

The differences in approach and clinical outcomes of venous leg ulcers managed in primary and secondary care

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There is evidence to suggest that venous leg ulcer (VLU) management in the NHS is an inconsistent service, prone to the lottery of geography and referral. Numerous 'best practice' statements and clinical guidelines have outlined standards of care and treatment pathways (for example, Scottish Intercollegiate Guidelines Network [SIGN], 2010 and National Institute for Health and Care Excellence [NICE], 2016), however, the limited healing rate data available strongly suggests that these documents are not being enacted into routine care. This current debate is designed to explore the issues surrounding care and not to ascribe reasons for the apparent failure to adopt best practice across the NHS. The implications for patients is clear: some will receive quality care and thus have every chance of healing, others will receive poor care and healing will be unlikely. Aside from quality of life issues, there are considerable health economic concerns associated with what might best be termed 'palliative care of venous ulcers'.

For many years, we have accepted the incidence data and demographics as cited in SIGN (2010) "Chronic venous leg ulceration has an estimated prevalence of between 0.1%

and 0.3% in the United Kingdom Prevalence increases with age and approximately 1% of the population will suffer from leg ulceration at some point in their lives (Callam et al, 1985; Cornwall et al, 1986; Callam et al, 1987; Baker et al, 1991; Nelzén et al, 1991a; Nelzén et al, 1991b; Callam, 1992; Baker et al, 1992; Nelzén et al, 1994)". These are clearly old and may reasonably be regarded as so out of date that current costs for care cannot be reliably calculated on this basis. Very recently, Guest et al (2015; 2016) have published data from an NHS-sourced database, giving a rather different picture.

Guest et al (2012) established that venous ulcer healing rates in UK GP-led primary care varied from 6–9% in six months. The authors are to be commended on the rigour of their methodology in extracting 'everyday' ulcer healing data from The Health Improvement Network database (THIN, 2016). The data presented in this article provide an interesting insight into the realities of ulcer care. It is important to illustrate this by emphasising a particular sample of the data. For example, the data from 255 patients with a mean age of 80.3 years was collected. The mean ulcer size was 79.2 cm² (i.e. big ulcers) with 70% judged to have 'light to moderate' exudate and 30% 'medium to heavy'. A wide range of dressings were used in conjunction with six different classes of compression. Notably 32% of patients did not receive any compression at all! Patient outcomes at six months (i.e. 26 weeks) were healing rate 9% (control), time to healing 5.1 months, infection rate 58%.

On first view, these outcomes are shocking to anyone familiar with ulcer care. Whilst the diagnosis of infection is open to interpretation, healing is not. On the assumption that the infection rate is correct to ±10%, it is reasonable to expect dressing selection to reflect this, i.e. some form of antimicrobial

dressing used. However, the control group antimicrobial dressing usage was reported at 12%. It is, however, conceivable that the majority of this group were treated with systemic antibiotics. If so, one would hope that the diagnosis was accurate. Healing rates obtained in numerous clinical trials lead us to believe that rates well in excess of 40% in 12 weeks, are routinely achieved: this may be ascribed to consistent and accurate use of appropriate compression systems (Guest et al, 2015). The reality is that in NHS primary care it is nowhere near this. This may be explained in part by the under-use of compression. It would be interesting to learn why one third of patients did not receive compression — what was the true aetiology of these ulcers? Was a Doppler ankle-brachial pressure index [ABPI] obtained? Was any clinical guideline followed? It is also a concern that aetiology is being assessed with any degree of confidence — are these patients having an ABPI measured skilfully, i.e. according to current guidelines (Benbow, 2014; Furlong, 2015)? Of the remainder, the low healing rate might be related to compression that may have been inadequately applied. A major concern is that these data be used by any Qualified Providers as evidence of current reality, and thus a target to be met, and exceeded! It must also be a concern that leg ulcer patients are very probably not being diagnosed accurately for wound infection and compression not being applied at all, or applied inappropriately. The question arises as to: "how many clinicians outside of dedicated wound centres can accurately diagnose infection in a chronic wound?" (Kirsner and Vivas, 2015).

A cursory look at data acquired from community wound clinics showed that, in contrast, healing rates for venous ulcers is 73% in 12 weeks and 100% in 24 weeks were obtained in one centre (White et al, 2012) and

similar in another (O'Halloran and Winter, 2013). These illustrate what can be achieved given adequate training and resources.

