment and performing ankle brachial index and/or toe brachial index and/or absolute systolic toe pressure at a minimum (in the absence of contraindications).

Consider also performing transcutaneous oxygen pressure and/or evaluating Doppler waveforms, as indicted by the physical examination findings.

Lower leg examination

- Conducting a lower leg examination while the individual is standing can assist in the identification and palpation of varicose veins.
- Perform direct palpation of all major arteries (i.e., femoral, popliteal, posterior tibial, and dorsalis pedis pulses).²⁰⁶ Assess the presence, intensity, rate and rhythm, and compare to the contralateral corresponding pulse.²⁰⁶ See <u>Resources</u> for further information.

- Examine and perform tests (e.g. ankle brachial index [ABI] and/or toe brachial index [TBI] and/or absolute systolic toe pressure [ASTP]) on both sides of the body. Compare the results to the contralateral limb.
- Pulses may be weaker or non-palpable in individuals with significant oedema or obesity due to the increased distance between the artery and the skin.⁷²
- In oedematous feet, massage oedema from the pulse site to facilitate palpation and auscultation of the pedal pulses using Doppler. Locate pedal pulses using anatomical landmarks and palpation or hand-held Doppler. Use a 5 mmHz probe when auscultating in presence of oedema.

Conducting and interpreting clinical investigations

- Use the correct clinical procedure when conducting and calculating ABI, TBI, ASTP and other investigations. See the <u>Resources</u> for procedural guidance and guidance on calculating values.
- Control for factors that may introduce error when performing ABI, TBI and ASTP. This includes instructing the individual to avoid pre-test exercise and stimulants (including caffeine and nicotine) for two hours prior to the investigation, positioning the individual correctly,^{199, 207, 208, 212, 216} using a correctly sized blood pressure cuff, and preparing a comfortable room temperature to prevent vasoconstriction from the cold.^{199, 217}
- A correctly sized blood pressure cuff should be greater than 20% of upper arm diameter or 40% of upper arm circumference and approximately two thirds of the upper arm length. If the cuff is too narrow, the reading may be falsely high and vice versa.
- Automated devices to perform the ABI and/or TBI are generally faster than manual methods, and may be preferred by health professionals, when available.^{167, 218} They require routine calibration.
- Use consensus guidance (see *Table 6.3* and *Box 6.5*) and consideration of the individual's clinical presentation when interpreting ABI, TBI, ASTP, pulse oximetry and other investigation results and diagnosing presence of PAD. Do not base a diagnosis on a single investigation.
- Consider weaker or non-palpable pulses and/or an ABI > 1.4 mmHg (or ABI > 1.3 with diagnosis of diabetes mellitus or chronic kidney disease) as indicative of potential calcified/non-compressible blood vessels and conduct TBI and/or ASTP if it has not already been performed, or consider referral.^{197, 198, 200}
- Re-assess the individual's vascular status on a regular basis, when new signs and symptoms emerge, or if healing does not occur on the expected trajectory.

Education and training

- Follow local policies and procedures regarding who is responsible for performing physical examination and clinical investigations. In some jurisdictions, specialist qualifications are required to undertake a lower leg examination or to perform clinical investigations.
- Health professionals should receive appropriate training before performing physical examination, Doppler ultrasound and other investigations.^{198, 199} The assessor's clinical skills^{203, 219} and their interpretation of the results can influence the reliability of screening for PAD.^{197, 204} In different geographic settings, the qualifications and training required to undertake vascular investigations varies. It is important to practice within local guidelines on scope.
Summary of evidence supporting the good practice statement

Relevant vascular^{165, 198-202} and diabetes-related foot disease^{207, 208, 212, 216} guidelines and systematic reviews¹⁹⁷ suggest that individuals with lower leg wounds and a history that might indicate PAD should be screened.^{72, 165, 197, 198, 202} At a minimum, the recommended clinical investigations are pulse assessment, ABI and TBI.^{165, 198-202}

Vascular assessment is considered a very high priority by stakeholders¹⁴² and most clinical investigations are generally tolerable.¹⁶⁷ The range of clinical investigations that are routinely performed appears to be influenced by the geographic and clinical context, scope of practice for health professionals, access to appropriate equipment and the health professional's training.^{60, 197-199, 201, 203, 204} Implementation of the recommendations could focus on supporting appropriate education and training, clinical assessment, procedural competency, interpretation of results and making referrals with documented care pathways.

Pulse palpation and assessment

Palpation for presence or absence of pedal pulses at both the dorsalis pedis and posterior tibial sites (bilaterally) is an important first step in clinical examination. Presence, strength and characteristics of palpable pulses provides an indication of possible involvement of arterial disease (see *Table 6.2: Pulses*); however, the findings should not be considered conclusive, nor should they be considered in isolation.^{71, 205} Establishing the pulse presence and strongest location is required to perform point-of care clinical investigations (e.g., ABI and TBI). See the <u>Resources</u> for procedural instructions for evaluating pulses.

Ankle-brachial index and toe brachial index measurement

In addition to the pulse assessment, first line point-of-care clinical tests to screen for PAD should include ABI and/or a TBI.^{197-199, 201, 202, 207, 208, 212, 220} Ankle brachial index is a non-invasive test performed with handheld (continuous wave) Doppler ultrasound that is the more frequently used point-of-care clinical investigation used to screen for arterial aetiology. A TBI may provide a more accurate assessment for any individual but is required for people with calcified/non-compressible blood vessels. The goals of an ABI or TBI assessment are:

- To diagnose and monitor PAD, and
- To exclude individuals from compression therapy that may dangerously compromise an already insufficient arterial system.

Interpreting ankle-brachial index and toe brachial index results

Interpretation of the ABI result depends on which goal is being considered. First, this is because a clinical diagnosis of underlying arterial or mixed disease is made with consideration to the person's co-morbidities and presentation. Additionally, there is consensus that for some people it is safe to apply compression therapy even in the presence of mild PAD, particularly when using low pressure compression. For example, the European Society for Vascular Surgery guideline recommends that sustained compression therapy is only contra-indicated when ABI is less than 0.6, ankle pressure less than 60 mmHg or ASTP is less than 30mmHg while defining the diagnostic criteria for PAD as an ABI less than 0.8.¹⁶⁵

	General population	People with diabetes or kidney disease
Normal ABI value ^{72, 198, 200-202, 208, 221, 222}	0.9—1.4	0.9—1.3
ABI value indicative of some arterial disease ^{165, 198, 201, 208, 216, 221}	< 0.9	< 0.9
ABI requiring urgent review in presence of additional clinical signs and symptoms ^{72, 198, 200-202, 208, 221}	< 0.6	< 0.6
ABI indicative of calcified/non-compressible vessels ^{197, 199, 207, 208, 212, 216}	> 1.4	> 1. 3
Safe ABI values for applying compression therapy	Refer to	discussion

Table 6.3: Interpretation of Ankle Brachial Index (ABI)

Clinical guidelines indicate compression can be used with caution for people with an ABI from 0.5 to 0.8 in the absence of arterial signs and symptoms.^{71, 198, 223}

Therefore, there is some overlap in ABI results that are indicative of PAD and those in which compression therapy might be considered. As illustrated in *Figure 6.4*, increase in risk from compression therapy is a continuum that is associated with aetiology, with ABI serving as a surrogate evaluation of that risk.

Figure 6.4: Association between vascular aetiology and risk of applying compression therapy



When considering the aetiology of disease and the likelihood of a PAD diagnosis, the interpretation of ABI results presented in *Table 6.3* and *Figure 6.4* is consistent with international consensus.^{165, 198, 199, 201, 207, 208, 216, 221, 222}

Recent vascular^{165, 198, 201, 207} and diabetic foot disease^{199, 208, 216} guidelines identify that PAD is less likely to be diagnosed with an ABI in the range of 0.9 to 1.3 in people with diabetes mellitus or kidney disease, and 0.9 to 1.4 for people with no comorbidities or signs and symptoms. The Canadian Cardiovascular Society also selects an ABI of 0.9 as the diagnostic cut off for PAD, and an ABI measure of 1.4 as indicative of likely arterial calcification.²²¹

Box 6.5: Interpretation of toe brachial index (TBI)^{197, 198, 224} and absolute systolic toe pressure (ASTP)^{197, 224, 225}

TBI results

Normal value: TBI > 0.7

Borderline value: TBI 0.6-0.7

Abnormal value: TBI < 0.6

Mild arterial disease: 0.4-0.59

Moderate arterial disease: 0.2-0.39

Severe arterial disease: < 0.2

ASTP results

Normal value: > 95 mm Hg

Higher risk of arterial disease: < 70 mmHg

High risk of non-healing wound: < 30 mmHg

Reproducibility of ABI is varied, with many factors potentially influencing the result, and a single measure may be inadequate for diagnosis.^{23, 219, 226} The method used to perform ABI (e.g. cuff size and its placement), advancing age, diabetes and/or hypertension, an oedematous limb, very painful or extensive ulceration and environmental factors can all influence the accuracy of readings.^{23, 72, 198, 199, 201, 217, 226-230}

Additionally, handheld, continuous wave Doppler ultrasound has low reliability in detecting obstruction and reflux in the deep venous system and is very limited in its ability to provide information on venous morphology and pathophysiological changes.¹⁶⁵ In the context of these limitations, there is no definitive value at which arterial insufficiency is considered to be present,^{191, 228} and cut-off points are arbitrary.^{165, 228}

Thus, ABI measurements should not be considered in isolation when either diagnosing PAD, evaluating the person's suitability for compression therapy, or selecting candidates for surgical interventions,¹⁶⁵ particularly in the presence of diabetes.²¹⁶

Toe brachial index (TBI) appears to be more sensitive than ABI for screening for arterial disease, particularly for people with diabetes and/or kidney disease.^{217, 224, 229} Toe brachial index can produce more accurate results in the presence of extensive PAD, because calcification of the small vessels in the foot is less common than calcification in the major leg arteries.²¹⁷ However, like ABI results, the TBI is influenced by the test methods and equipment, co-morbidities and advancing age.²²⁵ Current guidance on interpretation suggests a value of TBI > 0.7 is considered normal,^{197, 198, 224} and could be considered a reasonable cut-off point for applying compression therapy.

Given the complexity of interpreting the results of a vascular assessment and the risk that can arise when using compression therapy in the presence of inadequate vascular perfusion, it is important that health professionals who undertake and interpret the above clinical investigations have appropriate recent education and training.^{198, 226} (See <u>Resources</u> for procedural instructions for ABI and TBI). Additionally, it is important to practice within local guidelines that define the scope of practice for different health professionals. Clinical decisions should be made by an interdisciplinary team, and referral should made to appropriate specialists to

pressure interpretation¹⁹⁸ Normal value: ≥ 40 mmHg Abnormal value: < 40 mmHg Mild arterial disease: 30-39 mmHg Mod arterial disease: 20-29 mmHg Severe arterial disease: < 20mmHg

Box 6.6: Transcutaneous oxygen

assist in diagnosis and development of a management plan (see Chapter 9: Referral).

Duplex ultrasound

The gold standard in diagnosing venous disease is <u>Duplex ultrasound</u>.⁷² Duplex ultrasound is a noninvasive diagnostic tool that comprehensively evaluates both the superficial and deep venous systems, including valve function, to enable immediate identification of venous reflux and/or obstruction.^{70, 165, 200, ²⁰⁵ Duplex ultrasound uses two modes of ultrasound wave (Doppler and B-mode) to map the anatomy and the flow of the blood though the vascular system. Duplex ultrasound provides information about the size of vessel walls; characteristics of the lumen, walls and valves; presence and characteristics of thrombus; and presence of collateral veins, thereby providing an overview of the vascular system. Duplex ultrasound also evaluates blood flow pattern, including direction, intensity and echogenicity (ability to reflect sound waves). These features contribute to an evaluation of disease severity and the acuity of reflux and thrombus.²³¹}

Duplex ultrasound has greater reliability than both <u>ankle brachial index</u> (ABI) and <u>toe brachial index</u> (TBI) and it is recommended as the investigation of choice to establish an accurate picture of vascular aetiology, anatomical location of pathology and the extent of disease.^{23, 70, 165, 200, 205, 232, 233}

However, Duplex ultrasound is not available in most standard wound care settings and requires specialist skills to perform. *Chapter 9: Referral*, discusses indicators for referral, including Duplex ultrasound to gather a clear understanding of the location and extent of venous disease, and to assess the individual as a candidate for procedural interventions or surgery.

Additional point-of-care clinical investigations

Additional investigations also assist diagnostic reasoning, in addition to pulse evaluation, ABI and TBI. <u>Absolute systolic toe pressure</u> (also called absolute toe pressure) is highly recommended, especially in individuals with non-compressible blood vessels, diabetes mellitus and/or renal disease.^{197, 198, 201, 207, 212, 216, 234} There is a lack of consensus on what are considered to be arbitrary cut-off points for diagnosing PAD. The results should be considered alongside other assessment results and the overall clinical picture^{197, 235}.

When available, <u>transcutaneous oxygen pressure</u> measured using a transcutaneous oximetry device can supplement these assessments by providing an indication of the supply and delivery of oxygen to the underlying vasculature.^{198, 201, 202} However, the value of transcutaneous oxygen pressure is limited in the presence of oedema or infection,²⁰¹ and the requirement to raise the skin temperature above 40°C to perform the test²⁰¹ reduces its utility in many clinical settings.

Evaluation of pedal arterial Doppler waveforms (dorsalis pedis or posterior tibial artery) are highly recommended, especially in individuals with non-compressible blood vessels, diabetes mellitus and/or renal disease.^{197, 198, 201, 207, 212, 216, 234} Accurately evaluating Doppler waveforms is an advanced skill.

Additional assessments of the lower leg

A comprehensive physical examination of the lower leg should include a skin assessment, neurosensory assessment, and consideration of oedema and functional mobility.

Skin and subcutaneous tissue changes commonly occur as a consequence of increased extracellular fluid associated with sustained venous hypertension in the small vessels.^{7, 11} The severity of skin changes that occur as a part of CVI appear to correlate with vascular morphological changes.¹⁶⁵ As valve incompetency increases and the veins become more tortuous, endothelial changes in the capillaries lead to increased fluid leakage and inflammatory processes. This results in oedema, chronic inflammation, fibrosis, pigmentation, and calcification, with a loss of normal skin integrity.^{10, 165, 178} Leg ulceration represents progression of these skin changes,¹⁶⁵ and can be exacerbated by chronic lymphatic overload (i.e.,

phlebolymphoedema),¹⁰ as well as other triggers including penetrating injury, dry and itching skin, and contact allergic dermatitis.⁷¹

7. It is good practice to include skin assessment and assessment of neurosensory status, oedema and functional mobility when performing a physical examination of the lower leg and foot.

Implementation considerations

- Ensure the room is well lit and clothing adequately removed to enable a close visual inspection of the skin.
- When assessing the skin, inspect the legs and feet (including between the toes) for signs and symptoms associated with and/or contributing to severity of CVI (see *Table 6.2: Lower limb examination findings*). Ask about the person's hygiene regimen, skin sensitivities/allergies and triggers for skin changes.
- To evaluate lower leg neurosensory status, screen for loss of sensation with 10 g/ 5.07 Semmes-Weinstein monofilament, evaluate vibratory sensation with a 128 Hz tuning fork and evaluate the Achilles tendon reflex with a reflex percussion hammer.^{9, 71}
- Assess limb oedema above and below the knee to differentiate possible causes (*Table 6.7*) and the
 extent of oedema.¹⁰ Oedema related primarily to CVI generally presents as soft and pitting. For
 individuals using compression therapy, assess oedema using calf and ankle measurements pre- and
 post-compression to evaluate treatment effectiveness.
- Assess impaired walking function and non-joint related limb pain to identify <u>intermittent</u> <u>claudication</u>.
- Assess calf muscle pump function and toe and ankle range of motion in a functional mobility assessment (see *Table 6.8*). Specialised equipment and clinical training are required for a more comprehensive calf muscle pump function assessment and may not be available in all settings.

