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Canadian Consensus Statement for the Management of Venous Leg Ulcers

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ABSTRACT

To develop a concise Consensus Statement on the management of venous leg ulcers (VLUs) that incorporates existing standards and guidance on new technology, including improvement of calf muscle pump function and the utilisation of advanced wound therapies. A multidisciplinary panel of 19 wound healthcare providers from across Canada, who treat patients with VLUs, was formed. A draft document was created and four rounds of consultation and feedback were sought from the panel. The Consensus Statement was completed in June 2024 with 100% consensus on 20 sections and >85% consensus on the remaining three sections. The key elements are—Clinical assessment and investigations; Treatment-compression to improve calf muscle pump function, and wound treatment with the principles of Wound Bed Preparation; When not healing or only suboptimal compression can be used - add treatment with muscle pump activator by continuous Neuromuscular Electrical Stimulation of the common peroneal nerve to improve calf muscle pump function; When VLUs are not healing with optimal therapy - an algorithm for the use of advanced wound therapies; and Prevention of VLU recurrence. The Consensus Statement is a concise guide for healthcare providers to use at the bedside and has been endorsed by leading nursing and homecare associations in Canada that also have physician representation.

1 | Background

Venous leg ulcers (VLUs) take weeks or months to heal, cause distress, and are very costly for health services [1–3]. The key principle in treating chronic wounds is to treat the underlying cause, which for VLUs is to treat the ambulatory venous

hypertension [1–3]. Clinicians who treat patients with VLUs are often challenged with how to proceed with patient management when patients are not able to wear optimal compression therapy and when even in spite of optimal compression treatment, the VLUs do not enter into a healing trajectory or are very slow to heal. Existing guideline documents generally

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Summary

- This paper provides guidance on all aspects of the management of venous leg ulcers (VLUs), including guidance on what to do if the patient is not able to tolerate optimal compression or if the VLU is not responding to optimal therapy.
- Treat the underlying cause of the VLU, which is impaired calf muscle pump function.
- Enhance the function of the calf muscle pump with a muscle pump activator if unable to use or tolerate optimal compression, or if the VLU is not healing with optimal compression.
- Guidance on actions, including a structured approach to the use of advanced wound dressings if the VLU is not healing.

acknowledge new therapies, but do not provide guidance on how and when to use some of the new or advanced wound therapies [1–3].

There are multiple types of compression systems that are used for treating patients with VLUs [4–6]. These include multilayer compression with bandages that may be elastic or inelastic, compression stockings, compression wraps with hook and loop fasteners, and devices such as intermittent pneumatic compression [3]. There is general consensus that these should deliver compression levels of 30–40 mmHg at the ankle in patients with no arterial disease, so that they can achieve optimal improvement of the calf muscle pump. When patients are unable to tolerate optimal compression due to reduced arterial supply in the legs or due to factors of discomfort with compression, a common practice is to use a lower level of compression or to use minimal compression with a light bandage or a stockinette. In addition, many patients are unable to adhere to optimal compression therapy [7]. In patients with ankle brachial pressure index (ABPI) less than 0.5, compression bandages should be avoided [1–3]. In these circumstances, patients are not achieving optimal improvement of their calf muscle pump and consequently are not optimising the improvement in their microcirculation and their wound healing process.

There is a growing body of evidence that demonstrates that the calf muscle pump function can be improved using neuromuscular electrical stimulation (NMES) of the common peroneal nerve [8]. Studies on femoral, popliteal, and tibial veins using Duplex Ultrasound scanning have shown improvement in venous velocity and venous flow volume in both healthy volunteers and in subjects with venous disease. Studies on microcirculation in the skin using Laser Doppler techniques have demonstrated improved microcirculation in both healthy volunteers and in subjects with venous disease [9, 10]. In clinical practice, there is a muscle pump activator (MPA) device that can be applied for long periods to continually stimulate the common peroneal nerve. That device is geko (First Kind, UK) and is currently recommended for use up to 12h per day [11]. When patients are unable to tolerate optimal compression or cannot tolerate any compression, these studies indicate that the use of the MPA

device will contribute to the improvement in the calf muscle pump function.

