

# Using treatment pathways to improve healing of venous leg ulceration

**Background:** A leg ulcer prevalence audit carried out by staff working in community services within an NHS Trust identified an average wound duration time of 24 months, which impacted negatively on the patient and nursing capacity. **Aim:** To evaluate whether the implementation of evidence-based treatment pathways would lead to complete healing in 70% of people with venous leg ulceration at 24 weeks. **Methods:** Two evidence-based pathways were designed (standard and complex) with a key focus on wound bed preparation, appropriate compression and wound progression over 6 weeks. Patients ( $n=77$ ) were assigned to a pathway – 61 to the complex pathway and 16 to the standard pathway. Data relating to wound size and pain levels were requested every 6 weeks for 24 weeks or healing. **Results:** Out of the 77 people starting on a pathway, 45 remained for 24 weeks or until healing. Of these, 71% ( $n=32$ ) healed completely within 16 weeks, 20% ( $n=9$ ) improved by >70% and 9% ( $n=4$ ) remained static. There were 32 patients removed from the pilot for a range of reasons, predominantly poorly controlled co-morbidities and deterioration in their arterial status. **Conclusion:** Using an evidence-based treatment pathway can improve the healing rates of people with venous leg ulceration; however, a multidisciplinary approach to managing underlying co-morbidities is needed if outcomes are to be optimised.

## KEY WORDS

- ▶ Venous leg ulcers
- ▶ Treatment pathways
- ▶ Audit

The prevalence of active venous ulcers in the UK is approximately 1.5 per 1000 of the adult population, increasing to up to 20 per 1000 in people over the age of 80 years (Fowkes, 1996). Nationally, the majority of patients with leg ulceration are treated at home, with an overall cost estimated at £300–£600 million (Healthcare Commission, 2004). Treated correctly, the average healing rate for a venous leg ulcer is 16–24 weeks, but studies into wound duration have found leg ulcers often fail to heal in an orderly way (Vowden and Vowden, 2009) and analysis of treatment and referrals showed that not all patients were receiving the correct treatment or had been referred for specialist assessment and management in line with published recommendations (Vowden, 2010).

Historically, within Oxfordshire the actual number of people with leg ulcers was unknown. Anecdotally it was accepted that leg ulcer management varied across the county, with

standards differing significantly depending on who was providing the care. Leg ulcer care is delivered by a range of clinicians and in a range of settings. Predominantly this is by community nurses who carry out the care within patients' homes, some care from an informally run nurse-led clinic and the remaining care carried out in treatment rooms by practice nurses employed by GPs.

An initial prevalence audit carried out in 2011 identified that there were 427 people across the healthcare population with a minimum of one leg ulcer. This equated to 0.83 per 1000 of the adult population of Oxfordshire, with 7.44 per 1000 patients over the age of 80 and 0.06% of the GP patient population. This is under the national average of 1.5 per 1000 of adult population, possibly due to the demographics of a university city. Of those people with an ulcer, 68% had a venous ulcer with a mean wound duration time of 24 months and 65% were in full compression (40 mmHg).

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*“Every year these leg ulcers remained unhealed was costing £368 500 in nursing time.”*

It was not possible to offer an exact reason for why these ulcers were not healing but in referrals in the 12 months leading up to the audit, the tissue viability team identified key factors that were likely to be contributing to the poor healing rates of venous leg ulcers (*Table 1*).

The wound duration times were clearly unacceptable and impacting on the nursing capacity of the service and on the patients experiencing the unpleasant symptoms of venous ulceration. A costing model was applied to the number of people with venous leg ulceration identified from the audit, which concluded that every year these leg ulcers remained unhealed was costing £368 500 in nursing time. If that time was reduced to 24 weeks, £283 715 would be saved in nursing time, freeing up the capacity to deliver additional high-quality care.

With this in mind, one of the recommendations from the audit report was to design an evidence-based treatment pathway for clinicians to use when managing venous leg ulceration. It was anticipated that this would provide a consistent approach to care regardless of where that care was being delivered.