Summary of evidence supporting the good practice statement

Clinical guidelines and standards^{9, 71, 72, 205} recommend inspecting the lower leg for skin changes associated with progressing CVI, and screening neurosensory status and functional mobility. Guidelines recommend that lymphoedema be closely evaluated to confirm venous symptomology and differentiate potential other causes.¹⁰

Comprehensive skin assessment focuses on skin changes of the legs and feet associated with CVI (See *Table 6.2: Lower limb examination findings*) and skin colour, tone and temperature.^{9, 71, 72, 205}

Assessment of oedema focuses on confirming symptomology arising from CVI rather than another comorbidity that requires further investigation and management. The assessment includes evaluation of the severity of phlebolymphoedema and monitoring progress over time to inform ongoing management choices. Components of a comprehensive assessment are in *Table 6.7*.

Presentation and history**		
Findings	Considerations	
 Timing/duration Changes associated with positioning Unilateral vs bilateral Associated pain/tenderness Medications 	 Acute oedema: consider DVT, cellulitis, recent trauma, ruptured Baker's (popliteal) cyst, or recent medication changes (e.g. calcium channel blockers) Chronic, generalised oedema: consider chronic conditions (e.g. cardiac failure, renal or hepatic disease) Unilateral presentation: consider local causes such as DVT, CVI, venous and/or lymphatic obstruction (e.g tumour) Bilateral: consider systemic causes (e.g., severe malnutrition, cardiac failure, pulmonary hypertension, thyroid, renal or hepatic disease) Bilateral dependent oedema: consider conditions that limit mobility (e.g. spina bifida, paraplegia) 	
Physical examination** Findings	Considerations	
 AFTD-pitting test Press firmly behind medial malleolus, bony portion of tibia and dorsum of foot and areas where oedema is accumulating 	 Pitting (indentation appears and persists): consider diet or medication related fluid retention, DVT, venous insufficiency, cardiac failure, renal or hepatic disease Non-pitting (no indentation forms, feels firm): consider lipoedema, lipodermatosclerosis, lymphoedema, angioedema, thyroid disorders Document AFTD: anatomical location, force required to pit, amount of time (usually 10 seconds), and definition/categorisation (clarity of the impression/pitting that remains after the time) 	
Stemmer sign Tent/pinch the skin over dorsum of second toe	 Positive sign (inability to pinch the skin): consider phlebolymphoedema/ lymphoedema 	
Appearance Inspect colour, texture, temperature and tenderness	 Skin warmth over oedema: consider acute DVT or cellulitis Tenderness: consider DVT or other causes Redness/shiny skin or active ulcer: consider CVI 	
Measurement [#]		
Commonly used methods	Considerations	
Circumference measurements Measures circumference of leg using anatomical landmarks (e.g. defined distances along the limb such as every 2–10cms)	 To assess and evaluate oedema, the individual should be lying. Low validity due to inability to distinguish muscle, bone, fat and fluid Low reliability due to difficulty in consistently using the same anatomical location for measurement 	
Volumetry Measures the amount of water that is displaced from a container when the limb is submerged	 Consider skin integrity and infection control, particularly with active VLU Low validity due to inability to distinguish muscle, bone, fat and fluid May not detect change in less severe oedema Difficult to perform in many clinical settings 	
Bioimpedance spectroscopy Measures ability of extracellular fluid to conduct low frequency electrical current indicating change in fluid volume **Presentation, history and examination	 Requires specialised equipment, individual-use electrodes and non-conductive bed/table/chair Reliability established for measuring body composition Limited access in many clinical settings 	

Table 6.7: Assessing oedema^{9, 10, 71, 72, 236-240}

considerations are indicative only and not intended to be a complete list of differential diagnoses.
Measurement is not required for diagnosis but may be used to fit for compression therapy and to evaluate treatment effectiveness.
For all measurement methods, compare values to previous measurements and/or to the other limb to measure change over time.

Assessment of the calf pump muscle function

Examination of the leg should include an evaluation of calf pump muscle function.⁷¹ The deep veins in the legs are surrounded by calf muscles — the gastrocnemius and the soleus muscles — that assists venous blood return. When the calf muscles are relaxed, blood pools in the lower limb veins. When the calf muscles contract, the pumping action (referred to as calf muscle pump function) compresses the veins and propels blood in the deep venous system back to the heart.²⁴¹⁻²⁴⁴ The volume of blood that is expelled from the lower leg with each calf muscle contraction is referred to as muscle pump ejection fraction.²⁴²

Table 6.8: function ass	Components of calf muscle pump sessment ²⁴⁵
Minimal assessment	 Mobility level including assistive devices Gait analysis (heel strike, foot flat, heel rise and toe off) Gait speed Presence of bony deformities on the lower limb/foot that may arise from or influence gait or calf muscle pump functioning Footwear (sizing, impact on gait pattern, wear pattern and any orthotics)
Advanced assessment	 Muscle strength using a dynamometer (ankle, knee and hip) Range of motion using a goniometer (first toe and ankle)

The calf muscle pump function is optimised during heel-to-toe walking; that is, a stride consisting of a heel strike that precedes the toe being placed on the ground. Walking with a heel-to-toe motion maximises dorsiflexion of the foot, which promotes emptying of the distal calf pump before weight bearing occurs in the stride. Plantar flexion that occurs with toe placement allows the proximal calf pump to empty.²⁴⁶ Additional venous pump functions that occur within the foot also contribute to venous return.²⁴⁴ These processes are most efficient when the ankle has a sufficient range of motion and the calf muscles have sufficient strength.^{247, 248}

When any of the functions described above are altered, venous blood flow is reduced and the risk of developing venous hypertension increases. Objective measurement (e.g. ultrasound) demonstrates decreased efficiency of the

calf muscle pump function in up to half of people with CVI and venous ulceration.^{242, 246, 247} Ankle range of motion is often lower in people with venous symptoms that impede motion such as oedema, lipodermatosclerosis and neuropathy. This can contribute to reduced functional mobility, further complicating pathology.

Assessment of the calf pump muscle function includes the components listed in *Table 6.8*, noting that conducting an advanced assessment requires specialist equipment. Calf muscle pump function assessment should be performed by a health professional with expertise in this field. Aspects of the calf muscle pump function assessment also provide insight into the individual's general functioning, ability to engage in activities of daily living (ADLs), and lifestyle changes that may arise as a result of CVI.

Classifying and monitoring severity of venous disease

The 2020 CEAP classification (see <u>Resources</u>) is an international consensus method used to classify venous disease; noting it is not recommended to monitor symptom severity or progression. The CEAP classification incorporates clinical (C), aetiological (E), anatomical (A) and pathophysiology (P) categorisation of venous disease. The clinical scale, which is used most often in clinical practice, consists of seven main classifications from CO—C6 (with additional subcategories) that describe the clinical presentation at a specific point in time.¹⁹⁸ The CEAP C scale also includes subscripts to indicate whether

the person is currently symptomatic or otherwise, considered a fundamentally distinction to make when classifying CVI.²⁴⁹ Stages CEAP CO—C2 are considered mild disease while stages C3—C6 are indicative of advanced disease.²⁴⁹ Note that classification on the A and P scales requires Duplex ultrasound.

8. It is good practice to assess, classify and monitor venous signs and symptoms. Venous signs and symptoms should be described and classified using Clinical severity aEtiology, Anatomy, Pathophysiology (CEAP). Consider using venous disease severity tools/scales to assess and monitor venous signs and symptoms.

Implementation considerations

- Use Clinical-aEtiological-Anatomical-Pathophysiological (CEAP) classification (see <u>Resources</u>) to describe and document the presentation of venous disease, noting whether the individual is symptomatic or asymptomatic.^{71, 72, 165, 178}
- Consider using other venous disease severity tools/scales (see *Table 6.9*) to assess and monitor severity of disease over time and/or to monitor response to management.^{54, 165, 249} Use the same venous disease severity tool/scale each time an assessment is conducted, or document why the tool/scale was changed.
- Individuals with mixed aetiology leg ulcers generally require more frequent assessment of the severity of arterial disease.

Summary of evidence supporting the good practice statement

Clinical guidelines^{71, 72, 165, 178} recommend the most widely used tool, CEAP classification, to describe and classify the individual's venous disease. A range of venous disease severity scales/tools are available, and a wide body of primary research²⁵⁰⁻²⁵⁸ reports their reliability and validity for various sub-populations. There is no consensus on the most appropriate severity tool to use.²⁴⁹

Evidence suggests that the objective features described on the CEAP clinical scale reflect both pathophysiology and the subjective experience of signs and symptoms. People classified as CEAP C3 to CEAP C6 based on objective signs are more likely to report pain, swelling, burning sensations, night cramps and itching than individuals classified as CEAP 0 to CEAP 2,²⁵⁹ Significant relationships have also been established between vascular disease risk factors (higher BMI, older age and family history) and CEAP classification above C3.²⁵⁹ Classification on the CEAP scale has also been demonstrated to correlate well with on duplex ultrasound findings, CEAP C4 to CEAP C6 associated with saphenofemoral junction reflux of the saphenous vein and CEAP C3 or lower associated with competent saphenofemoral junction. This suggested that the more severe symptoms observed in people classified as CEAP C4 to CEAP C6 relate to underlying venous system pathology.²⁶⁰

Assessing severity of venous signs and symptoms

Structured venous assessment tools or scales are designed to facilitate a comprehensive evaluation. Scales and tools that has been tested for reliability and accuracy are available to evaluate severity of venous disease and to identify clinical problems that need to be addressed in the holistic management plan. The tools are sometimes used to monitor progression of disease and the impact of symptoms on the person over time. Commonly reported tools are in *Table 6.9*.

	Venous disease severity tool description	Tool use
Venous Severity Scoring system (VSS)	• Comprises the following scales, each reported below: Venous Clinical Severity Score (VCSS), Venous Segmental Disease Score (VSDS) and Venous Disability Score (VDS).	 Supplements the CEAP scale in evaluating severity of CVI Scales used independently or as a comprehensive system
Venous Clinical Severity Score (VCSS)	 Broad quantifies severity of CVI Rates ten clinical symptoms on a 4-point scale (0 to 3) to give an overall score (maximum 30). Symptoms include pain, varicose veins, venous oedema, skin pigmentation, inflammation, induration, number of active ulcers, active ulcer size, active ulcer duration and compression therapy 	 Used to evaluate disease progression Used to evaluate disease impact
Venous Disability Score (VDS)	 Unidimensional scale describing function level from (score 0 to 3; asymptomatic to unable to carry out usual activity). 	 Measures functional impact of CVI
Venous Segmental Disease Score (VSDS)	 Evaluates anatomical location of disease and disease features (i.e. reflux and/or obstruction) Reflux and obstruction are scored on 10-point scales, with an overall maximum score of 20. 	 Requires duplex ultrasound to assess the vascular system Appropriate for use by a sonographer or vascular specialist.
Villalta-Prandoni Scale (Villalta Scale)	 Rates 11 clinical symptoms on a 4-point severity scale (0 to 3) to give an overall score (maximum 30). The scale includes: pain, cramping, pruritus, paraesthesia, heaviness, oedema, redness, induration, venous ectasia, calf tenderness and hyperpigmentation. Categorises disease as mild (score 5–9), moderate (10–14) or severe (>14). 	 Used to classify PTS (secondary venous disease)

Table 6.9: Venous disease severity scales

6. Pain Assessment

Individuals with venous leg ulceration (VLUs) frequently experience pain that can negatively impact their lives, often for the long term. However, wound-related pain is often inadequately assessed, contributing to its inadequate prevention and management. This chapter discusses the experience of venous disease related pain and strategies for its assessment.

Clinical questions

- What is the pain experience of people who have a VLU?
- How should pain be assessed in people with or at risk of VLUs?

The experience of venous leg ulcer pain

Between 57% and 80% of individuals with a VLU experience wound-related pain.^{263, 264} Pain associated with leg ulceration is often moderate to severe in intensity, may exhibit characteristics of nociceptive and/or neuropathic pain,^{263, 265} and is frequently continuously present from the time the ulcer develops, often becoming chronic.^{140, 266} Regardless, the aetiology of pain and the person's experience is often not assessed.²⁶⁶

Research suggests there is no age or gender differences with respect to individuals who do or do not experience VLU pain.^{264, 267} However, people who experience VLU pain are more likely to have a long standing ulcer and/or a larger ulcer.²⁶⁷ They are also more likely to be taking antibiotics, which might reflect pain associated with infection.²⁶⁷ Although it is well-established that treatments for both chronic venous insufficiency (CVI) and VLUs may exacerbate pain, there appears to be no difference in the pain experience based on frequency of wound dressing changes or the use of compression therapy.^{264, 267}

The impact of pain on people who experience painful ulcers is substantial. Chronic pain is associated with low morale, lower self-esteem, depression and social withdrawal.^{265, 268} Pain is also closely related to decreased health related quality of life (HRQOL), and sleep disturbance.^{96, 263, 265} Pain can impede a person's ability to engage in self-care and to function normally in social, family/whānau and work roles.²⁶⁸ Wound-related pain is associated with anxiety and stress, which can influence the immune system and ability of the wound to heal.^{265, 268} Experiencing pain may decrease attendance at wound care appointments, and reduce concordance with disease and wound management strategies, including exercise and compression therapy. This can lead to poor outcomes, including increased healing time.



The pain experience for Indigenous populations

Cultural diversity influences the way a person perceives and experiences their pain, as well as the way they interact with the interdisciplinary team to report, describe and manage pain.²⁶⁹ As with people from other cultural backgrounds, Aboriginal and Torres Strait Islander people have wide experiences, beliefs and practices associated with pain. These vary from beliefs consistent with a biomedical model, to traditional beliefs in which pain is viewed as being a result of violating taboos or Aboriginal laws.²⁷⁰ It is not unusual for people from Aboriginal and Torres Strait Islander backgrounds to be reluctant to report pain or to feel the health professional is untrustworthy or does not listen.²⁷⁰ Believing that pain arises from breaking taboos or Aboriginal laws, having a cultural preference for bravery, a cultural preference for silence in response to pain, and a lack of trust in the Western health system are experiences and beliefs that might influence pain reporting.²⁷⁰ However, many Aboriginal and Torres Strait Islander people interpret, report and exhibit pain in the same way as other Australian people from other backgrounds.²⁷⁰ The experience is highly personal, variable according to gender and regional background and there should be no preconceived ideas regarding culturally specific notions of pain. Similarly, pain is a multidimensional experience for Māori and there is no universal cultural expression of pain. Some research has shown that Māori are more likely to experience pain than non-Māori people.²⁷¹ Other research suggests that Māori may use pain descriptors that convey the distressing impact of pain on their overall life and wellbeing, reflecting the multidimensional traditional Māori model of health.²⁶⁹

Barriers to assessing pain might include language and communication barriers, unsatisfying history of engagement with health professionals, and inability to articulate the pain experience. This highlights the importance of communication, establishing trust and using pain assessment descriptions, tools and frequencies that are consistent with the individual's beliefs and expectations.^{269, 270}

It is essential to conduct an initial pain assessment, and to frequently reassess pain using a range of assessment strategies. Information collected during a pain assessment should identify the presence of pain, and measure its type, quality and intensity. This information informs the development of an appropriate pain management plan.

9. It is good clinical practice to assess and document lower limb pain as a part of a comprehensive assessment of a person with venous disease and to assess and document wound-related pain when the individual has an active venous leg ulcer.

Implementation considerations

- Use multiple strategies to assess pain including talking to the person, observing their body language, facial expressions, and nonverbal cues (e.g. changes in interaction, activity and routines) and using an appropriate pain assessment tool.^{127, 266, 272}
- Select a pain assessment method in partnership with the person. Discuss the frequency with which assessment might be undertaken and the purpose for the assessment.^{270, 273}
- Consider the person's cultural background when evaluating pain. People from different cultural backgrounds express pain in varying different facial expressions, body language and words.²⁶⁹ No pain scale is universally relevant.
- Consider the individual's cognitive ability and communication skills when selecting a pain assessment method. Consider involving the person's family/whānau when assessing pain, particularly for people with factors that influence ability to verbally communicate pain.
- Consider the person's comorbidities and disease processes that might be associated with pain. Peripheral neuropathy, arterial disease, degenerative spinal conditions and other musculoskeletal conditions also cause pain and should be considered when conducting a full pain assessment.
- When documenting the pain assessment, use the descriptors that the individual uses to describe their pain.
- Completing a pain diary can help both the individual and wound clinician to more fully understand pain events, triggers, patterns and strategies that are helpful in managing the person's lower limb and/or wound-related pain.
- Document the person's analgesic regimen (e.g., type, frequency, route, etc.) and response.

