BEST PRACTICE RECOMMENDATIONS

Best practice recommendations for the implementation of a DFU treatment pathway

Wounds UK

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Foreword

Diabetic foot ulcers (DFUs) are estimated to cost around £1 billion per year in the NHS alone (Kerr, 2017; Guest et al, 2018) and represent a significant health challenge in the UK and worldwide. Central to tackling the impact of DFUs in the UK is the implementation of evidence-based practice.

A group of experts met to discuss the burden of DFUs and the challenges facing service delivery of DFU care in the UK. Based on their discussions and findings from the EXPLORER study (Edmonds et al, 2018), the group recommended adding evidence-based local wound care as a new pillar to DFU standard of care. A fast-track pathway for diabetic foot ulceration for implementation in the UK was also developed using the UrgoStart (TLC-NOSF) range as part of the standard of care.

The goal of this document is to provide clinicians with information and recommendations to improve healing rates and reduce healing time of DFUs.

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Northern Ireland: to be consulted for possible future endorsement

OVERVIEW OF THE BURDEN OF DIABETIC FOOT ULCERATION

Graham Bowen, Clinical Lead for Podiatry, Adelaide Health Centre, Western Community Hospital, Southampton
David Russell, Consultant Vascular Surgeon, Leeds Teaching Hospitals NHS Trust

Diabetes currently affects 4.5 million of the UK population, but this is projected to rise to 5 million by 2025 (Diabetes UK, 2016). Estimates suggest 64,000 of people with diabetes will have a diabetic foot ulcer (DFU) at any one time (National Diabetic Foot Care Audit [NDFA], 2018). The cost of DFUs is estimated at £1 billion per year to the NHS (Kerr, 2017), but this does not include the additional social costs, which are estimated at £13.9 billion per year.

DFUs also have a significant impact on patients' health-related quality of life (Frog et al, 2012). The mean time to DFU healing has recently been estimated at 4.4 months (Guest et al, 2018), and is predominantly determined by aetiologic factors, and less by wound size (Zimny et al, 2002). Improved healing rates at 12 weeks have been reported with early specialist review (such as patients self-reporting or referral to a specialist diabetic foot service within 2 weeks) when compared to delayed presentation, and in less severe ulcers (SINBAD score ≤2 versus ≥3) (NDFA, 2018).

The economic burden for DFU care is high, and the impact of a DFU on a patient can be unquantifiable. Prompt diagnosis and evidence-based treatment of DFUs are required to improve healing rates and reduce healing time.

"The slow, gradual destruction of nerve endings – irreparable once it has swept in quietly, unseen, dark, destructive"

Tim, a patient with a DFU

The impact of a DFU as told by a patient: Based on Tim's own words

My feet and fingertips feel like pins and needles permanently – I could step on a nail, a screw, a piece of broken glass, and not even feel it. Walking around barefooted is no longer an option. I have spent 30 years understanding the potential outcome of diabetes, hoping it wouldn't happen to me.

I was diagnosed with type 1 diabetes around my 14th birthday. Being a teenager in the 80s with diabetes was tough; public knowledge on diabetes was poor and I was constantly reminded of the careers and experiences I could no longer do because of my recent diagnosis. I felt the psychological support and compassion that a person with a long-term condition needs was lacking.

I had begun "training" for a life where I might lose my sight, but I had never considered amputation to be a real possibility. Summer 2016, I developed a diabetic foot ulcer while wearing new shoes at a wedding abroad. Once back in the UK, the wound was managed by the podiatry team: dressed with absorbent foam dressings and padded to offload the area. Advice was given to keep the wound dry. However, the bandage would often fall apart, aggravating the wound and causing more discomfort. The DFU began to restrict my day-to-day life, especially my ability to walk the dog – one of my favourite activities. It became increasingly difficult to manage night-time hypos as I would leave a trail of blood in my wake, and the odour impacted on my relationship with my partner.

The DFU became infected, and I developed sepsis and pneumonia, requiring a 1-week admission to intensive care. My family prepared for the worst.

Read the case study on page 11 to find out what happened next.

WHAT ARE THE SERVICE DELIVERY CHALLENGES IN DFU CARE?

