

MANAGEMENT OF PATIENTS WITH VENOUS LEG ULCERS

CHALLENGES
AND CURRENT
BEST PRACTICE



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Abbreviations

- AAWC: Association for the Advancement of Wound Care
- ABI: Ankle Brachial Index
- ABPI: Ankle Brachial Pressure Index
- ANA: Anti-nuclear antibodies
- ANCA: Anti-neutrophil cytoplasm antibodies
- ASVAL: Ambulatory selective varicose vein ablation under local anaesthesia
- AVCD: Self Adjustable Velcro Compression Devices
- AVF: The American Venous Forum
- AVVQ : Aberdeen Varicose Vein Questionnaire
- BMI: Body Mass Index
- CEAP Classification: Clinical class (C), etiology (E), anatomical distribution of reflux (A) and obstruction in the superficial, deep and perforating veins, and the underlying pathophysiology (P)
- CHIVA: Ambulatory conservative haemodynamic management of varicose veins
- CIVIQ: Chronic Venous Insufficiency Questionnaire
- CoI: Conflict of Interest
- CPG: Clinical Practice Guideline
- CRP: C-reactive protein
- CVI: Chronic Venous Insufficiency
- CVD: chronic venous disease
- CWIS: Cardiff Wound Impact Schedule
- CXVUQ: Charing Cross Venous Ulceration Questionnaire
- EDF: European Dermatology Forum
- ESR: Erythrocyte sedimentation rate
- ESVS: European Society for Vascular Surgery
- EU: European Union
- EVLT: Endovenous laser therapy
- EWMA: European Wound Management Association
- FRS: FACES Pain Rating Scale
- FPS: Functional Pain Scale
- GP: General Practitioner
- HCP: Health care professional
- HYTILU: Hypertensive ischemic leg ulcers (Martorell's ulcers)
- ICT: Information and Communication Technology

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- LFT: Liver function tests
 - LU: Leg Ulcer
 - MMPs: Matrix metalloproteinases
 - MPQ : McGill Pain Questionnaire
 - MUST: Malnutrition Universal Screening Tool
 - MD: Medical Doctor
 - NHG: Dutch College of General Practitioners
 - NRS: Nutrition Risk Screening
 - PAOD: Peripheral Arterial Occlusive Disease
 - PN: Practice Nurse
 - QoL: Quality of Life
 - RCT: Randomised Clinical Trial
 - RF/RhF: Rheumatoid Factors
 - RFA: Radiofrequency ablation
 - SEPS: Subfascial endoscopic perforator surgery
 - SIGN: Scottish Intercollegiate Guidelines Network
 - SVS: The Society for Vascular Surgery
 - TIME: Tissue management, Control of infection
 - and inflammation, Moisture imbalance,
 - Advancement of the epithelial edge of the wound
 - UK: United Kingdom
 - US: United States (of America)
 - VAS: Visual Analogue Scale
 - VEINES-QOL: Venous Insufficiency Epidemiological and Economic Study
 - VLU: Venous Leg Ulcer

I. Introduction

I.1 Background

It is well documented that the prevalence of venous leg ulcers (VLUs) is increasing, coinciding with an ageing population. Accurate global prevalence of VLUs is difficult to estimate due to the range of methodologies used in studies and accuracy of reporting.¹ Venous ulceration is the most common type of leg ulceration and a significant clinical problem, affecting approximately 1% of the population and 3% of people over 80 years of age² in westernised countries. Moreover, the global prevalence of VLUs is predicted to escalate dramatically, as people are living longer, often with multiple comorbidities. Recent figures on the prevalence of VLUs is based on a small number of studies and conducted in Western countries and the evidence is weak. However it is estimated that 93% of VLUs will heal in 12 months, and 7% remain unhealed after five years.³ Furthermore, the recurrence rate within 3 months after wound closure is as high as 70%.⁴⁻⁶ Thus, cost-effective adjunct evidence-based treatment strategies and services are needed to help prevent these ulcers, facilitate healing when they occur and prevent recurrence.

The impact of a VLU represents social, personal, financial and psychological costs to the individual and further economic drain to the health-care system. With this brings the challenge of providing a standardised leg ulcer service which delivers evidence-based treatment for the patient and their ulcer. It is recognised there are variations in practice and barriers preventing the implementation of best practice. There are

patients not receiving appropriate and timely treatment in the initial development of VLU's, effective management of their VLU and preventing recurrence once the VLU has healed.

Health-care professionals (HCPs) and organisations must have confidence in the development process of clinical practice guidelines and have ownership of these guidelines to ensure those of the highest quality guide their practice. These systematic judgments can assist in policy development, decision making, improve communication, reduce errors and improve patient outcomes.

There is an abundance of studies and guidelines that are available and regularly updated, however, there is still variation in the quality of the services offered to patients with a VLU. There are also variations in the evidence and some recommendations contradict each other which can cause confusion and be a barrier to implementation.⁷ The difference in health-care organisational structures, management support and the responsibility of VLU management can vary in different countries, often causing confusion and a barrier to seeking treatment. These factors further complicate the guideline implementation process which is generally known to be a challenge with many diseases.⁸

The expert working committee responsible for this document agree there is an urgent need to improve leg ulcer management, to identify barriers to implementation and provide facilitators to assist in the development of a leg ulcer service that

enhances the patient journey in the healing of these debilitating ulcers.

1.2 Document focus and aim

The European Wound Management Association (EWMA) and Wounds Australia have developed this document, aiming to highlight some of the barriers and facilitators related to implementation of VLU guidelines as well as provide clinical practice statements to overcome these and 'fill the gaps' currently not covered by the majority of available guidelines.

The expert working committee responsible for this document is composed of HCPs with different professional backgrounds and nationalities, to cover all aspects of VLU management and develop a document that takes the organisational differences across countries into consideration.

The document focus is leg ulcers of a venous origin. The authors of this document alert HCPs to the importance of a correct diagnosis of the type of ulcer being treated. Other types of leg ulcers are described to assist the HCP in determining arterial, mixed aetiology and atypical ulcers and when to consider referral.

Thus, the aim of this document is twofold:

- To identify barriers and facilitators in the implementation of best practice in the management of a VLU

- To provide clinical practice statements addressing key aspects to consider when developing an evidence-based leg ulcer service that enhances the patient journey

1.3 Target population

This document is intended for use by health-care organisations and HCPs involved in the management of VLUs, in health care settings in metropolitan, rural and remote areas worldwide. This information could also be used as an education resource for consumers and for use by policy makers and organisations wishing to develop an evidence-based leg ulcer service.

2. Methodology

2.1 Guideline consensus

This document presents comprehensive review of the assessment, diagnosis, management and prevention of VLU within the international health-care context, based on the recommendations reviewed from eight clinical practice guidelines and the opinion of the Expert Working Committee. It is designed to provide information to assist in the development of an evidenced-based leg ulcer service that assist HCP and health-care organisations overcome barriers and facilitate decision making.

Guidelines were identified via a search in the following databases: National Guideline Clearing House, Cinahl, Embase and Medline. A combination of the following terms was used: lower limb ulcer, VLU, varicose ulcer, venous insufficiency, varicose eczema, wound, ulcer, guideline, clinical guideline. The first search was performed in April 2015. However, guidelines published/updated later were evaluated for inclusion until September 2015.

Table 1. Guideline inclusion criteria

Inclusion criteria	Must explicitly state they are a guideline Guideline must include the management of venous leg ulceration Published/updated in 2010–2015 Available in English language
Exclusion criteria	Consensus or expert opinion documents

The focus of this work is the synthesis of clinical practice guidelines and thus our database search was limited specifically to documents which use the word ‘guideline’ in the title. Additional inclusion and exclusion criteria are outlined in Table 1.

2.2 Literature search

Two literature searches were carried out to identify additional relevant background literature for document sections 4 and 5:

1. Literature Search strategy - guideline implementation

Search question:

- Identification of generally applicable, potential barriers to and facilitators for guideline implementation (general, wound and VLU related)

2. Literature Search strategy – VLU management

Search questions:

- To identify recent evidence on the strategies used in clinical practice to define/classify, assess and diagnose, treat/manage leg ulcers, monitor outcome of leg ulcer management, refer patients and prevent leg ulcer recurrence
- To identify recent evidence on leg ulcer prevalence and incidence
- To identify recent evidence on patient

perspectives on leg ulcer management, as well as the health economic aspects and organisation of leg ulcer management

The identified literature was used to supplement the evidence from the reviewed VLU guidelines.

The search strategies are further outlined in Appendixes 1 and 2.

A systematic review of the identified literature is outside the scope of this document.

3. Overview and comparison of available guidelines

3.1 Identifying and comparing guidelines

The definition of the term guideline is explicit and states: CPGs ('guidelines') are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.⁸

Of 17 documents identified nine were excluded. Reasons for exclusion included: being consensus only (n=2); an older version of a current guideline (n=2); for compression therapy only and not limited to VLU (n=1); for management of wounds without specific reference to management of VLU (n=3); for varicose veins (n=1).

The inclusion criteria were met by eight guidelines (Table 1). A data extraction grid based on the themes of the AGREE II framework for appraisal of CPGs⁹ was developed. There were nine review group members, working independently, who entered data into the data extraction grid. The findings were discussed by the group and consensus achieved on the final content of this review.

Of the eight guidelines identified, all were published between 2010-2015; there were three from 2010; one from 2011; three from 2014 and one from 2015. There were two updates of previous versions.

The source of guidelines by country included one joint document from Australia and New Zealand; one joint document from the USA and Europe; two solely from groups in the USA; one each from Scotland and the Netherlands.

3.2 Guideline comparison—results

The following details were extracted:

Scope and purpose

All guidelines explicitly stated they were for the management of patients/clients with a VLU. One guideline was targeted specifically for use by dermatologists, one for general practitioners (GPs) only and the remainder were for all HCPs involved in the management of patients with chronic venous disease (CVD).

There was only one guideline which introduced health questions as a means of developing recommendations. Of the remainder, specific objectives were not stated but they did indicate the purpose was for the management of VLU. Surgical management was excluded by three guidelines.

Stakeholder involvement

There were two unidisciplinary guidelines and the remainder multidisciplinary. Vascular physicians

Table 2. Overview of the compared guidelines (sorted by publication year)

No	Title	Organisation	Published /updated	Country/ international collaboration
1	Association for the Advancement of Wound Care (AAWC) venous ulcer guideline ¹⁰	Association for the Advancement of Wound Care	(2005) 2010	USA
2	Management of chronic venous leg ulcers (SIGN CPG 120) ¹¹	SIGN (GB)–Scottish Intercollegiate Guidelines Network	2010	Scotland
3	Varicose ulcer (M16) [Varicose ulcer (NL: Ulcus cruris venosum)] ¹²	NHG (NL)–Dutch College of General Practitioners	2010	The Netherlands
4	Australian and New Zealand Clinical Practice Guideline for Prevention and Management of Venous Leg Ulcers ¹	Australian Wound Management Association and the New Zealand Wound Care Society	2011	Australia and New Zealand
5	Guideline for management of wounds in patients with lower-extremity venous disease ¹³	Wound, Ostomy, and Continence Nurses Society–Professional Association	(2005) 2011	USA
6	Guideline for Diagnostics and Treatment of Venous Leg Ulcers ¹⁴	European Dermatology Forum	(2006) 2014	Europe
7	Management of venous leg ulcers: Clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum ¹⁵	The Society for Vascular Surgery and the American Venous Forum	2014	USA and Europe
8	Management of Chronic Venous Disease, Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS) ¹⁶	European Society for Vascular Surgery	2015	Europe

and vascular surgeons predominated among the development groups. Details of the groups were provided on five occasions including the professional discipline, and in three guidelines names of group members were provided. Only one included patients in the development group.

Rigour of development

The methodology used to generate the guidelines varied, two reported using systematic reviews; five used literature reviews and literature searches; three used consensus in all or part of the process, but as they positioned themselves as guidelines in the title they were included. The draft guidelines were

opened for public consultation, as such patients would have had an opportunity to comment. Four opened the document for professional comments and consultation and one was peer-reviewed by four professionals. Cultural and diversity review by non-medical cultural groups was completed for one.

The Grading of Recommendations, Assessments, Development and Evaluations (GRADE) system (<http://www.gradeworkinggroup.org/>) was used by four guidelines, providing the strength of evidence to support the recommendations.

Clarity of presentation

Recommendations were generally explicitly stated.

Applicability

A specific implementation plan was developed by one guideline, one made recommendations to support implementation and of the remainder, no details were provided on how to implement or disseminate. None of the guidelines included an audit tool but one included an assessment tool.

Editorial independence

Declarations of conflicts of interest (CoI) of development group members were documented in four guidelines. The remainder did not provide any details of CoI.

The result of the guideline recommendations (content) comparison is summarised in Table 3.

Table 3. Guideline content summary

Assessment and referrals	
Patient assessment	The following factors have been recommended to be included when assessing the patient presenting with lower limb ulceration or with a venous leg ulcer (VLU): Clinical history [5 guidelines]; leg ulcer history [2 guidelines]; physical examination [1 guideline]; varicose veins either present, or having a history of, or surgery for [2 guidelines]. Five recommended that persons performing the assessment should be trained in that assessment and should have a knowledge of anatomy and physiology. Specific comorbidities to be recorded or taken account of included: peripheral vascular disease [1 guideline]; diabetes [2 guidelines]; deep vein thrombosis (DVT) [2 guidelines]; hypertension [2 guidelines]; obesity/body mass index (BMI) [3 guidelines]; trauma [1 guideline]; malnutrition [1 guideline]. Four guidelines did not refer to comorbidities.
Patient referral	Three guidelines did not make any recommendations about referral of patients. Two recommended that a multidisciplinary team approach is required. Timing and reasons for referral forward included: if the ulcer had not reduced by 25% in 4 weeks or failed to heal in 12 weeks [1 guideline]; if there is a lack of tendency to heal by 4 weeks [1 guideline]; if there is a lack of tendency to heal by 8 weeks [1 guideline]; doubts about aetiology or atypical ulcer presentation [3 guidelines]; ankle to brachial pressure index (ABPI) <0.8 [1 guideline]; where chronic venous insufficiency (CVI) is complicated by lymphoedema [1 guideline].
Leg assessment	The use of the clinical signs, aetiological cause, anatomical distribution, pathophysiological dysfunction (CEAP) classification score was referred to in only one guideline. Factors to be included in assessment of the limb included: varicose veins [2 guidelines], atrophie blanche [2 guidelines], oedema [2 guidelines], joint mobility [2 guidelines], hemosiderin deposits [1 guideline], lipodermatosclerosis [1 guideline], vascular dermatitis [1 guideline].