Implementation considerations for people at risk of a VLU

- Include the following in a lower limb pain assessment: location, timing, pain characteristics (e.g., variability; stinging, throbbing, cramping, and/or sharp/shooting; leg heaviness and achiness), intensity, duration, factors or triggers that increase or relieve the pain (e.g., leg elevation) and the impact on health related quality of life and functional ability.^{9, 166}
- In consultation with the person, assess and document their pain experience at every consultation, including with and without compression therapy.^{266, 272}

Implementation considerations for people with an active VLU

- Include the following in a pain assessment: location, characteristics, intensity, duration, factors or triggers that increase the pain, factors that relieve the pain, change in pain over time, and the impact on health related quality of life.^{9, 274}
- In consultation with the person, assess and document their pain experience at every consultation and before, during and after wound procedures.^{266, 272}

Summary of evidence supporting the good practice statement

Assessing VLU-related pain is considered a priority topic by people with VLUs and their formal and informal carers.¹⁴² Standards of practice, consensus guidelines and best practice statements suggest that pain assessment should be conducted in people at risk of a VLU,^{9, 71, 166} as well as those with an active VLU.^{9, 165, 270, 274} However, research also indicates that pain is a personal experience and gender, culture and history influence expression of pain and preferences regarding the way it is assessed.²⁷⁰ A pain assessment in people with CVI plays a role in identifying if there is adequate blood flow to the limb and differentiation between venous and arterial aetiology. Assessing the pain characteristics and timing and factors that exacerbate or relieve lower limb pain can inform this assessment. A lower limb pain assessment can also indicate the severity of venous disease.^{275, 276}

The most reliable indicator of pain is the individual's self-report, regardless of the cognitive status of the individual.²⁷⁷ A self-report of pain presence includes deliberate non-verbal communication, for example pointing to an area or nodding in response to a yes/no question.²⁷⁸ When an individual is unable to communicate, observational tools can be used to assess pain.



Culturally safe pain assessment enables Aboriginal and Torres Strait Islander people, Māori and Pacific Islander people to express their unique personal experience in a trusted environment, and to have that experience accurately interpreted by the health professional.^{270, 273 185}

For people with CVI, lower limb pain assessment can assist in differentiation of vascular disease in symptomatic people.^{166, 279} Pain characteristics indicative of venous disease and arterial disease are summarised in *Table 7.1*.

	Claudication from venous outflow obstruction ^{**}	Arterial, ischaemic claudication ^{**}
Intensity	 Pain varying from absent to extreme 	 Pain varying from absent to extreme
Pain characteristics	 Most commonly: dull aching, heaviness and discomfort Other: stinging, itching, tightness, cramps, restless legs 	 Most commonly: cramping, aching, fatigue, and weakening Other: throbbing, restless legs
Location	Affected limb	 Buttock, thigh, or calf muscles (depending on location of blockage) Localised in toes and distal foot
Timing	 May occur with exercise due to increased pressure on calf muscles and veins May occur at the end of the day with leg swelling 	 Occurs with exercise and relieved by rest Exertional (but non- joint-related) If experienced at rest, indicates more severe disease
Contributing and relieving factors	 May be relieved with leg elevation Increases when limb is in dependent position May decrease with compression therapy 	 Increases with lying down or leg elevation Decreases when lowering the leg or dangling it over the bed

Table 7.1: Pain characteristics indicative of lower limbvenous disease versus arterial disease166, 279, 280

** Concomitant neuropathy may mask pain symptoms

For people with an active VLU, woundrelated pain assessments should be conducted before, during and after wound dressing changes and <u>debridement</u> procedures, as well as when the wound dressing is intact and no procedures are in progress. Venous leg ulcer pain that increases and worsens over time can be an indicator of wound infection (See Assessment of the Venous Leg Ulcer).

For people with or at risk of VLU, pain should be assessed with and without the presence of compression therapy, and compression removed if its use is associated with increased pain.

The assessment of wound-related pain should be comprehensive and include both objective and subjective information. An initial assessment should include:

- a detailed pain history noting the quality, intensity, timing, frequency and duration of pain;
- a physical examination that includes a neurological component; and
- a psychosocial assessment.

Pain assessment tools

A large range of pain assessment tools (see *Table 7.2*) that incorporate various scales have been tested for their reliability and validity in assessing pain. Unidimensional scales assess one aspect of pain (e.g. intensity), while a multi-dimensional pain assessment tool incorporates an evaluation of different characteristics of the pain and its impact on the individual.²⁸¹

10. It is good clinical practice to use a pain assessment tool that has been tested for validity and reliability.

Implementation considerations

- Select a person-appropriate pain assessment tool. Consider the person's cognitive ability, comprehension, language, culture, education level and any personal preference of tool.^{9, 274}
- Use the same tool to assess pain consistently over time. However, if the person's circumstances change (e.g., stroke or cognitive decline) using a different assessment tool might be appropriate.

Summary of evidence supporting the good practice statement

The research indicates that assessing using a pain assessment tool that has been tested for reliability and validity is feasible and acceptable. There was evidence indicating that pain assessment is routinely conducted by most wound professionals.^{266, 272} There is no high level evidence reporting reliability or validity of tools used to assess wound-related pain specifically in people with VLUs. However, many generic pain tools are appropriate for assessing wound pain, and have been psychometrically tested in languages other than English²⁸² and in different cultural groups.

Venous-associated leg pain measured on either a Visual Analogue Scale (VAS) or a Numeric Rating Scale (NRS) could be used to monitor disease severity. ^{275, 276} The NRS score is related to disease classification on the CEAP scale, with higher pain levels experienced by people with more severe CVI.²⁷⁵ The VAS score is related to venous refilling time, with higher pain levels associated with shorter venous refill time that would indicate greater venous stasis.²⁷⁶

Reviews^{272, 282, 283} for related populations suggest a range of different pain assessment tools could be used to assess VLU-related pain, as summarised in *Table 7.2*.

Table 7.2: Summary of suggested tools to assess pain** 272, 282-285

	ΤοοΙ	Tool description	Use this tool for
SESSMENT	Numeric Rating Scale (NRS) <u>Available online</u>	 Unidimensional tool, self-report tool Includes a 0-10 (11 point) scale from which person selects a number most representing their pain intensity 	 Assessing intensity of pain Monitoring the severity and progression of CVI
GENERIC PAIN AS TOOLS	Verbal Descriptor Scale/ Verbal Rating Scale (VDS/VRS) • <u>Available online</u> • <u>Available online as</u> <u>thermometer</u>	 Multidimensional tool, self-report tool Includes 4 or 5 points based on verbal/language descriptors (e.g., none, mild pain, moderate pain, etc.) from which the person selects the most accurate description of their pain intensity 	 Assessing intensity of pain Assessing the quality of pain

**n.b. these tools have not been tested for reliability and validity for assessing pain in people with VLUs

	McGill's Pain Questionnaire (MPQ) • <u>Available online in an article</u> • <u>Available as an online</u> <u>calculator</u>	 Multidimensional tool, self-report tool Includes pain intensity that is measured on a 100mm VAS Includes assessment of present pain intensity, 6 number-word combinations and 15 pain words (in sensory and affective groups), all measured using a 4 point intensity scale 	 Assessing intensity of pain Assessing the quality of pain
	Visual Analogue Scale (VAS) <u>Available online</u> (needs to be printed to correct scale)	 Unidimensional tool, self-report tool Includes a 100mm line on which the person marks their pain level Pain intensity is measured using a ruler 	 Assessing intensity of pain Could be used to track change in pain intensity over time (based on moderate quality evidence) Monitoring the severity and progression of CVI Monitoring response to treatment
	Douleur Neuropathique 4 Questions (DN4) <u>Available online</u>	 Self-report tool Includes 7 items related to pain characteristics Includes 3 items related to physical evaluation, but could be performed by the person 	 Could be used to differentiate neuropathic pain Assessing characteristics of neuropathic pain
ATHIC PAIN	Short version Neuropathic Pain Questionnaire (NPQ-SF)	 Self-report tool Includes three descriptors (tingling pain, numbness and increased pain on touch) 	 Could be used to differentiate neuropathic pain Assessing characteristics of neuropathic pain
ESSING NEURO	Leeds Assessment of Neuropathic Symptoms and Signs Pain Scale (S-LANSS) <u>Available online</u>	 Self-report tool with 7 questions related to the characteristics of pain Evaluates dysesthesia, allodynia, paroxysmal pain, autonomic changes and burning sensation at painful site 	 Could be used to differentiate neuropathic pain Assessing characteristics of neuropathic pain
TOOLS FOR AS	Pain Detect Questionnaire (PDQ) <u>Available online</u>	 Self-report tool Includes current pain intensity, recent pain intensity and peak pain intensity Visual diagram of pain course and location Includes 7 questions on pain characteristics 	 Could be used to differentiate neuropathic pain Assessing characteristics of neuropathic pain
	ID-Pain <u>Available online</u>	 Self-report tool Includes pain location diagram Includes 6 questions about the characteristics and location of pain 	 Could be used to differentiate neuropathic pain Assessing characteristics of neuropathic pain

	Checklist for Non-Verbal Pain Indicators (CNPI) • <u>Available online</u> • <u>Tips for observing pain</u> <u>behaviours</u>	 Observational assessment tool Person to be observed resting and moving Includes 6 behaviour-based questions 	Screening for pain in cognitively impaired person or someone with difficulty communicating
E WITH DEMENTIA	Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC/ PACSLAC-2) • <u>Available online</u> • <u>Instruction manual</u> <u>available online</u>	 Observational assessment tool Prior knowledge of person's function is advantageous Includes facial expressions (11 items), verbalisations (5 items), body movement (11 items), change in interaction (2 items), change in activity (1 item) and mental state (1 item) 	Screening for pain in cognitively impaired person or someone with difficulty communicating
1ENT TOOLS FOR PEOPLI	 Doloplus-2 Scale <u>Available online</u> <u>Tips for observing pain</u> <u>behaviours</u> 	 Observational assessment tool Requires understanding of person's usual functional ability Some items may require longer observation Includes somatic reaction (5 items), psychomotor reactions (2 items) and psychosocial reactions (3 items) 	 Screening for presence of pain in cognitively impaired person or someone with difficulty communicating
PAIN ASSESSIV	Algoplus [®] Scale • <u>Available online</u> • <u>Tips for observing pain</u> <u>behaviours</u>	 Observational assessment tool Includes 5 behaviour-based questions 	 Screening for presence of pain in cognitively impaired person or someone with difficulty communicating Suggested for use during procedures
	Abbey Pain Scale • <u>Available online</u>	 Observational pain scale Includes six items: vocalization, facial expressions, change in body language, behavioural change, physiological change and physical change 	 Diagnosing pain in person with severe dementia or someone with difficulty communicating

7. Assessment of the venous leg ulcer

Initial and ongoing comprehensive assessment of a venous leg ulcer (VLU) is undertaken to inform the development of a wound management plan, and to monitor the progress towards healing. This chapter discusses the components that should be included when assessing a VLU, including the peri-wound skin.

Clinical questions

What should be included in an assessment of a VLU?

Components of the wound assessment

A comprehensive assessment of a VLU assists in developing the most appropriate management plan and ongoing monitoring of wound healing.

- 11. It is good clinical practice to conduct and document a comprehensive initial wound assessment and a re-assessment at each wound procedure. Assessment includes (but is not limited to):
 - wound history,
 - wound healing (phases),
 - wound measurements,
 - wound bed,
 - wound edge,
 - peri-wound skin,
 - exudate, and
 - signs and symptoms of infection.

Implementation considerations

- Consider using a wound assessment framework (e.g. TIME) to guide the wound assessment and clinical decision making.²⁸⁶⁻²⁸⁸
- Use a consistent method to measure the wound size to enable comparison over time to more accurately evaluate the progress towards healing.⁹ *Table 8.1* includes techniques for measuring the VLU size.
- Replicate the individual's position and the equipment (e.g. digital photography settings) as closely as possible when re-measuring the VLU to increase the accuracy of comparisons.⁹
- All wound measurements should be documented.⁹ The documentation system, which could include a psychometrically tested wound assessment tool^{9, 289} (see *Table 8.2*), should allow comparison of VLU characteristics over time to evaluate progress.
- Where possible, include digital photography in the wound assessment. Include both an anatomical locating photo and a close-up photo with a calibrated measurement. Complete training in using digital photography equipment and follow local guidance on consent, privacy and data storage.²⁷⁴

- Document a decision regarding whether the wound condition has improved, deteriorated or stayed the same since the last assessment.⁹
- Assess the peri-wound skin and surrounding skin as a part of the wound assessment. The peri-wound and surrounding skin can provide indicators the overall condition of the VLU and symptoms that might require management.
- Have a high degree of suspicion of local wound infection based on clinical signs and symptoms (see *Table 8.1*) that suggest the possibility of wound infection.
- Venous leg ulcers should not be routinely swabbed because bacteria will always be present. Semiquantitative wound swabbing and microbiology can be used to confirm presence, quantity and species of microbes in a wound when guidance is required on selection of antibiotic therapy.²⁹⁰

Summary of evidence supporting the good practice statement

Clinical guidelines, consensus documents and standards^{274, 290} identified that a comprehensive wound assessment should always be conducted at every wound procedure, documenting the domains listed in this good practice statement. A comprehensive review and consensus process developed a minimum data set for reporting wound assessment,²⁹¹ and included the elements in *Table 8.1*. A scoping review²⁸⁹ identified 14 wound assessment tools used to document assessment of wounds and identified those with adequate construct validity and responsiveness to change.

Wound assessment frameworks

Consider using a structured framework to conceptualise wound assessment and management. Wound assessment frameworks link the direct barriers to wound healing to the assessment process to guide clinical reasoning. Some more commonly used examples include:

- MEASURE: based around basic wound parameters, this framework is developed to encourage standardised and consistent appropach to assessment using sevent domains: Measure (length, width, depth, and area), Exudate (quantity and quality), Appearance (wound bed, including tissue type and amount), Suffering (pain), Undermining, Reevaluate, and Edge (condition of wound edge and surrounding skin).²⁹²
- **TIME:** based around the concepts of Tissue (non-viable or deficit), Infection/inflammation, Moisture Imbalance and Edge of the wound.²⁸⁷ This framework is one of the most popular, and has been used for almost 20 years to conceptualise wound assessment. Its more recent revisions incorporate a holistic approach (TIMERS) to wound assessment, or include a pathway for management (TIME-CDST).
- TIMERS: an update to TIME, based around the concepts of Tisusse (non-viable or deficit), Infection/inflammation, Moisure Imbalance and Edge of the wound, Regeneration and Social factors.²⁸⁶
- TIME Clinical Decision Support Tool (CDST): also referred to as TIME-ABCDE, based around the concepts of Tisusse (non-viable or deficit), Infection/inflammation, Moisure Imbalance and Edge of the wound, Assess, Bring the multidisciplinary team, Control/treat, Decide and Evaluate.²⁸⁸
- Triangle of Wound Assessment: Based around a study that explored patient and wound professional
 perspectives on the impact of wounds, this model describes three axes of wound healing" the wound
 bed, the edge of the wound and the peri-wound skin.^{293, 294}

Assessment of peri-wound skin and surrounding skin

At every wound procedure the condition of the peri-wound skin should be evaluated for common clinical conditions, as listed in *Table 8.1: Peri-wound skin*. The peri-wound area comprises the area immediately adjacent to the <u>wound edge</u>, extending out 4cm and including any skin that is covered by the wound dressing.^{292, 294, 295} Beyond the peri-wound tissue is referred to as surrounding skin. The surrounding skin should also be assessed at each wound procedure for indications of pathology that might require management.⁹

Parameter	Considerations in assessment		
Wound healing	• Healing phase classified as: haemostasis, inflammation, reconstruction,		
	maturation/remodelling		
	Classify as improved, deteriorated, or stayed the same		
Wound	• Wound area calculated from tracing of the wound margins or computerised calculation		
measurement	(planimetry)		
	• Length, width and depth measured at the longest, widest and deepest locations of the		
	relevant technologies		
	 Consider measuring wound volume using sterile fluid or filler inserted into the VLU 		
Wound bed	 Classify wound bed tissue as non-granulation, granulation, hypergranulation. 		
	epithelialisation, slough, necrosis/ eschar, exposed bone or tendon, foreign body, unable		
	to be visualised, consider inflammation/infection		
	 May require probing to identify structures (e.g. tendon or bone) 		
Wound edges	Use a sterile probe to identify undermined edges or sinus tracking		
	 Commonly classfied as level, raised, rolled, undermined 		
	Consider maceration and dehydration		
Peri-wound skin	• Consider: colour (e.g. erythema, pallor), temperature, oedema, induration, maceration		
	and/or excoriation, desiccation, dermatitis/eczema, callus or hyperkeratosis.		
Exudate	• Type and colour classified as: serous, haemoserous/serosanguineous, sanguineous,		
	seropurulent, purulent		
	Viscosity classified as: thick or thin Amount		
	Anount Odour		
Signs and	Odour Consider early signs of local wound infections increased (shanged service evulate)		
symptoms of	delayed/stalled healing discolouration of granulation tissue pocketing malodour and		
infection	friable granulation tissue		
	 Consider signs of local wound infection: localised inflammation and oedema, new or 		
	increased pain, increased exudate, purulence, heat		
	• Consider systemic signs of infection: pyrexia, chills, rigours, hypotension, and multiple		
	organ failure		
Digital	Take photographs after wound cleansing and debridement		
photography	Take a wide photograph to indicate the anatomical location clearly		
	 Take a close up that includes a calibrated measure in the photograph 		
	 Check that photos are clear before completing the wound assessment 		

The peri-wound tissue and skin can provide an indication of the overall condition of the VLU (e.g. erythema, warmth and swelling indicates potential presence of local or spreading infection) and can indicate factors that may influence the ability of the VLU to heal (e.g. adequate perfusion).^{294, 295}

The peri-wound and surrounding skin can be affected by moisture (e.g. maceration and excoriation) or may have dryness, hyperkeratosis, callus or eczema.^{294, 295} Contact dermatitis and skin trauma associated with wound dressings and adhesives are commonly observed in surrounding skin of people with a VLU. Assessment criteria for the surrounding skin is discussed in *Chapter 6: Lower Leg Assessment* and detailed in *Table 6.2*.