According to Guest et al (2016): *“the NHS managed an estimated 2.2 million patients with a wound during the period 2012/13. These patients were predominantly managed in the community. The cost was £1.94 billion for managing 731,000 leg ulcers. Resource use associated with managing the unhealed wounds was substantially greater than that of managing the healed wounds (these wounds resulted in ~20% more practice nurse visits and over 100% more community nurse visits). The annual cost of managing wounds that healed in the study period was estimated to be £2.1 billion compared to £3.2 billion for the 40% of wounds that did not heal within the study year. Within the study period, the cost per healed wound ranged from £698 to £3,998 per patient and that of an unhealed wound ranged from £1,791 to £5,976 per patient. Hence, the patient care cost of an unhealed wound was a mean 135% more than that of a healed wound”*. The vast difference between these data and the previous emphasises the extent of the problem, and of using old data for cost projections.

Many authors have written on the costs of wound care to the UK healthcare system, usually in the hope of raising the profile on economic grounds, to ensure adequate resourcing (Bennett et al, 2004; Posnett and Franks, 2008). However, with the Guest et al (2016) publication, we have at last quality data to show the parlous state of leg ulcer care in one part of the community. Will this be sufficient to ensure that the relevant clinicians are adequately trained and, given sufficient time to manage leg ulcer patients?

This debate merely touches on the nature and extent of the problems associated with VLU care in the NHS. There can be little doubt that current evidence dictates that this whole therapeutic area merits further, detailed consideration at the highest level in order that patients may receive quality care in the community. *Richard White*

1. With the increasing focus on primary care in the NHS, how do you see the prospects for VLU management?

SW: Most will agree that services are under pressure due to a lack of funding, staffing and resources. VLUs in 2012–13 were estimated to cost the NHS between £788 (healed) and £4,472 (unhealed) (Guest et al, 2016). The prevalence of VLUs increases with age so this figure is predicted to rise with an ageing population. We need a new approach to management — savings need to be made and standards need to be raised for better healing outcomes. Primary care offers good opportunities for early identification, diagnosis and timely referral to secondary care for vascular assessment if standardised pathways are followed. It can also offer good opportunities for prevention of wound progression and wound recurrence if the Leg Club model is implemented in communities. This model places emphasis on a ‘well leg programme’ in a semi-social setting, with early identification of patients at risk and maintenance after healing being key.

AH: Whilst there will be an uplift in income for general practice, in reality no real additional money is heading towards primary care. The NHS is in deficit and there are billions to find. However, despite this gloomy scenario there is so much waste in leg ulcer treatment through repeated ineffective management, that savings are there to be found if only the will was there to look.

In theory, the agenda to reduce costs associated with long-term conditions and preventing unplanned admissions should support the development of community-based leg ulcer management. Unfortunately, the various ‘funding pots’ for management have hindered a collaborative and comprehensive approach in many boroughs in the UK. No one doubts there is the need for this, but it can be systems and personalities that can get in the way. Prospects for this group can improve if we,

as specialists, make the most of the new agenda and systems coming into place. We need to understand where and how change will be delivered by the vanguards and Sustainability and Transformation Plans and the opportunity this brings to primary care level; we must ensure that awareness is raised for this unrepresented group and articulate where we fit, to improve prospects and demonstrate tangible benefits to commissioners.

JE: In the UK, GPs occupy key positions in primary care. They act as gatekeepers, referring patients to hospital doctors or specialist services if their condition requires this (Loudon, 2008).

The vision is that GPs will become the ‘expert generalist’ by 2022 (Royal College of General Practitioners, 2013). On the other hand, in the same document, it is reported that *“The plan is unachievable without investment in primary care manpower, premises, infrastructure and technology”*. In this new role, it is envisaged that GPs will:

- ▶▶ Develop the new generalist-led integrated services,
- ▶▶ Develop enhanced GP skills
- ▶▶ Increase community based academic activity to improve effectiveness, research and quality
- ▶▶ They will form federations or groups of primary care teams, working together, sharing expertise and resources to deliver patient-focussed services (Royal College of General Practitioners, 2010).

It is anticipated that patients with many comorbidities and long-term conditions will be better served by this model of care.