Investigations	
ABPI	One guideline did not refer to the use of ABPI, the remainder recommended its use as part of the assessment process. Four guidelines recommended that persons trained in performing ABPI should complete this, with one stating it should be performed in a vascular lab. The remaining two did not state who should perform this.
Pulse oximetry	Five guidelines did not refer to this investigation. The remaining three stated it was not necessary in routine practice but may be used in conjunction with other tests.
Assessing the ulcer	Two guidelines did not provide recommendations on assessing the ulcer. Of those that did, four recommend measuring ulcer size and repeating this serially, although the frequency of repeat measurements was not stated [4 guidelines].
Biopsy	It was recommended that biopsies should be performed on atypical ulcers [4 guidelines]; non-healing ulcers [2 guidelines]; ulcers not healing at 4-6 weeks [1 guideline]; and ulcers not healing at 12 weeks [1 guideline].
Bacteriological swabs	Two guidelines made no recommendation. Five stated that routine swabs are not indicated; six stated swabs should be taken when there are signs of infection and one recommended swabs prior to surgery.
Management of eczema	Three guidelines made no recommendations. Two recommended the use of zinc bandages or zinc based ointments; three recommended patch testing and three recommended topical steroid therapy if indicated.
Reassessment	Seven guidelines made no recommendation about reassessment. The one that did recommended that patients are reassessed at 12 weeks if no progress was evident, then reassessment should be completed at 12 weekly intervals. If the ulcer remained unhealed then a biopsy should be performed [1 guideline].
Ulcer management	
Cleansing	Water of sound (safe) quality was recommended for routine cleansing in four [4 guidelines] and a non-irritating, neutral, non-toxic solution was recommended by three [3 guidelines].
Debridement	Two guidelines did not make recommendations. All methods of debridement were suggested, with two making it explicit that surgical and sharp debridement is performed by persons trained in such procedures. Only one guideline recommended that debridement is performed at the initial assessment and periodically thereafter; none of the others made recommendations on frequency.
Wound dressings	One guideline did not refer to dressings at all. The remainder recommend that non-adherent dressings are suited to most cases and thereafter according to patient need.
Topical antimicrobials	Three guidelines did not make reference to the use of topical antimicrobial agents. Of the remainder, it was recommended they should not be used in routine care or when there were no signs of infection [3 guidelines]. In addition, it was recommended that topical agents can be used when there is local infection and in addition to culture guided systemic antibiotic therapy.
Peri-wound area	Five guidelines recommend the use of moisturising agents in the peri-wound area.
Compression therapy	The decision to apply compression is based on holistic assessment which includes ABPI. In addressing which patients should be offered compression therapy based on the recording of the ABPI the following was recommended: when ABPI 0.8-1.2 [1 guideline]; ABPI >0.8 [3 guidelines]; ABPI >0.9 [1 guideline]; ABPI > 0.5 [1 guideline] the latter recommended a reduced level of compression. Three guidelines did not make any recommendation.
Hosiery	None of the guidelines recommend hosiery for management of active open ulcers as a first line of treatment. One recommended that once the ulcer has healed, bandages should be applied for two weeks, followed by hosiery [1 guideline]. Hosiery should be replaced every 12 months [1 guideline].

Systemic therapies	Pentoxifylline was recommended if there were no contraindications to its use [3 guidelines]. Antibiotics should be used only in the presence of confirmed infection [1 guideline]. Analgesia may be required and the use of eutectic mixture of local anesthetics cream for debridement was recommended [2 guidelines]. However while acknowledging that pain may be an issue, no clear recommendations were made for pain management or how pain should be assessed.
Surgery	Five guidelines addressed the issue of surgery in the management of VLU. Of these, it was recommended that all patients with a VLU should see a vascular surgeon and be considered for surgery [2 guidelines], in patients with VLU C6, ablation of the incompetent veins in addition to compression to improve ulcer healing [1 guideline], in patients with VLU C6 and incompetent superficial veins that have axial reflux directed to the bed of the ulcer ablation of the incompetent veins in addition to standard compressive therapy to prevent recurrence was recommended [1 guideline], surgical treatment of isolated insufficiency of the superficial system may promote healing and reduce recurrence rate [1 guideline].
Other aspects of management	
Costs	While costs were acknowledged by four guidelines, no recommendations were made with regards to routine collection of data to assess costs.
Patient education	This was alluded to in four guidelines. These recommended education of the patient on the following factors: cause of the ulcer [2 guidelines], use of compression [3 guidelines], mobility and exercise [2 guidelines].

For each item listed below the number of guidelines making this recommendation or including this item is presented in brackets.

guidelines here shows considerable variation in the development process and strength of recommendations. Nonetheless some key points have emerged:

3.3 Key points/summary of findings

Ideally guidelines need to contain evidence-based practice recommendations that provide a clear description of desired performance and specific advice about what to do in which situation and which factors should be taken into account. However, only two of the reviewed guidelines used the GRADE classification system.

Many frameworks are readily available to guide the development of CPGs to support the rigour of the development process and strength of recommendations (www.Sign.org, <http://www.g-i-n.net>). Therefore one could reasonably expect that documents using the term 'guideline' would meet the requirements as outlined in these frameworks. However, review of the eight

- All patients presenting with lower limb ulceration must have a comprehensive assessment including assessment of systemic, regional and wound factors and this assessment must be completed by clinicians educated and trained in this assessment. There are no recommendations on the nature or extent of this training and education.
- All patients must have an ankle brachial pressure index (ABPI) completed as part of the assessment process and before commencement of compression therapy. There is no consensus among these guidelines on the minimum ABPI value that is required prior to commencement of compression. There is no consensus on the frequency of repeat ABPI measurement with only one recommending re-measurement after 12 weeks.

- The use of compression therapy in the form of inelastic material (bandages or Velcro devices) is recommended for the management of venous leg ulceration. Compression hosiery is recommended for healed ulcers. While hosiery may be used for active ulcers they are not recommended as the first line of treatment.
- There is no consensus on when patients should be referred forward. However as routine wound measurement is advocated and the milestone of 4-weeks post initiation of treatment is referred to in four guidelines, this could be considered as a time to reflect on healing progress and review of the treatment plan. Biopsy of the wound is recommended for atypical ulcers or those that are not responding to therapy.
- Widespread agreement exists that routine bacteriological swabs are not indicated, routine antimicrobial therapy is not indicated.
- Simple non-adherent dressings are suited for the majority of wounds.
- Pain should be assessed and managed, but specific guidance on how this is achieved was not evident.
- There was scant reference made to patient quality of life, patient wellbeing, patient education and costs.
- It is well recognised that individual patients and carers can play a proactive role in self-care ulcer management including amongst other things changing of dressings and compression bandages/hosiery/wraps. The HCP should support the patient to enhance self-care activities.

4. Clinical adherence to guidelines—barriers and facilitators

4.1 Introduction

Evidence-based CPGs are designed to improve quality of care and reduce practice variation by providing graded recommendations based on the best available evidence. They are intended as instruments of knowledge transfer to support decision-making by physicians, other health professionals and patients in clinical practice. Efficient and effective guidelines, which are thoroughly implemented, impact patient safety and quality by increasing the consistency of behaviour and replacing idiosyncratic behaviours with best practices.¹⁷

Difficulties arise when introducing evidence and guidelines into routine practice. Many are not used after dissemination and implementation activities frequently produce only moderate improvement in patient management.^{18–20}

Many approaches have been published offering potential solutions of barriers to guideline implementation, mostly in areas other than wound care. Substantial evidence suggests that behaviour change is possible, but this change generally requires comprehensive approaches at different levels (doctor, team practice, hospital, and health system environment), tailored to specific settings and target groups. Plans for change should be based on characteristics of the evidence or guideline itself and barriers and

facilitators to change. In general, evidence shows that no one approach for transferring evidence to practice is superior in all situations.^{21,22}

A systematic review of the effectiveness and costs of different guideline development, dissemination and implementation strategies reported on a four-step approach, consisting of guiding questions, to direct the choice of the most appropriate components of an implementation intervention^{23–25}

1. Who needs to do what, differently?
2. Which barriers and enablers need to be addressed?
3. Which intervention components (behaviour change techniques and mode(s) of delivery) could overcome the modifiable barriers and enhance the enablers?
4. How can behaviour change be measured and understood?

In the following chapters we will outline potential barriers and facilitators for clinical practice guideline implementation related to the various players. Some of these are specific for leg ulcer management.

4.2 The health-care system/organisation—the payer and provider perspective

Various factors defined by structures of the health-care systems as well as traditions and structures defined by specific health-care organisations may influence an organisation's ability to successfully adapt leg ulcer management to guideline recommendations.

These may facilitate implementation, or work as barriers to implementation, depending on the actions and preferences they support. In both cases, guideline implementation planning is likely to benefit from taking these into consideration.

4.2.1 Reimbursement of patients and health-care organisations

Reimbursement for wound care products is frequently cited as the reason for failure to change practice. Much of this will depend on who pays for care. For instance, if the patient is required to buy their own bandages and dressings this will have a major impact on what is available according to their financial situation. The health-care system may also be unable to afford best practice treatments.²⁶

In a comprehensive health system, inequalities of this nature are less likely to occur but may occur as a consequence of other issues, such as the care providers' knowledge and understanding of when and where different products should be used. Efficiencies in leg ulcer services can be a trade-off between increased costs of bandages with reductions in nurse time to treat patients. As an example, until the changes in Drug Tariff (list of treatments available to be prescribed compiled by the UK National Health Service), this additional cost of bandages had to be borne by the community nursing service. In a study of service development nurses acknowledged that while compression bandages were expensive they could be cost-effective due to the improvements in healing.²⁷ This was sometimes an area of conflict between the nurses and GP and health trust managers who held the finances. Much of this was resolved upon the addition of multi-layer compression on the Drug Tariff in the UK. Reimbursement for products and services can therefore facilitate implementation, whereas restrictions on these can lead to failure to change practice.

While limited access to products may prevent the adoption of recommendations on treatment, the health system may also impact on the implementation of guidelines. Payment by Diagnostic Related Groups (DRGs) will provide resources on the basis of the condition and the

expected cost of care. This may or may not provide all the care needs that patients may require to provide an effective management protocol. GPs and hospital doctors may also be paid according to the number of patient visits. This may have a positive influence, or may limit patient contacts according to the contract they have with the funding agency (government health provider or insurance agency).

4.2.2 Pursuing cost-effective care

Implementing guidelines does not necessarily require evidence of cost-effectiveness, but the increasing need to reduce health-care costs may lead to recommendations supported by evidence of cost-effectiveness being more likely to be successfully implemented. In VLU management there is some evidence on effectiveness but little evidence on the relative cost-effectiveness of different interventions. The comparison of VLU guidelines showed that recommendations for routine collection of cost data is not included in the guidelines.

Cost-effectiveness examines the relationship between costs of care and outcomes of treatment. Cost effectiveness can be defined as:

$$\text{Incremental cost per additional outcome} = \frac{\text{Cost of treatment 1} - \text{Cost treatment 2}}{\text{Outcome 1} - \text{Outcome 2}}$$

For venous leg ulceration the outcome is routinely the number of ulcers healed or alternatively the ulcer-free weeks following healing. The latter is usually preferred as this can include a further period of healing that may occur following a recurrence of the original ulcer.

Having defined the outcome, one must develop

a system that captures the appropriate costs of care. This may include health professionals' costs, dressings and bandages used together with adjunctive therapies and on-costs associated with the care of these patients. It is important to consider that the cost-effectiveness relates only to those treatments or systems being tested. A blanket statement of cost-effectiveness is meaningless without an understanding of what has been tested, and particularly what has not been tested. As an example of this, one might undertake a study of three products. Product A may be more cost-effective than product B but less cost effective than product C. It would not be appropriate to call product A cost effective without the proviso that it is in relation to product B. The plethora of dressing and bandage systems makes the statement that any of these are 'cost-effective' should thus be treated with caution.

A brief outline of the current evidence on the cost effectiveness of dressings and bandage systems are provided below:

The key rationale for all health-care organisations is to provide the best care for patients within the financial constraints of the organisation; to provide a cost-effective service. Thus, the level of care will be dependent on the resources available to it.

A potential barrier to implementation of a CPG may be the misinterpretation of health economic data in relation to the costs of care provision. While the costs of dressings and bandages and other medical devices are clear for all to see, what is still frequently forgotten or ignored is the cost of delivering the care through staffing.² High cost products may appear more expensive to use but may reduce the time and frequency of visits made by the health care professional. Any changes that are undertaken to improve practice

Table 4. Cost effectiveness, dressings and bandage systems

<p>Dressings</p>	<p>The Cochrane collaboration has examined clinical trials data for both alginates²⁸ and foam dressing.²⁹ Although the data were generally poor with studies including a high proportion of small ulcers they indicated that there was no evidence to suggest that either dressing types were able to heal more ulcers than other less expensive products. The implication is that if the outcomes are identical then the decision to use should be according to the relative cost of the dressings.</p>
<p>Bandage systems</p>	<p>There are a plethora of bandages and bandage systems available in the management of venous ulceration, few of which have been compared in randomised controlled trials (RCTs) and fewer again that have been evaluated according to their relative cost-effectiveness. The Cochrane Wounds group have undertaken a meta-analysis of types of compression used in venous ulcers.³⁰ Their conclusions were that compression increases ulcer healing rates compared with no compression, and multi-layer systems were more effective than single-component systems. Elastic bandages appeared to be more effective than inelastic bandages. Two-component bandage systems appeared to perform as well as the 4LB. For many, the 4LB is the current gold standard by which other bandage systems are compared. The dynamics of the 4LB are complex as it combines both elastic and inelastic properties. Thus it is difficult to state that studies using 4LB are comparing simple elastic bandaging with other compression types. Also, these studies did not report on compression pressure, expertise of the HCP and unwanted effects. As with all reviews of this nature, the cost-effectiveness was rarely undertaken in these studies, though one study indicated that 4LB was more cost-effective than short-stretch bandaging.</p>

through guideline usage must therefore take into consideration not only the cost of products used in care but also the impact on the health professionals' time in caring for the patients.³¹⁻³³

Clearly the type of professionals who administer care, what they deliver, where it is delivered, and the frequency of care delivery will define costs. In some countries the majority of care is provided by community nursing staff in the patient's own home. This can provide for a very cost-effective service compared with hospital visits, provided that the nursing staff are given adequate training and support for referral when necessary. While this is well established in a number of countries, others see this as the way forward in both reducing costs while maintaining a quality service.³⁴

During the process of implementation of clinical practice guidelines it is likely that overall costs may increase as more expensive products may be used to treat patients. However, the long term benefits may outweigh this initial increase in costs, as increased healing will lead to fewer patients

needing treatment. Cost efficiency may also be demonstrated by the reduction in visit frequency.³⁵ See table 4 for specific considerations related to dressings and bandage systems.

4.2.3 Ehealth as a facilitator for implementation/integrated care

Much has been written on the development of electronic systems/information and communication technology (ICT) to enhance services among other things. Electronic health records have been associated with improved practitioner knowledge, though its use in improving guideline adherence in the management of diabetes has provided conflicting results.³⁶ For similar reasons, telemedicine has been evaluated as a means to providing more effective services.

Within wound care, telemedicine most often refers to the establishment of systems which allow for details of a patient to be sent to an expert in wound care for their opinion without the

need of a face-to-face meeting. In most of the established telemedicine services implemented in wound care, the patient information is sent by community care nurses to hospital-based wound experts. In areas where specialised HCPs may not be available, for example rural areas, telemedicine may thus offer an opportunity to provide specialised assistance for assessment, diagnosis and treatment of a VLU patient.³⁷ Patient information is, in most cases, entered into a patient profile and stored in online databases. Thus, telemedicine services may provide a good opportunity to support the use of specific patient records by all the involved health-care providers.

Telemedicine has also been described as a way to increase the knowledge and involvement of the patient in his or her disease and treatment.^{38,39} Thus, these services have an integrated potential to enhance the knowledge about leg ulcer care of patients and private care givers, as well as non-specialised nurses and GPs in primary care. By serving this educational purpose, telemedicine may be a valuable tool to support guideline-driven care in hospitals as well as community care settings.⁴⁰

Additional services aiming for more independent involvement of the patients are on their way to the market may, in the future, further develop the opportunities related to supporting implementation of guidelines via telemedicine services.

Several studies have indicated positive outcome of telemedicine in wound care, with regards to providing a good structure of care and the services have in general been received well by patients and health care professionals.³⁷ Only a few of these focus on leg ulcer care.⁴¹

An overview of the available evidence as well as considerations about general benefits and challenges related to use of telemedicine in wound

care (e.g. leg ulcer care) is provided in a EWMA Document published in 2015.³⁷

4.2.4 Management support

The importance of management support for change is well established,⁴² and may constitute a barrier as well as a facilitator for implementation. Clearly successful implementation support from the most senior management can help those undertaking change. Previous studies have shown that management behaviours have important impact on how nurses use research.^{27,43} A systematic review identified lack of support from managers and other staff to be one of the greatest barriers to the ability for nurses to use research.⁴⁴ Lack of high-level support from management will cause difficulties in accessing additional resources that may be required for successful change in wound management practices.

As part of the management process it is essential to ensure the availability of suitably trained staff, and of a critical mass to allow the implementation process to flourish. There is need for a skill mix to allow for appropriate delegation of particular duties. Referral routes need to be established to ensure that patients are seen by the appropriate professional allowing for a seamless service between the community and acute sectors.