The pathways would be evaluated as a pilot with a primary objective of measuring the effectiveness of using pathways as a model of care. An internal

target was set of healing 70% of venous leg ulcers within 24 weeks. Although the timescale is at the upper threshold of 16–24 weeks, many of the ulcers were chronic in nature and therefore this was deemed as more realistic and achievable.

To keep the pilot uncomplicated, it was only to be applied to those patients who currently had their care provided by community nurses.

A secondary objective to measure the impact of applying an evidence-based pathway on leg ulcer associated pain was also agreed.

## METHODS

### Literature review

Part of the project strategy was to carry out a comprehensive literature review to understand and interpret existing literature in relation to the use of pathways in clinical practice.

The search was undertaken using the databases CINAHL, Pubmed, Cochrane and Scopus. Emerald and HMIC (Healthcare Management Information Consortium) were also used for their management focus. Other databases including Department of Health, NICE, Google Scholar and Web of Knowledge were also accessed using a key word approach. The literature on patient care pathways

**Table 1. Risk factors for non-healing.**

Risk factor	Rationale
Lack of holistic assessment/wound assessment that included baseline wound size measurements.	Assessment will assist identification of underlying causes and associated diseases and influence decisions about prognosis, referral and management (RCN, 2006).
No pain assessment.	Pain contributes to poor quality of life, reduced well-being and delayed healing.
Poor wound bed preparation.	The presence of devitalised tissue in the wound is recognised as a potential factor for delayed healing and infection.
Ineffective exudate management.	If a wound produces high levels of exudate and is not managed appropriately, the wound bed will become over-hydrated, causing moisture to leak out onto the periwound skin and making the skin more prone to damage.
Sub optimal bandaging technique and/or bandage choice not appropriate for patient's level of mobility.	Graduated high compression systems that are maintaining 40mmHg should be the first line treatment for uncomplicated venous leg ulcers.
No formal reassessment and measurement of progression over a period of time (6 weeks).	A wound size reduction of 40% at 4–6 weeks can be used as a predictor for healing.
Failure to refer on in a timely way.	Referral to a specialist service at an early stage will ensure the correct care is given and optimises the potential for healing.

*“If the concept of a treatment pathway is to be accepted into leg ulcer practice then it is necessary to critically review the benefits or disadvantages of this model of care.”*

was extensive. It appears that pathways are used extensively across both health and social care, including mental health and learning disability organisations.

#### Review of findings

Treatment pathways, also known as care pathways or integrated care pathways (Currie and Harvey, 2000), are used in a number of clinical areas to ensure the quality of care delivered to patients is consistent and efficient (Griffith, 2009), and are seen as multidisciplinary outlines of anticipated care for patients with a similar diagnosis or set of symptoms (De Bleser et al, 2006). If the concept of a treatment pathway is to be accepted into leg ulcer practice then it is necessary to critically review the benefits or disadvantages of this model of care. There is a plethora of literature that supports the use of pathways to improve patient care (Currie and Harvey, 2000; Edick and Whipple, 2001; Scott and Cook, 2005). The idea originated in industry and was introduced into healthcare in the USA in 1985 (Vanhaecht et al, 2006). A care pathway is a model of care that reflects locally agreed standards based on available evidence for managing a specific group of patients (McDonald et al, 2006) and should ensure that multidisciplinary care can be monitored and outcomes measured.

There is evidence in the literature that the type and quality of care delivered to patients with the same condition and within the same healthcare economy will often vary (Dy and Gurses, 2010) and that introducing a care pathway is a way of addressing inequity. Evans (2001) discusses the benefits of introducing an integrated care pathway for the management of leg ulceration after audit had identified varying levels of wound care, poor healing rates and either inappropriate or no referrals to specialist teams when ulcers fail to heal. The paper advocates the need for a multidisciplinary approach to the pathway's development and the need to engage effectively with staff prior to the implementation of the tool if success is to be achieved.

