

Optimising care for patients with diabetic foot ulcers: overcoming the barriers

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Key words

- Efficiency
- Evidence-based care
- Positive patient outcomes
- Resource utilisation

Article points

1. Evidence-based practice is possible and should be the aim.
2. NICE guidance (2019) now supports the use of UrgoStart (TLC-NOSF) in people with VLUs and DFUs.
3. Business cases are a vital tool in changing practice.

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This article covers the key topics discussed during a symposium at the 15th Masterclass on the Foot in Diabetes UK (FDUK) Annual Conference held in Harrogate on November 5, 2019. This symposium, sponsored by Urgo Medical, aimed to provide practical information on optimising care for patients with diabetic foot ulcers (DFUs) and strategies to overcome the barriers that affect wound healing and service delivery. This symposium was presented by Benjamin Bullen and James Cowden and facilitated by Richard Shorney.

Richard Shorney kicked off the session on the topic of the current health landscape in the UK and the only factor that remains constant — which, paradoxically, is change. For example, there have been vast changes led by an in-depth review of funding and directed healthcare policies. In line with these changes, discussion was centred on how to overcome challenges facing service delivery of DFU care, including delays in referral to specialist foot care teams (Manu et al, 2018) and an increasing demand for clinical services (Guest et al, 2017).

The role and importance of business cases in supporting the development of clinical care, based on robust clinical evidence, were also highlighted. According to clinical evidence, in the field of DFU management, improving patient outcomes, increasing ulcer-free days and reducing healing time are achievable goals when the appropriate standard of care is provided.

What does standard care mean when treating DFUs?

To support practitioners in the prevention and management of DFUs, scientific societies/medical associations regularly review guidance and recommendations, in line with current clinical evidence (NICE, 2015; SIGN, 2017; Wounds UK, 2018; IWGDF, 2019; Meloni et al, 2019).

The five key elements of standard of care for

DFUs (*Figure 1*) are:

- Offloading
- Metabolic control/holistic management
- Assessment of infection
- Assessment of perfusion/ischaemia
- Evidence-based local wound care.

Use of evidence-based research

Supporting the choice of a wound care product with robust clinical evidence (i.e. with high-quality randomised controlled trials [RCTs]) is possible, as shown with the UrgoStart range of products (*Table 1*). These dressings benefit from the Technology LipidoColloid with Nano Oligo Saccharide Factor (TLC-NOSF), a lipidocolloid matrix containing sucrose octasulfate potassium salt (*Box 1*). Based on the results of double-blind RCTs, the efficacy of TLC-NOSF dressings in enhancing wound healing, reducing healing time, and reducing cost have been proven in leg ulcers and DFUs (Meaume et al, 2012; Augustin et al, 2016; Edmonds et al, 2018; Lobmann et al, 2019). This evidence has led to the recently published NICE guidance recommending UrgoStart (TLC-NOSF) treatment for people with venous leg ulcers (VLUs) and DFUs (NICE, 2019).

The performance and safety of the treatment are also supported by a large range of clinical studies, highlighting consistent and positive outcomes, regardless of the indications treated.

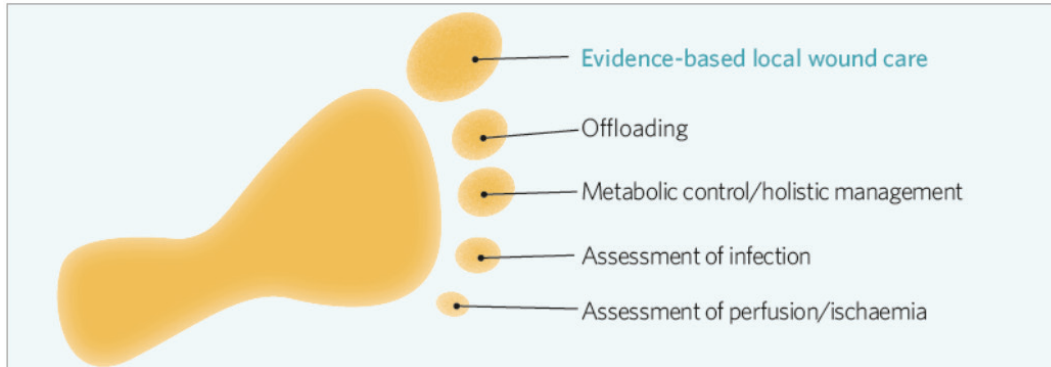


Figure 1: Five key objectives for standard of care for diabetic foot ulcers.

Table 1. Evidence available on the UrgoStart range of products.