4.3 Health-care professionals—barriers and facilitators

In daily clinical practice, HCPs have a large responsibility for the provision of guideline-driven care. However, it is well documented that the main responsibility for LU management is placed with different groups of HCPs in different countries (and perhaps also with local variations). An Australian cross-sectional study reported that nurses worked in collaboration with GPs to

determine the treatment plans.⁴⁵ This is in contrast to a study which surveyed US family physicians⁴⁶ where treatment and management of VLU patients is undertaken primarily by the physician. A UK survey reported that 71% of practice nurses (PNs) reported being solely responsible for determining the patient's VLU treatment plan⁴⁷ and an Australian study of GPs in 2006 reported that nursing assistance for leg ulceration management was an integral part of general practice.⁴⁸ In addition, our results from the review of existing guidelines show that two were unidisciplinary in their approach, thus mitigating against a team approach to care.

HCPs also work in diverse settings, have different levels of expertise and may work very differently. Some workplace solutions in one organisation may not be directly transferable or applicable to another health-care environment or patient group.

Depending on the structure of diagnosis and treatment of VLUs and the groups of HCPs with primary responsibility for the various aspects of management, barriers related to the HCP role may include:

- HCPs may experience that their practice environment is not understood and reflected in the guidelines. Thus, when the potential adopters seek the best fit between evidence and their clinical practice setting this may lead to lacking implementation of the evidence-based guidelines⁴⁹
- Implementation of guidelines requires both access and knowledge. Varying levels of knowledge among the HCPs involved in VLU management have been reported^{50,51} and may constitute a barrier for implementation. If we use compression therapy as the example; becoming familiar with the many different types of bandages, contraindications of application, adverse effects, and monitoring require improved education and improved training

in wound care to lead to better wound care outcomes for patients.^{52,53} Although randomised controlled trials (RCTs) and published systematic reviews in wound care inform evidence-based decisions about the use of multicomponent compression therapy as best practice treatment for people with VLUs, there are still examples of lack of compression application by some community and PNs^{54,55}

- Even when HCPs know and accept guideline recommendations about what needs to be done, with high workloads they may forget or neglect to do it.^{56,57} Clinicians increasingly experience excessive workloads, inadequate practice organisational support and financial pressures/lacking resources⁵⁸

Guideline implementation from the bedside may benefit from addressing these barriers.

With regards to methods to facilitate guideline implementation within a health-care organisation/service, the following activities have been demonstrated to be effective:

- Addressing the demand versus ability to change practice (The size of changes required should be compared with available resources and collaboration)^{59,60}
- Developing dissemination strategies that serve to increase relevancy to everyday practice (focus on implementation in context),^{59,49} ensuring a clear professional motivation to implement guidelines, demonstrated by the influence of individual perception of the guidelines and personal commitment to improved practice⁵⁹
- Incorporating local CPGs in professional training, and linking guideline adherence to key performance indicators⁶⁰

- Developing a collaborative, cooperative, democratic environment that involves all stakeholder groups including the patient^{59,61–64}
- Using technology to facilitate CPG accessibility.⁶⁰

These facilitators may obviously have varying relevance and/or effects, depending on local situations. The list above is intended to provide areas to consider when planning an implementation programme addressing the role of frontline HCPs.

Other facilitators are related to the content of the CPGs and include:

- Expanding guidelines to incorporate detailed educational content⁴⁹
- Updating the guidelines regularly and keeping the content simple with specific sections for allied health workers.⁶⁰

Finally, addressing general challenges related to supporting standardised VLU management may, in time, have a positive effect on CPG implementation. For example, efforts could be made to decrease wound care product confusion by developing standardised product naming and improve the quality of wound-care research to increase nurses' confidence in the evidence.⁴⁹

4.4 Patient-related barriers and facilitators

We have dedicated this final section to considerations about the role of the patient in CPG implementation. Guideline implementation may benefit from taking the patient role and opinion into consideration, as this may influence the general outcome.

CPGs link clinical practice to underlying evidence and aim to improve the quality of care. What is not clear is if guidelines take into account what patients want and value. Clinical practice guidelines all agree that adherence to compression improves healing rates for people with VLUs. There is little evidence about patient-related barriers to guideline recommendations such as patient adherence to compression therapy.

One potential reason could be that guidelines do not take patient preferences into account and may not include published evidence about patient perspectives in the process of guideline formulation. Our review of guidelines found that only one included patients in the development process. As described in the previous section, clinicians may not implement guidelines because they perceive a direct conflict between considering patient preferences and applying guideline recommendations. Clinical practice variations, influenced by factors that are extrinsic to the patient, such as costs of compression, occur among clinicians, hospitals, and health-care systems. These variations in practice do not serve the best interests of patients. Patients may not understand key facts that are critical to making decisions and, despite the interest of patients to participate in decisions, clinicians are often unaware of patient preferences and weigh the risks and benefits based on CPGs differently to patients.

Limited research has evaluated reasons for non-adherence to VLU treatment. However, the following potential influencing factors have been identified for LU patients, in particular for compression, as well as more generally:^{65,66}

- Competing claims and advice from clinicians
- Adverse effects or fear of the recommended treatment

- Lack of funding, for example to pay for compression treatments
- Psychosocial influences
- Interpersonal relationships. For example patient trust in the nurse as central to treatment adherence. Adherence has been reported to be more likely when nurses provided care beyond patients' expectations, such as understanding patient preferences and attending to pain.⁶⁷

There is also a paucity of clinical trials that have investigated which interventions promote adherence to compression therapy for venous ulcers.⁶⁸ Some potential approaches to support patient adherence have been investigated, but none of these revealed a real benefit over usual care in terms of healing rates, prevention of recurrence of VLUs, or quality of life.^{69,70} The small number of participants may, however, have hidden a real benefit. These tested approaches included an investigation of:

- Socialisation and support as a method to improve adherence to compression⁶⁹
- Leg exercises and walking via counselling and behaviour modification as a method supporting improved adherence to compression⁷⁰
- The relevance of patient education.⁷¹

The paucity of rigorous process and impact evaluations limits current understanding of how best to improve patient involvement in guideline development and implementation.⁷² CPGs are mainly developed to inform health professionals' decisions rather than foster patient involvement in decision making. The question is how to adapt clinical practice guidelines in such a way that both the professionals' perspective as care provider and the patients' preferences are equal in

the decision-making process.⁷³ Including patients in the guideline development process is the first important step to ensure patient perspectives inform future guideline process.^{72,74}

4.5 Conclusion

It is an issue that many of the available guidelines for VLU management as well as other disease areas are not effectively integrated into clinical practice. Therefore, action is required to improve the strategies related to CPG implementation.

Could it be as simple as change in behaviour at different levels (doctor, nurse, team practice, and environment), tailored to specific settings and target groups? In general, evidence demonstrates that no singular approach in CPG uptake is superior in all situations. Characteristics of research evidence may affect whether it is accepted and used in clinical practice. Some research findings are more easily adopted, however change is rarely easy if the innovation requires complex changes in clinical practice or improved collaboration between disciplines or changes in the organisation of care.⁷⁵

With regards to VLU guideline implementation, studies are needed to identify specific enablers and barriers to adherence to clinical practice guidelines for the management of people with VLU.

5. Current best practice leg ulcer management—clinical practice statements

5.1 Introduction

This section aims to provide an overview of the required basis for high-quality service provision, with a focus on the 'good patient journey'. This section is organised in 5 chapters focusing on key elements of the VLU patient's journey:

- Differential diagnosis and assessment
- Treatment delivery: invasive and non-invasive
- Monitoring outcome
- Referral structures
- Secondary prevention.

All sub chapters will be finalised with a set of number of key clinical practice statements, which refer back to the comparison of evidence-based VLU guidelines (Table 2). Disagreements between recommendations in the available guidelines are only highlighted in case these affect the overall agreement between the guidelines, which include a recommendation on a specific aspect of VLU management.

5.2 Differential diagnosis and assessment

While there are a number of definitions that are

available to describe leg ulceration, it is generally held that they are a defect in the dermis located on the lower leg. LUs are not a disease entity per se, but rather a symptom of an underlying disease. Vascular diseases are the most common problem leading to skin ulcerations on the lower legs. However, there is a large variety of infectious diseases, immunological diseases, physical factors, skin tumours and other skin diseases that lead to skin ulcerations, many of which manifest themselves mostly on the lower legs (Table 5 and Table 16 Appendix 3).^{76–80} The treatment approaches to these different disease entities vary greatly.⁸⁰ Every LU must therefore be assessed to identify the underlying disease. The success of any LU treatment will be higher if it is aimed primarily at the underlying disease and not only at correcting local factors that impair wound healing. However, the aetiological assessment and classification score was not described in the majority of the guidelines reviewed for this document.

5.2.1 Key characteristics of different aetiologies—how to differentiate

Venous leg ulcers

The majority of LUs are seen in the context of chronic venous insufficiency (CVI). This type of ulcer, VLUs, are the focus of this document and make up about 50–60% of all LUs.^{80,81} CVI

can either be caused by a primary varicosis or by post-thrombotic syndrome. Each of these causes are responsible for about half of all VLUs.^{82,83} Both lead to a venous hypertension, which in turn leads to microvascular changes such as elongation of capillaries, micro-thrombosis, fibrin cuffs around vessels and leukocyte leakage.⁸⁴ VLUs are usually located on the medial aspect of the lower leg and around the medial ankle. However, a minority are caused by an isolated varicosis of the lesser saphenous vein or a congenital aplasia of venous valves, and are located on the lateral or dorsal aspect of the foot, respectively.⁷⁷ Diagnosis of CVI is based on clinical characteristics; there are the skin changes that are caused by chronic venous hypertension: oedema, visible capillaries around the ankle (corona phlebectatica), trophic skin changes such as hyperpigmentation caused by hemosiderin deposits, atrophie blanche, induration of the skin and underlying tissue (dermatoliposclerosis) and stasis eczema. Apparative diagnostic procedures are mostly used to confirm venous hypertension and to exclude concomitant arterial or other disease.

Arterial and mixed ulcers

Peripheral arterial occlusive disease (PAOD) can be an underlying disease or a contributing factor leading to lower leg ulcerations.⁸⁵ Arterial disease always has to be regarded in the clinical context of generalised arteriosclerosis and often occurs in

combination with other manifestations, such as coronary heart disease or cerebrovascular disease.

While peripheral necrosis of the toes is the typical presentation of PAOD stage IV, there are a number of LUs that are caused solely by arterial occlusion or in combination with venous insufficiency (mixed ulcers). These LUs are not represented in the commonly used La Fontaine classification of PAOD, some authors call this a 'complicated stage II'. Arterial ulcers are typically located on the lateral or ventral aspect of the lower leg or on the dorsum of the foot. They tend to be deep and sharply demarcated with irregular borders.

Arterial impairment occurs in 15–20 % of venous ulcers.⁸⁶ Mixed venous-arterial ulcers usually combine clinical characteristics of CVI and of arterial ulcers. They can be located in the medial or lateral aspects of the leg and circumferential extension is not rare.⁸⁷

A frequently under-recognised cause of LUs related to arterial ulcers is microvascular occlusion in hypertensive ischemic leg ulcers (HYTILU or Martorell's ulcers).⁸¹ These ulcers occur in persons with marked arterial hypertension, arterial examinations are usually normal. Most of these ulcers are very painful and located on the lateral lower leg or over the shin. The ulcer surroundings are highly inflammatory. Due to their clinical

appearance, they are often misdiagnosed as pyoderma gangrenosum. The diagnosis of these ulcers requires a large, deep biopsy that includes some of the ulcer base but also at least 1 cm of surrounding skin and underlying soft tissue to show the arteriosclerosis.

Arterial assessment is essential for all LUs as the clinical characteristics are not sufficient to rule out arterial disease and arterial occlusion requires special treatment. Furthermore, arterial disease can complicate many other underlying diseases of LUs and its treatment speeds up healing of these ulcers of combined aetiologies.⁸⁸

A summary of aspects of the differential diagnosis of the primary types of LUs can be found in Table 5.

Atypical ulcers

Approximately 10–20% of all LUs are caused by other, miscellaneous causes.⁷⁷ These causes are often referred to as ‘atypical ulcers’, they

are summarised in Appendix 3, Table 16. They include infectious ulcer causes, different forms of vasculitis, ulcerating skin diseases such as pyoderma gangraenosum, haematological and microvascular disorders, physical causes and ulcerating skin tumours.⁷⁶ Many of these ulcer causes can be recognised due to their clinical characteristics, for example palpable purpura in the surrounding skin which is typical for vasculitis, highly inflammatory borders in pyoderma gangraenosum or tissue growth resembling hypergranulation in ulcerating skin tumours. Infectious diseases as cause of a LU require microbiological examination, often a skin biopsy is necessary to provide the deep tissue sample needed for this. Vasculitic ulcers, some skin diseases and all skin tumours need histological assessment of a skin biopsy to make the diagnosis. Ulcerating skin tumours are the cause of up to 3% of all LU, and they are frequently misdiagnosed as LUs of other aetiologies.⁸⁹ Therefore, biopsy is recommended in all ulcers with atypical appearance and/or no healing tendency after six months of treatment.

Table 5. Differential diagnosis and assessment of venous, arterial and mixed leg ulcers^{76,77,88–90}

Underlying disease		Clinical characteristics	History	Assessment
Vascular	Chronic venous insufficiency (CVI) (50%)	Ulcer location: retromalleolar, mainly medial. Surroundings: oedema, hyperpigmentation, purpura, atrophie blanche. Stasis eczema /allerg. Contact dermatitis, dermatoliposclerosis	Thrombosis, Varicosis, heavy legs, oedema	Doppler-/ Duplex-Sonography
	Arterial (10%)	Lateral and ventral aspect of leg, dorsum of foot Surrounding skin: atrophic, shiny, hair loss	Cardiovascular risk factors, intermittent claudication	Palpation peripheral pulses, ABI, Duplex-Sonography, Angiography
	Mixed venous-arterial (20%) Other aetiologies (20%), See Appendix 3	Medial and lateral, signs of CVI, ABI<0.8	Cf venous and arterial	Cf venous and arterial

5.2.2 Patient assessment and vascular assessment

Responsibility for assessing the patient HCPs should meet the qualification, registration and/or licensing requirements of their geographic region before undertaking a role in assessing patients with LUs. Whether HCPs other than medical doctors have the right to diagnose and prescribe varies across countries (See chapter 5.4 'Referral structures'). The HCP conducting patient assessment should have the appropriate anatomical and physiological knowledge. Assessment of venous ulcers is complex, and post-basic education and training is recommended. HCPs should have appropriate training in the use of diagnostic equipment (for example performing an ABPI). Although there is a paucity of literature on the effectiveness training, the available research and consensus opinion suggests that patient outcomes are superior when a HCP with specific training in venous ulcer assessment and management is engaged in the patient's care.¹

Patient assessment

Comprehensive clinical assessment should include:^{1,11,10}

- Medical and surgical history in the context of a VLU, including assessment of comorbidities
- LU history
- Vascular assessment
- Biochemical investigations
- Mobility and functional status
- Pain history
- Psychosocial status, cognitive status and quality of life (QoL).

- Physical examination including examination of the leg and ulcer, including microbiological investigation when applicable.

Medical, surgical and leg ulcer history

A demographic and clinical background indicative of a LU with venous origin include those factors presented in Table 6. Evaluation of these factors is essential in diagnosing an ulcer of vascular origin and identifying risk factors for delayed healing and/or ulcer recurrence that require address in the patient's treatment plan.^{1,10}

Comorbidities can influence management of venous disease and require concurrent management^{1,11}

Patients should receive screening for, and investigation of, the conditions in Table 7, along with other comorbidities relevant to the patient's presenting signs and symptoms and past history.