A randomised controlled trial (RCT) on the use of the MPA device with standard-of-care compression compared to standard-of-care compression alone, demonstrated that there was a significant improvement in healing when the MPA device was added [11]. This supports the concept that when the MPA device is added to standard-of-care compression, it will improve VLU healing in those patients who are not responding to standard-of-care compression alone.

Part of the treatment of VLUs is to dress the wound itself, in addition to treating the underlying problem with the calf muscle pump function. Many of the dressings and topical treatments that are available allow the clinician to incorporate the principles of Wound Bed Preparation, that is, summarised in the TIME algorithm (Tissue, Moisture, Infection and inflammation, Edge) in treating VLUs [12, 13]. This incorporates debridement of devitalized tissue (T); managing infection if present (I); keeping the wound not too moist and not too dry, but at optimal moisture levels (M); providing treatments to aid the epithelial edge of the wound to advance over the wound base to close the wound (E). Clinicians have guidance on how to use available dressings to address Tissue, Infection and Moisture components of the TIME algorithm, but there has been little guidance on how to systematically address the Edge component when the wound is not healing or is only doing so at a minimal rate. Existing guidelines on VLU management mention advanced wound therapies but do not provide guidance to clinicians on how to use such products to improve wound healing.

A recent publication has identified key categories of advanced wound therapies that impact the healing process for VLUs once the underlying cause has been optimally treated [14]. Those key categories are—treating biofilm and bacteria; reducing increased protease levels; improving the wound base by Negative Pressure Wound Therapy or by adding matrix substitutes; adding growth-promoting factors to the wound bed; and finally adding healthy cells to the wound such as skin grafts, cultured cells or stem cells. The approach that has been recommended is to use these in a stepwise fashion and to reassess the response with each step, and if the wound is still not healing to progress to the next step. This approach provides guidance to clinicians on what to do when the VLU is not healing after improvement of the calf muscle pump function has been optimised.

There is a need for a concise document of best practice that incorporates this guidance for clinicians, that is a few pages in length, that can be readily used in the clinical setting, and that is a supplement to much larger reference documents such as most guidelines [1–3]. Consensus methods are a way of synthesising information and conflicting opinions with the aim of defining the degree of agreement within a group of selected individuals with expertise in the area of interest [15, 16]. They are particularly useful where the opinion of professionals is not unanimous due to the absence of data, where data has a low level of evidence, or where it may be contradictory [17]. An area where data from RCTs are not available is the management of patients who are not able to tolerate optimal compression, due to reduced ABPI or other reasons. In circumstances

such as these the expert opinion of panellists is relied upon for recommendations within a consensus statement such as this.

The goal of this work was to create a concise Consensus Statement on the management of VLUs that incorporates these new methods of VLU management and that provides guidance for clinicians on the next steps when the VLUs are not healing after optimal treatment has been initiated appropriately.

2 | Method

The initiative was led by the three first authors and the acknowledged special advisor. This group acted as the steering committee for the development of this consensus statement.

A panel of healthcare providers from across Canada was assembled to develop and have input into the Consensus Statement. The goals were to have representation from different clinical disciplines and from across different geographical regions in Canada. The panellist's disciplines included—Vascular Surgery (2), Rehabilitation Medicine (1), Dermatology (1), Family Medicine (1), General Surgery (1), Nursing (NSWOC 10, Nurse Practitioner 1, Nurse Researcher 1), Occupational Therapy (1). The intent was to involve healthcare providers who had experience in treating patients with VLU, some experience with the muscle pump activator device, and some experience with advanced wound treatments. This process sought to use the clinical expertise of this panel of clinicians combined with their knowledge of the current literature to come to consensus on how best to incorporate these elements into managing patients with VLUs.