Wound infection

All hard-to-heal wounds such as VLUs are contaminated with bacteria, but this does not mean they are all clinically infected. Wound infection occurs when there is replication of one or more microorganisms in a wound at a level that provokes a series of local (in the wound) and systemic responses that cause tissue damage, impair the normal process of healing and delay complete wound healing.²⁹⁸⁻³⁰¹ Whether a wound becomes infected is directly related to the body's ability to resist infection and the number and virulence of the microorganisms to which it is exposed.²⁹⁰ Biofilm, which is a particularly tenacious form of infection, frequently occur in wounds and cause chronic inflammation and delaying wound healing.^{290, 302-307} These concepts are illustrated in the International Wound Infection Institute's Wound Infection Continuum (IWII-WIC)²⁹⁰ (see *Figure 8.4*).

Assessment Tool	Psychometric testing	
 Bates-Jensen Wound Assessment Tool (BWAT) 	 Tested in pressure injuries Inadequate research on construct validity and responsiveness to change Available online 	
 Pressure Ulcer Scale for Healing (PUSH) v2. Revised: Pressure Ulcer Scale for Healing (PUSH) v3 	 Tested in many types of wound, including VLUs Adequate construct validity and responsiveness to change <u>Available online</u> 	
 DESIGN-tool Revised : DESIGN-R tool 	 Tested in pressure injuries Adequate construct validity and responsiveness to change Available online Manual available online 	
 Photographic Wound Assessment Tool (PWAT) Revised: Photographic Wound Assessment Tool (revPWAT) 	 Tested in pressure injuries, vascular ulcers and general wounds Adequate construct validity and responsiveness to change <u>Available online</u> 	

Table 8.2: Wound assessment tools to assess VLUs308

Wound infection is associated with new or increasing wound pain, decreased healthrelated quality of life (HRQOL),¹⁰⁸ and time taken for a VLU to heal.³⁰⁹ The signs and symptoms of wound infection, including increased wound exudate, malodour, swelling and erythema are often difficult for people to manage, leading to loss of time from work, social activities and family/whānau roles.^{96, 99, 100, 111, 310} These issues can also lead to maceration and break down of the peri-wound and surrounding skin, and other skin conditions including pruritus and dermatitis, and further contributing to pain and delayed healing.³⁰⁹

Wound infection assessment

In VLUs, signs of infection and presence of biofilm may not be quite so obvious. Be aware of subtle or covert signs of infection that are early indicators that the wound is clinically infected and may contain biofilm.²⁹⁰ Note that biofilms themselves cannot be visualised by the naked eye but their presence can be suspected based on the wound history and characteristics of the wound, including presence of covert signs of local wound infection.²⁹⁰

Cov	vert signs and symptoms ^{290, 311-314}	Overt signs and symptoms ^{290, 314-317}
•	Hypergranulation	Erythema
•	Bleeding, friable granulation tissue	Local warmth
•	Epithelial bridging and pocketing	Local swelling
•	Increased exudate	 Purulent discharge
•	Delayed/stalled healing	 Wound breakdown and enlargement
		 New or increasing pain
		 Increasing malodour

Table 8.3: Local signs and symptoms of wound infection

Figure 8.4: International Wound Infection Institute's Wound Infection Continuum²⁹⁰

(reproduced with permission)



Investigations to support a diagnosis of wound infection

For the most part, diagnosis of wound infection is based on the visual identification of clinical signs and symptoms of local wound infection (see *Figure 8.4*). Some advanced point-of-care techniques could be used to assist in assessing signs and symptoms of infection.⁹ For example, thermography can detect changes in the wound bed and peri-wound temperature. Fluorescence scanning is another advanced technology that can identify bacteria in a wound based on its properties under light spectrums.

Microbiology assists in the identification of wound infection.⁹ Because wounds are generally contaminated with bacteria, the decision to collect a wound specimen for culture should only be undertaken when there are obvious signs of spreading and/or systemic infection, or in the presence of local signs of wound infection where guidance on antimicrobial/antibiotic therapy is required.³¹⁸ The three

most commonly used methods of culturing a wound are wound swabbing, needle aspiration and tissue biopsy.²⁹⁹ Tissue biopsy is not used routinely because it is painful, invasive, expensive, and requires trained health professionals to perform the procedure.²⁹⁹ However, it is considered the gold standard.

A wound swab is a universally accepted method of obtaining a <u>wound culture</u>. There is general consensus that the Levine technique should be used to take a wound swab.³¹⁹⁻³²¹ Local procedure manuals should be followed. In brief, there are key components to obtain the best results. Semi-quantitative analysis using the Levine technique requires cleansing the wound bed with normal saline before collecting the sample. The specimen is obtained from a limited area within the wound, excluding the wound edge or peri-wound skin. Two sterile cotton-tipped swabs are used. The swabs are pre- moistened with sterile 0.9% normal saline and then rotated over a 1cm² area of the wound bed with sufficient pressure to express fluid within the wound.³¹⁹⁻³²¹ The number of swabs required is driven by local policies and procedures.

Biochemical analysis (e.g. white blood cell count, erythrocyte sedimentation rate and C-reactive protein) may also be used to support a diagnosis of wound infection.⁹

Clinical Signs and Symptoms Checklist ³¹¹ <u>Published in online</u> <u>article</u>	Sensitivity, specificity, positive and negative predictive values of the individual signs and symptoms are good, but the checklist not tested. ^{311, 322}	Includes 12 signs and symptoms of infection (pain, erythema, oedema, heat, purulent exudate, serous exudate with concurrent inflammation, delayed healing, discoloration of granulation tissue, friable granulation tissue, pocketing at wound base, foul odour, and wound breakdown)
Infection Management Pathway ³²³ Published in online article	The pathway is not formally tested	Standardised assessment of delayed healing related to both biofilm/covert infection and local infection.
NERDS and STONES ³²⁴	Sensitivity and specificity is good when used to assess infection in a range of wound types ³²⁵	 Diagnose superficial infection in the presence of ≥ 3 /5 clinical signs/symptoms of superficial infection (NERDS).³²⁴ Diagnose deep infection in the presence of ≥ 3/5 clinical signs/symptoms of superficial infection (NERDS) plus presence of signs/symptoms of deep infection (STONES).
		NERDS: Non-healing, Exudate, Red friable tissue, Debris (discolouration) and Smell. STONES: Size increasing, Temperature elevation, Os (probe to bone), New breakdown, Erythema/oEdema, Exudate and Smell
WUWHS criteria ³²⁶ Published in online article	Good reliability when used when used to assess infection in a range of wound types	Includes 15 signs and symptoms of local and spreading wound infection and (pain, delayed healing, oedema, friable tissue, malodour, discolouration, exudate, induration, pocketing, bridging, wound breakdown, erythema, spreading crepitus, lymphangitis, malaise)

Atypical wound presentation

Lower leg wounds that have an abnormal presentation (i.e., do not present with the characteristics listed in *Table 6.2*) and that do not heal within 4—12 weeks with an appropriate management plan should be referred for further investigation.¹⁴³ Non-healing wounds with atypical presentations should be referred urgently and considered for biopsy and histopathology to identify malignancy or a wound caused by inflammation or other chronic illness/aetiology.^{9, 143} Appropriate referral pathways are driven by the local policies and procedures. As outlined in *Table 9.1*, referral options include (but are not limited to) dermatologist, <u>vascular expert</u>, tissue viability/wound clinic or rheumatologist.¹⁴³

8. Referral

People who present with chronic venous insufficiency (CVI) with or without an active venous leg ulcer (VLU) should have multidisciplinary input into their assessment, management and treatment. Early referral facilitates access to contemporary management strategies that include procedural interventions and surgery. A holistic approach to wound care includes input from health professionals with a range of specialist skills. This chapter discusses appropriate indicators for referral.

Clinical question

• When should a referral be made for an individual with or at risk of VLUs?

Vascular referral

At an initial presentation and when indicated by disease progression, a comprehensive assessment should be conducted by a <u>vascular expert</u> with access to Duplex ultrasound. Early referral to a vascular expert and/or a wound management clinic can ensure the person has access to appropriate assessment, diagnosis and management. The venous, arterial and lymphatic mapping that is undertaken in a Duplex ultrasound contributes to the comprehensive assessment and provides more clinical information for diagnosis. Vascular mapping also informs the decision on whether surgical or procedural interventions are appropriate options to prevent disease progression, including recurrent ulceration. Duplex ultrasound investigates the soft tissue structures, so assists in assessment and differential diagnosis of lower leg swelling.³²⁷ A range of other potential indicators for referral to a vascular expert are in *Table 9.1*.

In locations where specialist services are not readily available (e.g. rural or remote areas), consultation could be made with a vascular expert using telehealth services, particularly when diagnostic equipment is available at the point-of-care.³²⁸⁻³³⁰ However, this is not to be considered a replacement for review by a vascular expert as there is limited research on the efficacy of vascular assessment conducted with the assistance of telemedicine.³³⁰ Good practice in wound management can be implemented while awaiting an expert review and screening for candidacy for advanced procedural interventions or surgery.

The health professional's own skills and experience, their scope of practice in the clinical setting and the local care services and resources influences and guides referral and care pathways.^{60, 63} People who have previously been evaluated by a vascular expert and who are being managed by an interdisciplinary team with expertise in conducting a lower leg assessment, may not require referral to a vascular expert.

- **12.** It is good practice to refer to a vascular expert for further assessment and interventions:
 - Individuals with venous symptoms and/or with active ulcer/s who have not had an initial review by a vascular expert,
 - Individuals with screening results indicating significant peripheral artery disease, and
 - In contexts where clinical investigations to screen for peripheral artery disease cannot be conducted.

Implementation considerations

• Early referral is important to ensure preventive care (e.g. procedural interventions and/or surgery) can be initiated if appropriate. Early intervention can reduce disease progression and development or recurrence of VLUs.

- Individuals presenting with venous symptoms are at risk of VLU and should be referred for a full vascular assessment, including Duplex ultrasound.⁷²
- All individuals with or at risk of a VLU should be screened for PAD. If the clinical setting/health professional does not have resources/training to undertake the recommended clinical investigations a referral should be made.^{197, 198, 200}
- Early referral to a vascular expert facilitates appropriate management of underlying vascular conditions, including access to possible procedural and surgical interventions and appropriate medical management.
- Refer individuals with decreased or non-palpable pulses and/or an ABI > 1.4 (or ABI > 1.3 with diagnosis of diabetes mellitus or renal disease) that are indicative of potential calcified/noncompressible blood vessels to an appropriate health professional for conducting a TBI and/or ASTP if these cannot be conducted in the clinical setting.^{197, 198, 200}
- Refer individuals who have an ankle brachial index (ABI) < 0.6 and/or toe brachial index (TBI) < 0.5, and/or absolute systolic toe pressure (ASTP) < 70 mmHg for further investigation by a vascular expert.⁷² Also consider referring individuals with an ABI < 0.9 and/or a TBI < 0.6, ASTP < 95 mmHg and/or with biphasic/monophasic Doppler waveforms for further investigation by a vascular expert.^{9, 69-71, 197-199, 207, 212, 216}
- Refer individuals with varying left and right brachial systolic pressures for further investigation for upper limb arterial disease.
- Refer individuals who have thigh-level oedema for further investigation.
- Refer individuals presenting with a traumatic leg injury and history of CVI to a vascular expert or a wound clinic as a matter of urgency due to risk of DVT.
- Follow local policies and procedures regarding who is responsible for performing physical examination and clinical investigations. In some jurisdictions, specialist qualifications are required to undertake a lower leg examination or to perform clinical investigations and referral is required.
- Health professionals should receive appropriate training before performing physical examination, Doppler ultrasound and other investigations.^{198, 199} The assessor's clinical skills^{203, 219} and their interpretation of the results can influence the reliability of screening for PAD.^{197, 204} In different geographic settings, the qualifications and training required to undertake vascular investigations varies.

Summary of evidence supporting the good practice statement

Clinical guidelines^{165, 198-202, 207, 208, 212, 216} concur that all individuals presenting with a lower leg ulcer require a comprehensive clinical assessment conducted by a health professional with the required expertise. While vascular assessment is considered a very high priority by stakeholders¹⁴² and is generally tolerable,¹⁶⁷ its routine conduct is influenced by the time available, access to appropriate equipment and the health professional's skill in performing tests and interpreting the results.^{60, 197-199, 201, 203, 204} Implementation could focus on referral pathways and appropriate education and training for wound clinicians.

Multidisciplinary care

Consult with and refer to appropriately skilled health professionals who can contribute to clinical assessment. An interdisciplinary approach to management is essential to optimise healing and long term outcomes for the individual and their informal carer.

Many of the clinical investigations that should be conducted as a part of a lower leg assessment require advanced skills, and training is required to ensure accuracy and reliability. Where the wound clinician does not have the training, skills or scope of practice to perform these assessments, referral should be made to other health professionals/ health services.

13. It is good practice to involve the multidisciplinary team in assessment, diagnosis and care of individuals with or at risk of a VLU.

Implementation considerations

- Referral for assessment should be conducted in a timely manner to facilitate appropriate care planning.
- Initial care planning and management should not be delayed while awaiting assessments and care planning input from the multidisciplinary team.
- People identified with or at risk of malnutrition or who are suspected to have other nutritional issues should be referred to an accredited practicing dietitian for nutrition assessment, intervention and monitoring.¹⁹¹
- Consider the individual's biopsychosocial background when considering the experts who could contribute to assessment and care planning. Suggested indicators for referral and disciplines that may address these needs are summarised in *Table 9.1*.
- Referral should be initiated when there are questions regarding the aetiology, co-morbidities and/or failure of the VLU to progress within an expected time frame. Suggested referral pathways are in *Table 6.1*.
- Health services and wound consultants could develop referral pathways relevant to the context of their client base, geographic location and health networks.
- Follow local policies and procedures regarding who is responsible for performing physical examination and clinical investigations. In some jurisdictions, specialist qualifications are required to undertake a lower leg examination or to perform clinical investigations. Refer the individual for assessments as soon as possible.

Summary of evidence supporting the good practice statement

Clinical guidelines^{165, 198-202, 207, 208, 212, 216} concur that all individuals presenting with a lower leg ulcer require a comprehensive clinical assessment conducted by a health professional with the required expertise. Implementation could focus on both referral pathways and strategies to build networks and an interdisciplinary care model.