A nutritional screening should be undertaken by the HCP performing the comprehensive patient assessment.⁹¹ It is recommended that HCPs use of a valid and reliable nutrition screening tool appropriate to the patient demographics that includes, but may not be limited to, factors such as weight/body mass index (BMI), recent food and fluid intake, hair and skin changes,

Table 6. Clinical factors associated with venous leg ulcers^{1,10}

- Venous disease including post-thrombotic syndrome, venous insufficiency (superficial or deep), deep vein thrombosis, phlebitis or varicose veins, previous ulcer diagnosed as being of vascular origin
- History of vigorous exercise or occupation/lifestyle with prolonged standing or sitting
- Chest pain, haemoptysis or pulmonary embolism
- Surgery or trauma of the affected leg
- Family history of venous leg ulceration
- Multiple pregnancies
- Obesity
- Increasing age >50 years
- Duration of the ulcer

Table 7. Comorbidities and conditions that may influence the treatment of vascular disease and venous leg ulcers^{1,11,91}

- Peripheral arterial disease
- Rheumatoid arthritis
- Vasculitis
- Diabetes mellitus
- Previous history of skin cancer
- Under-nutrition
- Obesity (BMI $\geq 30\text{kg/m}^2$)
- Impaired mobility

appetite, and weight history (including any recent, unintentional weight loss).¹ No nutritional screening tools have been validated specifically for use in screening patients with VLUs, however there are a range of screening tools available (see Table 8 for examples), many of which are validated for patient groups applicable to people with venous disease. Patients who are screened at risk of malnutrition should be referred to a dietician for a comprehensive nutritional assessment.⁹¹

Taking a comprehensive LU history provides a clinical picture that provides diagnostic indicators to the ulcer aetiology and realistic expectations of the healing trajectory. History should include duration of the ulcer, any previous ulcers, time spent without ulcers, effectiveness of strategies

Table 8. Examples of commonly used nutritional screening tools⁹¹

Screening Tool	Patient Group
Short Nutritional Assessment Questionnaire (SNAQ)	Patients in hospital
SNAQRC	Patients in residential care
SNAQ65+	Patients aged ≥ 65 years
Nutrition Risk Screening (NRS-2002)	
Mini Nutritional Assessment	Patients aged ≥ 65 years
Malnutrition Universal Screening Tool (MUST)	

used in managing and the time taken to heal any previous ulcers.¹

Vascular assessment

Vascular assessment must be undertaken to determine underlying aetiology of the ulcer (venous, arterial or mixed) and to determine severity of disease. Adequate arterial perfusion is essential for wound healing and patients with insufficient arterial supply require revascularisation before compression therapy or surgical wound repair.¹⁵

Inspection of the leg is an important component of a vascular assessment. Pale or bluish colouring, cool temperature, decreased hair growth, hypertrophied nails and muscle atrophy are indicators for arterial disease. Examination of the leg appearance, including level and characteristics of oedema (for example pitting), skin presentation (see 5.2.3 How to assess the leg and ulcer) and visibility of varicose veins are also used in identifying and classifying venous disease.

The patient's clinical symptoms may also provide indications of active venous disease (Table 9).^{10,11,15}

A range of clinical investigations (Table 10) can be used to confirm disease aetiology and diagnose anatomical and pathophysiological involvement when venous disease is identified. Clinical investigations are also used to determine severity of vascular disease and determine prognosis with respect to ulcer healing.^{10,11,15} In most cases, clinical examination, venous duplex ultrasound

Table 9. Clinical symptoms indicative of venous disease^{10,15}

- Leg ache and pain
- Tightness
- Skin irritation
- Feeling of heaviness
- Muscle cramps
- Tiredness of the legs

Table 10. Investigations used in vascular assessment^{1,10,11,15}

Investigation	Purpose
Ankle brachial pulse index (ABPI)	Provides estimate of central systolic blood pressure and presence and severity of arterial disease. In patients with incompressible arteries due to calcification (for example patients with diabetes or renal disease), a toe brachial pressure index (TBPI) may be more reliable. ABPI <0.8 is suggestive of arterial disease and requires investigation by a specialist.
Venous duplex ultrasound	Ultrasonography technique that identifies blood flow, patterns of venous obstruction (for example superficial versus deep vein involvement), and venous reflux.
Photoplethysmography (PPG)	Used to measure venous refill time and investigate deficiency of the calf muscle pump function. Venous refill time >20 seconds is indicative of venous insufficiency and potential delay in ulcer healing.
Computed tomography venography (CTV)	Used to increase diagnostic accuracy and suggested for patients with suspected thrombosis or non-thrombotic venous obstruction.
Pulse oximetry	A secondary diagnostic tool to measure level of oxygenation of the blood and assess arterial disease.
Transcutaneous oxygen tension (TCPO ₂)	Used to determine arterial aetiology and identify ulcers that have potential for delayed ulcer healing.
Skin perfusion pressure	Used to determine extent of venous disease and potential for delayed ulcer healing.
Blood pressure measured in both arms	Indication of a range of cardiovascular diseases.

Table 11. Basic CEAP Classification System^{1,15}

Clinical Classification	Description
C0	No visible or palpable signs of venous disease
C1	Telangiectasies or reticular veins
C2	Varicose veins
C3	Presence of oedema
C4a	Eczema or pigmentation
C4b	Lipodermatosclerosis or atrophie blanche
C5	Evidence of a healed venous leg ulcer
C6	Active venous leg ulcer symptoms
Aetiology Classification	Description
Ec	Congenital
Ep	Primary

Es	Secondary (post-thrombotic)
En	No venous aetiology
Anatomic Classification	Description
As	Superficial veins
Ap	Perforator veins
Ad	Deep veins
An	No identified venous location
Pathophysiologic Classification	Description
Pr	Reflux
Po	Obstruction
Pro	Reflux and obstruction
Pn	No venous pathophysiology identified

and ABPI is enough to make a diagnosis or clarify whether further examination is needed.

The findings from the vascular assessment must be used to categorise the clinical severity of venous disease and expected response to treatment using the internationally recognised CEAP (clinical, aetiology, anatomy, pathophysiology) Classification System (Table 11).^{1,10,15}

Biochemical investigations

Biochemical investigations should be undertaken to investigate the venous disease and comorbidities. Laboratory investigations may include:¹

- Blood glucose level (BGL) and/or haemoglobin A1c (HbA1c)
- Haemoglobin (Hb)
- Urea and electrolytes
- Serum albumin
- Lipids
- Rheumatoid factor (RhF)
- Auto antibodies
- White blood cell count
- Erythrocyte sedimentation rate (ESR)
- C-reactive protein (CRP)
- Liver function tests (LFT).

Mobility and functional status

Functional status, particularly mobility level, should be assessed as part of the diagnostic process, as well as to ensure that the VLU management plan developed for the patient is feasible to implement.

Lower leg joint mobility is a component in calf muscle pump function, which assists in venous return in a healthy venous system. Calf pump muscle function haemodynamic performance is related to the strength of calf muscles and the mobility of the ankle joint.¹¹ No significant differences are noted in time spent exercising between people with and without venous ulceration⁹² however, it is important to assess and understand the patient's physical abilities (for example flexibility) in order to develop a feasible treatment plan to which the patient can adhere (for example ability to elevate legs, ability to put on and take off compression stockings).

Pain assessment

A pain assessment should be conducted using a pain tool that is reliable and valid (Table 12). Select an appropriate tool based on the patient's demographics and comorbidities (for example dementia). A pain assessment should include:¹

- Location of ulcer-related pain
- Severity of the pain
- Quality/characteristics of the pain
- Frequency of the pain and when it occurs (for example at dressing changes, background pain)
- Any triggers and effective relievers
- Impact of the pain on the patient's quality of life and functional ability.

Psychosocial status, cognitive status and quality of life

Comprehensive patient assessment includes evaluating the patient's cognitive ability (for example, using the mini-mental state examination), social support networks and overall QoL and screening for mental health problems.

Table 12. Examples of commonly used pain assessment tools⁹³

Screening Tool	Patient group
Visual Analogue Scale (VAS)	Adults
Wong-Baker FACES Pain Rating Scale (FRS)	Appropriate for adults and people with dementia
McGill Pain Questionnaire (MPQ)	Appropriate for adults and people with dementia
Functional Pain Scale (FPS)	Adults

If mental health conditions are suspected after screening, the patient should be referred to a HCP with experience in assessing and managing mental health. A range of disease-specific QoL tools (Table 13) have been shown to have high sensitivity when used to assess people with venous disease.^{1,15}

5.2.3 Local ulcer assessment

How to assess the leg and ulcer

In general, VLU tend to be shallow and irregular in shape, often occurring in the lower third of the leg (pre-tibial, anterior to medial malleolus).^{1,11}

A comprehensive assessment of the leg and ulcer should be made on initial presentation and at frequent intervals to guide ongoing management.¹

Ulcer assessment should include measurement of the ulcer size,^{1,11} by measuring the length, width and depth with a disposable ruler. This will record the progress of wound healing over time. Where resources are available, computerised calculation, digital photography or wound tracing of the ulcer area should be attended at frequent intervals.

The type of exudate should include a description of the colour, consistency and amount. For example serous (yellow fluid), haemoserous (blood and serous fluid) sanguineous (old blood) or purulent (green fluid).

Table 13. Valid and reliable quality of life (QoL) tools for populations with venous disease^{1,15,94,95}

Generic QoL assessment tools
36 Item Short Form Health Survey (SF-36)
Cardiff Wound Impact Schedule (CWIS)
Venous disease-specific QoL assessment tools
Chronic Venous Insufficiency Questionnaire (CIVIQ)
Venous Insufficiency Epidemiological and Economic Study (VEINES-QOL)
Aberdeen Varicose Vein Questionnaire (AVVQ)
Charing Cross Venous Ulceration Questionnaire (CXVUQ)
Wound-QoL

Recording the amount of exudate as accurately as possible. Is the exudate minimal or soaked through the dressing? The presence of any odour can indicate infection. Loss of an excessive amount of exudate can cause maceration of surrounding skin and requires monitoring with the appropriate dressing to manage the exudate. It can also cause electrolyte imbalance.⁹⁶

The appearance of the ulcer bed should describe the tissue in the wound bed. For example, black or necrotic tissue (dead eschar), yellow or sloughy tissue (old fibrin), green or infected tissue (clinical signs of infection exist), red or granulating (healthy tissue), hypergranulating (over granulating or proud flesh), pink or epithelisation (new epithelium evident).

The condition of the ulcer edges should be assessed for raised or rolled edges (any undermining), changes in colour (red, purple, white) or evidence of contracting or epithelisation, (healing).⁹⁶ Raised or rolled edges can delay healing and be a sign of hypergranulation or malignancy.⁹⁶ Colour changes can indicate decreased tissue perfusion, redness or erythema indicating infection or a purple/

blue colour indicating malignancy, pyoderma gangrenosum or vasculitis.⁹⁶ Any abnormalities should be further investigated and referred to a trained HCP.

Inspection of the peri-ulcer area and surrounding skin should be assessed for dryness, scaly, maceration, erythema, pruritis, cellulitis, oedema, contact dermatitis or venous eczema.⁹⁶ Pedal and leg pulses are palpated.

There are many associated changes in the leg as a result of CVI. The changes are described in Table 14.

Microbiology and histopathology

When should you take a bacterial swab? All leg ulcers are contaminated with microorganisms. Bacteria exist on the skin as natural flora and migrate to a wound, however, bacterial swabs do not need to be taken unless clinical signs of infection are present.^{1,11,97}

Signs and symptoms of a wound infection in a chronic ulcer may be subtle⁹⁶ and include one or more of the following:

- New, or increased wound-related pain⁹⁶
- Delayed healing⁹⁶
- Friable, hypergranulating tissue
- Increased heat
- Increased exudate
- Change to green/purulent exudate
- Increase odour from wound.
- Increased white cell count
- Pyrexia

Table 14. Associated changes in the leg as a result of CVI^{1,10,11}

Haemosiderin deposit	Red cells leak out in the tissue causing reddish brown staining of the skin
Dilated and torturous veins	As hypertension increases over time the larger veins become affected and visible through the skin
Lipodermatosclerosis	The limb becomes hard and woody to touch as a result of malnourished tissue and fibrosis
Atrophie blanche	A vascular or white skin scarring as a result of thrombosis and obliteration of capillaries in the deeper dermis—can be very painful often appears in areas where there is hyper-pigmentation or lipodermatosclerosis
Eczema	Malnourished skin becoming dry and flaky
Hyperkeratosis	A build-up of dry skin
Hypersensitivity	The skin can become very sensitive and many substances can cause irritation and allergic responses
Ankle flare	Venous congestion—tiny capillaries become swollen and are visible through the skin
Altered shape of lower leg	Inverted champagne bottle
Oedema	Capillaries swell and fluid leaks into the tissues
Evidence of healed ulcers	Scar tissue present
Hair	Present on the limb

- Increase erythema or cellulitis
- Malaise
- Increased swelling/localised
- Oedema of lower limb.

Investigations may include:¹

- Bacterial wound swab or biopsy for bacteriological analysis
- Wound biopsy if malignancy or other aetiology such as vasculitis is suspected
- Wound biopsy for patients with a non-healing or atypical LU.

When to refer to a specialist?

If the aetiology of the ulcer on initial presentation is unable to be determined by the HCP currently responsible for assessment and management of the ulcer, referral to a HCP trained and competent in the assessment and management of VLUs is required. Patients with a non-healing or atypical leg ulcer should be referred for further investigations, including consideration of biopsy.¹

Referral pathways are described in Chapter 5.4

5.2.4 Clinical practice statements

- *Statement 5.2.a: All patients presenting with lower leg ulceration must receive a comprehensive assessment.*

Comments: This must include medical/surgical history; vascular assessment; laboratory investigations; LU history and symptoms; pain; mobility and function; psychosocial status;

QoL and examination of the leg and ulcer.¹ A comprehensive clinical assessment and treatment plan must be developed and documented.

Basic assessment before initiation of treatment should include clinical assessment of the ulcer and leg as well as ruling out arterial disease by performing ABI measurements.

- *Statement 5.2.b: Patient assessment must be conducted by a HCP with appropriate clinical knowledge and skills who has the required qualifications, registration and licensing for the health system in which they practice^{1,11}*
- *Statement 5.2.c: Following a comprehensive assessment, a recognised classification system (for example the CEAP Classification System) should be used to classify the extent of venous disease*
- *Statement 5.2.d: A patient must be reassessed if the ulcer does not heal on the expected trajectory or when the patient's clinical or social status changes.*

Comments: Further assessment to exclude other underlying diseases must be performed after three months or if there is cause for concern before this.

Patients with a non-healing or atypical LU must be referred to a HCP trained and competent in the management of LUs for further assessment and consideration of biopsy.¹

- *Statement 5.2.e: Bacterial swabs should not be taken routinely unless clinical signs of infection are present.^{1,11,97}*

For information about level of evidence available to support these statements, we refer to the following guidelines:

- Association for the Advancement of Wound Care

(AAWC) Venous Ulcer Guideline, A.f.t.A.o.W.C. (AAWC), Editor. 2010¹⁰

- Management of chronic VLUs. A national clinical guideline, S.I.G.N. (SIGN), Editor. 2010, SIGN Publication: Edinburgh, Scotland¹¹
- Australian and New Zealand Clinical Practice Guideline for Prevention and Management of VLUs¹

5.3 Treatment delivery

From the comparison of VLU CPGs, it becomes clear that consistency across guidelines is lacking with regards to the various treatment options. There are few contradictions in the available guidelines, but significant variations in the available information about what, how and when to perform various therapies. In this section we provide key clinical practice statements concerning the available non-invasive and invasive treatment options.

5.3.1 Non-invasive treatments

5.3.1.1 Compression therapy

Compression therapy is based on the simple concept of applying an external pressure to the limb, which is able to improve venous haemodynamics⁹⁸⁻¹⁰¹ control oedema,¹⁰²⁻¹⁰⁶ reduce inflammatory mediators,¹⁰⁷⁻¹¹⁰ improve microcirculation,^{111,112} improve arterial inflow,^{110,113-115} and improve the lymphatic drainage.¹¹⁶⁻¹²² All the reported effects are extremely beneficial in promoting ulcer healing and the first conclusion of the recent Cochrane review providing the most complete overview of randomised controlled compression trials in VLUs states that 'compression increases ulcer healing rates compared with no compression'³⁰ confirming data reported in previous studies.¹²³⁻¹²⁵

Selection of devices for compression therapy

Compression therapy may be applied by means of different devices: elastic or inelastic or short-stretch bandages, elastic stockings or elastic kits, adjustable Velcro compression devices, pneumatic pumps.