In 2010 a Cochrane review included studies that compared patients following care pathways to those receiving 'usual care' and found that care pathways contributed to a reduction in hospital complications and the improvement in

documentation without it negatively impacting on length of stay and hospital costs (Rotter et al, 2010). Although this review analysed data specific to inpatient care it is reasonable to suggest that its findings could be transferable to other healthcare settings when organisations are tasked with improving quality and outcomes without it impacting on increased financial spend.

It is evident from the literature that the trigger for implementing a care pathway is commonly associated with the need for change (Springett et al, 1999; Griffith, 2009). This hypothesis is supported by work undertaken by the Effectiveness Interventions Unit (2003) which suggests that care pathways are ideally useful in response to criteria such as high volume and high-cost interventions, significant variability in practice and reliance on multidisciplinary teams. Springett et al (1999) support this theory in their paper on the development and implementation of a care pathway in pressure area management. Pre-pathway audits had indicated the need to improve care relating to pressure ulcer prevention and it was agreed within the organisation that a care pathway model may address variances in practice and ultimately improve quality. Although the pilot study found that implementing a care pathway improved clinical decision-making, pressure ulcer management and documentation, it did highlight difficulties in the acceptability of the pathway by staff and the need to provide support and education to monitor and maintain the change process. These findings are important and raise issues that relate to effective change management that will need to be considered when introducing pathways into practice.

Although the support for treatment pathways appeared generally positive, Griffith (2009) raises a legal concern for those developing pathways which others then follow, warning that they could be held liable if patient harm occurs as a result of a nurse following its recommended interventions. He recommended that pathway developers must be able to demonstrate that the evidence has been robustly evaluated and has passed through the scrutiny of the organisation's governance team.

In summary, one of the key findings from the literature is that care pathways should not become sets of rules but should be developed to provide evidence-based guidance that optimises clinical

outcomes. This review has helped to demonstrate that introducing a treatment pathway into leg ulcer management within the organisation may go some way in helping to eliminate inconsistencies and inequity in the current model of care. However, it is evident that there can be difficulties in implementing a pathway; it will not be successful unless the value is evident to the clinicians. Engaging with clinicians throughout the development and implementation phases will be key if change is to be adopted.

### Development of leg ulcer pathways

For a pathway to be accepted by clinicians and effective in practice the following components are necessary (Evans, 2001):

- It reflects the views of the stakeholders involved in the project.
- It is evidence-based.
- It supports local resources.
- It supports holistic care.
- It provides a time frame for care/ best practice.
- It is simple to follow.
- It reflects the aim of the project.
- It is measurable.

The pathway design was based on the Any Qualified Provider (AQP): Venous Leg Ulcers (and the associated wound) Service (Supply2Health, 2012) with an aim to improve the quality of life of the patient with a venous leg ulcer by reducing the time to heal. The pathway was to be implemented over a 24-week period or up until the point of healing if sooner.

The decision to produce two pathways was made on evidence that suggests that the more chronic a wound is and the larger the surface area, the more likely it will be hard to heal (Flanagan, 2003). The inclusion and exclusion criteria are set out in *Tables 2* and *3*.

Patients were allocated to a pathway by the project lead based on the information supplied in the audit. The pilot had 77 patients included – 61 on the complex pathway and 16 on the standard pathway.

### TREATMENT

The treatment underpinning the pathways was selected to address the contributing risk factors and provided the means of applying evidence into the everyday management of patients with venous leg ulceration.

**Table 2. Inclusion criteria**

#### Standard inclusion criteria

- Ankle–brachial pressure index: 0.8–1.13.
- First ulcer.
- Ulcer less than 6 months old.
- Less than 3 episodes of local wound bed infection.
- Less than 100 cm<sup>2</sup> in size.
- Patient currently in or willing to have high compression therapy (40 mmHg).

#### Complex inclusion criteria

- Ankle–brachial pressure index: 0.8–1.3.
- Ulcer greater than 6 months old.
- More than 3 episodes of local wound bed infection.
- Greater than 100 cm<sup>2</sup> in size.
- Possibility of elevated protease activity..
- Patient currently in or willing to have compression therapy (40 mmHg).