The Delphi technique of achieving consensus was used in this process [18, 19]. A collection of statements that would contribute to the consensus statement was prepared by the steering committee and there were four rounds of consultation with the panel of health care providers [18–21] (Figure 1). Comments and feedback from the panel of experts were taken into account as they arose in each round of consultation and evaluation, and a modified series of statements incorporating the feedback was sent back to the group with each subsequent round of consultation. In accord with published data, the goal was to achieve at least 80% agreement by panellists on each of the key statements that were contained in the final Consensus Statement [21]. In the final stages of the consultation process, panellists were asked to provide an assessment of their level of agreement as—Strongly agree; Agree; Disagree; or Strongly Disagree. Consensus agreement was regarded to have been achieved if the rating was either Strongly Agree or Agree. All panellists provided independent and thoughtful feedback throughout the process.

This process was conducted independent of input from any companies and relied solely on the input from the 19 members of the panel. A number of the panellists do have consultancies or speaking engagements for different companies, but no organisation or grant supported this process, and panellists provided their time voluntarily. Conflicts of interest of the different panellists at the time of undertaking this initiative are provided at the end of the paper. This study did not involve patients or the collection of any patient information, and hence no

ethics approval was sought for this study. All panel members were free to express themselves and to not participate further in the study.

3 | Results

At the completion of the process for the development of the Consensus Statement, there was 100% consensus on 20 of the 23 elements and > 85% consensus on the remaining three elements. The full Consensus Statement on the management of VLUs that was developed by this panel is contained in Figure 2. The key components of the Consensus Statement are as follows:

- Clinical assessment
- Investigations
- Diagnosis
- Treatment of the underlying cause
- Management of the ulcer
- Options when not entering a healing phase
- Management post ulcer healing

The key novel areas of this consensus statement are as follows:

- An approach on how to treat the underlying cause of VLU if patients are not able to tolerate optimal compression. While there are not RCT data to support all of the recommendations, this relied on the experience of the panellists and their knowledge from case and cohort studies.
- An approach on how to manage patients who are not healing as expected after 4 weeks of treatment. This involves the key elements to be re-evaluated at that point to ensure that the diagnosis is correct and that optimal therapy has been instituted. There is also a sequential approach on how to utilise advanced wound therapies once the diagnosis has been confirmed and optimal therapy is in place.

The three elements on which 100% consensus was not reached after the four rounds of consultation were:

- A concern for clarity about not using any form of compression if $ABPI < 0.05$. This was accommodated in the final document by only recommending the use of any form of modified compression if ‘...ABPI is reduced but greater than 0.5, ...’
- A concern about using any cleansing products in non-healable wounds. This was accommodated in the final document by ‘...Treat ulcers deemed to be non-healable—cleanse with saline, clean potable water or antimicrobial solutions;...’
- Concerns in relation to ‘Actions if not on a healing trajectory—no size reduction in 2 to 4 weeks, or reduction less than 30% at 4 weeks after initiating treatment’
 - A concern about emphasising the need to reassess the ulcer diagnosis as the key priority, was addressed by making that the first item in this section.