Which kind of compression should be used in VLUs treatment is still debated.

Inelastic materials or short-stretch multicomponent bandages that do not give way to the expanding muscle during walking are able to produce great differences between resting and working pressure and high pressure peaks. Such bandages are both comfortable at rest and more effective in improving venous haemodynamics in standing position and during muscle exercise compared to elastic bandages or compression stockings.^{99,100,126,127} These materials give way to the muscle expansion and exert a sustained pressure that is similar in supine and standing position and during work without any pressure peaks.

Multicomponent bandages are more effective than single component bandages in achieving ulcer healing, perhaps due to the ability to maintain pressure and stiffness. They are cost-effective as well as effective in reducing healing time, thereby shortening the treatment period.^{30,128-133}

As VLUs are ultimately due to the impaired venous haemodynamics leading to ambulatory venous hypertension, the compression devices which support improvement of the venous haemodynamics should theoretically be more effective in promoting ulcer healing.

If we restrict our observation to guidelines and studies reporting the compression pressure, it is clear that when correctly applied to exert a strong to very strong pressure, inelastic bandages are very effective in achieving ulcer healing.^{1,11,14,134} It is also

clear that the stronger the pressure the higher the healing rate^{135–138} which favours inelastic materials that are able to achieve a very strong pressure. This is also, even if indirectly, in favour of high stiffness which is the main physical characteristic of inelastic, short-stretch materials.

Short-stretch multicomponent bandages require skill, competent and trained staff to be properly applied.^{12,13} Self-Adjustable Velcro Compression Devices (AVCD) may not be as stiff as short-stretch bandages but may represent an effective alternative even if we have just one report on their effectiveness on ulcer healing. In addition, they may aid self management with related significant costs savings.¹³⁹

Role of elastic stockings

In the most recent meta-analysis comparing the effectiveness of elastic stockings and inelastic bandages in promoting VLU healing,¹⁴⁰ the claimed superiority of stockings can mainly be explained by the fact that in most analysed papers, good stockings have been compared with poor bandages. In addition, almost all the studies included in this meta-analysis are burdened with the flaws previously reported and in some cases with erroneous interpretations of included trials, making the conclusion hard to accept.

It must be noted that in all the included studies not a single elastic stocking but an elastic kit made up of two stockings exerting a pressure ≥ 40 mmHg was compared with inelastic bandages.

Even if we do not believe that elastic kits are more effective than inelastic bandages in ulcer healing, we need to highlight that they were able to promote ulcer healing in an average of 64.2% of patients in three months (four months just in one study).

We may conclude that elastic kits exerting a pressure ≥ 40 mmHg may be used in ulcer

treatment, especially in small ulcers, and by caregivers without the adequate expertise to apply a good bandage.

Intermittent pneumatic compression

We do not have any comparative study between intermittent pneumatic compression (IPC) and sustained compression in promoting ulcer healing. When compared with no compression, IPC is able to increase the VLU healing rate.^{141,142} It may improve ulcer healing rate when added to standard compression.¹⁴³

Compression therapy—mixed ulcers

In 15–20% of VLU an arterial impairment exists:^{86,144} they are named mixed ulcers. Due to high prevalence of arterial disease in patients with leg ulcers, a simple but accurate screening for arterial disease is mandatory in order to choose the best compression modality if the arterial impairment is light or moderate, or to immediately refer the patients to a vascular specialist for revascularisation procedure, avoiding compression therapy as first step. It must be noted that if the treating HCP is not trained and competent in the assessment and management of mixed ulcers, the patient must be referred to the appropriate service.

Arterial impairment is assessed by measuring the ratio between the ankle and the brachial pressure ABPI and is >0.95 in normal subjects.¹⁴⁵ Compression therapy is often contraindicated in mixed ulcers and considered an exclusion criteria in enrolling patients in many VLU healing studies when ABPI is <0.8 .¹⁴⁶ Despite these recommended restrictions, compression therapy is used in mixed ulcers with modified, reduced compression pressure provided the ABPI is higher than 0.6.^{87,144,146–149} Sustained compression pressure is contraindicated in chronic, severe, critical limb ischaemia.¹⁵⁰ Compression in mixed ulcers does not reduce distal pressure measured at toe level.¹⁵¹ It increases the arterial peri-wound

flow and arterial flow distal to the bandage¹¹⁵ and improves the impaired venous haemodynamics.¹¹⁵ Compression therapy may increase the healing rate in mixed ulcers.¹⁵²

5.3.1.2 Clinical practice statements

- *Statement 5.3.a: Compression therapy is recommended over no compression in patients with a VLU to promote healing.*^{1,10–16}

Comment: we have a great number of studies comparing compression with no compression therapy and confirming that VLUs heal more quickly with compression therapy.^{30,123–125}

- *Statement 5.3.b: In patients with a VLU strong compression pressure over low compression pressure is recommended to increase healing.*^{1,11,13,14}

Comment: there is evidence that a strong compression (higher than 40mmHg) is more effective than a low compression pressure (≤ 20 mmHg) in promoting ulcer healing.^{30,135–138}

Compression should be applied by means of a multicomponent system, which increases pressure and stiffness rather than single component bandages.^{128–133} Adjustable Velcro compression devices or elastic kits may be considered effective alternatives especially when trained personnel are unavailable.^{10,137,139}

- *Statement 5.3.c: In patients with VLUs we suggest using IPC when other compression options are not available or cannot be used. When possible we suggest using IPC in addition to standard compression*^{14,15,153}

Comment: there is evidence that compared with no compression, IPC is able to increase the VLU

healing rate.^{141,142} There is also limited evidence that IPC might improve healing of venous ulcers when used in addition to standard compression.¹⁴³

- *Statement 5.3.d: In patients with VLUs and arterial impairment (mixed ulcers) we suggest applying a modified compression in patients with less severe arterial disease: ABPI >0.5 or absolute ankle pressure >60 mmHg.¹⁵ This should only be applied by a trained HCP in mixed ulcer management and where the patient can be monitored. We have enough data that in patients with arterial impairment compression may be applied with reduced pressure provided arterial impairment is not severe.^{87,144,146–149} When arterial impairment is moderate (ABPI > 0.5) a modified, reduced compression pressure does not impede the arterial inflow^{115,151} and may favour ulcer healing.¹⁵² Compression must be avoided in severe, critical, limb ischaemia.^{15,150}*
- *Statement 5.3.e: In patients with a healed VLU, compression therapy is recommended to decrease the risk of ulcer recurrence.*¹⁵

Comment: even if available trials have some flaws, the evidence regarding the effectiveness of compression by stockings in ulcer recurrence prevention is strong. Some evidence is in favour of the strongest possible compression, which seems directly related to the effectiveness in ulcer recurrence prevention.^{154–156} A recent paper underlines the adherence of the patients wearing elastic stockings, which seems even more important than pressure itself.¹⁵⁷

For information about level of evidence available to support these statements, we refer to the following guideline:

- Management of VLU: Clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum¹⁵

5.3.1.3 The role of dressings in venous leg ulcer management

Local dressings applied to VLUs are one of the treatments to prepare the wound bed to 'ensure formation of good quality granulation tissue leading to complete wound closure, either naturally or through skin products or grafting procedures.¹⁵⁸ Modern dressings produce and maintain a moist microclimate on the ulcer-dressing interface and claim to be beneficial in ulcer treatment in conjunction with compression therapy. In particular they promote autolytic debridement,^{159–161} control exudate,^{28,29,162,163} manage wound infection,^{163–168} reduce pain,^{168–170} and are cost-effective.^{169–180}

Despite all the positive effects of new and advanced dressings, a number of published papers does not report any advantage on ulcer healing time when compared with traditional and advanced dressings applied under compression therapy. Almost all of them are included in the Cochrane review on venous ulcer dressings in 2006 and reviewed in 2014.¹⁸¹

Nevertheless, a careful reading of these studies reveals some limits of clinical RCTs and a number of serious methodological flaws: The initial ulcer size was not reported in some studies; when reported, the ulcer size was usually small (lower than 10 cm²) and the randomisation scheme was adequately described in only 6 out of 24 studies.^{179,182–186} The sample size was often not powered for statistical significance, and a blinded outcome assessment was rarely carried out. In addition, many exclusion criteria made the ulcer patients highly selected.^{28,29}

Summarising, all the studies involved patients with small venous ulcers and often without other concomitant or complicating conditions.

Unfortunately we do not have one single study assessing the effectiveness of modern wound dressings in patients with large ulcers, infected or covered with fibrin slough, with comorbidities like arterial disease or rheumatic diseases: all of them well known factors making such ulcers difficult-to-heal¹⁸⁷ and where dressings could prove to be effective in increasing the healing rate.

It can therefore be argued that the extensive conclusion of the reported meta-analysis:¹⁸¹ 'The type of dressing applied with compression therapy did not demonstrably influence ulcer healing' should be restricted to: 'The type of dressing applied with compression therapy did not demonstrably influence healing of small venous ulcers which are not complicated by comorbidities'.

In addition, the effectiveness in pain and infection control results in an improvement of patients QoL and reduction of resource consumption related to global care management (including pain killers, antibiotics, swab costs, hospital admission), and should be taken into consideration. This may lead to a reduction in the number of biopsy cultures needed to monitor infection, as well as the use of antibiotics and analgesic agents.¹⁸⁸ Furthermore, costs savings with advanced dressings have been documented, even with healing rates equal to those achieved with conventional dressings.¹⁸⁹ Finally, there is some evidence that some modern dressings and procedures that modulate MMPs may be effective in improving healing rates.^{190,191}

All these factors support the targeted use of modern dressing in VLU management.

Thus, the HCP should select an appropriate dressing based on the following factors:^{1,192–196}

- Ulcer size and location, wound bed and tissue characteristics

- Wear time
- The specific ulcer stage (inflammatory, granulating, in re-epithelisation phase)
- Amount and type of exudate
- Level of bacteria and/or topical infection
- Presence of pain and odour
- Assessment of peri wound and surrounding skin
- Patient tolerance and preference
- Ease of application and removal
- Cost and availability.

Ulcer dressings must be correctly applied according to the manufacturer's instructions.

Management of surrounding skin

The surrounding skin of a patient with a VLU requires attention and care. The skin can become red, infected, macerated or dry. This can be related to infection (local or cellulitis), venous eczema, hypersensitivity (contact dermatitis) or maceration from exudate. The HCP can consider using topical barrier preparations to reduce erythema and maceration from VLUs. The dressing can be reviewed for possible hypersensitivity to the product. A topical barrier preparation can be applied to the surrounding skin to protect it from the exudate. Venous eczema can be treated with short term topical steroids, zinc impregnated bandages, or other dermatological preparations.¹

Clinical Infection

Wound infection delays the normal healing process. A comprehensive assessment of the patient and their VLU is required to determine the severity of the infection and appropriate treatment

implemented. Antimicrobial therapy such as silver, honey and cadexomer iodine dressings can be prescribed when a VLU exhibits signs of infection.

Maintenance debridement

Maintenance debridement has been proposed as a therapeutic intervention to address the problem of chronic wounds characterised by an adequate wound bed but absent or slow healing.¹⁹⁷ If the inflammation is not controlled, the excess of inflammatory mediators favours the breakdown of the new epithelialisation tissues and of the endogenous proteins biologically active, as the growth factors and the cytokines. Also the peri-wound skin, often already compromised by previous skin alterations (lipodermatosclerosis, atrophie blanche, hyperpigmentation, dry, scaling and atrophic skin and venous stasis dermatitis) may be further damaged in these conditions and lead to an increase of ulcer size.

In conclusion, 'maintenance debridement' can be useful for the wound bed and peri-wound skin in order to guarantee improvement of the biological microenvironment and increase the healing chance for ulcers which do not heal despite an adequate wound bed.

The clinical practice statements provided below are based on the available evidence referred to in the reviewed guidelines or supporting literature.

5.3.1.4 Clinical practice statements

- *Statement 5.3.f: No specific dressing product is superior for reducing healing times in VLUs.¹ Simple non-adherent dressings are recommended in the management of VLUs.¹¹ This applies to the majority of small and non complicated VLUs.*

Dressings are selected based on assessment of the

stage of the ulcer bed, cost, access to dressing and patient and HCP preference.^{1,13,15}

Comment: If the VLU is exuding heavily, select a dressing that has a high absorptive capacity that can also protect the peri-wound from maceration.

- *Statement 5.3.g: Concerning management of the surrounding skin, the HCP can consider using topical barrier preparations to reduce erythema and maceration from VLUs. Venous eczema can be treated with short-term topical steroids, zinc impregnated bandages, or other dermatological preparations^{1,11}*
- *Statement 5.3.h: Concerning use of wound dressings in the case of clinical infection, a comprehensive assessment of the patient and their VLU is required to determine the severity of the infection and appropriate treatment implemented. Antimicrobial therapy such as silver, honey and cadexomer iodine dressings can be prescribed when a VLU exhibits signs of infection.^{1,13-15}*

Comment: The use of topical antimicrobials should not be used in the standard care of VLUs with no clinical signs of infection (1, 13-15).

- *Statement 5.3.i: Regarding wound dressings and cost saving, the standard care of treating VLUs reduces the cost of ulcer management.^{1,13}*

Comment: we have sufficient evidence to support that ulcer dressings are effective in exudate management, in controlling ulcer infection and in allowing cost savings.^{28,29,160-180}

- *Statement 5.3.J: Ulcers characterised by an adequate wound bed but absent or slow healing may need a maintenance debridement of wound bed and peri-wound skin.¹⁹⁷*

For information about level of evidence available

to support these statements, we refer to the following guidelines:

- Association for the Advancement of Wound Care (AAWC) venous ulcer guideline, Malvern, Pennsylvania: Association for the Advancement of Wound Care (AAWC). December 2010¹⁰
- Management of chronic venous leg ulcers. A national clinical guideline, S.I.G.N. (SIGN), Editor. 2010, SIGN Publication: Edinburgh, Scotland¹¹
- Australian and New Zealand Clinical Practice Guideline for Prevention and Management of Venous Leg Ulcers¹
- Guideline for management of wounds in patients with lower-extremity venous disease, O. Mount Laurel (NJ): Wound, and Continence Nurses Society (WOCN), Editor. 2011¹³
- Management of venous leg ulcer: Clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum¹⁵

5.3.2 Invasive treatments

Multifactorial pathogenesis, differences in the anatomical distribution of venous pathology, as well as the vast variety of different surgical and endovascular procedures available make it difficult to provide clear and generally acceptable recommendations on how to perform invasive treatments of VLU.¹⁹⁸

This is why a recent guideline for operative/ endovascular management of VLU categorise these anatomically as 1. Superficial, 2. Perforator and 3. Deep-iliocaval and/or infrainguinal venous disease to cover all possible treatments and relate them to clinical situations (Fig 1).^{15,153} Nevertheless, quality of the evidence available from the published papers for invasive treatment is low (Primarily level C).

5.3.2.1 Primary types of invasive treatments in venous leg ulcers management

Local treatments:

- **Debridement:** Refers to deeply removing adherent, dead or contaminated tissue from a wound (such as necrotic material, eschar, devitalised tissue, serocrusts, infected tissue, hyperkeratosis, slough, pus, haematomas, foreign bodies, debris, bone fragments or any other type of bioburden) with the objective to promote wound healing. Debridement options are available today, include mechanical, autolytic dressings, larvae therapy and various debridement technologies.¹⁹⁹ Debridement is an important part of the TIME strategy for treatment of chronic wounds: Tissue debridement, control of Infection and inflammation, Moisture imbalance, and advancement of the epithelial Edge of the wound.²⁰⁰
- **Shave therapy:** A local surgical technique, based on sharp removal of scar tissue by 'shaving' it with dermatome. The ulcer should be shaved layer by layer until reaching a healthy looking tissue and capillary bleeding. In longstanding VLU when chronic inflammatory process leads to fascial scarring and thickening the fasciectomy, shave therapy is needed followed by skin grafting. The shave therapy must be carried out by a surgeon in standard operating conditions under local or even general anaesthesia in an inpatient setting. To date there is no single RCT to assess efficacy of this treatment although there are some retrospective studies reaching a healing rate of 80% at 12 weeks in treated patients. Interestingly, the recurrence rate was significantly reduced to about 25% after 2.5 years of follow-up.²⁰¹ This technique is popular in German speaking countries, France and Poland.