Indicator to consider referral	Expert referral	
 No previous Duplex ultrasound Diagnostic uncertainty Referral for these arterial disease indicators: ABI < 0.6, TBI < 0.5, ASTP < 70 mmHg Also consider referral for these peripheral arterial disease indicators: ABI < 0.9, TBI < 0.6, ASTP < 95 mmHg Decreased or non-palpable pulses and/or ABI > 1.3 Ulcers without improvement within three months Recurring ulceration Atypical ulceration distribution Venous bleeds 	 Sonographer Vascular expert 	
• Traumatic injury and history of CVI (e.g., due to DVT risk)	Vascular expertWound expert	
 Suspicion of malignancy Contact dermatitis Atypical ulceration distribution Other dermatological conditions (e.g. dermatoporosis) 	Dermatologist	
Presence of foot ulcers	Vascular expertPodiatristHigh risk foot clinic	
 Underlying conditions (e.g., diabetes, rheumatoid arthritis, lymphoedema, vasculitis) requiring assessment and management 	 According to condition consider: Endocrinologist Rheumatologist Vascular expert Lymphoedema expert 	
 Antibiotic resistant infected ulcers Ulcers non-responsive to systemic antibiotics 	PathologistInfectious disease expert	
Nutritional screening identifies nutritional risk	Accredited practicing dietitian	
Ulcers causing uncontrolled pain	 Pain expert Wound expert/clinic Dermatologist Vascular expert 	
Functional limitations	 Physiotherapist Occupational therapist Podiatrist Orthotist 	
 Underlying cultural or psychosocial issues impacting assessment, prevention and management of the wound Language or cultural requirements 	 Social worker Psychologist Indigenous health worker Translator 	
Lack of local expert with appropriate skillsLack of diagnostic tools	Wound expert/clinic	

Table 9.1: Indicators for potential referral^{9, 68, 72, 143, 198, 200-202, 208, 221}

9. Healing expectations

People with venous leg ulcers (VLUs), their informal carers and the interdisciplinary team have expectations that a wound will heal when it receives evidence based management. When a VLU is slow to heal, there can be a significant impact on health related quality of life (HRQOL). Ongoing monitoring and recognition of abnormal progress is important to enable prompt re-evaluation of the VLU when healing does not progress as expected.

Healing trajectories

Wounds do not heal at the same rate, and healing may not occur on a linear progression. This is because a wide range of factors influence the wound healing process and its trajectory.³³¹ These factors include the person's general health, environmental factors, and factors associated with the wound and tissue. For example, recurrent VLUs in the same anatomical location can lead to fibrotic tissue formation and decline in tensile strength, increasing the time to healing.

A healing trajectory (percent healing over time) describes the continuum of wound healing,^{149, 332} and is used to evaluate treatment efficacy. Consensus guidance suggests that the following vascular profile indicates a VLU has sufficient perfusion to achieve healing: a palpable dorsalis pedis pulse and/or posterior tibial pulse, an ankle brachial index (ABI) of >0.6 to <1.4, an absolute systolic toe pressure (ASTP) of 30 to 35 mmHg, and an audible handheld Doppler (triphasic or biphasic waveform sounds).³³³ However, more research is required to explore the reliability of these indicators.

Early identification of a VLU that is not on a healing trajectory is important because duration of the VLU is directly associated with risk of failure to heal and recurrence. Early identification allows a complete re-evaluation of the individual and their clinical presentation, and a comprehensive re-evaluation of the management plan. Some evidence indicates that the progress of the VLU as early as two weeks after commencing an evidence-based management plan provides a good indication of the likelihood that the VLU will heal without delay.^{127, 334}

 It is good clinical practice to review the diagnosis of venous leg ulcers that do not exhibit 25— 40% healing within 2—4 weeks of commencing a best practice management plan.

Implementation considerations

- Assess the wound at every wound procedure and evaluate progress towards healing.
- Percent change in wound surface area can be used to predict the healing of a VLU.^{331, 335} Failure of the VLU to achieve 25% healing with two weeks is an early indicator that healing may be delayed.^{127, 334}
- A review of the diagnosis should include a complete re-assessment of the individual, the lower limb and the wound, and identification of factors that could indicate the VLU is at risk of delayed (see *Box* 10.1).
- Referral should be initiated when there are questions regarding the aetiology, co-morbidities and/or failure of the VLU to progress within an expected time frame. Suggested referral pathways are in *Table 9.1*.

Summary of evidence supporting the good practice statement

Consensus documents and standards^{142, 143} identified that a comprehensive re-assessment should be conducted when a wound does not heal in an expected time frame. Identifying failure to progress at an early stage and re-evaluating management is associated with decreased health care costs and increased health related quality of life.^{133, 334, 336}

Cumulative research indicates that the healing rate demonstrated in the first two to four weeks correlates with overall healing rates.^{127, 335, 337-339} An optimum healing trajectory for a VLU is considered to be 25—40% reduction in wound surface area within two to four weeks of commencing a best practice management plan.^{335, 337} Evidence indicates that the progress towards healing at two weeks provides a reliable indication of the likelihood that the VLU will heal in a timely manner.^{127, 334} However, even when a VLU is deemed to be on a healing trajectory, there is still a high likelihood it will not be completely healed after 12 months of treatment,¹⁴⁹ or that it might recur in future.

Digital health and wound records commonly include automated calculation of wound healing rates. These can provide a good evaluation of whether the wound is progressing towards healing at the expected rate. Percent change in wound surface area has been shown to be a reliable method to estimate whether a VLU is on a healing trajectory.^{127, 331} Other methods that could be used to evaluate progress towards wound healing include reduction in the absolute wound area, linear advancement from the wound edge,^{331, 340} and scores on the PUSH tool, which has been tested for reliability and validity for VLU assessment.³⁴¹⁻³⁴³

Box 10.1: Factors that might influence healing time^{127, 333, 334, 336, 339, 341-344}

- Inadequate wound bed perfusion
- Having had a previous VLU (especially in same location)
- Larger wound size (≥ 5cm)
- VLU present for > 6 months
- VLU surface area reduction of ≤ 25% in 4 weeks
- Location and severity of CVI
- Larger calf circumference
- <u>Non-concordance</u> with standard treatment
- Higher PUSH score
- Lower self-efficacy
- Living alone

Delayed healing

Venous leg ulcers can take many months to heal and are at high risk of recurring. The complex pathophysiological course of CVI leads to skin and tissue changes (e.g., chronic inflammation) that can prevent a smooth progression through the normal stages of wound healing.³⁴⁵ About one-third of VLUs do not heal within six months.^{127, 346} Aside from the large economic cost and burden on health systems of non-healing VLUs, there are large psychosocial implication for people with VLUs when healing is delayed.⁵⁴

There are limited studies on factors that might delay healing of a VLU. However, the current research indicates that delayed wound healing time can be influenced by CVI factors, the presentation of the VLU and social determinants of health (*Box 10.1*).

10. Glossary

Absolute systolic toe pressure (ASTP; also called absolute toe pressure, ATP): A measure of microvascular perfusion/peripheral arterial function that is used in conjunction with other investigations to detect peripheral arterial disease (PAD). The systolic toe pressure is used to calculate the toe brachial index (TBI).²¹⁷

AFTD-pitting test: A test for pitting that can be performed by the examiner applying pressure with one of more fingers to different anatomical locations to assess oedema. AFTD describes the dimensions of the test: Anatomical locations the assessment was performed; Force required to pit; amount of Time over which pressure was applied (usually in seconds); and Definition of oedema.²³⁹

Ankle brachial index (ABI): A non invasive test that measures arterial perfusion. The test compares the blood pressure in the ankle to the blood pressure in the arm to evaluate adequacy of arterial perfusion in the limbs. It is used in differential diagnosis to detect peripheral arterial disease (PAD) and to evaluate the safety of using compression therapy. The test uses a hand-held device for measuring blood pressure with an inflatable cuff, and blood pressure measurements are taken at the upper arm and above the ankle.²²²

Ankle flare: see corona phlebectatica.

Arterial disease: Impaired/reduced blood flow that occurs due to narrowing or blockage of the arteries by plaque. Plaque is thought to consist of fat, cholesterol, calcium, fibrous tissue and other substances found in the blood. See also: peripheral arterial disease.

Arteriovenous fistula: an abnormal connection between the arteries and the veins occurring due to congenital abnormality or created by trauma or surgery.

Atrophie blanche: A morphological feature seen in people with CVI and healed venous ulcers, presenting as ivory/white/pale pink (depending on skin tone) satellite scars, often with hyperpigmentation and peripheral spider veins.³⁴⁷

Biofilm: Biofilm, a tenacious form of infection, is thought to primarily compose of aggregated microorganism species (although single species biofilm have been observed) that co-exist in a manner that makes their eradication from a wound more difficult. In in-vitro conditions, biofilm has been observed as aggregated microorganisms that exist in an extracellular matrix.²⁹⁰

Body mass index (BMI): An individual's weight in kilograms divided by the square of the individual's height in metres.

Buerger's test: A test for lower limb ischaemia based on observation of colour changes in the foot. With the person in supine positioning, elevate the leg 60° and after 2 minutes observe the soles of the feet for <u>elevation pallor</u>. Next, let the legs hang vertically down and after 2 minutes observe the soles of the feet for <u>dependent rubor</u>. If the described colour changes are observed, Buerger's test is positive, and the limb is more likely to be ischaemic.³⁴⁸

Calf muscle pump function: The calf muscle pump refers to the mechanism by which contracting of the calf muscles compresses the deep veins and contributes to propelling blood back to the heart. The calf muscle pump function is optimised during heel-to-toe walking.³⁴⁹

Chronic venous insufficiency (CVI): An advanced stage of venous disease that occurs over the long term, usually as a result of venous hypertension that causes venous wall damage, ischaemia and inflammation.¹¹

Claudication: Pain or a sensation of constriction in the lower leg, thigh and/or buttock that occurs on physical exertion and subsides on rest.²⁶³ It occurs due to either reduced venous flow (venous claudication)²⁶³ or reduced arterial blood flow (intermittent claudication).²²²

CEAP classification: An international consensus method of assessing venous disease. It incorporates Clinical, aEtiological, Anatomical and Pathophysiology evaluation. The clinical (C) scale is used most in clinical settings; the A and P scales require ultrasound investigation to identify the extent of venous disease.¹⁶⁵

Corona phlebectatica (also called ankle flare): Distended/dilated veins in the foot arch or ankle region that appear as a small, spiderlike pattern of veins caused by blood pooling and stretching the small vessels.²⁴⁴

C-reactive protein (CRP): A blood test that provides an indirect measure of inflammation activity; an early indicator of acute inflammatory stage of a range of different diseases, including wound infection.³⁵⁰

Debridement: The removal of <u>devitalised</u> (non-viable) tissue from or adjacent to a wound.²⁹⁰ Debridement also removes exudate and bacterial colonies (e.g. biofilm) from wound bed of and promotes a stimulatory environment. Methods of debridement include autolytic debridement (promotion of naturally occurring autolysis), biological debridement (e.g. larval therapy), conservative sharp debridement, enzymatic debridement, mechanical debridement, low frequency ultrasonic debridement and surgical sharp debridement.^{290, 351, 352}

Dermatitis/Eczema: A reaction of the skin that often occurs rapidly (acute dermatitis/eczema), but may be gradual and long standing (chronic dermatitis/eczema). It is characterised by a red rash, often blistered and swollen, that may be surrounded by darker, thickened skin (in chronic cases) and is generally dry and itchy. It may be caused by irritants (e.g. products, chemical or even friction) or allergic response, and can become infected.³⁵³

Dependent rubor/erythema: An erythematous discoloration of soles of the feet associated with peripheral artery disease. Redness is observed when the leg is in a dependent position (e.g., hanging over the edge of the bed) and resolves when the leg is raised above the level of the heart.³⁵⁴

Devitalised tissue: Dead tissue presenting as necrotic tissue or slough.³⁵⁵

Duplex ultrasound: Duplex ultrasound is a non-invasive, gold standard diagnostic tool that evaluates both the superficial and deep venous systems to identify venous reflux and/or obstruction.^{70, 165, 200, 205} Duplex ultrasound uses two modes of ultrasound wave (Doppler and B-mode) to map the anatomy and the flow of the blood though the vascular system.

Dystrophic nails: Abnormal changes in the shape, color, texture, and growth of the fingernails or toenails.

Elevation pallor: Describes changes in the soles of the feet that indicates impaired arterial perfusion. Elevate the affected leg to 60 degrees and observe the color of the soles of the feet. Arterial perfusion deficit is indicated by pallor in a person with light toned skin or ashen hue in a person with dark toned skin.³⁵⁴

Erythrocyte sedimentation rate (ESR): A blood test that provides an indirect measure of inflammation activity in the body.

Erythema: superficial reddening of the skin.⁹

Eschar: Necrotic, devitalised tissue that appears black or brown, can be loose or firmly adherent and hard or soft, and may appear as leathery.³⁵²

Exogenous: Originating outside the body.

Exudate: fluid that is excreted from the wound bed as part of the inflammatory response and is composed of serum, fibrin and white blood cells. Exudate has a healing function, for example through providing a barrier to restrict bacteria and debris entering the wound.^{356, 357} Exudate types include:^{356, 357}

Serous: Thin, watery and clear exudate.

Haemoserous: Thin, watery and pink exudate.

Sanguineous: Bloody red drainage, fresh bleeding.

Seropurulent: Murky, yellow or brown exudate with a thick or creamy consistency.

Purulent: Thick, opaque pus with an offensive odour.

Fibrosis tissue: Thickening or scarring of the tissue.

Friable: Fragile, easily injured/bleeding tissue.

Gaiter: Part of the leg that is below the knee and above the ankle.

Gangrene: Gangrene is the death of localised body tissue. It may be wet (occurring due to necrotising bacterial infections)³⁵⁸ dry (occurring due to tissue ischaemia due to a range of causes including peripheral arterial disease, thrombosis, trauma frostbite or embolism).³⁵⁹ Early signs of wet gangrene include blisters, bruising that precedes skin/tissue necrosis, crepitation and cutaneous numbness. These symptoms require urgent investigation.³⁵⁸

Granulation tissue: New connective tissue and microscopic blood vessels that appears as pink/red, moist, shiny tissue that glistens, with a granular or 'cobblestone' surface. Granulation tissue extracellular matrix contains fibroblasts, keratinocytes, endothelial cells and immune cells (e.g. neutrophils, macrophages).⁹

Glycosylated haemoglobin (HbA1c): A test that indicates an individual's average blood glucose level over the preceding 10 to 12 weeks.

Good practice statement: A statement developed by the VLU Guideline Committee used to describe interventions and actions that the Committee considers with a high level of confidence to be associated with achieving more good than harm for most people. Good practice statements are used in this document to address all clinical questions on diagnosis, assessment and referral, and to address topics for which there is no substantial research providing direct evidence related to the intervention. For evidence on intervention topics, <u>evidence-based recommendations</u> will be made. (See *Appendix 1: Methodology*).

Haemosiderin deposit: A reddish brown pigmentation (or dark brown to black pigmentation in dark skin tones) that appears in the lower legs of people with CVI. The pigmentation is due to haemosiderin deposits that arise due to release of iron that occurs when erythrocytes leak into surrounding tissues. The iron binds with proteins to form ferritin, which undergoes oxidation reactions to produce haemosiderin.³⁶⁰

Health history: Past or concurrent diseases or comorbidities (including cognitive and psychological), congenital abnormalities, trauma, surgical interventions, medication (prescribed and over-the-counter) regimens, topical creams/lotions/etc, and other health related factors of relevance to current health status and wound prevention and management.

Health literacy: The cognitive and social skills, knowledge, motivation and capacity of an individual to access, understand, evaluate and apply information to make effective decisions about health and health care.⁸²

Health professional: An individual who works within a branch of health care who has completed a professional degree or who works in a role that is regulated in their country.

Health related quality of life (see also, quality of life): The impact of health status on <u>quality of life</u>, usually considered as a multi-dimensional concept.³⁶¹

Hyperkeratosis: Thickening of the outer surface of the skin (stratum corneum).³⁶²

Hypergranulation: Raised, soft, shiny, friable red tissue that lacks the granule appearance of granulated tissue. Hypergranualtion is present when there is excess granulation tissue such that the tissue progresses above the base layer of the wound bed, resulting in slowing of the healing process.^{9, 290}

Hyperpigmentation: Darkening of the skin; in CVI this usually occurs locally and due to haemosiderin depositing.³⁶³

Induration: Hardening of soft tissues.9

Indigenous: People who inhabited the land from the earliest times before colonisation. In Australia this refers to Aboriginal and Torres Strait Islander people and in New Zealand this refers to people from a Māori or Pacific Island background.