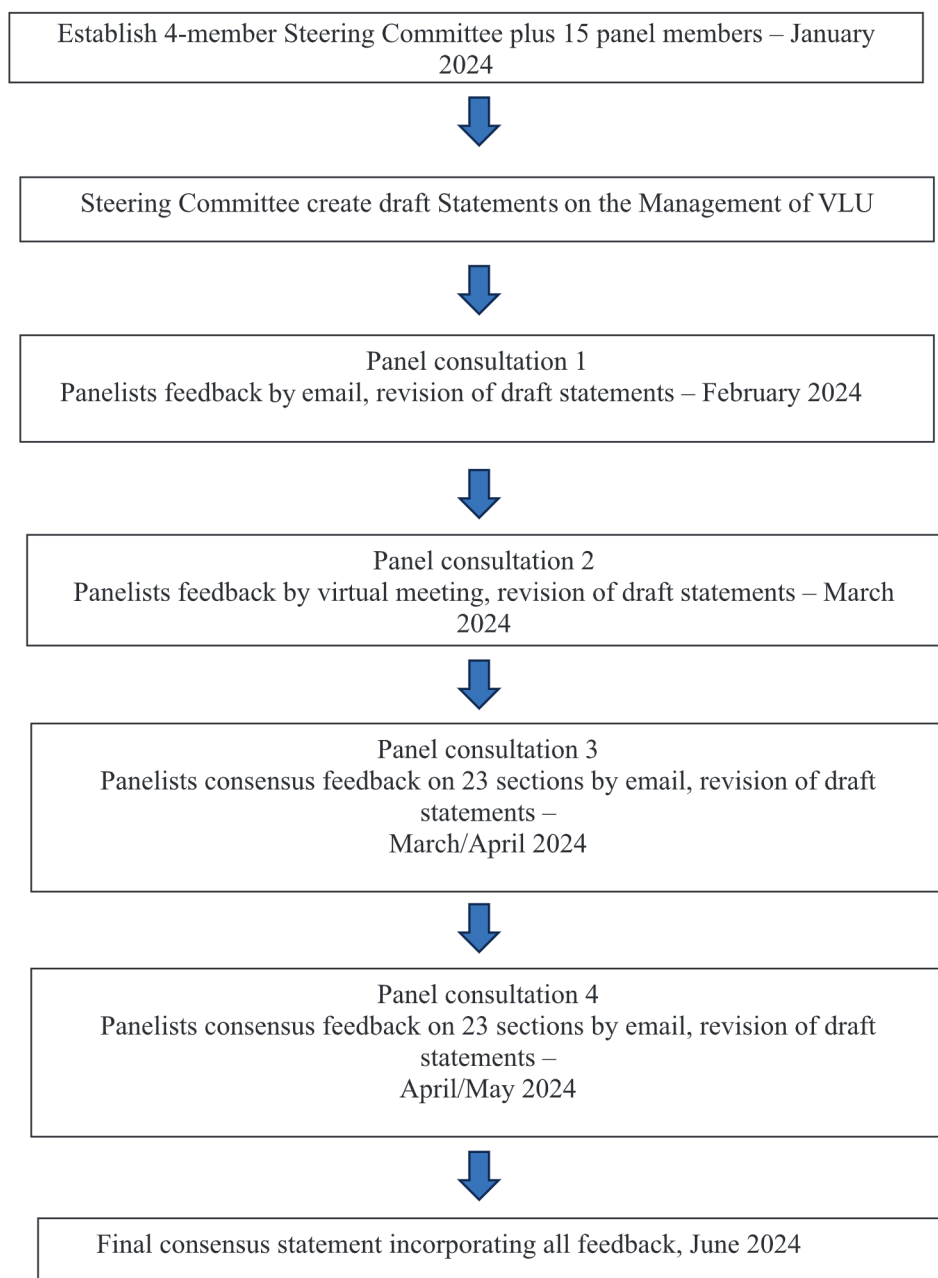


FIGURE 1 | Process for development of the Consensus Statement.

- A concern that lack of adherence to the treatment plan may also be due to suboptimal application of dressings and compression. This was addressed by adjusting the wording to ‘... Assess if treatment protocol has been properly implemented and is being adhered to...’

All other sections had 100% consensus. As described above in the three sections in which there was not 100% agreement, the comments from the panellists in the final round of consultation were accommodated in the final Consensus Statement.

4 | Discussion

Consensus is an explicit and critical agreement that occurs after analysing the problem with a reasoned discussion

between people who are concerned about the outcome and its consequences [22]. Using this definition, a consensus is valid to the extent to which it expresses a proposal to which all of those involved have given their assent, and which they are prepared to support to their peers [22]. The process involved in the development of this consensus statement has followed the methodological steps to ensure alignment with these principles.