Systemic treatments, related to the venous bed:

- **Venous stripping:** An operative treatment under local or general anaesthesia to remove the whole length of the vein. It usually deals with insufficient great saphenous vein (GSV) or small saphenous vein (SSV) because of reflux. The surgery requires incision in the groin, high ligation of GSV at the sapheno-femoral junction, insertion of a plastic or metal stripper into the vein and removal of attached vein to the stripper downwards usually in eversion fashion.²⁰²
- **Endovenous Laser Therapy (EVLT):** A minimally invasive, ultrasound-guided technique for treating varicose veins by means of laser energy. Under tumescent local anaesthesia catheter bearing laser fibre is inserted into GSV or small SSV respectively to the level of sapheno-femoral junction or sapheno-popliteal junction. Then, the laser fibre with carefully applied energy is slowly withdrawn, causing obliteration of saphenous trunk. The EVLT technique can also be used to close perforating veins.^{203,204}
- **Radiofrequency Ablation (RFA):** A technique and method similar to EVLT but instead of laser fibre a radiofrequency catheter is used and radioenergy is applied under the same circumstances.²⁰⁵
- **Foam sclerotherapy:** A technique where foamed sclerosant is injected under ultrasound guidance into GSV, SSV, perforating vein or even smaller veins located under the venous ulcer to obliterate them. This non-surgical technique has in recent years revolutionised treatment of venous reflux and varicose veins.²⁰⁶
- **Subfascial endoscopic perforator surgery (SEPS):** A minimally invasive operative technique used to treat VLU caused by incompetent perforator veins. SEPS represents a minimally invasive

alternative to the Linton procedure which originally involved a long medial calf incision to expose all posterior, medial and paramedial perforators. Using endoscopic techniques, the perforating veins are clipped or divided by endoscopic scissors. The procedure can be done in the hospital or outpatient setting by general or vascular surgeon under local anaesthesia. To date there is ongoing debate concerning the general efficacy of perforator ligation in the surgical management of advanced chronic venous insufficiency and venous ulceration.^{207,208}

- Venous stenting of deep ilio caval and/or infrainguinal veins: The introduction of minimally invasive venous stenting using Venography and Intravenous Ultrasonography (IVUS) provides the ability to treat the 'obstructive' component of the VLU. The stenting procedure requires femoral vein puncture in the groin or popliteal vein puncture behind the knee with respect to localised obstruction of the vein. A guide wire is then passed up high into the normal caval vein, crossing the narrowings or obstructions of the femoral or iliac veins making a way to insert the balloon. By inflating the balloon, the diameter of the vein increases and then safe deployment of the stent is possible. The stent must cover the entire area of diseased vein to provide a long standing effect of endovascular treatment. Stents usually keep the vein open, improving patient's symptoms of leg swelling and leading to faster ulcer healing. In follow up, instent stenosis can occur and the rate of restenosis is about 5% for patients with extrinsic compression syndrome and over 10% in a case when obstruction of the vein was because of prior venous thrombosis.²⁰⁹

The main objectives for operative/endovascular treatment for VLUs are:

- To accelerate ulcer healing

- To prevent ulcer reoccurrence.

5.3.2.2 Selecting between invasive treatments

Recently published SVS/AVF American guidelines on management of VLUs and its revised version of International Union of Phlebology (UIP) present 17 recommendations related to the invasive treatment of venous bed in patients with VLU.^{15,153} Of the recommendations four related to superficial venous reflux and VLU, 4 are related to perforator venous reflux and VLU, and the remaining 9 cover deep venous obstruction/reflux and VLU. All of them except one have a C level of evidence demonstrating that in fact there is a lack of properly conducted RCTs in this field.¹⁵

Only prevention of VLU recurrence after surgical treatment and compression therapy reached higher level of recommendation, means 1B. The ESCHAR study (The Effect of Surgery and Compression on Healing and Recurrence) illustrated that there is no significant difference in healing time and healing rate between superficial venous surgery plus compression and compression alone. However, the 12-month recurrence rate in the study was considerably lower for patients treated with surgery. The ESCHAR study emphasised that 85% of the patients with VLUs would benefit from surgery.²¹⁰

Fig 1 illustrates what to consider when selecting an invasive treatment of VLU, taking the current evidence base and current guidelines into consideration.^{15,153}

5.3.2.3 Clinical practice statements

- *Statement 5.3.k: To improve ulcer healing in patients with VLU and incompetent superficial veins,*

surgery (high ligation/stripping) or alternatively any new ablation techniques should be suggested in addition to standard compression therapy.^{15,153}

Comment: Traditional surgery has a slightly higher level of evidence than new ablative techniques, probably because they have not been sufficiently studied for this purpose.^{211,212}

- Statement 5.3.l: To prevent ulcer recurrence in patients with active or healed VLU and in-competent superficial veins, the surgery (high ligation/stripping) of incompetent veins in addition to standard compression therapy is recommended.^{15,16,153}
- Statement 5.3.m: To prevent ulcer recurrence in

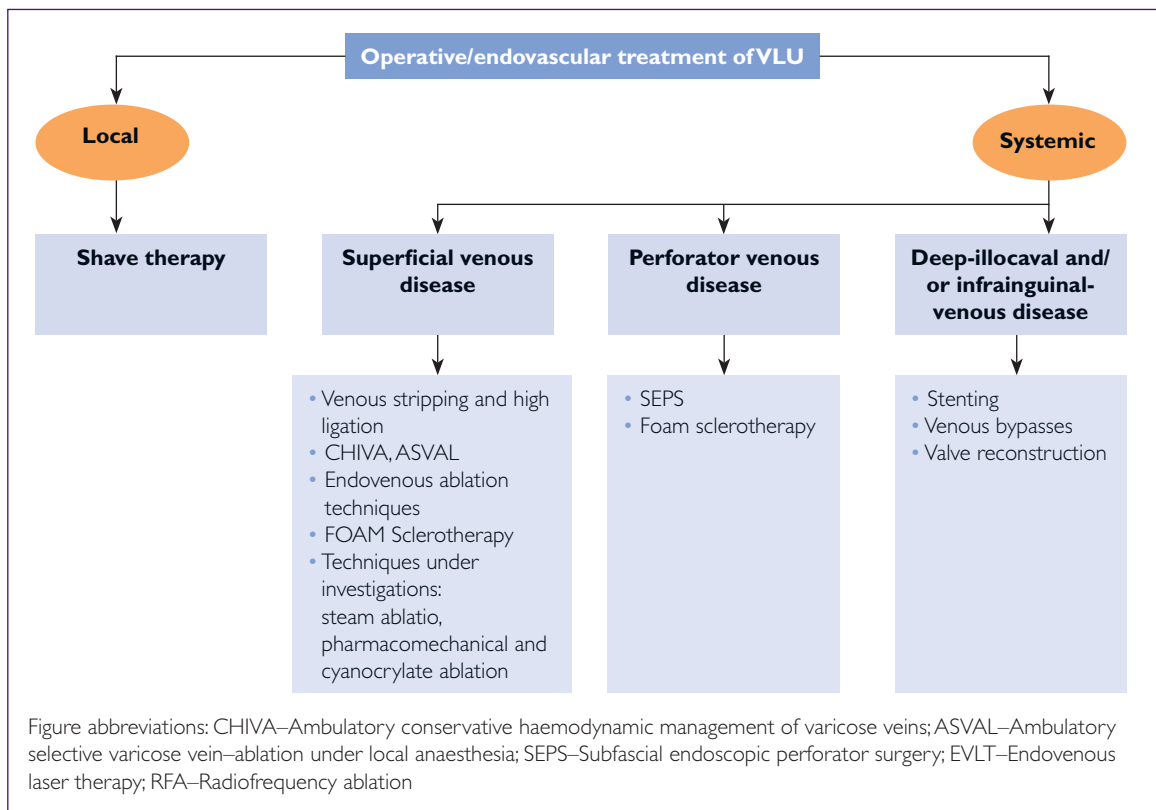
patients with active or healed VLUs and incompetent superficial veins, ablation technique in addition to standard compression therapy is suggested.^{11,14,15,153}

Comment: Open surgery for prevention of ulcer recurrence when superficial veins are involved is the only well documented treatment.^{210,212,213}

New ablation techniques still require more studies so this is why the evidence of using them is much lower.^{203,204}

- Statement 5.3.n: To improve ulcer healing and prevent recurrence in patients with a VLU and incompetent superficial veins with pathologic perforating veins and with or without deep venous

Fig 1. Selecting between operative/endovascular venous leg ulcer (VLU) treatments



disease, surgery or ablation of superficial and perforating veins is suggested in addition to standard compression therapy.^{15,153}

Comment: Every treatment of perforating veins is controversial, because of lack of well-designed RCTs and uncertainties whether abolition of axial reflux or closure of insufficient perforator is more beneficial for improving healing of LU.²¹⁴⁻²¹⁶

- *Statement 5.3.o: To improve ulcer healing and to prevent recurrence in patients with active or healed VLU and isolated pathologic perforating veins, surgery or alternative ablation technique of perforating veins is suggested in case of failure of standard compression therapy.*^{15,153}
- *Statement 5.3.p: To close the pathologic perforator veins in patients with VLU, percutaneous techniques, which do not need incisions in the areas of compromised skin are recommended over open venous perforator surgery.*^{15,153}

Comment: Avoidance of any incision within a region of compromised skin is crucial. This is why the minimally invasive techniques, from a ultrasound-guided foam sclerotherapy to SEPS should be taken into consideration when treatment is planned.¹⁵³

- *Statement 5.3.q: In patients with infrainguinal deep venous reflux and active or healed VLU the recommendation is against deep vein ligation of the femoral or popliteal veins as a routine treatment.*^{15,153}

Comment: This is an old surgical procedure which fortunately currently is rarely performed.^{217,218}

- *Statement 5.3.r: To improve ulcer healing and to prevent recurrence in patients with total occlusion or severe stenosis of inferior vena cava and/or iliac veins, venous angioplasty and stenting is recommended in addition to compression therapy.*^{15,153}

- *Statement 5.3.s: No specific debridement method has been documented to be optimal for treatment of VLUs.*¹³

Comment: The most commonly used methods of debridement are surgical (sharp), conservative sharp, autolytic, larval, enzymatic and mechanical. Surgical debridement is rapid, although it requires either general or local anaesthetic and can be painful. Conservative sharp debridement is the removal of loose avascular tissue without pain or bleeding.¹

- *Statement 5.3.t: Mechanical debridement methods, such as ultrasound, high-pressure irrigation or wet to dry dressings, may be useful for reducing non-viable tissue, bacterial burden and inflammation.*¹

For information about level of evidence available to support these statements, we refer to the following guidelines:

- Management of venous leg ulcer: Clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum¹⁵
- Australian and New Zealand Clinical Practice Guideline for Prevention and Management of Venous Leg Ulcers.¹

5.4 Referral structures

5.4.1 Managing patients with venous leg ulcers between primary and secondary health-care settings

Internationally there has been a move to manage more patients with chronic conditions in the home or community care setting.³⁴ This has come about due to the ever-changing population demographics (an ever increasing elderly population) and pressure on health-care resources, in particular the cost of funding hospitals and keeping acute beds 'open for business'. With the predicted

increase in the numbers of individuals with chronic conditions such as leg ulceration, this will inevitably mean that there will be a corresponding increase in the prevalence and incidence of wounds into the future.

With this in mind, it is therefore evident that if patients are moving constantly between primary and secondary health-care settings that all HCPs involved in that patient's care should have a good understanding of each other's roles in order to optimise the care offered to and outcomes achieved for the patient with a chronic leg ulcer. This constitutes a basic requirement for establishing or maintaining effective referral structures.

5.4.2 The multi-disciplinary team in venous leg ulcer management

'Multi-disciplinary' can be defined as, 'a group of health-care workers who are members of different disciplines (professions), such as psychiatrists and social workers, each providing specific services to the patient. The team members independently treat various issues a patient may have, focusing on the issues in which they specialise.'²¹⁹

The essence of the multi-disciplinary team approach in wound management is that the team is interdependent and team members share responsibility and are accountable for attaining the desired results. However, a team may be defined within the literature and within an individual country setting, there is substantial evidence that when individual professionals come together with a shared goal that is patient focused, enhanced clinical outcomes can be achieved.²²⁰

The roles and competencies required for all members of the multi-disciplinary team are very important and need to be fully understood by all

HCPs involved in the management of patients with leg ulceration.

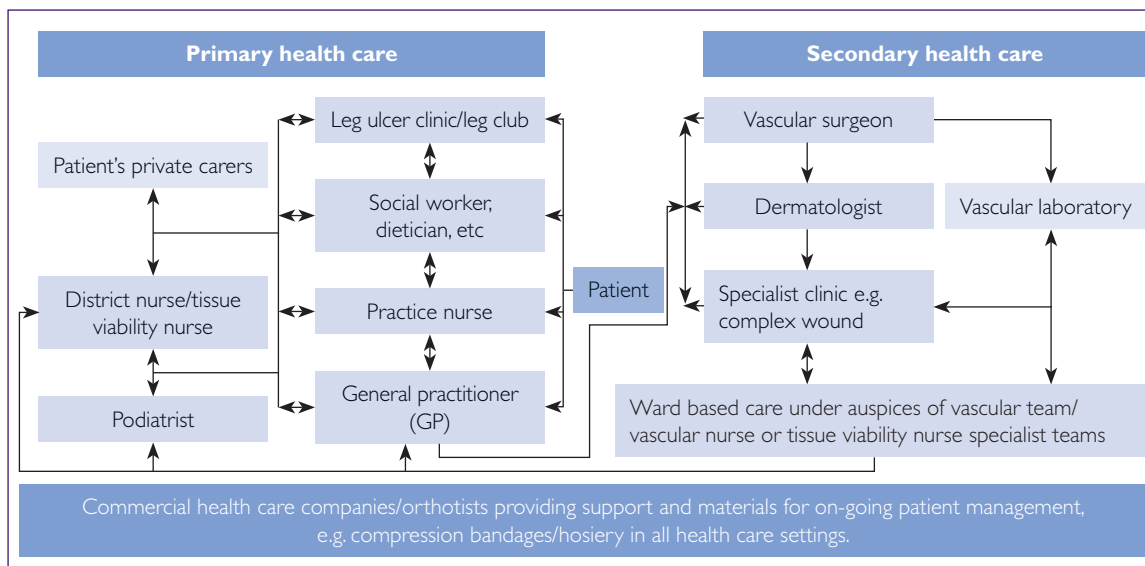
Treatment pathways vary greatly from country to country. In many countries, all medical treatments must be done under the supervision of a medical doctor and only medical doctors have the right to prescribe. In other countries, specialised nurses coordinate treatments and have extended practice that includes the right to prescribe, refer and order investigations. In addition, there is a lack of specialised HCPs in the rural areas, which means that specialist referral may not be possible.¹

The example provided in Fig 2 illustrates the patient referral structures in the UK, and the HCP profiles and health-care organisations that contribute to the management of patients with a VLU. It also illustrates that the patient's journey through the system may have different starting points, depending on local structures and patient situations. This may complicate the establishment of clear cut referral structures for individuals.

An outline of the roles and responsibilities of members of the multidisciplinary team in VLU management, as presented in Fig 2, can be found in Table 15.

The referral pathways described above with the example of the UK differ from the situation in many other European countries. For example, in German speaking countries (Germany, Switzerland, Austria), the competency to perform most of the diagnostic procedures and the right to prescribe lies with medical doctors. Most patients with a LU would therefore be followed by a primary care physician, in most cases an independent GP, who could delegate some basic diagnostic procedures to community-based nursing services or wound care specialist nurses. After the initial appearance of an ulcer, the GP would refer the patient to a specialist for further assessment. This would usually be

Fig 2. Example of a patient referral pathway between primary and secondary health care for a patient with a chronic leg ulcer in the UK



performed by a vascular surgeon, an angiologist or a dermatologist for vascular assessment, or in the case of prolonged healing failure, to a dermatologist for further diagnostic work to exclude other differential diagnoses.