Individual/person: In this document, individual/person refers to a person receiving health care who has or is at risk of a VLU (i.e. a patient, resident or client).

Infection: when the quantity of microorganisms in a wound become imbalanced such that the host response is overwhelmed, and wound healing becomes impaired. Transition from non-infected to infected is a gradual process determined by the quantity and virulence of microbial burden and the individual's immune response.^{9, 290} The transition is theoretically categorised as:

Contamination: The presence within the wound of microorganisms that are not proliferating. No significant host reaction is evoked and no delay in wound healing clinically observed.²⁹⁰

Colonisation: The presence within the wound of microorganisms that are undergoing limited proliferation. No significant host reaction is evoked or observed.²⁹⁰

Local infection: The presence and proliferation of microorganisms within the wound that evoke a response from the host that often includes delayed wound healing. Early sign and symptoms of local infection are covert, subtle and may be difficult for a novice to identify. As infection increases, the local signs and symptoms become classic and overt.^{9, 290}

Spreading infection: Microorganisms spreading from the wound into adjacent or regional tissues, evoking a response in the host in the structures in the anatomical area beyond the peri-wound region.²⁹⁰

Systemic infection: Microorganisms spreading throughout the body via the vascular or lymphatic systems, evoking a host response that affects the body as a whole.²⁹⁰

Informal carer: In this document an informal carer refers to a non-employed person who provides support for an individual with a wound (e.g. a member of the person's family/whānau).

Interdisciplinary team: In this document, the term interdisciplinary team refers a collaborative team of health professionals (e.g. nurses, medical practitioners, surgeons, physiotherapists, accredited practicing dietitians), who all work together with health care workers, the individual, family/whānau and other informal carers to develop and implement a care plan aimed at achieving mutually agreed upon the goals of care.³⁶⁴

Lipodermatosclerosis: A condition that affects the skin immediately above the ankle in individuals with long-standing CVI that appears as fibrosis of the underlying subcutaneous tissue.⁷

Maceration: Wrinkled, soggy and/or hyperhydrated soft peri-wound skin that occurs due to excessive

exposure to moisture. Peri-wound skin presenting as white/pale in the context of excessive moisture is at increased risk of breakdown.^{290, 365}

Mixed aetiology ulcer: An ulcer due to combination of venous and arterial disease.

Necrotic tissue/necrosis: Dead (devitalised) tissue that is dark in colour and comprised of dehydrated, dead tissue cells.

Non-concordance: Disagreement between an individual and members of the collaborative team regarding goals of care of the way in which care will be undertaken.

Oedema: Oedema is swelling of the tissues caused by accumulation of fluid. Chronic oedema primarily occurs due to failure of the lymphatic system, with secondary causes including venous insufficiency, cardiovascular disease, immobility and obesity. When oedema has been longstanding, tissue can become fibrotic and firm (referred to as "brawny") and unable to be indented (i.e., non-pitting)³⁶⁶ (also see <u>phlebolymphoedema</u>).

Patient-reported outcome: Patient reported outcomes are measurable outcomes of care that are reported specifically from the individual's perspective. They are reported directly by the individual without interpretation from other people and include personal experiences such as pain, quality of life, wellbeing and functional status. These outcomes are usually reported using tools/instruments that have been tested for reliability and validity that are referred to as patient-reported outcome measures (PROMs).³⁶⁷

Peripheral arterial disease (PAD): Impaired/reduced blood flow to the legs (and less often, the arms) arising from narrowed arteries from build up of plaques. See also: arterial disease. When severe, people with PAD may exhibit ulceration and critical limb ischaemia (gangrene), which may lead to leg amputation.²²²

Peri-wound: The area immediately adjacent to the wound edge extending out 4cm, and including any skin under the wound dressing.²⁹⁴

Phlebolymphoedema (also called phleboedema or venous lymphoedema): Oedema that occurs due to a combination of lymphatic and venous insufficiency (also see <u>oedema</u>).

Pruritus: Itchy skin.³⁶⁸

Pocketing: Describes a wound bed in which granulation tissue does not grow in a uniform manner across the entire wound or when healing does not progress from the bottom up to the top of the wound. Pockets can harbor bacteria.²⁹⁰

Post thrombotic syndrome (PTS): Signs and symptoms that occur due to long term complications of lower limb deep vein thrombosis. Signs and symptoms include leg aching and cramping, itching, heaviness, skin discoloration and VLU.

Prevalence: The proportion/percentage of individuals in a defined population who have a defined condition at a specified point in time.

Psychometric properties/testing: The statistical evaluation of whether an assessment or measurement tool/instrument is reliable and valid for measuring the construct/variable it is designed to measure.³⁶⁹ It includes a range of specific evaluations, some of which are described below.

Validity: Whether a clinical tool measures what it is intended to measure.³⁶⁹

Reliability: Whether a clinical tool/instrument is stable and consistent, or how well it measures the intended construct/variable across repeated measures.

Responsiveness: How well a clinical tool/instrument detects changes in the individual's condition.

Construct validity: The degree to which a clinical tool is consistent with theoretical components or hypotheses about a specific construct/variable.³⁶⁹

Discriminant validity: The degree to which the tool/instrument's measurement of a construct/variable is improperly related to different constructs/variables that are not related.³⁶⁹

Internal consistency: A test of whether all subparts/domains within the clinical tool/instrument whether the same characteristic.³⁶⁹

Structural validity: The degree to which one measure on a tool/instrument captures a specific dimension of the overall construct.³⁶⁹

Test-retest reliability: how well a clinical tool/instrument measures the intended construct/variable across repeated measures over time.

Test-retest reliability: how well a clinical tool/instrument measures the intended construct/variable when used across different raters.

Purpura (also called purpuric rash): Discolouration similar to small bruises or blood spots, that occur when the small blood vessels leak blood under the skin. Spots present as red/purple and may change colour (e.g. to orange, brown, blue and green) over time as the extravasated blood breaks down.³⁷⁰

Quality of life: A person's perception of their life position within the context of their own values, beliefs, and goals, and the cultural and social systems in which they live.³⁷¹

Recommendation: An evidence-based statement on clinical interventions made by the Guideline Development Committee based on the best available evidence. Recommendations are based on evidence from the highest tier available that has been critically appraised and evaluated using an evidence-to-decision framework to reach a guidance statement that is then given an overall grade identifying the trust health professionals can have in the recommendation achieving the best outcomes for the most people (See *Appendix 1: Methodology*). In this document, evidence-based recommendations are supported by good practice statements.

Reticular veins: visible veins below the skin that appear blue-purple in colour.

Slough: Soft, generally moist, non-viable tissue. It may be white, yellow, tan, or green, and it may be loose or firmly adherent, with its appearance determined by the tissue's hydration status, the depth of the non-viable tissue and any interaction between the slough and topical agents or wound dressing material.^{9, 372}

Stemmer sign: Stemmer sign is a physical examination as part of an assessment of oedema. Inability to tent/pinch the skin over the dorsum of the second toe indicates a positive Stemmer sign. If the skin can be pinched and lifted, then the Stemmer sign is negative.³⁷³

Telangiectasias (spider veins): Small dilated blood vessels and broken capillaries that can be seen as linear, red blood vessels on the surface of the skin.³⁷⁴

Toe brachial index (TBI): A non invasive test that measures arterial perfusion. The test compares the blood pressure in the toe to the blood pressure in the arm to evaluate adequacy of arterial perfusion in the limbs. It is used in differential diagnosis to detect peripheral arterial disease (PAD) and to evaluate the safety of using compression therapy. The test uses a hand-held device for measuring blood pressure with an inflatable cuff, and blood pressure measurements are taken at the upper arm and the toe.

Transcutaneous oxygen pressure: The amount of oxygen reaching the skin through blood circulation. Transcutaneous oxygen pressure is measured via transcutaneous oximetry, which involves electrodes

placed on the skin that create a local hyperaemia that intensifies blood perfusion and maximises oxygen pressure (mmHg).³⁷⁵

Varicose veins: Enlarged, swollen and bulging veins that occur due to vein damage and are a sign of CVI.¹¹

Vasculitis: Inflammation of small arteries or veins with resulting fibrosis or thrombosis. Vasculitis is often associated with autoimmune diseases such as rheumatoid arthritis or systemic lupus erythematosus.

Vascular expert: A health professional (e.g. vascular surgeon, endovascular surgeon, PAD specialist, vein specialist, advanced nurse practitioner, sonographer) with the appropriate knowledge, skills and scope of practice to provide an advanced assessment of the person's vascular status and screen candidacy for interventions, procedures and/or surgery.

Venous eczema/dermatitis: Dry or wet itchy, scaly skin (pruritis).

Venous disease severity scales: Scales and tools that are used to evaluate the severity of venous disease. Most tools include assessment of signs and symptoms that are typically experienced by people with CVI.

Venous leg ulcer: (also called <u>venous ulceration</u>). A full-thickness defect of the skin that persists due to venous disease of the lower leg. Venous ulceration is a chronic condition that is generally considered to result from venous occlusion, incompetent calf muscle pump function or venous valvular failure, giving rise venous hypertension.⁹

Venous disease: Venous disease is related to or caused by pathology or functional abnormality in the veins that leads to sluggish venous blood flow. Either superficial or deep veins may be affected. Pathology includes venous obstruction (e.g. from blood clotting), swelling of the veins or stretched/weakened venous valves leading to venous hypertension.¹¹ See also, <u>chronic venous insufficiency</u>.

Venous hypertension: Elevated blood pressure in the veins that occurs due to venous obstruction (e.g. due to plaque) or incompetent venous valves. Pooling of the blood in the veins leads to an increase in pressure and, in the long term, CVI.

Venous ulceration: see venous leg ulcer.

Wellbeing: A dynamic matrix of factors, including physical, social, psychological and spiritual. Wellbeing is inherently individual, will vary over time, is influenced by culture and context, and is independent of wound type, duration or care setting.³⁷⁶

Whānau: Māori word referring to extended family group.

Wound culture: A sample of tissue or fluid taken from the wound bed and placed in a sterile container for transportation to the laboratory. In the laboratory the sample is placed in a substance that promotes growth of organisms and the type and quantity of organisms that grow is assessed by microscopy. Wound cultures are used to determine the type and quantity of microorganisms in a wound.^{377, 378}

Wound dressing: A material applied to a wound for a variety of reasons, including prevention or management of infection; optimisation of moisture balance, temperature and wound pH; protection; absorption or drainage of exudate; control of odour or to reduce pain.

Wound edge: The external margin or rim of the wound. The wound edge may be well defined or have unclear margins, and its condition is an indicator of wound healing progression. A healthy wound edge is moist, intact and level with the base of the wound. An unhealthy wound edge may be macerated, dehydrated, undermining or have rolled edges.²⁹⁴
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CEAP Classification

Use Clinical-aEtiological-Anatomical-Pathophysiological (CEAP) classification to describe and document the severity of venous disease, noting whether the individual is symptomatic or asymptomatic. Note that classification on the A and P scales require Duplex ultrasound.

Clinical class		(A)etiological class		
СО	No visible or palpable signs of venous disease	Ep	p Primary	
C1	Telangiectasias or reticular veins	Es	Secondary	
C2	Varicose veins	Esi	Secondary - intravenous	
С3	Oedema	Ese	Secondary - extravenous	
C4	Changes in skin and subcutaneous tissue secondary to CVI	Ec	Congenital	
C4a	Pigmentation or eczema	En	No aetiology identified	
C4b	Lipodermatosclerosis or atrophie blanch			
C4c	Corona phlebectatica (ankle flare)			
C5	Healed ulcer			
C6	Active venous ulcer			
subscript 'S' or subscript 'A'	 S: symptomatic, including ache, pain, tightness, skin irritation, heaviness, and muscle cramps, and other complaints attributable to venous dysfunction A: asymptomatic 			
Anatomical class		Pathophysiologic classification		
As	Superficial	Pr	Reflux	
Ad	Deep veins	Ро	Obstruction	
Ар	Perforators	Pr,o	Reflux and obstruction	
An	No location identified	Pn	No pathophysiology identified	

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Palpating Pulses

After gaining consent, directly palpate major arteries.

Assess the presence, intensity, rate and rhythm, and compare to contralateral corresponding pulse.

Posterior tibial pulse	Dorsalis pedis pulse
 Curl fingers anteriorly around individual's ankle 	Position individual in recumbent position with ankle

•

•

palpate

spine

- Indent the soft tissues in the space between the medial malleolus and the Achilles tendon, above the calcaneus
- Provide stability with thumb on opposite side of the ankle



Popliteal pulse

- relaxed
- Stand at foot of table
- Place fingertips transversely across dorsum of forefoot, near centre of the long axis of foot, lateral to the extensor hallucis tendon



Femoral pulse

Stand on the same side as the pulse you will

Press fingertips firmly into groin, beneath

inguinal ligament, one-third of the distance from symphysis pubis to anterior superior iliac

Position individual in supine

- Position individual in supine with knee slightly flexed and leg relaxed
- Encircle and support knee from each side

•

Palpate pulse by pressing deeply into popliteal • space with supporting fingertip





Procedure for Ankle Brachial Index (hand-held Doppler assessment)

Contraindication for ABI: suspected or untreated deep vein thrombosis, severe pain in lower leg, recent lower leg or upper arm surgery and presence of casts.

Prepare the individual

- 1. In advance of the appointment, instruct the individual to prepare by avoiding pre-test exercise and stimulants (e.g, caffeine or nicotine) in the two hours preceding the procedure.
- 2. Prepare the environment to a comfortable room temperature.
- 3. Explain the procedure, assess for contraindications and gain consent.
- 4. Have the individual lie flat for at least 10 minutes prior to the procedure. If the individual is unable to lie flat, raise the legs to heart level or consider referral for Duplex scan.
- 5. Remove any tight clothing from the arms, legs and feet.
- 6. Consider using the physical examination as an opportunity to provide education and health promotion by discussing artery health, the quality of pulse signals, and what the index means in relation to arterial blood supply to the lower legs and feet.

Perform the procedure – arm measurement

- 1. Perform hand hygiene.
- 2. Select and apply the right sized blood pressure cuff above the elbow.
- 3. Palpate the brachial artery and apply ultrasound gel to the area.
- Apply the hand-held Doppler probe at 45— 70° locate the loudest pulse signal. Increase the Doppler volume as required.
- 5. Inflate the blood pressure cuff until the pulsatile sound obliterates, then slowly release the cuff and note the pressure value when the pulsatile sound returns. Document this as the brachial systolic pressure.
- 6. Repeat on contralateral arm. If both arms are not assessed due to contraindications, document which arm was assessed.



Tip: Anchor or rest your hand on the person to prevent moving off the pulse site during cuff inflation. Image © Amanda Pagan

7. Use the higher brachial systolic pressure value between arms for the ABI calculation.

Perform the procedure – arm measurement

1. Apply a protective layer (e.g., cling wrap or dressing pack towel) over the lower limb if the individual has an active lower limb wound, exudate or "wet" eczema/dermatitis.

- 2. Apply the blood pressure cuff to the ankle above the malleolus.
- 3. First palpate the pedal pulse, then locate using the Doppler. Gently massage any pedal oedema fluid away from pulse site to improve signal auscultation.
- 4. Locate the dorsalis pedis and the posterior tibial pulse landmark where able. Both pedal pulses should be assessed. The dorsalis pedis can be palpated over the anterior aspect of the most prominence of the navicular bone/intermetatarsal space or between the big and second toe. The posterior tibial pulse can be palpated over the soft tissue in the space between the medial malleolus and the



Archilles tendon, above the calcaneus. When the dorsalis pedis pulse is unpalpable or absent (approximately 10% of people have no dorsalis pedis pulse), use the anterior or posterior tibial pulse.

- 5. Apply ultrasound gel, increase the Doppler volume to the maximum and place the Doppler probe on the pedal pulse being assessed finding the location with the loudest sound.
- 6. Evaluate the quality of pulses signals (i.e., monophasic, biphasic or triphasic).
- 7. Inflate the blood pressure cuff until the pulsatile sound obliterates, then slowly release the cuff and note the pressure value when the pulsatile sound returns. Document the ankle pressure in both pedal pulses.