There are two novel areas in the Consensus Statement that were agreed upon unanimously by the panel—the use of MPA to treat the underlying cause of VLUs in patients who cannot tolerate optimal compression or whose wounds do not enter a healing phase with optimal compression; and an approach to the use of advanced wound therapies in a sequential manner when optimal therapy, including MPA, has been implemented.

Canadian Consensus Statement on the Management of Venous Leg Ulcers (VLU)

This consensus statement is a practical guide for clinicians from all backgrounds and levels of experience for managing patients with Venous Leg Ulcers (VLUs) and is an adjunct to published guidelines on the treatment of VLUs

Diagnosis of VLU

- A. For patients with a leg ulcer, it is necessary to assess the cause of the ulcer, their health literacy, environmental factors and goals of care, before proceeding to treatment. Clinical assessment includes a thorough history of ulceration, venous disease, arterial disease, underlying medical conditions, and medications; and a thorough examination of the patient, their ulcer, and palpation of pulses. Investigations will include assessment for venous and arterial disease as well as other causes of ulceration and impaired healing. Ulcers may have mixed etiology.
- B. **Clinical Features**
- Location – from the sub-malleolar region to the knee, most often in the medial gaiter area, and occasionally on the dorsum of the foot
 - Ulcer Appearance does vary, but typical features may include -
 - Superficial ulceration not extending below the deep fascia
 - Size may be small or large, with irregular, serpiginous, and sloping edges
 - Surface – combination of coagulated exudate, slough and granulation tissue. Additional diagnoses such as micro or macrovascular arterial disease, vasculitis, trauma, surgical etiology, severe infection or inflammatory disorders are suggested by the presence of black necrotic tissue, visible fascia, visible tendon, undermined edges or sinuses
 - Exudate is often heavy, but may vary from light to heavy depending on the degree of edema control with compression and elevation, or the presence of infection
 - Surrounding tissue may have some of the following features of venous disease –
 - Hemosiderin staining; stasis dermatitis; pigmented, brawny and indurated skin (lipodermatosclerosis); visible varicosities and spider veins; atrophy blanche around the malleoli without a livedoid pattern of the surrounding vasculature
 - Edema – may also be caused by lymphedema, cardiac, renal or other systemic disease, especially if bilateral or above the knee, and is increased with dependency
 - Surrounding skin - maceration if excess exudate is not wicked away; sometimes dry, crusty, scaly or itchy; sometimes with contact dermatitis
 - Pain, if present, has features of aching, heaviness or tightness that may be relieved by leg elevation and may be more severe with infection, atrophy blanche and more advanced disease
- C. **Investigations**
- Diagnosis of venous disease (if limited access, management may start prior to investigation as long as arterial status has been established)
 - Non-invasive lower limb venous Duplex ultrasound to assess for
 - Deep veins – assess for incompetence or previous deep vein thrombosis
 - Superficial veins – identify sites of incompetence
 - Vein mapping to assess for suitability for venous ablation
 - Diagnosis of other co-existing conditions
 - Arterial status
 - Ankle-brachial pressure index (ABPI) and/or toe-brachial pressure index (TBPI) or toe pressure. TBPI especially in patients with diabetes and ABPI above 1.4
 - In areas without access to the above, assessment of audible waveforms on hand held Doppler with access to online waveform assessment (multiphasic waveforms indicate adequate arterial supply)
 - Non-invasive lower limb arterial Duplex ultrasound when available
 - Blood panel CBC, liver function, renal function, HbA1C
 - Investigation of other identified clinical conditions e.g. rheumatoid arthritis, lymphedema, etc
 - Assess gait and altered ankle mobility that may impair calf muscle pump function

FIGURE 2 | Canadian Consensus Statement on the management of Venous Leg Ulcers (VLU).