*If ulcer is recurrent – automatically allocated to complex pathway*

Dressings were based on the current Trust formulary and supported by local wound care policy and guidelines.

Standard pathway treatment objectives (*Figure 1*):

- Debridement.
- Management of local wound bed infection.
- Exudate management.
- Maintaining optimal wound bed environment.
- Optimising therapeutic compression levels.
- Healing.

Complex pathway treatment objectives (*Figure 2*):

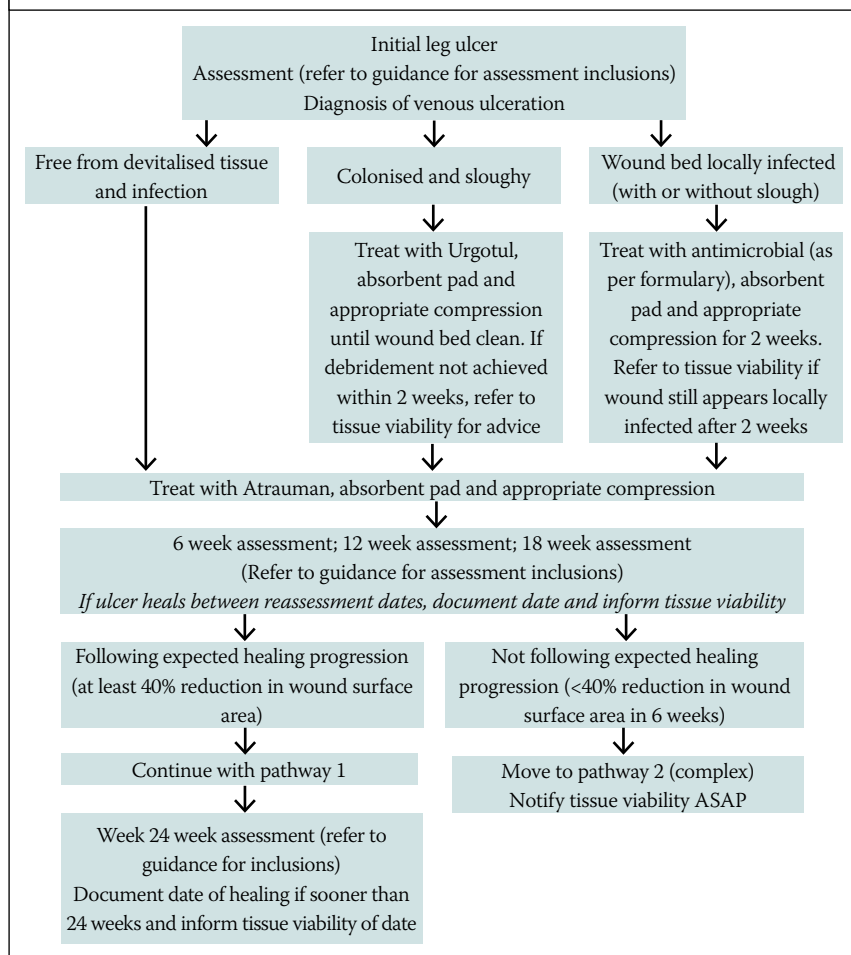
- Debridement.
- Management of local wound bed infection.
- Exudate management.
- Maintaining optimal wound bed environment.
- The reduction of elevated protease activity (EPA).

**Table 3. Exclusion criteria**

- Ankle brachial pressure index: < 0.8 or >1.3.
- Patient non-concordant.
- Inability to optimise management of underlying comorbidities (e.g. persistent anaemia, hyperglycaemia).
- End-of-life status.

*“Care pathways should not become sets of rules but should be developed to provide evidence-based guidance that optimises clinical outcomes.”*

Figure 1. Venous leg ulcer pathway 1 (standard)



- Optimising therapeutic compression levels.
- Healing.