Calculate and document the result

1. To calculate the ABI:

ABI = <u>highest systolic pressure at dorsalis pedis (DP)and posterior tibial (PT) sites</u> highest systolic pressure brachial value

In people with varying DP/PT readings or diabetes mellitus, calculate ABI for both limbs by dividing the <u>lowest</u> systolic pressure value of dorsalis pedis or posterior tibial pulse of that foot by the highest systolic pressure value of the left or right brachial pressure value.^{199, 216} Where there is wide variation between left or right brachial pressure values, specialist advice should be sought.

2. Document the examination results, the pulse sites assessed, non-palpable pulse sites, and any health education provided during the physical examination.

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Procedure for Toe Brachial Index (hand-held Doppler assessment)

Prepare the individual

- 1. In advance of the appointment, instruct the individual to prepare by avoiding pre-test exercise and stimulants (e.g, caffeine or nicotine) in the two hours preceding the procedure.
- 2. Prepare the environment to a comfortable room temperature and ensure toes are not cold.
- 3. Explain the procedure, assess for contraindications and gain consent.
- 4. Have the individual lie flat for at least 10 minutes prior to the procedure. If the individual is unable to lie flat, raise the legs to heart level or consider referral for Duplex scan.
- 5. Remove any tight clothing from the arms, legs and feet.
- 6. Consider using the physical examination as an opportunity to provide education and health promotion by discussing artery health, the quality of pulse signals, and what the index means in relation to arterial blood supply to the lower legs and feet.

Perform the procedure – arm measurement

- 1. Perform hand hygiene.
- 2. Select and apply the correct sized blood pressure cuff size above the elbow.
- 3. Palpate the brachial artery and apply ultrasound gel to the area.
- 4. Apply the hand-held Doppler probe at 45—70° locate the loudest pulse signal. Increase the Doppler volume as required.
- 5. Inflate the blood pressure cuff until the pulsatile sound obliterates, then slowly release the cuff and note the pressure value when the pulsatile sound returns. Document this as the brachial systolic pressure.
- 6. Repeat on contralateral arm. If both arms are not assessed due to contraindications, document which arm was assessed.
- 7. Use the higher brachial systolic pressure value between arms for the TBI calculation.



Tip: Anchor or rest your hand on the person to prevent moving off the pulse site during cuff inflation. Image © Amanda Pagan

Perform the procedure – toe measurement (two options)

Option 1: Manual Doppler (auditory)

Select the correct cuff size for the toe (either the great toe or second toe if a sufficiently small cuff is available). The toe cuff should be sufficiently wide to apply pressure over the area (around 2.5cm to 3cm wide) and long enough to overlap.

Option 2: Photo plethysmography**

- ** General guidance only. Systems vary and manufacturer's directions should be followed.
- Select the correct cuff size for the toe (either the great toe or second toe if a sufficiently small cuff is available). The toe cuff should be sufficiently wide to apply pressure over the area (around 2.5cm to 3cm wide) and long enough to overlap.

- Apply the cuff around base of the toe so it is close fitting with no excess pressure (as this can occlude the artery) and attach to the sphygmomanometer.
- 3. Apply ultrasound gel above the cuff on the medial aspect of the great toe, turn up the Doppler volume to the maximum and locate the pulse with the loudest signal. Headphones are advised because toe pulse signals are much quieter than pedal signals. Document number of signals heard and/or review doppler waveforms.
- 4. Inflate the blood pressure cuff slowly until the pulsatile sound obliterates, then slowly release the cuff and note the pressure value when the pulsatile sound returns. Document this as the systolic toe pressure.
- 5. Repeat on contralateral toe.



Image © Amanda Pagan

Calculate and document the result

1. To calculate the TBI:

TBI = <u>Systolic pressure value from each toe</u> highest brachial systolic pressure value

2. Document the examination results for each body side, and any health education provided during the physical examination.

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- Apply the cuff around base of the toe so it is close fitting with no excess pressure (as this can occlude the artery) and attach to the sphygmomanometer.
- 3. Place the photo plethysmograph (PPG) transducer on the plantar pad of the great toe. Secure to toe as recommended.
- 4. Attach the PPG transducer to the PPG unit and view the waveform on the screen.
- Inflate the blood pressure cuff until the waveform disappears. Continue to inflate for an additional 20-30mmHg above the reading when the waveform disappeared.
- 6. Slowly release the cuff until the first regular waveform reappears. Document this as the systolic toe pressure reading.
- 7. Repeat on contralateral toe.



Image © Amanda Pagan

Ankle-Brachial Index (ABI) and Toe-Brachial Index (TBI) using Doppler Ultrasound

Information for Consumers and Their Family/Whānau

People with lower leg or foot concerns such as wounds, pain, or swelling are often asked to have a Doppler ultrasound test on their lower legs (and sometimes feet). This is a simple test to check the blood flow from your heart down to your legs or feet. It is normal for people to feel worried or uncertain. For most people, it is a simple procedure and not painful. Please feel free to bring a support person or whānau.

Please ask questions. Please advise if you have any cultural needs, before or during the appointment. You will be asked to consent before the test is done.

What do I need to do before the test?

- Wear loose clothing on your upper arms and lower legs.
- If you have a pacemaker the test will not affect this.
- Take your usual medication.
- Avoid smoking.
- Avoid drinks that contain caffeine (for example: coffee, tea, Coca-Cola, Diet Coke, Pepsi, chocolate milk, energy drinks).
- Do not exercise for at least 2 hours before your test.
- For your comfort, please use the toilet prior to the test.
- The results of the test might change your care, such as the use of bandages. Consider bringing wider-fitting or adjustable shoe/s (or slippers) to wear home.

What is a Doppler ultrasound? What does the test tell me?

The Doppler is a hand-held machine with a pencil-sized microphone that sends and receives a sound signal from your heart to the blood vessels in your arms, legs, and feet. The microphone is called a Doppler probe.

The test tells us whether the blood pressure in your arm blood vessels is about the same in your lower leg or foot. This helps us to understand if blood flow to the leg or foot is 'good' or 'impaired'.



Why are both arms and legs tested?

The test tells us the difference between the blood pressure in the top half of the body and the lower legs. Each arm and leg may give a different reading.

How long will the test take?

Including rest time (lying flat for at least 10 minutes) and taking your health history, the test will take between 30-60 minutes, although this can vary. If you cannot lie flat, please discuss this at the appointment.

Will I need to undress?

You will need to wear loose clothing on your arms and legs. You will be asked to take off your shoes, socks, tights and or stockings and unbutton tight trousers.

Does it hurt?

It may feel uncomfortable as the blood pressure cuff fills with air and presses on your arms and legs, or over a wound. Before your appointment, please take your normal pain relief, or rongoā (traditional Māori medicine). Please let us know if the test is too painful for you. **No needles are used for this test.**

How is the test done?

- The test is just like having your blood pressure taken, but the ultrasound is used to hear your heartbeat.
- To get the best results, you will be asked to lie quietly, and as flat as possible for at least 10 minutes before the test.
- A blood pressure cuff is applied to each of your arms and legs in turn. If you have a wound or weeping skin where the blood pressure cuff is placed, the area will be covered during the test.
- On the arms, it is placed just above the elbow. On the legs, it is placed just above the ankles.
- You also may need to have the pressure measured in your toes. A very small cuff is placed over your toe, usually your big toe.
- A small amount of clear gel will be put on the inside elbow on each arm, on the inside of your ankles and on top of both your feet.
- The doppler probe is put on the gel, at each location. You may hear your heartbeat through the machine while this is being done. Sometimes it is difficult to hear the heartbeat so the person doing the test for you might wear headphones.
- The blood pressure cuff will be pumped up to stop the heartbeat from being heard. Then the pressure is slowly let down again until the heartbeat is heard again. This may feel quite tight for a brief amount of time.
- Recordings will be taken at each arm, leg, and may include the big toe.



What happens with the results of the test?

- Your results will be discussed with you.
- It will help us to decide the best care for you. This might be wearing a bandage or stockings.
- You may be referred to your general practitioner (GP) or nurse practitioner, or a specialist for more tests.

What happens after the test?

- If you have a wound the dressing will be done after the test.
- You will be able to continue with your normal daily routine.
- Your results will be discussed with you and shared with your health team (e.g. your nurse or GP).
- Future appointments may be booked with your consent.

Investigations Commonly Used in Vascular Assessment

Blood pressure (BP)	Measures pressure of the blood on the vessel walls using a sphygmomanometer. It provides an indication of the possible presence of a range of cardiovascular diseases.
Absolute systolic toe pressure (ASTP)	A non-invasive vascular test using Doppler ultrasound and/or photo plethysmography to evaluate the vascular status of the foot. The test is particularly useful because it is more reliable than ankle systolic pressure, especially for people with arterial calcification.
Ankle brachial index (ABI)	A non-invasive vascular test using Doppler ultrasound that identifies large vessel peripheral arterial disease in the leg. It is used to differentiate vascular disease and to evaluate arterial blood flow in the leg before use of compression therapy. The systolic BP is measured at the brachial artery (both arms) and at the ankle level (both ankles). ABI is calculated as the higher systolic BP from the foot arteries (either dorsalis pedis or posterior tibial artery) divided by the higher brachial systolic BP.
Computed tomography (CT scan)	A form of x-ray that takes images from different angles to produce cross sectional body images, providing a three-dimensional impression that is used for diagnostic or therapeutic purposes.
Duplex ultrasound	A non-invasive test that uses high frequency sound waves to evaluate the blood flow through arteries and veins. Duplex ultrasound uses two different modes of ultrasound (Doppler ultrasound and B- mode) to map the anatomy and the flow of the blood though the vascular system, identifying obstructions and/or insufficiency.
Magnetic resonance imaging (MRI)	A non-invasive medical imaging technique that uses magnetic field and radio frequency pulses to create images of the internal body. In contrast to x-ray, MRI creates more detailed image of organs, soft tissues, bone and other internal structures.
Pulse oximetry	A non-invasive test that measures the red and infrared light absorption of oxygenated and deoxygenated haemoglobin in a digit. Oxygenated haemoglobin absorbs more infrared light and allows more red light to pass through a digit. Deoxygenated haemoglobin absorbs more red light and allows more infrared light to pass through the digit. There is insufficient evidence to recommend this investigation as the primary diagnostic tool.
Toe brachial index (TBI)	A non invasive test that compares the systolic pressure in the toe to the arm to evaluate adequacy of limb arterial perfusion. The test uses a hand-held device for measuring BP with an inflatable cuff, and BP measurements are taken at the upper arm and the toe. A toe cuff is applied to the hallux, or second toe and BP measured on both sides of the body, as per ABI. TBI is more reliable in people with incompressible arteries due to calcification (e.g. due to diabetes and renal disease).
Transcutaneous oxygen pressure (TCPO ₂)	Measures the amount of oxygen reaching the skin through blood circulation. There is insufficient evidence to recommend this investigation as the primary diagnostic test.

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ASSESSMENT OF PEOPLE WITH OR AT RISK OF VENOUS LEG ULCERS

Pan Pacific Clinical Practice Guideline for People with or at Risk of Venous Leg Ulcers: Assessment



Person presents with venous symptoms and/or lower leg ulcer Working with the individual and their carers Working with multdisciplinary teams COLLABORATIVI Gain consent before undertaking assessment Facilitate involvement of an advocate/whānau/family carer Work within scope of practice, clinical expertise and local policies and procedures CARE Involve the multisciplinary team in assessment and diagnosis Make referrals based on the person's biopsychosocial needs, with questions regarding aetiology and/or with failure of a VLU Use culturally-appropriate models of care Discuss preferences for engagement in health assessment Select person-appropriate, valid and reliable assessment tools Assess language, comprehension and health literacy to heal Establish care goals Use the assessment process as an opportunity to provide education and health promotion Develop local networks and referral pathways Health history **Ulcer history** Lower limb venous symptoms Vascular surgery/procedures and Ulcer cause or recurrent ulcer Evaluate for venous disease risk factors • Cardiac, renal, liver or kidney disease Ulcer duration · Consider using venous disease severity tools History past ulcers/time to heal/ to assess disease over time • Aterial, venous and/or lymphatic HISTOR) ulcer-free time disease Past interventions/compression use Health-related quality of life assessment Skin cancers, skin disorders, Nutrition screening Screen nutrition and hydration • Blood or autoimmune disorders Use HROOL assessment tools Assess needs related to culture, religion, life Metabolic disorders, diabetes mellitus Neuropathic disorders satisfaction, coping, optimism, social and Pain assessment engagement Use a pain assement tool Lower leg pain characteristics Cognitive and psychological diagnoses Medications and topical preparations Consider the impact of caring on the person's advocate/whānau/family carer Leg ulcer associated pain Treatment-related pain Lower limb examination Lower limb point of-care tests Ulcer and surrounding area · Observe leg in dependent and Palpation of major lower limb arteries and Use wound assessment frameworks EXAMINATION Propagatori organizational and the state of the non-dependent positioning and wound/infection assessment tools Limb shape Healing phases Location on the leg Comprehensive skin assessment, including temperature, pigmentation, Absolute systolic toe pressure Measurement (length x width x depth) visible vasculature, integrity Neurosensory status Transcutaneous oxygen pressure and undermining Neurosensory function Lower limb (ankle/calf) measurement Tissue type Infection and inflammation signs and Calf muscle pump function symptoms assessment Range of motion and muscle strength Oedema assessment Moisture imbalance · Edge of the wound, periwound and surrounding skin Characteristics suggesting **NVESTIGATIONS** Characteristics suggesting arterial ulcer Consider additional investigations venous ulcer Further investigations as indicated by history and examination including: Associated leg changes • Possible oedema (especially Associated leg changes Haemosiderin deposit Evidence of healed ulcers Blood profile including inflammatory markers Arterial and/or venous Duplex scanning X-ray, MRI, CT-scan Wound swab with infection) Thin, shiny skin · Dilated and tortuous superficial Minimal hair growth Atrophic nails veins and/or varicose veins Atrophie blanche Wet or dry venous eczema Maceration, pruritis and scale Ankle flare Wound biopsy Straight/thinly shaped leg Limb cool to touch Becomes pale if leg/toes are Classify venous Differentiate · Firm/brawny and/or leaking elevated signs and aetiology based on Weak/absent pedal or leg oedema symptoms using CEAP classification history, examination and investigations Warm limb, heat and itch pulses Ulcer characteristics • Well demaracted ulcer Lipodermatosclerosis Inverted "champagne bottle" leg Absolute indications for referral/expert AND REFER DIAGNOSE Ulcer characteristics margins consultation Anterior to medial malleolus/ pretibial area (lower third of leg) Poorly perfused wound bed Necrotic tissue that may be • ABI, TBI, photoplethysmography if unable to perform at point-of-care Refer early for vascular/surgical and medical Shalllow with ragged irregular tenacious Minimal exudated unless edges management Weak or absent pulses Ruddy granulation tissue Moderate to high exudate infected Prone to infection ABI>1.4 (or ABI>1.3 with diabetes) ABI<0.6, TBI<0.5, and/or ASTP<70 mmHg May be odorous Pain Claudication or rest pain Pain Oedema above the knee Traumatic leg injury with venous history May be relieved by leg elevation · Often worse at night or with leg elevation Extensive non-viable tissue or extreme pain Characteristics suggesting atypical ulcer • None or minimal characteristics hinting at venous or arterial ulcers AND EVALUATE IMPLEMENT Document all health assessments More extreme pain Regularly reassess based on clinical · Unusual appearance or atypical distribution Suspicion of malignancy Deterioration in ulcer or recrotic tissue present presentation and needs Develop a person-centred management plan · Ulcer not healed within 3 months based on assessment outcomes

This is a companion document to Pan Pacific Venous Leg Ulcer Alliance, Pan Pacific Clinical Practice Guideline for People with or at Risk of Venous Leg Ulcers: Assessment. Emily Haesler (Ed.). Hong Kong Enterostomal Therapists Association, New Zealand Wound Care Society, Wounds Australia and the Wound Healing Society of Singapore. 2024. Refer to full document for good practice statements, context, interpretation and implementation considerations. © PPVLUA 2024

Case Presentations

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Venous symptoms



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In darker pigmented skin the healed ulcer presents as pink skin (see right lateral lower leg). Also visible are areas of atrophie blanche, haemosiderin deposits in both legs, lipodermatosclerosis (skin firming) in the gaiter region, limb narrowing at the ankle and widening calf (champagne-bottle shaped leg).