Treatment of VLU

- A. Treat the underlying cause of impaired calf muscle pump function**
- Apply an optimal compression system if - ABPI is normal (0.9 to 1.4); ABPI is elevated and TBPI or toe pressure is normal; or if the hand-held Doppler waveform is multiphasic
 - Optimal multi-layer bandage system (30 – 40 mm Hg at the ankle)
 - Other compression system options include elastic (bandages or stockings), inelastic (bandages), adjustable wrap systems with hook and loop fasteners, intermittent pneumatic compression systems, other compression socks. The selection may depend on patient mobility, pain, patient tolerance, ability to apply, environment and access.
 - Encourage calf muscle contraction exercises, especially a daily walking regimen, to improve calf muscle pump function. Consider support from physiotherapy or rehabilitation medicine, and daily leg elevation above the heart, if limited ankle motion, strength, mobility or impaired gait
 - If not able to tolerate optimal compression, if ABPI is reduced but greater than 0.5, or if the patient has significant congestive heart failure which requires cardiologist evaluation -
 - Apply a lower compression multilayer system that the patient will tolerate, with the aim to progress to optimal compression as symptoms and tolerance allow
 - Use caution at ABPI between 0.65 and 0.9, and extra caution between 0.5 and 0.65 when stockinette with tubular or longitudinal compression may be considered in place of compression wraps
 - Add Muscle Pump Activator (MPA) which is a form of neuromuscular electrical stimulation of the common peroneal nerve, as an adjunct treatment once it is established that the patient/caregiver can access it and can follow the treatment protocol. This activates the calf muscle pump and is not a compression system
 - If not able to tolerate any compression due to pain or other causes -
 - Add MPA once it is established that the patient/caregiver can access it and can follow the treatment protocol, with the aim to progress to add lower compression and then optimal compression
 - Recommend daily leg elevation above the level of the heart and a regular exercise regimen to improve calf muscle pump function, especially a daily walking regimen, and consider support from physiotherapy and rehabilitation medicine
- B. Treatment of the ulcer**
- Wound management
 - Cleanse the ulcer and surrounding skin. Saline or clean potable water may be used, and if available or accessible, use an antimicrobial solution e.g. hypochlorous acid
 - Debride devitalized tissue if vascular perfusion is normal, depending on the scope of practice, skills and experience of the health care provider. Methods may include - enzymatic, biological, mechanical, sharp debridement (under topical/local anesthesia if needed) or autolytic to debride de-vitalized tissue and to allow healthy granulation tissue formation. Different methods may be used sequentially as access and wound needs change
 - Apply a dressing that ensures adequate moisture balance and that supports moist wound healing – if excess exudate, use a moisture absorbing and/or wicking dressing; if dry, use a moisture retentive or donating dressing
 - Treat infection in deep and surrounding tissue with antibiotics and antimicrobial dressings
 - Manage pain if present – may need to reduce or delay compression until pain has reduced
 - Treat surrounding skin irritation or dermatitis; protect surrounding skin from excess exudate; and maintain good skin care
 - Treat ulcers deemed to be non-healable - cleanse with saline, clean potable water or antimicrobial solutions; and use dressings to support wound maintenance goals
 - Ulcers should be measured using a consistent method weekly or at each visit if seen less often
- C. Treat underlying conditions**
- Ensure that all underlying medical conditions that may impact ulcer healing (e.g. diabetes, heart failure, anemia, nutritional and metabolic deficiencies, etc) and physical and mental wellbeing are being actively treated. Involve other health care providers as indicated.

FIGURE 2 | (Continued)

D. Actions if not on a healing trajectory – no size reduction in 2 to 4 weeks, or reduction less than 30% at 4 weeks after initiating treatment