Jenny Allam, High Risk Foot Lead, Bristol
Andrew Sharpe, Advanced Podiatrist, Blackpool Teaching Hospitals NHS Foundation Trust and Lecturer Practitioner, University of Huddersfield

Prompt referral

DFUs can increase in severity rapidly – 85% of amputations are preceded by an ulcer (Edmonds, 2013) – and the cost of treating DFUs increases as the ulcer severity increases (van Acker et al, 2014). Therefore, patients should be referred promptly to a specialist multidisciplinary foot team (MDFT) within 1 working day to reduce the risk of amputation and cost of treatment (NICE, 2015).

Despite differences in healthcare structures across Europe, delays in referral to specialist foot care teams appear to be a common theme (Manu et al, 2018). The EDUCARE study (Manu et al, 2018) assessed the referral patterns of DFUs from primary care to specialised diabetes foot care units in France, Germany, Spain and the UK (Box 1). The study analysed data on recently managed DFU cases and investigated GPs' perceptions of referrals for DFUs. The authors identified an ongoing need to raise awareness of the risks of DFUs among GPs, nurses and patients and highlighted the importance for prompt referral to specialist diabetic foot teams (Manu et al, 2018).

Box 1: EDUCARE study key facts (Manu et al, 2018)

- 600 GP questionnaires and over 1000 patient DFU cases collected
- 95% of patients had type 2 diabetes
- Patients' complaints led to a DFU diagnosis 60% of the time
- DFU diagnosis was an incidental finding during a consultation 13–28% of the time
- Only 40% of GPs completely agreed that they had clearly identified DFU clinical practitioners working in a hospital facility
- In 55–66% of cases, the duration of DFU was unknown or DFU diagnosis was delayed by more than 3 weeks from the onset of the wound
- On average, 48% of patients were referred after an unknown duration or more than 1 month from the onset of DFU.

Care gaps

The role of the primary care physician is paramount to provide early referrals to specialist care, as well as initiating the direction intervention should take. Research has shown that GPs often have insufficient instruction in diabetic foot care, and that regular comprehensive foot examinations for patients with diabetes are infrequent (Miller et al, 2014). There is an increasing demand for clinical services as identified in the Burden of Wounds study (Guest et al, 2017), associated with an increasing diabetes prevalence and an ageing population (Office for National Statistics, 2017).

Based on recent research, there is an ongoing need to educate clinicians and patients of the risk of DFUs, and to emphasise the importance of prompt referral to specialist diabetic foot teams. Further standardisation of care across the UK, which should include treatment strategies that focus on improving healing rates and reducing healing time, would improve the outcomes of patients with DFUs.

EXPLORER STUDY: AN INTERNATIONAL, MULTICENTRE, DOUBLE-BLIND RCT

"In the EXPLORER study, 60% more patients had wounds that healed in the TLC-NOSF dressing group compared to the control group."

Chris Manu, Consultant Diabetologist and Diabetes Foot Medicine, King's College Hospital NHS Foundation Trust
David Russell, Consultant Vascular Surgeon, Leeds Teaching Hospitals NHS Trust

Research into DFU healing has historically been of low quality with endpoints that are not clinically relevant, inappropriate inclusion/exclusion criteria and short treatment period (typically 12 weeks). Therefore, despite large numbers of DFU wound healing trials, most only report on improved wound healing. Many studies have been limited to patients with neuropathy, even though ischaemia is identified in more than 50% of DFU patients at presentation. There is a strong need for robust evidence and studies with high quality methodology. Reporting standards are now available to ensure patient cohorts, intervention comparators, endpoints and data analysis in DFU trials are subject to a degree of rigour (Jeffcoate et al, 2016).