The decision to introduce a protease inhibitor dressing (UrgoStart Contact®, Urgo) to the complex pathway was based on evidence that suggests that chronic wounds commonly have EPA. Tissue viability had been routinely using this product (which sat within the specialist category of the formulary) following the publication of robust evidence (Schmutz et al, 2008; Meaume et al, 2012) and the completion of local clinical evaluations. As no diagnostics were being used at the time of the pilot, it was agreed to assume that those ulcers that were greater than 6 months old were likely to have EPA.

Compression therapy was allocated based on the patient's level of mobility and on a hypothesis that short stretch compression is therapeutically more effective if applied to a patient with an active

calf pump. From clinical experience many elderly housebound patients have very limited mobility and lack motivation to carry out the regular calf pump foot exercises that would enhance the benefits of short stretch compression. With this in mind it was decided to allocate immobile or patients with limited mobility (defined as restricted to walking to the bathroom, bedroom and kitchen, but spending long periods of time sitting) to a two-layer compression system (K-Two®, Urgo) and more mobile patients to a short stretch bandage (Actico®, Activa Healthcare).

### EDUCATION

To maximise success of the project it was necessary to implement a programme of education that in addition to communicating the objectives, supported both the theoretical and practical components of care. Involvement and communication are vital for cooperation and support – involving and informing people creates a sense of ownership and empowerment which optimises a culture for success. The educational strategy was supported by senior management who endorsed the importance of the work to the community nursing teams.

Eight 3-hour workshops were rolled out across the county over a 6-week period which included 2 hours of practical bandage training. Studies have found that a large number of community nurses do not apply compression bandages to a therapeutic standard, but with training this does improve (SIGN, 2010). Therefore all nurses were expected to take part in the practical session, regardless of their experience. This enabled the trainers to assess levels of skills in order to improve competency. Insisting that all nurses participated did identify suboptimal bandaging skills in some nurses who deemed their practice to be of a high standard, but the teaching styles used by the trainers avoided any defensiveness from being challenged and the feedback from the events was enthusiastic and positive.

In addition to the practical training, each nurse was given a resource pack which included detailed information on the pathways, the products supporting treatment, a wound measurement guide and a pain measurement guide. These were also made available electronically via the Trust intranet.



### Productive care – Patient Status at a Glance

Part of the *Productive Community Services – Releasing Time to Care* initiative (NHS Institute for Innovation and Improvement, 2013), Patient Status at a Glance (PSAG) is a visual display of vital patient and team information (Figure 3).

PSAG allows teams to accelerate their decision-making, review patient status and constantly monitor workload. It was hoped that using PSAG to visually highlight key milestones, would help clinicians with systematic engagement with the pathway pilot and the supporting data.

### Patient education

Prior to implementing the pathway pilot, a letter was issued to all patients who were to be included which informed them why they were being invited to be part of the project and the potential benefits of the model of care.

Leaflets were also produced for some of the treatment therapies, particularly the decision to include honey as the first-line management for local wound bed infection. It is commonly known that honey can cause a “drawing sensation” that some people find unpleasant – it was hoped that having information about how honey works and why this sensation sometimes occurs would improve concordance with this therapy.