- Review the assessment and diagnosis of ulceration to exclude other ulcer etiologies or causes of impaired healing e.g. skin cancer, autoimmune conditions, medications that impeded healing, smoking, etc.
- Assess if treatment protocol has been properly implemented and is being adhered to
- Reassess if infection is present and being managed
- When above have been addressed, review and optimize treatment of calf muscle pump function
 - Reassess the compression system that is in place to ensure that it is optimal
 - Review exercise and walking regimen
 - Add MPA if not already in place
 - Consider referral to appropriate source for superficial venous ablation if indicated
- When diagnosis is confirmed and calf muscle pump function is optimized, consider the introduction of advanced wound treatments, depending on local availability, in a sequential manner with assessment of the healing response at each step –
 - A dressing that is antimicrobial and that can disrupt or eradicate biofilm
 - A dressing with protease inhibition properties
 - Improve the wound bed with negative pressure wound therapy or with a matrix substitute
 - Deliver growth factors through dressings that release physiological growth factor levels
 - Add new cells to the wound as skin grafts, cultured cells or skin substitutes
- Consider other adjunctive treatments as appropriate, such as – oral pentoxifylline, electrical stimulation of the wound bed, topical oxygen therapy, hyperbaric oxygen therapy or therapeutic ultrasound. Some might be introduced earlier and for some evidence in VLU may be equivocal

Treatment post VLU healing

A. Prevent VLU recurrence

- Lifelong compression therapy, initially continuing compression wraps for at least 2 weeks or longer to ensure full ulcer healing. This is especially important in those with recurrent ulcers, more advanced disease and those awaiting appropriate compression systems
- Fit compression stockings (below knee in most cases) in most instances. If not feasible, use a compression wrap system with hook and loop fasteners. Compression ideally at 25 – 40 mm Hg, or adjust to a lower pressure suitable for arterial disease, or that the patient can tolerate and will continue to wear
- Encourage calf muscle contraction exercises, especially a daily walking regimen, to improve calf muscle pump function. Consider support from physiotherapy or rehabilitation medicine for those with limited mobility
- Reinforce education regarding venous disease and prevention of ulcer recurrence, protecting the skin from trauma, the need for life-long compression garments and their replacement, and the need for exercise to activate the calf muscle pump
- Consider referral for superficial venous ablation by surgery or other less invasive techniques if appropriate

Endorsed by

- ▶ Nurses Specialized in Wound, Ostomy and Continence Canada, 2024



- ▶ Canadian Home Care Association



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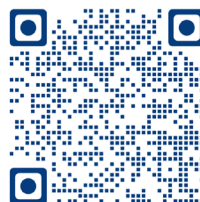


FIGURE 2 | (Continued)

At the time of submission for publication, the Consensus Statement has been endorsed by Nurses Specialised in Wound, Ostomy and Continence Canada (NSWOCC), 2024, a leading organisation in Canada for nurses who manage patients with VLU in both the community and in hospital settings; and by the Canadian Home Care Association (CHCA), which is a national body that facilitates knowledge sharing, creates connections, informs policy and practices and advocates for integrated home and community care for all Canadians. Both of these organisations have active involvement of physicians in addition to nurses in developing their policies and procedures. The Consensus Statement has been presented at annual national professional conferences in Canada that include—Nurses Specialised in Wound, Ostomy and Continence Conference; The Canadian Society for Vascular Surgery; and Wounds Canada. The consensus has also been presented in a number of Webinars that are directed to clinicians who care for patients with VLU in Canada.

The Consensus Statement is contained in full in Figure 2, and can also be accessed online for a free download at <https://sites.google.com/view/vluconsensus>.

5 | Conclusion

VLUs have an estimated prevalence of 0.32% [23], are the most prevalent chronic wound of the lower leg [24], and are a significant burden not only on the patients, but also on the healthcare system [25]. This Consensus Statement is a practical guide that clinicians can use at the bedside to enable the application of best practices for patients with VLU, and to improve the quality of their care in the most cost-effective manner.

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Conflicts of Interest

Conflicts of Interest involving consultancies or speaking engagements related to companies or wound care organisations at the time of developing the consensus statement were declared by members of the panel. Those companies and organisations and the number of conflicts declared were Essity—2, Health Espresso—1, Hollister—1, Medline—2, Molnlycke—2, Perfuse Medtec—3, Solventum—1, Strerasure (Biomiq)—1, Urgo Medical—1, WoundPedia—2, and Wounds Canada—1.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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