VLUs are not specifically mentioned in the list of long-term conditions. Leg ulcers are not of themselves a diagnosis. They manifest as a result of many underlying disease processes including peripheral artery disease, rheumatoid arthritis and diabetes mellitus. Holistic assessments are an essential component in the management of all long-term conditions, the same is true of VLUs. Sadly, the current focus is more

about wound care and bandage application. Factors such as obesity, malnutrition and intravenous drug use contribute to the formation of leg ulcers. Neoplasm or neoplastic changes are not common in VLUs. All suspicious lesions require a biopsy and specialist service referral.

In order for this model to work for patients with leg ulceration, more GPs with special interest in VLU management or tissue viability specialist nurses would be required to offer expertise and support to the wider GP community and to oversee the care of patients with VLUs.

Currently diagnostics are accessed through the consultant referral system, reported upon and interpreted by specialist vascular consultants who would recommend a treatment plan that may or may not include surgery. Referrals to secondary care include patients who require a treatment plan for compression therapy.

If there was a direct route for diagnostics, such as Duplex, and the results interpreted, then patients with 'normal results' would be managed in the community with referral to specialist services, such as vascular, for consideration of surgical options available for those patients who would benefit from that.

2. Do you think it is widely accepted that the differences in healing rates between primary and secondary care (or specialist community centres) are so large?

SW: I do not think it is widely accepted that healing rates differ significantly between primary and secondary care. Evidence supports better healing rates in specialised clinics as opposed to the community — a leg ulcer trial in Scotland demonstrated healing rates of 45% in the community compared to 70% in specialist clinics (SIGN, 2010). A significant factor is the diverse patient caseload and high-patient numbers dealt with by community nurses, currently overstressing resources. A lack of time for continuing leg ulcer education can lead to inadequate assessments and incorrect

application of compression bandaging and hosiery, with dressing choices not always being entirely appropriate. Community nurses also have local dressing formularies to adhere to for financial reasons but these can be restrictive. These factors combine to constrain healing rates in the community and are very tangible targets for service improvement.

AH: I do not think anyone would dispute that patients seeing generic staff have less satisfactory outcomes than specialist centres. Unfortunately, there is little data to translate this hard reality into real costs for the providers or commissioners for a population; the variation is unknown. In order to support the transformation of services and an 'invest to save' approach, a case needs to be made. Convincing arguments often require stories or data from our own patch, not a published cost for a non-healing leg ulcer per annum. Unlike diabetes or heart disease, primary care does not automatically collect or know the number of patients with leg ulcers, let alone those who are missing out on focussed care that would change their lives, and, let me add, enable more effective resource management.

Unfortunately, there is a prevalent view about many people with terrible ulcers hidden at home that 'all that could be done, has been done', developing a palliative approach to care. And whilst we can all give exceptions to this rule, we have to critique ourselves and look at the reality. King (2016) recently reported that a local survey within district nursing found only 53% of patients with lower leg ulcers had received an assessment. No assessment will simply result in repetitive ineffective management and the Five Year Forward View (NHS, 2014) is clear on the need to move away from this approach. Within general practice, leg ulcer assessment and management is even more limited; there is little time provided for management and no incentive of a Quality and Outcomes Framework.

Thus we should not be surprised by this disparity but be pushing for change; high-

quality and consistent leg ulcer management can create an immediate impact on patients' lives, nursing activity and costs incurred by the local health economy. This should be a 'win-win' scenario for all.

JE: It has been well documented that patients in specialist clinics have better healing outcomes, including pain, quality of life, self-esteem, functioning ability, and reduced recurrence rates compared to those managed in community nursing services (Edwards et al, 2009; O'Meara et al, 2009).

It is my experience practice nurses (PNs) realise that they are struggling with VLU management. They have limited education, time and specialist support to deliver gold standard care to patients. They are often as frustrated as patients with the poor outcomes. They are dependent on specialists to assess patients and initiate treatment plans involving compression therapy. They have limited access to other services for support for assessment and commencement of therapeutic treatment plans.

In most geographical areas, PNs cannot access the skills available within the district nurse (DN) teams. Service-led agreements with the GP practices and community providers include only those patients who are housebound. People who can travel to the surgery, library or town, cannot access the services or resources of the DN teams because by definition they are not housebound.

DNs have more specialist care in the management of patients with leg ulcers, have more access to Doppler assessment within their teams although staffing levels and time constraints on the teams often mean that this assessment is delayed.