### DATA COLLECTION

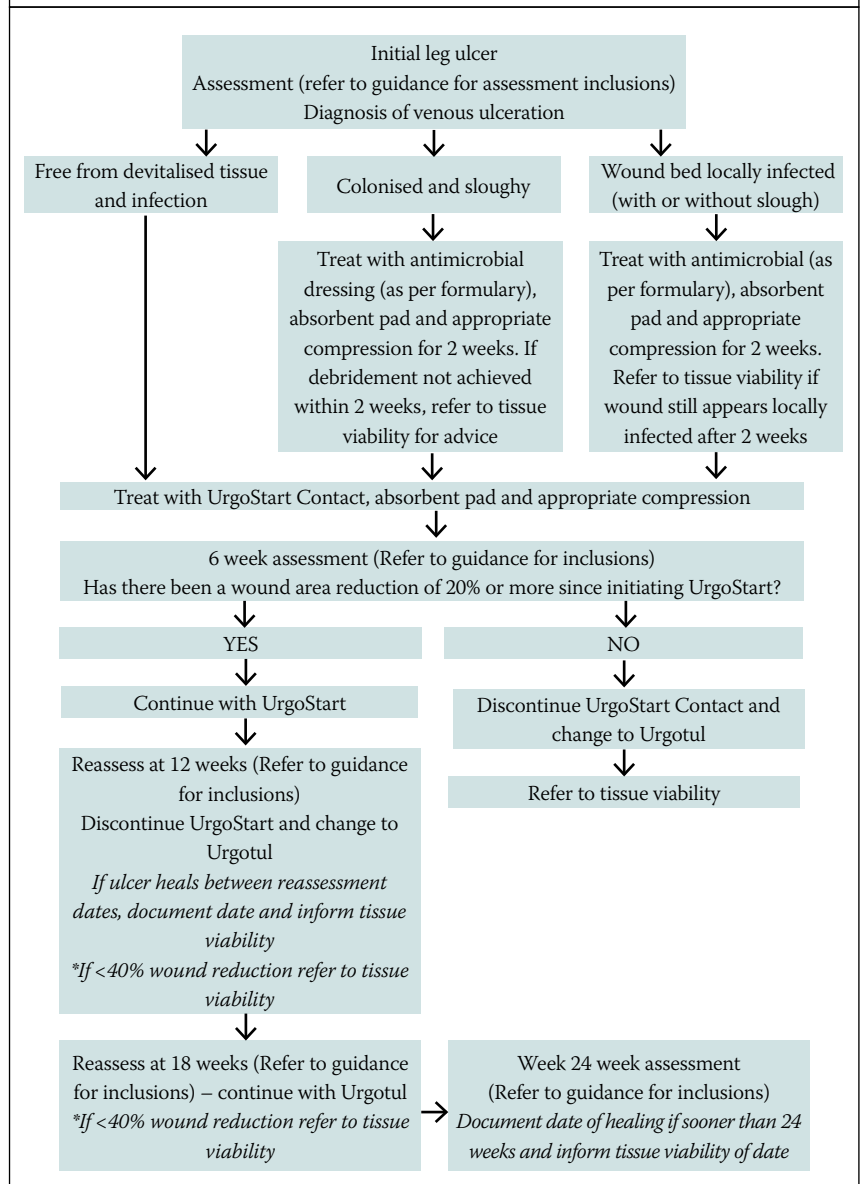
As there is strong evidence to support the prediction of effective healing over time (Flanagan, 2003; Kantor and Margolis, 2000), it was decided to collect data based on 6-weekly reassessments.

Initial or baseline data was requested at the time of commencing the pathway which included wound area in cm<sup>2</sup> and pain score (0–5 scale). Community nursing teams were then asked to send in 6-weekly data on wound size in cm<sup>2</sup>, percentage reduction since last measurement and a pain score.

At 24 weeks, unless healed sooner, data was to be sent on final wound size in cm<sup>2</sup>, overall percentage reduction since commencing the pathway and a final pain score (0–5). If the ulcer had healed by this point, nurses were asked to record the date of healing and the pain score.

Information was sent electronically and entered on to a database spreadsheet.

Figure 2. Venous leg ulcer pathway 2 (complex)



### RESULTS

Unfortunately, following the submission of initial baseline measurements, the reporting of 6-weekly data was inconsistent and the completion of pain scores so minimal that it made analysis impossible. Although final healing dates and wound sizes were obtained, the rate of progression was not possible to calculate due to the lack of regular data.

Of the 77 patients put onto a treatment pathway, 45 remained on the pathway for the pilot duration or until the point of healing. From those remaining on the pathway, 32 healed within the 24 week time

Figure 3. An example of Patient Status at a Glance



frame and of those who remained unhealed, nine had improved by greater than 70%; the remaining four were deemed to be static.

In total, 32 patients were removed from the pilot over the course of the 24 weeks and this possibly reflects the complexity of leg ulcer management (Table 4).