Meta-analyses and systematic reviews	<ul style="list-style-type: none"> • NICE recommends UrgoStart dressings for VLU and DFUs (NICE, 2019) • 2020 systematic review on MMP-inhibiting dressings highly recommend to treat leg ulcers and DFUs with UrgoStart dressings (Dissemond et al, 2020)
Double-blind RCTs	<ul style="list-style-type: none"> • EXPLORER: double-blind, international, RCT (vs neutral dressing) 240 patients with a DFU, neuropathy and peripheral arterial disease → Increases wound closure regardless of the characteristics of the patient and wound, reduces healing time, reduces cost, and achieves optimal outcomes when initiated sooner (Lazaro et al, 2016; Edmonds et al, 2018; Lobmann et al, 2019) • CHALLENGE: double-blind, multicentre, RCT (vs neutral dressing) 187 patients with a leg ulcer of venous or mixed aetiology → Promotes faster healing, reduces cost and improves patients' quality of life (Meaume et al, 2012; Augustin et al, 2016; Meaume et al, 2017)
RCTs	<ul style="list-style-type: none"> • WHAT: international RCT (vs another MMP-inhibiting dressing) 117 patients with a leg ulcer of venous or mixed aetiology → Superior efficacy on the wound healing process (Schmutz et al, 2008)
Interventional studies (non-comparative)	<p>Prospective, multicentre clinical trials:</p> <ul style="list-style-type: none"> • NEREIDES: 37 patients with a leg ulcer of venous or mixed aetiology (debridement stage) (Sigal et al, 2019) • CASSIOPEE: 51 patients with a leg ulcer of venous or mixed aetiology (granulation stage) (Sigal et al, 2019) → Effective, safe and simple treatment for the local management of leg ulcers and DFUs
Observational studies	<ul style="list-style-type: none"> • REALITY: Pooled analysis of 8 observational, prospective, multicenter studies conducted in European countries 10,220 patients with a chronic wound (7,903 leg ulcers, 1,306 DFUs and 1,011 pressure ulcers) treated under real-life conditions (Münter et al, 2017) → Reduces healing time compared with data from the national healthcare database, achieves optimal results when initiated sooner and the wound healing outcomes were consistent with the results from the RCTs
Case series/Case reports	Numerous case series and reports detailing UrgoStart dressings as an effective, safe and simple treatment for the local management of chronic wounds (White et al, 2015)
Preclinical studies	<p><i>In vitro</i> studies on human dermal fibroblast, macrophages and epidermal keratinocytes and on 3D dermal skin equivalent model → Reduces MMP activity compared with control (White et al, 2015)</p> <p><i>In vitro</i> studies on human umbilical venous endothelial cells → Enhances the proliferation and migration of the cells compared with control (White et al, 2015)</p>

Box 1. UrgoStart treatment.

The sucrose octasulfate dressings in the UrgoStart treatment range contain Technology Lipido-Colloid-Nano-Oligo Saccharide Factor (TLC-NOSF), which inhibits matrix metalloproteinase (MMP) production (White et al, 2015; Lazaro et al, 2016) and promotes angiogenesis through migration and proliferation of endothelial cells (White et al, 2015; Edmonds et al, 2018). The actions of TLC-NOSF restore balance within the wound bed, supporting the development of robust granulation tissue. The UrgoStart Plus treatment range has the added advantage of polyabsorbent fibres, which clean the wound and keep it clean throughout healing.

In particular, very similar positive outcomes were achieved with the TLC-NOSF dressing with polyabsorbent fibres (UrgoStart Plus dressings), regardless of the wound healing stage at initiation of the treatment (Sigal et al, 2019), while optimal wound healing outcomes were reported when the dressing was used as a first-line treatment.

Embracing change

Embracing certain new treatments can be challenging; however, it is important for clinicians to have the capability, resources and willingness to embrace, adopt and implement new standard care. The barriers to implementation of standard care can be overcome through education, motivation, optimising practicalities, ownership of wound assessment and skills to encourage deliberate practice. Ultimately, knowledge of diabetic foot aetiology is ever-growing and, as a result, standard of care continues to improve.

Thereby, the updated edition of the IWGDF guideline on interventions to enhance healing of DFUs includes 13 new recommendations (IWGDF, 2019). Among them, and for the first time, the use of a specific dressing has been recommended: the sucrose octasulfate dressings (UrgoStart; see *Box 1*). This recommendation was made based on the recent double-blind RCT conducted with the dressing used on patients with a neuroischaemic DFU (IWGDF, 2019).

Overcoming organisational barriers

Access to a multidisciplinary team and use of pathways for DFU management that optimise standard care, glucose control, infection control and re-vascularisation (if required), can help to overcome organisational barriers.

Furthermore, there is a need for clinicians to demonstrate that they are engaging with evidence-based cost-effective practice. For example, NICE Medical Technology Guidance (MTG42; NICE, 2019) states that there is convincing evidence to support the adoption of UrgoStart dressings to treat VLUs and DFUs in the NHS, after any modifiable factors such as infection have been treated. Building a business case (as described in the next section) using the evidence and resources

available for the UrgoStart Treatment range may help to overcome some of the organisational barriers to implementing this evidence-based treatment into clinical practice. In addition, it is important for clinicians to be confident in the available evidence, to utilise resources and to confirm cost savings.