The treatment (compression treatment or local wound care) is prescribed by the GP or one of the specialists consulted, and can be carried out by practice staff of the GP, community-based nurses or wound care specialist nurses at wound care centres. Even though patients are increasingly treated in ambulatory settings most countries, due to the increasing need to cut costs, patients may still be hospitalised for their treatment if they have hard-to-heal wounds or need surgical intervention. Networks between hospitals and community-based nursing services or wound care centres are often established to ensure the continued care of patients after their discharge from the hospital.

To sum up, generally applicable referral structures for VLU patients cannot be defined across different

national or even regional and local settings. It should also be highlighted that the CPGs currently available includes few recommendations about general referral patterns, and these are generally not supported by high level evidence.¹ Given the general shift towards management of patients within home or community care settings there is an increasing need to ensure that home and community care staff have sufficient education to evaluate when specialist referral is needed and understands the roles and responsibilities of the multi-disciplinary team members.³⁴

5.4.3 Clinical practice statements

- *Statement 5.4.a: LU management must be undertaken by trained or specialised HCP.^{1,11-13}*

Comment: However, individual patients and carers can play a proactive role in self-care ulcer management including among other things changing of dressings and compression bandages/

Table 15. Members of the multi-disciplinary team responsible for VLU management (UK example)

HCP/stakeholder	Tasks in VLU management
The practice nurse (registered nurse) (RN)	<p>Assess, screen, treat and educate all ages of patients and members of the community.</p> <p>Work within the GP practices to provide nursing and medical care²²¹ with both a preventative and management focus.</p> <p>Often the first health-care professional to be aware of a patient with a leg ulcer.</p> <p>May not have all of the desired competencies for the long-term management of patients with venous leg ulcers (VLUs).</p>
The general practitioner (GP)	<p>Employed by the relevant Health Service (NHS) as independent contractors to work within local communities.</p> <p>Typical responsibilities include patient consultations at home and within the surgery, physical examinations, diagnoses and treatment of illnesses/ailments, minor surgery, health education, practice management and administration, liaison with other health-care professionals and/or hospitals.²²²</p>
The dermatologist	<p>Physician specialising in treating conditions of the skin, hair and nails. Often receives the first secondary care referral from the GP in primary care.</p> <p>Trained in the assessment and treatment of venous disease and can take also care of other underlying diseases, leading to skin ulcerations and accompanying skin problems.</p>
The vascular surgeon	<p>Specialising in the diagnosis and management of patients with a variety of conditions that affect the patient's venous or arterial circulation. Can prescribe or undertake a variety of investigations in order to confirm a suspected diagnosis, such as venous/arterial LU, as well as perform a variety of non-invasive or invasive surgical procedures to correct identified circulatory deficiency.</p>
The Specialist Nurse: Vascular Nurse Specialist (VNS) / Tissue Viability Nurse (TVN)	<p>The VNS act as a central member of the vascular team.</p> <p>They see and support patients in hospital and in the out-patient clinics and helps to coordinate care for patients and provides a simple means of communication between the hospital services and the community.²²³</p> <p>The TVN promote and ensure 'evidence-based and cost-effective care of all patients managed within an acute care and outpatient clinic setting. They help to coordinate care for patients and provide a simple means of communication between the hospital services and the community.</p>
The vascular laboratory technician	<p>Schedule and prepare patients for investigations and assist in the delivery of prescribed treatments by assisting with the application of modalities such as ultrasound and x-ray. Work in settings such as fixed or mobile laboratories, doctors' offices and specialist clinics. Not independently involved in the treatment of the patient.</p>
The district nurse (DN)	<p>Should be involved in 'The planning, provision and evaluation of appropriate programmes of nursing care', particularly for people discharged from hospital and patients with complex needs; long-term conditions, those who have a disability, are frail or at the end of their life.²²⁴</p> <p>Clinical competencies in VLU care: the application of compression therapy—bandages and hosiery.</p>
Podiatrist	<p>Podiatrists provide preventative care, diagnosis and treatment of a wide range of problems affecting the feet, ankle and lower legs. Their specialist skills focus on managing infections, ailments, defects and injuries of the foot and lower leg, as well as treating foot and nail conditions related to other major health disorders (for example diabetes/leg ulceration).</p> <p>They also provide preventative care and advice on improving mobility, independence and the quality of life for their patients.</p> <p>Podiatrists are also known as chiropodists and this profession exists primarily in the Anglo-Saxon countries.</p>

The patient	<p>Patients are expected to seek medical assistance for the diagnosis and on-going management of their leg ulcers (LU), and then report any changes/on-going issues, for example pain/comfort/ change in exudate levels/associated odour related to the planned management of their ulceration. In addition they will be encouraged to be concordant with the agreed management plan and the rationale underpinning the professional expectation.</p> <p>Concordance has been defined as 'a new way' to define the process of successful planning and delivery of health care based on partnership, which has three essential elements:</p> <ul style="list-style-type: none"> • The patient has knowledge to participate as a partner • Consultations involve patients as partners; Patients are supported during their treatment (adapted from Medicines Partnership, www.medicines-partnership.org)²²⁵ • Patients can play a proactive role in self-care ulcer management including e.g. changing of dressings and compression bandages/hosiery/wraps (In collaboration with the health-care professional responsible for the ulcer management)
Patient carers	<p>All patient carers should be fully involved in the care process in an informed manner (as highlighted above for patients) and should be aware of any on-going management decisions that have/are being made to optimise the patient with a leg ulcers outcomes—both clinical and psychological. They should also be aware of any potential issues that may arise and have a clear referral pathway agreed that is relevant to the care set-ting in which they are currently operating. Patient carers may also play an active role in changing dressing and compression bandages/ hosiery/wraps.</p>

hosiery/wraps. The HCP should support the patient to enhance self-care activities.

- *Statement 5.4.b: Specialised LU clinics are recommended as the optimal service for treatment of VLU in the community (primary care) setting¹¹*
- *Statement 5.4.c: In rural areas, where specialised HCPs may not be available, telemedicine can offer an opportunity to provide specialised assistance for assessment, diagnosis and treatment of a VLU patient³⁷*

5.5 Secondary prevention

5.5.1 Need for services/education in place to monitor patients with a healed venous leg ulcer

To prevent VLU reoccurrence it is important to support VLU patients to acquire skills and knowledge through trained HCPs about preventive and therapeutic interventions. The literature demonstrates that patients with a VLU do not have enough knowledge about pathophysiology of VLU to conduct effective self-management.²²⁶⁻²²⁹

The guideline comparison in this document highlighted that 4 of the 8 guidelines included recommendations for patient education, but that the types of secondary prevention actions that were recommended varied across the guidelines.

There are only a few studies demonstrating the effectiveness of education interventions with VLU patients that are improving the skills and knowledge regarding aetiology/pathophysiology and adherence. After the wound closure most of the patients are left on their own and do not receive any aftercare. Hence, they are responsible for the care of their legs. To prevent a recurrence, education has to take place before completion of the treatment. The content of the education should allow effective self-management. There is little published evidence available that describes education programmes/services.

Studies demonstrate that the recurrence rate can be lowered as much as nine times by delivering information leaflets.^{230,231} O'Brien et al.²³² present in their qualitative study with 10 patients a patient-centred 12 week-intervention programme. This

programme consists firstly of information material about leg elevation to heart level and movement. Secondly, six follow-up telephone calls. The results demonstrate how VLU patients learn to understand the connection between their wound and the adherence. A RCT illustrated this by delivering a patient information brochure that showed the yearly recurrence rate could be lowered from 36% to 4% (Log-Rang-Test = 8.28, $p=0.004$).²³¹

5.5.2 A venous leg ulcer has healed—what next?

The risk with every healed VLU, will it recur or a new area of ulceration develop? Once a VLU has healed, ongoing management is essential and the focus and effort is on preventing recurrence. CVI is a causative risk factor, it is a chronic condition; a lifelong commitment to preventing recurrence and its associated implications requiring an individual to be active in their management with support from the health-care system.^{1,233}

A recurrence of a VLU is a burden which challenges individuals and health-care providers; it can represent social, personal, financial and psychological costs to the individual and further economic drain to the health-care systems which support them.

How to reduce the risk of recurrence of a venous leg ulcers

To reduce the risk of recurrence of VLUs, the evidence recommends the continued use of compression therapy.¹ In most countries, patients have to cover the cost of compression hosiery. The cost does vary and this can cause financial difficulty for some patients. It is one of the significant barriers to adherence to wearing compression hosiery and the patient is disadvantaged as they have a high risk of recurrence and the associated implications that this brings.

It is well documented that delivering effective interventions with a collaborative approach will prevent VLU recurrence and promote patient wellbeing and independence. The need for services with the aim to implement maintenance strategies is crucial and can be provided in the home setting, a clinic or ambulatory care setting, with virtual technology such as eHealth in partnership with the clinician, patient, family and caregivers.

Type of service

A service with trained HCPs¹¹ that provides education, support and prevention strategies to the patient in the home setting, specialised clinics or via eHealth or telemedicine. For example, online video calling, apps and smart phone support. Education through patient information booklets/brochures, apps, DVDs, and online tutorial webinars can be readily available and offered in multiple languages and for the visually impaired.^{1,11,234} An individualised management care plan can be developed in collaboration with the patient and carer/family.

Patient assessment

The patient should be assessed for suitability and strength of compression, identifying any peripheral artery disease and functional ability to apply and remove compression hosiery. The patient and their home should be assessed and the necessary support services implemented.

The appropriate compression hosiery

The patient requires lifelong medical grade compression hosiery providing 18–40mmHg to reduce the long-term effects of venous disease.^{1,11} To determine the strength of compression, peripheral arterial disease needs to be determined by performing a comprehensive clinical assessment of the patient and the leg. The choice of compression hosiery is influenced by several factors, such as the preference of the individual and HCP, cost, and shape of limb.²³⁴ Accurate

measurement and the appropriate class of compression are essential to ensure the stocking provides adequate compression and is worn safely, with-out risk of injury to the skin.²³⁴ To avoid any development of peripheral oedema, compression hosiery is usually applied first thing in the morning after a shower or upon getting out of bed, and removed before going to bed at night.²³⁴

Stocking aids or donners may be used to assist the patient or caregiver with application and removal of compression hosiery.²³⁴ When the person is applying their own stocking, these appliances may assist those with limited strength, reduced manual dexterity and who are unable to reach their feet.²³⁴ For the professional care giver, stocking aids may reduce the physical effort required during application and removal, and prevent injury. This is an important factor for consideration when protecting the occupational health and safety of the caregiver.²³⁴

The patient should consider replacing compression hosiery every six to twelve months and/or per manufacturer's recommendation.¹

The benefits of a daily skin care programme

The benefit of a daily skin care programme promotes the health of legs and reduces the risk of VLU recurrence.^{1,11} An effective skin care programme is essential to promote the normal skin pH to prevent and/or manage dry, irritated skin.¹ Skin cleansers and moisturisers should be applied at least daily. For very dry and scaly skin, such as varicose eczema, an oil or emollient-based moisturiser is more effective than a cream or lotion and helps to maintain skin integrity. Zinc-based creams and bandages and short-term steroid cream/ointments can be applied to the skin to treat varicose eczema.¹

The benefit of exercise and leg elevation

Exercise and movement benefit the patient and

enhance calf muscle pump.^{1,11,235} Progressive resistance exercisers have been shown to promote calf muscle function.^{1,235} Patients who are unable to ambulate or have limited mobility can be educated on the benefits of progressive resistance exercise.

The benefits of leg elevation have been well documented. Elevation of the limbs when sitting and avoidance of standing for prolonged periods assists in controlling lower leg oedema.^{1,11}

Patient wellbeing

Support groups such as 'The Leg Clubs' can promote acceptance and adherence with practices that help maintain skin integrity and provide long-term psychosocial support and improve patient wellbeing.

How frequent and for how long to monitor the patient

CVI is a lifelong medical condition and requires commitment to prevention strategies and is a permanent lifestyle change for the patient. Each patient requires different levels of support. Consider monitoring the patient for six to twelve months after the VLU has healed.

Surgical options to prevent ulcer recurrence

For information about the surgical options to prevent ulcer recurrence, see chapter 5.3.3 on invasive treatment options.

5.5.3 Clinical practice statements

- *Statement 5.5.a: When a VLU has healed, the patient requires lifelong medical grade compression hosiery providing 18–40mmHg to reduce the long term effects of venous disease^{1,11}*
- *Statement 5.5.b: The patient must be assessed by a trained HCP for suitability and strength of compression^{1,11}*

- *Statement 5.5.c: The patient should consider replacing compression hosiery every six to twelve months and/or per manufacturer's recommendation¹*
- *Statement 5.5.d: The benefit of a daily skin care programme promotes the health of legs and reduces the risk of VLU recurrence^{1,11}*
- *Statement 5.5.e: Exercise and movement has a positive benefit for the patient and enhances calf muscle pump.^{1,235} Progressive resistance exercise has been shown to promote calf muscle function*
- *Statement 5.5.f: Elevation of the limbs when sitting and avoidance of standing for prolonged periods assists in controlling lower leg oedema^{1,11}*
- *Statement 5.5.g: Consider monitoring the patient for six to twelve months after the VLU has healed*

For information about level of evidence available to support these statements, we refer to the following guideline:

- Australian and New Zealand Clinical Practice Guideline for Prevention and Management of Venous Leg Ulcers¹

5.6 Monitoring outcome

To finalise this section focusing on clinical practice in VLU management, we have chosen to focus on a discussion concerning relevant outcome measures in chronic wounds and VLU management. This discussion feeds into the evaluation of the evidence base available to support recommendations for VLU management, which is presented in most of the evaluated guidelines (See Chapter 3).

The approach to treating a chronic or delayed healing wound such as a VLU has evolved greatly during the last 15 years.²³⁶ A wide range of approaches and products are available for treating

chronic wounds, but it is widely acknowledged that many of them lack high-level evidence which robustly demonstrates their benefits. 'Evidence-based practice' specifically refers to clinical decision making that is based on the best available evidence, with practitioners reviewing information from powerful data, instead of relying on single observations or customs.²³⁷ However, the extended definition by Sackett (1996) may be more relevant in the wound sector today. This proposes that evidence-based medicine is not restricted to randomised trials and meta-analyses, but involves the exploration of all types of best external evidence.²³⁸

5.6.1 Relevant endpoints in venous leg ulcer studies

An endpoint is defined as the objective of an evaluation or study.²³⁷ Study outcomes are more convincing when they apply to a single or small number of clearly defined objectives.

These objectives should include:

- A precise statement of the degree of benefit expected from the intervention, and its duration
- Clear statements on the time frame of the study (especially in relation to how quickly the benefits might start)
- A definition of the patients for whom the benefit is sought²³⁷

Wide variations in endpoints of trials of VLU have been reported together with a lack of endpoints related to QoL or patient identified endpoints.²³⁹

All studies on VLUs must include compression as part of standard care. However, epidemiological data suggest that ulcers that are the result

of varying degrees of arterial disease and other confounding factors are increasingly being presented. To date, only limited data is available on the natural outcome of arterial and mixed aetiology leg ulcers.²³⁷

Wound healing-related outcomes (wound closure, reduction rate and healing time)²³⁷ which are relevant to the assessment of improvement for patients with leg ulceration may include:

Wound closure defined as 'total epithelialisation without discharge' should be confirmed by an independent source such as photography. Definitions of 'healing' as a clinical outcome have been debated for some time. However, recent recommendations from the FDA support the view that complete closure of a chronic wound is the most clinically meaningful endpoint.

Reduction rate should be confirmed by tracing and consider 'reduction rate error'.²³⁷ Currently, there is an on-going debate over the usefulness of using reduction in wound area as a primary outcome as the 'clinical benefit of incremental wound size changes has not been fully established'. However, some studies have shown that reduction in wound area within a specified time frame can indicate the potential to achieve complete healing in the future.²³⁷

Use of wound healing time as an outcome measure has received increasing interest due to its importance from the clinical perspective and with regard to resource use and economic costs. For most studies reporting wound healing time, the major concern is that it is only reported for the minority of patients who have healed within a specific observation period, generally of 4–12 weeks.²³⁷

Changes in wound condition should also be noted.