Although not having all of the planned data is disappointing, on a positive note the 32 people (71%) who remained on the pathway healed well within 24 weeks (from the data, this appeared to be within 16 weeks), 9 (20%) had a wound surface area that had reduced by >70% and only 4 (9%) remained static.

**DISCUSSION**

This small study has demonstrated that by applying an evidence-based treatment pathway to venous leg ulcer management, healing rates can be improved. It has also highlighted the challenges faced when caring for a group of patients who

commonly have a range of co-morbidities that require careful management.

It is unlikely that one single component of the pathway was responsible for the improvement and suggests that the multifaceted treatment approach to pathway design is important when managing the complexities of chronic leg ulcers.

The initial audit that preceded the pilot identified a significant number of ulcers which were termed as “locally infected” and as this can be responsible for tissue damage and delayed healing (Cooper, 2005), the need to focus on wound bed preparation as the catalyst for healing has been an important aspect of the pathway.

Wound bed assessment skills were likely to have been enhanced by using a locally developed tool which supported the treatment options on the pathway, and although there was a risk of some nurses seeing it as “annoyingly prescriptive”, optimising wound bed health by having local wound bed infection treated in line with local policy provided a consistent and safe approach to care.

There were clear difficulties in collecting the 6-weekly data that would have measured the rate of wound progression and if concerns had been raised about tissue viability sooner this may have resulted in fewer patients being removed from the pilot. In reality, there will always be competing pressures within services and the information being asked for by the project lead was just one of many data requests expected from community nurses. Interestingly, those teams using PSAG were more consistent in sending the data and appear to be those teams reporting good healing rates. This observation demonstrates the value of using a visual display technique to improve quality and productivity in clinical practice and should certainly be considered as an ongoing tool for caseload management.

The pilot did highlight some concerns, namely the number of people found to have mixed aetiology disease and those needing to be removed because of poorly controlled co-morbidities.

These findings demonstrate the importance of carrying out a holistic leg ulcer assessment prior to implementing a treatment pathway in order to determine aetiology and any factors that may affect healing. Assessment needs to be undertaken by nurses who are skilled in leg ulcer management

Table 4. Reasons for removal from pathway	
Reason for removal	Number
Ankle brachial pressure index found to be <0.8 following referral to tissue viability	8
Sub optimum management of comorbidities	7
Patient non-concordance	8
Transferred out of area	2
Referred to secondary care provider	1
End of life	1
Deceased	5

(Royal College of Nursing, 2006), and although attendance at local training within the Trust is good, it raises the need to have robust systems in place for monitoring clinical competence and standards of care if positive patient outcomes are to be achieved.

The number removed because of underlying co-morbidities was disappointing and highlights the complexities of managing this group of patients and the need for a multidisciplinary approach to leg ulcer care. GPs need to take responsibility for optimising the health of patients through robust management of their underlying diseases and associated pain.


Interestingly, at the outset of the pilot a significant number of patients were changed to a multilayer compression from a short stretch bandage due to having reduced levels of mobility. Although, as stated previously, it is unlikely that one element of the treatment pathway is responsible for the improvements in healing rates, it would be useful to explore this possible correlation more thoroughly in the future.

## CONCLUSION

The evaluation of using an evidence-based treatment pathway for the management of venous leg ulcers within a community setting has shown that complete healing can be achieved in 70% of patients within 24 weeks.

Due to the factors that affect healing, pathway design needs to be multifaceted with a clear focus on wound bed preparation and eradication of local infection. Due to the chronic nature of these leg ulcers, advanced dressings to help reduce elevated protease activity should be seriously considered and possibly used alongside a diagnostic tool to ensure appropriate use.

The decision to allocate the compression system based on level of mobility appears to have had some impact on healing, although the intensive bandaging training may be responsible for overall improvements in skills. Future work relating to this correlation will need consideration within the Trust.

Using a visual display of the key milestones that underpin the pathway (such as PSAG) is worthy of note as this encourages systematic engagement of all those involved in leg ulcer management, thus improving quality and patient outcomes. 

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