The role of business cases

As pointed out by Lord Carter in his review, Operational productivity and performance in English NHS acute hospitals: Unwarranted variations (2016), Trusts should rationalise their use of resources in the most cost-effective manner. In order to do so, a systematic approach is required, which should include the effective use of business cases.

Business cases are particularly useful for illustrating clinical experiences or sharing wound management issues. They may be helpful in order to rationalise and clinically justify the need for a resource, and to support potential changes to a Trust's corporate service. Local and national NHS templates for a business case are available, e.g. at NHS Improvement (2018) and NHS Digital (2020). Business cases enable us to identify:

- Purpose
- Stakeholders
- End product
- Success criteria.

Of note, in the case of patients with a DFU, when optimising care, it is essential to truly understand the journey of the patient from the first occurrence of their wound and to take into account the metrics of quality of care, which can be broken down into three domains: patient safety, patient experience and effectiveness of care.

How business cases can implement change

James Cowden was part of the College of Podiatry Leadership Programme cohort 2019, where one task of the course was to develop and submit a business case. The development of the business case was to justify increasing the size of service in Sheffield Teaching Hospitals NHS Foundation Trust. James presented what the business case involved, challenges faced and outcomes.

This business case comprised two parts:

The first part was with a view of patients with current ulceration, and this included the integration of a Podiatric Surgery Team into the Diabetic Foot Unit to assist in the management of diabetic patients with current foot ulceration and/or infection. It was expressed that more research/evidence is needed on this, particularly with regards to theatre capacity, utilisation of resources, ward staff and number of patient beds. However, despite this, there is evidence for surgical intervention in this area. This part concluded with successfully appointing a new Vascular Specialist Podiatrist and Musculoskeletal (MSK) Specialist Podiatrist to work in the Diabetic Foot Clinic in Sheffield.

The second part of the business case focused on preventing ulcer occurrence in those patients at risk of ulceration, and included the implementation of a 'predict and prevent' approach, with a screening service for medium- to high-risk patients. This involved a triad of clinicians: vascular specialists, MSK specialists and a podiatric surgery team, looking to identify those at risk of ulceration, and ways to reduce ulcer occurrence in the first instance. The service was designed to work alongside the current DFU setup with medical management of diabetes, although it would involve a system overhaul along with significant time, staff and financial input. The biggest challenge on this side of the business case was that this was very much a long-term vision, and there was a need for data to be gathered to show statistical significance in the reduction of ulceration figures.

Nevertheless, evidence does not determine the success of a business case in all situations and it is important for the following to be taken into account:

- Who decides and how/why do they come to the decision?
- Does it fit into the bigger organisational aims and objectives?
- Is the cost/reward benefit significant enough to warrant the outlay?
- Are the stakeholders going to benefit from the implementation?
- Is there funding available?
- Is a project/treatment realistic to implement?

What are the barriers to developing a business case?

There are also organisational barriers to overcome when developing a business case, and it is important to take the following three phases into account:

Phase 1 → Develop the plan	<ul style="list-style-type: none"> • What is the need and why is it needed? • What is the end goal? • What are the facts and figures? • What is the evidence, where is it and how good is it? • What resource is required? • Speak the right language • Research your audience – managers, business planning team
Phase 2 → Present the plan	<ul style="list-style-type: none"> • To the right people • Convey your message well in the limited time given • Persuade them to look at the bigger picture • You've researched the panel – it should shape the presentation • Appreciate their position – the bigger the project, the more risk for the trust but equally as important, for them and their position
Phase 3 → Post-implementation	<ul style="list-style-type: none"> • The panel will want metrics – they strive for high-quality outcomes and financial evidence • Write into it time to undertake metric reporting • Review and adapt – things are rarely perfect at first attempt

Along with this, it is important that the right language is learnt, time is spent putting in the legwork, that it appeals to the audience it is being presented to and, most importantly, that the case is shouted, presented and published — it is only by completing these business cases that the DFU speciality will widen.

Conclusion

In conclusion, according to the interesting discussions exchanged between experts during this symposium, it appears that the key principles to overcoming barriers can be applied to all business cases that seek to implement evidence-based

practice (in particular looking at this in the context of wound care management), which can lead to great outcomes. When treating patients with DFUs this can mean:

For clinicians:

- Improved patient outcomes
- Confidence in selecting the best treatment based on the highest level of evidence.

For patients:

- Increased ulcer-free days
- Reduced pain
- Improved quality of life and reduced risk of infection and associated complications.

For the health economy:

- Cost savings associated with reduced healing time
- Reduced variation. ■

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