3. The King's Fund has identified three big challenges for the NHS in England:

▶▶ **Sustaining existing services and standards of care**

▶▶ **Developing new and better models of care**

▶▶ **Tackling these challenges by reforming the NHS 'from within'**

What do you see as being possible for leg ulcer services in primary care?

SW: I believe that these are both exciting and challenging times for VLU management. The need to improve standards whilst driving down costs goes hand in hand in the context of improved healing rates. Specialised centres that can deliver excellent wound care and compare outcomes are key; one proven model for these centres is the Lindsay Leg Club. The Leg Club model is cost effective and the improved healing rates achieved can reduce the cost of a healed ulcer by 58% (Gordon et al, 2006). In addition to nursing care, it provides the benefit of a social aspect, encouraging attendance and patients taking ownership of their treatment and post-healing care. Patients are able to support one another and return regularly enabling maintenance and prevention wound breakdown/recurrence. Within this model, patients still need holistic patient assessment and a standard vascular referral pathway needs to be in place.

AH: Lower leg ulcer or wound management needs a comprehensive community model within a long-term condition framework. The model required is quite simple. A focus on early intervention at primary care and triage into a specialist team for those with red flags or triggers would have a dramatic effect on those entering a non-healing way of life and reduce leg ulcer prevalence (Hopkins and Worboys, 2015). But to deliver this, a whole health economy approach is required. After all, lower limb wounds and ulcers managed ineffectively in primary care is the district nursing activity of the future. Patients must stop being divided up according to their mobility but seen by a service who will get them healed fast. This will save money and time for everyone.

With the new provider models and a hastening deficit, this should be an opportunity to change from within. It is possible but it will need passionate clinicians with local data to drive the change. But we

also need to challenge a guideline framework that only guides practice for the standard venous leg ulcer. There is no real world plan for patients that do not tolerate this or for whom this is ineffective. There are also a swathe of patients, especially in primary care, who have functional (not overt) venous disease contributing to the slow healing trajectory of a simple traumatic wound.

JE: Leg ulcer management is costly. With a rising elderly population, the cost to the NHS is increasing. The cost to a large population of people in terms of poor quality of life, reduced mobility and low self-esteem is immeasurable.

It is, therefore, essential that patients are assessed at the earliest possible opportunity and ideally within two weeks of sustaining a wound to the lower leg.

There are several guidelines available for the management of leg ulcers (SIGN, 2010; Royal College of Nursing, 2015) to support practitioners in the management of patients with leg ulcers.

Guidelines are not always adhered to in primary care. Weller and Evans (2012) found that less than 20% of PNs used best practice guidelines to direct treatment.

Doppler assessment is frequently not carried out when patients sustain a VLU and attend PN clinics for management. In line with the findings of Weller and Evans (2012), it is my experience that PNs lack the competencies, experience and time to carry out this diagnostic.

Patient appointments last ten minutes in general practice. This is not long enough to assess or to carry out effective skin care, holistic assessment or compression therapy.

In many surgeries, a tissue viability or vascular specialist referral is made before compression is initiated. PNs reported that their responsibility is in the management of compression therapy once the treatment plan had been initiated (Weller and Evans, 2012).

In my experience, many of the referrals I receive from PNs are for Doppler assessment and advice on the compression system to

be commenced. Patients are frequently referred after several months, with different dressings being trialled but no diagnostics or compression initiated.

The delay in having a holistic assessment and treatment plan means that the wound becomes chronic and that patients become disengaged from the possibility of healing with compression systems and reconciled to the fact that the leg ulcer will not heal. They are also frustrated with the restrictions on their lives over a prolonged period of time.

It is essential that patients receive better care for VLUs when they occur, in line with current research and guidelines. This can be achieved with little change to the current primary care pathways.

4. What, in your experience, can be done to provide 'high quality care for all'?

SW: Early identification and diagnosis of a VLU is fundamental and referral of an ulcer that has not healed within two weeks for vascular assessment is vital (NICE, 2015). A standardised leg ulcer vascular referral pathway is essential as it facilitates thorough assessment of the ulcer and timely treatment of the underlying cause(s) where tractable.

After the vascular assessment, VLU care can continue under tissue viability nurses towards healing. To ensure high-quality care for all, healthcare staff need to be educated in implementing best practice for the prevention and treatment of VLUs. Patient choice should be accounted for wherever possible and outcomes must be measured both locally and nationally to ensure transparency and standardised care of the highest quality.