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Atrophie blanche (areas of white skin shown in the close-up photo), lipodermatosclerosis (skin firming) in the gaiter region with limb narrowing at the ankle and widening calf (champagne-bottle shaped leg).

Note areas of haemosiderin deposits (hyperpigmented skin that presents brown in light pigmented skin).

Atrophie blanche: scarring prone to spontaneous break down.

Varicose veins; the veins appear more prominent in the standing position.



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Varicose veins presenting in combination with reticular veins (visible veins below the skin surface).

Telangiectasia (spider veins) in darker pigmented skin.



Corona phlebectatica (ankle flare) located medial aspect of the ankle and foot (can also present laterally).

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Haemosiderin deposits, lipodermatosclerosis (skin firming) with evidence of guttering (longitudinal skin wrinkling) indicating that oedema is being managed with compression

therapy.

Note the presence of a venous ulcer on the medial lower leg and evidence of a healed ulcer (pale healed skin).

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Hyperkeratotic and pruritic skin presenting around an active venous leg ulcer. Deep marks/grooves are signs of lower limb oedema.



Non-blanchable erythema from tightly applied compression bandage. This indicates the presence of a Stage 1 pressure injury (medical device related).

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Pigmentation changes and hyperkeratosis (leg and foot) in an uncompressed limb, related to infrequent skin cleansing and venous hypertension. Patient has no associated skin itch.

Spider veins appear like spider-webs on the lower legs.

Venous leg ulcers



Venous leg ulcer located medial malleoli region with ankle flare. Note the irregular wound edges, distal skin maceration, ruddy granulation tissue, areas of haemosiderin deposits and foot and lower leg oedema.

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Venous leg ulcer with granulation and slough. Note the haemosiderin staining that presents black or darker in dark pigmented skin.

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Venous leg ulcer presenting with granulation tissue and proximal wound edge undermining (shown by the probe location). Also evident are areas of haemosiderin deposit and past healed ulcers that present as pale pink skin in people with dark pigmented skin.



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Venous leg ulcer presenting with signs of local infection: ruddy granulation tissue, wound breakdown, increased exudate, wound malodour and pain. Periwound maceration from wound exudate.

In the second image, the wound infection has progressed to spreading infection. The ulcer has increased in size, spreading erythema >2cm from wound edge, heat and note green exudate (*Pseudomonas aeruginosa*).

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Long-term recurrent venous leg ulcer in the medial gaiter region, with irregular and raised wound edges. Corona phlebectatica (ankle flare), lipodermatosclerosis (skin firming in the gaiter region) and surrounding red, scaling skin (skin scrapings diagnosed a fungal infection).

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Venous leg ulcer presenting with signs of spreading infection/cellulitis with associated warmth, pain, and blistering.

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13. Appendix 1: Methodology

Purpose

The purpose of the Venous Leg Ulcer Guideline (VLUG) Project is to develop resources for assessing. preventing and treating venous leg ulcers (VLUs) in the Pan Pacific region. The following Pan Pacific wound organisations partner on this project:

- Hong Kong Enterostomal Therapist Association (HKETA)
- New Zealand Wound Care Society (NZWCS)
- Wounds Australia
- Wound Healing Society of Singapore (WHSS).

The VLUG project updates the Australian clinical guidance on prevention and management of VLUs. The last published guideline in the Pan Pacific, the *Australian and New Zealand Clinical Practice Guideline for the Prevention and Management of Venous Leg Ulcers (2011)*¹ was developed by the Australian Wound Management Association (AWMA, now Wounds Australia) and New Zealand Wound Care Society (NZWCS) in 2011 and endorsed by the National Health and Medical Research Council (NHMRC).

The current project consists of a series of clinical guidelines to update consensus statements and evidence-based recommendations on assessment, diagnosis, prevention, and management of VLUs, and includes resources to support their implementation. The series of clinical guidelines is intended to inform decision making by health professionals and consumers in Australia, New Zealand, Hong Kong and Singapore. The clinical guidance is informed by the best evidence over the project timeframe and relevant to people with VLUs and who are at risk of VLU recurrence.

The purpose is to:

- Contribute to reduction in incidence and prevalence of VLUs,
- Promote appropriate wound care,
- Support assessment, diagnosis, prevention and management of VLUs,
- Improve VLU-related knowledge,
- Optimise care participation, self-management and health related quality of life (HRQOL), and
- Inform benchmarking, research, policies and quality improvement activities.

Content should be considered in the context of existing standards of wound care.² The guideline series is not intended to have a regulatory effect.

Project Oversight

The Venous Leg Ulcer Guideline Development Committee (the project team) consisted of representatives of participating organisations from a range of health disciplines, and a consumer representative. A methodologist assisted the project team. The project team was responsible for oversight of the project, including:

- reporting project progress to their respective organisations,
- oversight of the Stakeholder Survey,³
- selecting and approving the methods used to develop this clinical guideline,
- appraising the evidence and extracting data from studies,
- reviewing and reaching consensus on the good practice statements,
- conducting a stakeholder review process, reviewing and addressing the feedback,
- developing resources to support the guideline and
- reaching agreement on the final content.

Table A1.1: Summary of topics to be addressed in the VLU Project

Assessment of VLUs				
	Aetiology and risk factors for VLU			
guideline	Diagnosis of VLUs			
	Diagnosis and assessment of of people with or at risk of VLUs or people with CVI			
Assessment	Assessment of VLUs and methods to monitor their healing			
Preven	tion of VLU recurrence			
þ	Compression therapy			
To be produce	Lifestyle interventions (e.g., elevation, exercise, nutrition and hydration)			
Manag	ement of VLUs			
	VLU-related pain assessment and management			
	Lifestyle interventions (e.g., elevation, exercise, dietary)			
pa	Management of peri-ulcer skin			
quc	Compression therapy			
To be pro	Biophysical agents (e.g., extracorporeal shockwave therapy, electrical stimulation, topical oxygen therapy, hyperbaric oxygen therapy)			
	Psychosocial interventions (support groups, wellbeing- based interventions)			
	Pharmacological interventions			
VLU ed	ucation			
	Education for patients and their carers			
Irces	Education for people delivering formal healthcare			
Resou	Information about surgical and minimally invasive interventions			
General care of wounds				
_	Preparation of the wound bed for healing			
nced	Topical agents			
rodi	Wound dressings for managing exudate			
To be p	Other types of wound dressings and devices (e.g., negative pressure wound therapy)			
	Assessment and management of infection and biofilms			

Conflict of Interest Management

Transparent and trustworthy clinical guidelines require a rigorous conflict of interest process. A conflict of interest (COI) arises through direct or indirect pecuniary or personal interests in aspects of the guideline development, including the questions that are asked, the evaluation of evidence and arrived at recommendations and their grades. All members of the project team completed a COI disclosure declaring potential or actual COIs the preceding three years and over throughout the project development. To manage COIs, any team member with a moderate or high COI was excluded from evaluating studies, discussing the evidence, and developing best practice statements on that topic.

Target audience

The project includes resources intended for use by health professionals and health workers formally engaged in delivery of VLUrelated healthcare; people with VLUs or at risk of VLU recurrence, informal carers, organisations representing healthcare consumers, and people working in health administration, policy, industry, academia and education settings.

The resources are relevant to healthcare settings throughout Australia, Hong Kong, New Zealand and Singapore, and other regions within the Pan Pacific.

Focus of the Guideline Series

The focus of the guideline series is on leg ulcers of venous origin. The guideline series does not seek to provide comprehensive resources for other types of wound, including lower leg ulcers arising from other aetiologies or ulcers arising from mixed aetiologies.

Р	Patient population	For example: • People with or at risk of VLUs
		 Considerations: Demographics: age, culture, languages, geographic language Specific co-morbidities: overweight, living with disabilities Settings: Acute facilities, rehabilitation, wound services, aged and other residential care, general practice, district/visiting nursing services, community- based services, own home
I	Intervention	 For example: Strategies for primary prevention or preventing recurrence Strategies for treating VLUs Promoting health related quality of life (HRQOL)
С	Comparison	 For example: Alternative intervention/therapy, placebo, or no intervention/therapy
0	Outcome	 For example: Healing Improved signs and symptoms Adverse outcomes

Table A1.2 PICO format for clinical questions⁴⁻⁷

Accurate diagnosis of wound aetiology is an imperative before implementing recommendations designed to assess and manage VLUs. Although chronic venous insufficiency (CVI) is the primary underlying condition associated with developing a VLU, the focus is on assessment, diagnosis, prevention and management of VLUs rather than management of any underlying pathologies. Co-morbidities, including lymphoedema, arterial disease and atypical leg ulcers are associated with leg ulceration in many people and these conditions require comanagement. While some of the guideline content is appropriate for addressing comorbidities and mixed-aetiology wounds, these are not the primary focus.

The context of the topics in Table A1.1 has been considered for routine patients and carers in the Pan-Pacific region. In addition, and based on the results of the Stakeholder Survey,³ consideration was given people who are overweight or obese, people from different cultural backgrounds, and Indigenous populations.

Overview of the methods

A mixed approach was adopted for this guideline series to make recommendations and

good practice statements. For the first part of this series on VLU assessment, a consensus-based approach was undertaken to make good practice statements on diagnosis and assessment. The stages included:

- developing clinical questions,
- appraising primary research evidence,
- synthesising evidence relevant to clinical questions,
- reaching agreement on good practice based on the most recent evidence, and
- developing implementation considerations/ practice points to facilitate translation into clinical practice.

Developing Clinical Questions

A stakeholder survey³ was conducted to inform the VLU Guideline Committee's development of clinical questions, and to collect other perspectives on VLU-related topics to increase relevance of the project to stakeholders.

Identifying and Selecting Evidence

A literature search to scope VLU-related literature published since the last search (2016) was undertaken. The search is outlined in Box A1.3. The search strategy was developed by the 2011 project team¹ and has been reviewed and refined for a search in 2016 and again in 2023. The search identified evidence relevant
to people with or at risk of VLU, including people with a history of varicose veins, venous disease, phlebitis, DVT and/or previous leg injury/surgery. The search also considered people who have previously experienced a VLU. Search dates for the current scoping were 01 January 2016 through 30 December 2023. A broad strategy was used to identify research of all types that might contribute to various components of future guideline development, including other clinical guidelines. Additional, targeted searches were conducted for high level evidence (particularly evidence-based guidelines) for topics outside the VLU searches (e.g. identifying people at risk of peripheral arterial disease). The searches were supplemented with evidence sources considered pertinent by the project team.

Box A1.3 Search strategy

Cochrane Review Library

#1 MeSH descriptor: [leg ulcer]

#2 MeSH descriptor: [varicose ulcer]

#3 MeSH descriptor: [venous insufficiency]

#4 MeSH descriptor: [venous pressure]

#5 varicose NEXT ulcer* or venous NEXT ulcer* or leg NEXT ulcer* or stasis NEXT ulcer* or crural NEXT ulcer* or ulcus NEXT cruris or lower NEXT extremit* or venous NEXT insufficiency

#6 chronic NEXT venous or or venous NEXT hypertension or vein NEXT disease or venous NEXT disease

#7 (#1 or #2 or #3 or #4 or #5 or #6) in Cochrane Reviews

#8 limit to [2016-Current]

Ovid MEDLINE(R) <1946 to Present> via OvidSP

#1 leg ulcer/ or varicose ulcer/ or venous insufficiency/ or venous pressure/

#2 (varicose ulcer* or venous ulcer* or leg ulcer* or stasis ulcer* or crural ulcer* or ulcus cruris).ti,ab,kw

#3 (varicose eczema or venous hypertension or venous disease or venous insufficiency).ti,ab,kw

#4 (#1 or #2 or #3)

#5 limit #4 to (english language and yr="2016-Current")

PubMed via National Center for Biotechnology Information (NCBI)

#1 leg ulcer/ or varicose ulcer/ or venous insufficiency/ or venous pressure/

#2 (varicose ulcer* or venous ulcer* or leg ulcer* or stasis ulcer* or crural ulcer* or ulcus cruris).ti,ab

#3 (varicose eczema or venous hypertension or venous disease or venous insufficiency).ti,ab

#4 (#1 or #2 or #3)

#5 limit #4 to (and yr="2016-Current")

Filters: Case Reports, Clinical Study, Clinical Trial, Clinical Trial, Phase I, Clinical Trial, Phase II, Clinical Trial, Phase II, Clinical Trial, Phase IV, Comparative Study, Controlled Clinical Trial, Guideline, Meta-Analysis, Multicenter Study, Observational Study, Practice Guideline, Randomized Controlled Trial, Systematic Review, Technical Report, Validation Study, English.

Embase Classic+Embase <1947 to Present> via OvidSP

#1 leg ulcer/ or vein disease/ or venous pressure/ or chronic vein insufficiency/

#2 (varicose ulcer* or venous ulcer* or leg ulcer* or stasis ulcer* or crural ulcer* or ulcus cruris).ti,ab,kw

#3 (varicose eczema or venous hypertension or venous disease or vein disease or venous insufficiency).ti,ab,kw

#4 (#1 or #2 or #3)

#5 limit #4 to (english language and yr="2016-Current")

AMED <1947 to Present> via OvidSP

#1 varicose ulcer/ or venous insufficiency/

#2 (varicose ulcer* or venous ulcer* or leg ulcer* or stasis ulcer* or crural ulcer* or ulcus cruris).ti,ab,kw

#3 (varicose eczema or venous hypertension or venous disease or vein disease or venous insufficiency).ti,ab,kw

#4 (#1 or #2 or #3)

#5 limit #4 to (english language and yr="2016-Current")

Searches were conducted in the following databases for studies published in English:

MEDLINE[®]

- PubMed[®] (including filters based on source type)
- Excerpta Medica Database (Embase)
- Allied and Complementary Medicine (AMED)
- The Cochrane Review Library.

Searches established a comprehensive library of VLU-related evidence relevant to clinical questions, implication considerations, and resources. PICO-based searches of the VLU-related evidence library were undertaken using search terms relevant to each clinical question. Additionally, the PICO terms were used to search in Medline to ensure the full body of relevant evidence was captured.

Addressing Assessment and Diagnosis with Good Practice Statements

A good practice statement is used to describe interventions and actions that the project team consider with a high level of confidence to be associated with achieving more good than harm for most people.⁸ In this clinical guideline series, good practice statements will be used to address all clinical questions on diagnosis, assessment and referral.

Implementation Considerations

Additional subsequent statements (implementation considerations) that provide more information on how, when, how often or who have been developed. Implementation considerations describe practical information or core principles to assist in implementing recommended practice, providing information considered pertinent to the recommendation. Implementation considerations are supported by:

- Identified primary evidence (e.g., observational studies, diagnostic studies and qualitative research) clinical guidelines,
- Evidence-based and consensus-based clinical guidelines,
- Expert opinion.

Case Presentation Resources

This guideline includes case presentations to illustrate different clinical presentations, signs and symptoms of VLUs and chronic venous insufficiency. A consent form that met the requirements of health services in the Pan Pacific region was developed for this project. The project team discussed the project with patients/consumers and written consent was gained for the use of photos and case information in this guideline. The project team extends its thanks to those patients and community members who consented to have their photos and anonymous information presented in this guideline. <u>Photos are not available for reproduction</u>.

Stakeholder Input and Review

A stakeholder is anyone with an interest in VLUs who wished to provide input into the guideline. Stakeholders included patients and their carers, health professionals, academic, researchers, educators, industry representatives/companies and any other interested parties. Opportunities for formal stakeholder involvement included participating in the stakeholder survey³ undertaken in the project planning stage in 2022 and reviewing the draft document and providing feedback. The stakeholder review was open to any interested stakeholders (e.g., members, patients, consumer organizations, industry groups, professional networks and cultural diversity groups). The opportunity to review was advertised in May – June 2024 via the websites of the partner organisations and direct email to previous stakeholders, including those who provided feedback on the 2016 update, and those who participated in the stakeholder survey. Responses were received from 66 individuals from six countries. All stakeholder comments were reviewed and considered by the project team and incorporated into the final version of this guideline when appropriate.

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