Due to the introduction of more targeted treatment strategies that focus on specific aspects of symptom management, rather than aiming for complete healing, it is important to ensure that the chosen outcomes reflect the modality under investigation. These endpoints may include exudate level, necrosis/slough, odour, and fibrous/fibrotic tissue.

It should also be considered that a range of issues involving wound dressings have a significant impact on activities of daily living, particularly mobility. Bulky bandages, compression devices and different types of foot off-loading can interfere with daily living to such an extent that concordance with treatment is jeopardised, while frequent dressing changes can result in a life dominated by clinical appointments.

In recent years, health-related quality of life (HRQoL) has become a more routinely accepted outcome in health-care studies. As an outcome, HRQoL can be measured using three different approaches:

- Generic measures
- Condition-specific measures
- Utility measures.

In each case, it is important that assessments are made using tools with established psychometrics as this will ensure that they are valid, reliable, sensitive to change and can discriminate between health states.

HRQoL has been defined as, 'Personal health status'. HRQoL usually refers to aspects of our lives that are dominated or significantly influenced by our mental or physical wellbeing'.²³⁶

Finally, in order to maximise the value of investments in future clinical research, all studies

should be designed to address the relative cost-effectiveness of the alternatives being tested from the outset, as well as their efficacy (safety) and clinical effectiveness,²³⁷ especially in an era of resource constrained health-care provision.

5.6.2 Patient-centred outcomes

HCPs have a variety of treatment options at their disposal. This range of therapeutic options come with a variety of caveats for patients, including potential pain, discomfort, inconvenience, expense/unavailability and burden (time and social) to both the patient and their caregivers. Despite this, patients with chronic wounds do not always feel engaged in the decisions made regarding their care, and patient concerns are often not aligned with the concerns of their health-care providers (See Chapter 4.4. Patient related barriers and facilitators).

It has therefore been suggested that research that involves patient-centred outcomes will help patients and their caregivers to communicate more productively and make better informed choices about their health care.

Traditionally, patient-reported outcomes have been defined as the patient's assessment of how they function or feel with respect to their health or associated health care. Patient-reported outcome metrics provide a patient's perspective on treatment benefit, allows for direct measurement of treatment benefit beyond survival, disease, and physiological markers. They are often the outcomes of greatest importance to patients. Reports from patients may include the signs and symptoms reported in diaries, the evaluation of sensations and symptoms, reports of behaviours and abilities, general perceptions or feelings of wellbeing, and reports of satisfaction with treatment, general or HRQoL, and adherence to treatments.²³⁶

Patient-reported outcome metrics can complement traditional clinical study outcomes data, and they can be particularly valuable when more objective measures of disease outcomes are challenging to obtain, are long-term, or otherwise unavailable. It is important to remember that patient-reported outcomes are not always patient-centred outcomes, and researchers need to ensure that a patient-reported outcome questionnaires focus on outcomes that are important to the patient, by keeping the following questions in mind:

- Are patient-reported outcome measures meaningful to patients?
- Do they capture patient experiences?
- Are the important outcomes measurable?
- Do questions reflect what patients think and feel about their experiences, i.e. beyond simply reporting symptoms and side effects?
- Are questions clear and concise?
- Is the length of the questionnaire appropriate?
- Is the time at which patient-reported outcomes are captured appropriate?

Patient-reported outcomes are developed by capturing information directly from patients through interviews, self-completed questionnaires, focus groups, diaries, and other data collection tools. They can also be collected using condition-specific^{95,240} or generic instruments.

To be patient-centred, it is important to be proactive in obtaining information directly from patients and their caregivers in order to understand what is truly important to them. Patient advisory groups and focus groups can be helpful. It is also critical to account for the diversity of patients

and the impact of cultural factors on patient-centred outcome variables. To be meaningful, measurements of patient-centred outcomes should be fully integrated into point-of-care communication, quality improvement initiatives, and research efforts.

Items that have been top-ranked for impact on life by patients with chronic wounds include: impact on family, wound drainage, and lack of participation in social activities. The lower ranked items, representing those of least concern to the six patients with chronic wounds, include: difficulty with bandaging, sleep disturbance, and odour. The highest ranked wound-specific item was associated with the statement: 'I was confident my wound would heal,' but the next highest ranking score was associated with the worrying about a 'recurrence of the wound'.²²⁷

5.6.3 Clinical practice statements

- *Statement 5.6.a: EWMA published study recommendations for clinical investigations in LUs and wound care in 2014. These may provide relevant guidance for future VLU studies.*²⁴¹

6. Conclusion

It is well established that VLU prevalence is on the increase, more often in older adults, which will escalate the cost to the patient and health-care organisations in the coming decades. More than ever there is a substantial need for international consensus on prevention and management strategies of these chronic wounds, which is cost effective, with positive outcomes for the patient. There is a need for a multidisciplinary team approach of all health-care professionals across different health sectors to work collaboratively in the future to reduce the development and recurrence of these wounds.

This document presents a comprehensive review of the assessment, diagnosis, management and prevention of VLUs from 8 CPGs (published 2010–2015) and compares the recommendations provided in these guidelines. While there is little evidence of contradictions between the guidelines, the differences are largely related to omissions and/or exclusions of information. The differences may in part be a reflection of the target audience for each document, with greater emphasis on sections that relate directly to the practitioners who will use them and the way that evidence has been collected. 'Clinical Practice Statements' to assist HCPs and organisations guide practice have been developed on the basis of the review of guidelines undertaken.

It is clear that the development of a guideline does not change practice per se but is the start of a change process. This document examines the barriers and facilitators for implementation of guidelines. While there is some evidence

from implementing LU guidelines, information has also been used from other diseases and conditions to provide a more rounded approach to implementation strategies.

It has been identified there are variations in practice and barriers preventing the implementation of best practice from the HCP, patient and organisation perspective. HCPs work in varied and sometimes challenging settings, have different levels of expertise, skill set and knowledge and may work very differently. Some workplace processes in one organisation may not be directly transferable or applicable to another health-care environment or patient group.

For the HCP, becoming skilled and competent with the many different wound products, assessment skills, adverse effects and potential complications, and ongoing monitoring, requires education and training in wound care to lead to better VLU management. Incorporating CPGs in professional training and expanding guidelines to incorporate detailed educational and competency skills, in the clinical environment with senior management support, is a strategy for putting 'evidence into practice'.

While it is not possible to prove cost-effectiveness of guideline implementation, it would be expected that patient and clinical outcomes would improve when using the best available evidence. Along with clinical outcomes such as improved ulcer healing should come greater efficiency in resource allocation as the number of patients reduces with

health resources used more appropriately in those whose ulcers remain.

There has been a move in recent years to manage patients with a VLU at home in the community setting. This has occurred due to the changing population demographics, increasing elderly population and increased pressure on health-care resources, in particular the cost of funding hospitals. With access to specialised LU services, where trained HCPs may not be available, for example rural areas, telemedicine may offer an opportunity to provide specialised assistance for patients who are not able to access services.

EWMA and Wounds Australia as expert bodies can lead the way in providing education and evidence-based publications on VLU management and ensure this chronic, debilitating, often slow-healing wound is kept on the agenda as an international health priority.

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Appendix I: Literature search strategy—guideline implementation

The search was divided into three separate searches.

Databases

All searches were performed in the following databases: Cinahl, Embase, Cochrane, Medline

Exclusion criteria applied to all three searches:

Intervention specific guidelines, RCTs/studies of specific interventions (not general guideline implementation), evaluation of specific guidelines, implementation in developing countries/health-care systems outside Europe, Canada, USA, Australia

Search 1: General facilitators or barriers for implementation

Search question:

Identification of generally applicable, potential barriers to and facilitators for guideline implementation

Search terms:

Clinical guideline [AND] Implementation [AND] Barriers [OR] facilitators [OR] health care professional [OR] clinician [OR] patient [OR] costs [OR] budget [OR] training [OR] resources [OR] service redesign [OR] organisation [OR] attitude

[OR] perception [OR] skills [OR] awareness [OR] accessible [OR] adherence

Period: 2010–2015

Search 2: Specific on guidelines on chronic wounds

Search question:

Identification of generally applicable, potential barriers to and facilitators for guideline implementation, focusing on wound management

Search terms:

Clinical guideline [AND] Implementation [AND] Barriers [OR] facilitators [OR] health care professional [OR] clinician [OR] patient [OR] costs [OR] budget [OR] training [OR] resources [OR] service redesign [OR] organisation [OR] attitude [OR] perception [OR] skills [OR] awareness [OR] accessible [OR] adherence [AND] wound

Period: 2005–2015

Search 3: Specific on leg ulcer guidelines

Search question:

Identification of generally applicable, potential

barriers to and facilitators for guideline
implementation, focusing on VLU management

Search terms:

Clinical guideline [AND] Implementation
[AND] Barriers [OR] facilitators [OR] health care
professional [OR] clinician [OR] patient [OR] costs
[OR] budget [OR] training [OR] resources [OR]
service redesign [OR] organisation [OR] attitude
[OR] perception [OR] skills [OR] awareness [OR]
accessible [OR] adherence [AND] leg ulcer [OR]
venous leg ulcer [OR] lower limb ulcer [OR]
varicose ulcer [OR] venous insufficiency [OR]
varicose eczema

Period: 2005–2015

Appendix 2: Literature search strategy—venous leg ulcer management

The search was divided into nine separate searches.

Databases

All searches were performed in the following databases: Cinahl, Embase, Cochrane, Medline

Period: 2005–2015

Search questions:

1. To identify recent evidence on the strategies used in clinical practice to define/classify, assess and diag-nose, treat/manage leg ulcers, monitor outcome of leg ulcer management, refer patients and prevent leg ulcer recurrence
2. To identify recent evidence on leg ulcer prevalence and incidence
3. To identify recent evidence on patient perspectives on leg ulcer management, as well as the health economic aspects and organisation of leg ulcer management

Search 1: Definition

Search terms: Leg ulcer [OR] Venous ulcer [OR] Varicose ulcer [OR] Venous insufficiency [OR] Varicose eczema [AND] Definition [OR] Classification [OR] Etiology [OR] Prevalence [OR] Incidence

Search 2: assessment and diagnosis

Search terms: Leg ulcer [OR] Venous ulcer [OR] Varicose ulcer [OR] Venous insufficiency [OR] Varicose eczema [AND] Diagnosis [OR] Diagnosis, Differential [OR] Assessment [OR] Sensitivity [OR] Specificity [OR] Predictive

Search 3: Treatment delivery / management

Search limited to include systematic reviews only. Additional literature was identified via the evaluated guidelines.

Search terms: Leg ulcer [OR] Venous ulcer [OR] Varicose ulcer [OR] Venous insufficiency [OR] Varicose eczema [AND] Dressings [OR] Compression [OR] Debridement [OR] Hydration [OR] Surgery [OR] Oxygen [OR] Ultrasound [OR] Negative pressure [OR] Nutrition [OR] Drug therapy [OR] Wound bed preparation [OR] Wound cleansing

Search 4: Monitoring outcomes

Search terms: Leg ulcer [OR] Venous ulcer [OR] Varicose ulcer [OR] Venous insufficiency [OR] Varicose eczema [AND] Method [AND] Healing

[OR] Ulcer free period [OR] Quality of life [OR]
Cost effectiveness

Search 5: Referral structures

Search terms: Leg ulcer [OR] Venous [OR] Varicose
ulcer [OR] Venous insufficiency [OR] Varicose
eczema [AND] Referral criteria

Search 6: Secondary prevention

Search terms: Leg ulcer [OR] Venous ulcer [OR]
Varicose ulcer [OR] Venous insufficiency [OR]
Varicose eczema [OR] Varicose veins [OR] Venous
hypertension [AND] Prevention [AND] Surgery
[OR] Compression [OR] Skin care [OR] Exercise
[OR] Activity

Search 7: Patients' Perspective

Search terms: Leg ulcer [OR] Venous ulcer [OR]
Varicose ulcer [OR] Venous insufficiency [OR]
Varicose eczema [AND] Patient [AND] Compliance
[OR] Concordance [OR] Adherence

Search 8: Organisation

Search terms: Leg ulcer [OR] Venous ulcer
[OR] Varicose ulcer [OR] Venous insufficiency
[OR] Varicose eczema [AND] organization and
administration [AND] Competence, clinical [AND]
Nursing treatment [OR] Medical treatment [OR]
Nursing education [OR] Medical education

Search 9: Health Economics

Search terms: Leg ulcer [OR] Venous ulcer [OR]
Varicose ulcer [OR] Venous insufficiency [OR]
Varicose eczema [AND] Cost

Appendix 3: Diagnosis and assessment of atypical leg ulcers

Table 16. Differential diagnosis and assessment of atypical leg ulcers

Underlying disease		Clinical characteristics	History	assessment
Vasculitis	Small vessel: leukocytoclastic (infection tumour /drug induced/autoimmune disease such as rheumatoid arthritis, Lupus Erythematoses, Sclerodermia, Sjögren's Syndrome) Middle and large vessel (Polyarteritis nodosa, Nodular Vasculitis, Wegener Granulomatosis)	Dorsum of foot, pretibial, calf Sharply demarcated, punched-out appearance, deep, multiple, confluence, necrotic Surrounding skin: palpable purpura	Autoimmune disease, medication, infection, tumour	Vasculitis Serology: RF, ANA, ANCA, C3, C4, anti-dsDNS, Cryoglobulins Biopsy Rule out infection / tumour
Neuropathic	Diabetes mellitus, Tabes dorsalis, Poliomyelitis, peripheral nerve lesions	Weight bearing areas Sharply demarcated, punched-out appearance, deep, sometimes pus (Osteomyelitis) Surrounding skin: thick callus, Anaesthesia, Hyperesthesia.	Polyneuropathy (Diabetes, alcohol, renal insufficiency, vitamin deficiency, borrelia, lepra, drugs)	Reflexes, sensibility. HbA1c, Creatinin, Vitamin B12. Probe to bone (Osteomyelitis)
Metabolic	Diabetes mellitus	Bullosis diabeticorum, arteriopathy / Microangiopathy, delayed healing of ulcers of other aetiologies	Diabetes	
	Calciophylaxis	Palpable calcium deposits, necrotic ulcers	Renal insufficiency	Ca++, Phosphate
	Gout, Cholesterol emboli		Gout	

Haematologic	Erythrocytes: sickle cell anaemia, Sphärozytosis, Thalassemia, Polycythemia Leukocytes: Leukaemia Dysproteinemias: Cryoglobulinemia, cold agglutinins, Macroglobulinemia			Blood analysis, RF, Cryoglobulins
Trauma	Pressure, cold, post-actinic, burn, artefact		History of trauma, psychiatric disorder	
Neoplasia	Epithelial tumours (Basal cell carcinoma, squamous cell carcinoma), Sarkoma, Lymphoproliferative, Metastasis	Primary ulcerating tumour on healthy skin, secondary in long-standing venous ulcer or scar	History of skin cancer, sun exposure	Biopsy
Infectious	Bacteria, Mycobacteria, Spirochetes, deep Mycosen, Protozoa often mixed infections (tropical ulcers)		Trips to tropical countries, drug use, immuno-suppression	Microbiology from swab or biopsy
Panniculitis	Alpha-1-Antitrypsin deficiency, Pancreatic fat tissue necrosis			Biopsy
Ulcerating skin diseases	Necrobiosis lipidica	Atrophic plaque with nodular borders	Diabetes mellitus	HbA1c, Biopsy
	Pyoderma gangraenosum	Highly inflammatory edge, purulent ulcer base Cave Pathergy-Phenomenon	Inflammatory bowel disease, RA, MDS	Diagnosis by exclusion!
	Necrobiotic Xanthogranuloma			
Genetic diseases	Sickle cell anaemia, Klinefelter Syndrome	Resembling venous ulcers		
Drug induced	Topical and systemic, e.g. Hydroxyurea			