AH: Unfortunately, there is nothing like a target to improve quality and reduce harm. It focuses everyone's attention because they have no choice. The national drive to reduce pressure ulcers has shown what can be done, but of course this initiative also had unintended consequences; anecdotally, it appears that people with leg ulcers have reduced access to tissue

viability support, which once again has become the Cinderella service in many areas. But there are also hot spots of great care that are also hidden.

Commissioners should put a service in place that can demonstrate good outcomes and adherence to the accepted quality standards. Whilst no one is looking, outcomes are deteriorating and dressing costs spiralling. I was never fond of the Any Qualified Provider model, but I do promote the need to provide reports for a population that are comparable. How can we improve, if we do not have data to challenge our assumptions or service model?

The development of local skills and competencies are essential but without a supervised model and tracking of outcomes, early gains will be lost and the default button of light compression will be pushed.

JE: There is no benefit to patients in deferring access to diagnostics. Patients must have early referral for Doppler assessment and direct access to Duplex where appropriate.

Doppler assessment is currently a pivotal diagnostic requirement prior to applying any compression therapy. New diagnostics, more easily interpreted by PNs, DNs and other community practitioners will ensure that patients have a more robust diagnosis of any arterial disease. Diagnostic technology must become more portable, robust and available for use in a clinic setting or in the patient's home.

Compression systems easily managed by patients who are equal partners in the therapeutic process will ensure that there is improved concordance with compression systems that they can manage.

Patients can have sensitivities to the components or products used in leg ulcer management. They suffer from itch, pain, and poor skin integrity. It has been my experience that this is not always well managed. Practitioners are not always aware of the breadth of leg ulcer management and compression systems or how to access them

when the local formulary products are not suitable for their patient.

It is essential that alternative systems to the current bandaging systems are designed. Emerging technologies will ensure that the compression systems are easier to apply and cause less sensitivity problems.

5. Is the focus on conservative leg ulcer management in primary care justified, especially when there is good evidence for invasive interventions?

SW: Not all patients will want or accept invasive interventions, or indeed be suitable to receive them. Compression bandaging is still considered the gold standard for healing leg ulcers (Young et al, 2013). Early recognition and assessment of VLUs is key. After a full holistic assessment, conservative leg ulcer management needs to be implemented before referral via the vascular pathway. With a focus on high-quality wound care, referral to secondary care may not be required.

AH: For over 25 years, I have promoted conservative community leg ulcer management. It is my firm belief now that nurses do not use the 'potent tool' of compression therapy effectively. As long as it stays up and is on the leg, the assumption is that care is being delivered. Through education and guidelines, nurses have also been frightened away from applying high compression bandaging, always erring on the side of caution. You only have to review the increase in usage of light compression systems to see the evidence for this.

For most patients, this can often be enough; any compression bandage or system will work. But for those that do not respond to standard high compression management, or even deteriorate, they need something else. Unfortunately, current guidance does not have a plan B. And before defaulting to other modalities or invasive interventions, let us first focus on delivering therapeutic compression. This may require bespoke extra high

compression, proper pain management or simply consistent management by someone who is a great bandager — who adapts her art to the limb, ulcer site and the patient in front of them.

When this focussed approach has not worked, then other modalities must be reviewed because this is also about effective resource management. But only if we have the data to support this and anecdotal evidence is no longer enough.

JE: It is my opinion that specialist leg ulcer services can be provided in the community. This may be a real opportunity to improve leg ulcer services and to reduce the financial cost burden. The cost of treatment per year for a leg ulcer was costed between £1,298 and £1,526 in 2001 (Iglesias et al, 2004). It is imperative that there is an improvement in the healing rates and reduction in re-occurrence to reduce the financial burden on the NHS and improve the lives of those people unnecessarily living with chronic, poorly managed VLU conditions.

Previous models for VLU care in community services have not always been well managed. They have not been financed and patients have not always been attended to by practitioners with specialist skills in their management.

Improvements in technology will be critical to the success of the primary care model. ABPI and pulse oximetry tools are current assessment tools. With possibilities of Duplex scans being available in the community as they become smaller, more accurate, less time consuming, and more portable. Emerging technologies are essential to enable appropriate assessment of all VLU sufferers.

Accepting patients as equal partners in their leg ulcer management and ensuring that they are well informed and have access to a range of products and systems they can manage with support from well-educated