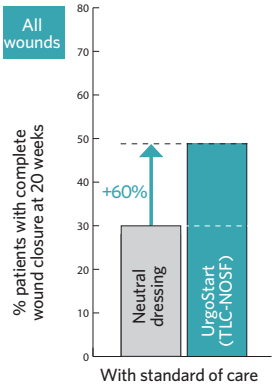


Figure 1: 60% more patients achieved complete wound closure at 20 weeks following TLC-NOSF treatment compared to neutral control dressing

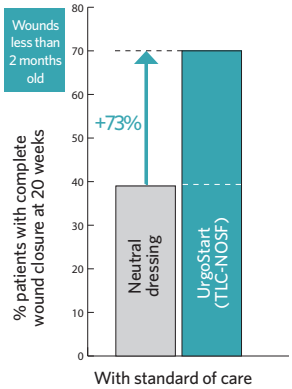


Figure 2: Post-hoc analysis: 73% more patients achieved complete wound closure at 20 weeks (wounds less than 2 months) following TLC-NOSF treatment compared to neutral control dressing (Rayman et al, 2018)

The EXPLORER study

The EXPLORER study aimed to assess the efficacy of a sucrose octasulfate (TLC-NOSF) dressing (UrgoStart, Urgo Medical) versus a neutral control foam dressing in the management of neuro-ischaemic DFUs (Edmonds et al, 2018). Eligible participants were adult in- or outpatients with diabetes and a non-infected neuro-ischaemic DFU >1 cm^2 and of grade C1 or C2 (Texas Classification). The study comprised a 2-week screening period of standard care with the control dressing, and only the DFUs with a wound area reduction of less than 30% were randomised into the trial.

The primary endpoint was the proportion of DFUs healed at 20 weeks, and secondary outcomes included estimated time to reach wound closure; absolute and relative wound surface area regression and quality of life. Offloading devices were specified within the trial. Patients were reviewed at 2 weeks' post-randomisation and then assessed on a monthly basis or until wound closure.

After completion of the screening period, 240 patients from 43 diabetic foot clinics in five European countries (France, Germany, Italy, Spain and UK) were eligible for randomisation. After 20 weeks, wound closure occurred in 60 patients (48%) in the TLC-NOSF dressing group and 34 patients (30%) in the control group (adjusted odds ratio 2.60 [95% confidence interval (CI), 1.43–4.47], p=0.002); 60% more wounds healed in the TLC-NOSF dressing group compared to the control group (Figure 1).

The estimated mean time to closure was 60 days shorter (95% CI, 47–75) in the TLC-NOSF dressing group than in the control group (120 vs 180 days; p=0.029) suggesting that TLC-NOSF significantly reduces healing time. *Post-hoc* analysis suggests that for wounds present for less than 2 months, 73% more patients healed in the TLC-NOSF dressing group compared to the control group, indicating better healing outcomes may be achieved if TLC-NOSF is initiated earlier (Figure 2; Rayman et al, 2018). In the EXPLORER study, there was no significant difference in adverse events between groups, including infection, hospitalisation or amputation, and there was no significant difference in quality of life.

The full economic analysis has not yet been published, but the clinical results suggest that use of a TLC-NOSF dressing is likely to be cost-effective, as it improves healing rates, reduces healing time, and reduces the number of dressing changes as part of an evidence-based multidisciplinary management approach in neuro-ischaemic DFUs.

The EXPLORER study is the first randomised controlled trial (RCT) in wound management published in *The Lancet Diabetes & Endocrinology*, the results of which provide clinicians with a robust evidence base to support the use of TLC-NOSF dressings in routine clinical practice.

To the study authors' knowledge, the EXPLORER study is the first double-blinded RCT conducted on neuro-ischaemic DFUs. The design and implementation of the EXPLORER study met all the key reporting standards of DFU studies recommended by Jeffcoate et al (2016), and demonstrates that TLC-NOSF can be considered as part of the standard of care for DFU treatment.

INTRODUCING TLC-NOSF LOCAL TREATMENT

When considering the established hierarchy of evidence, TLC-NOSF appears to have robust evidence, both qualitative and quantitative, as a local treatment in the standard of care on various wound aetiologies (Figure 3). The EXPLORER study demonstrated the TLC-NOSF dressing significantly increases complete wound closure rate in neuro-ischaemic DFUs compared to control dressing (Edmonds et al, 2018), and *post-hoc* analysis indicates that if TLC-NOSF treatment is initiated earlier, better outcomes may be achieveable.

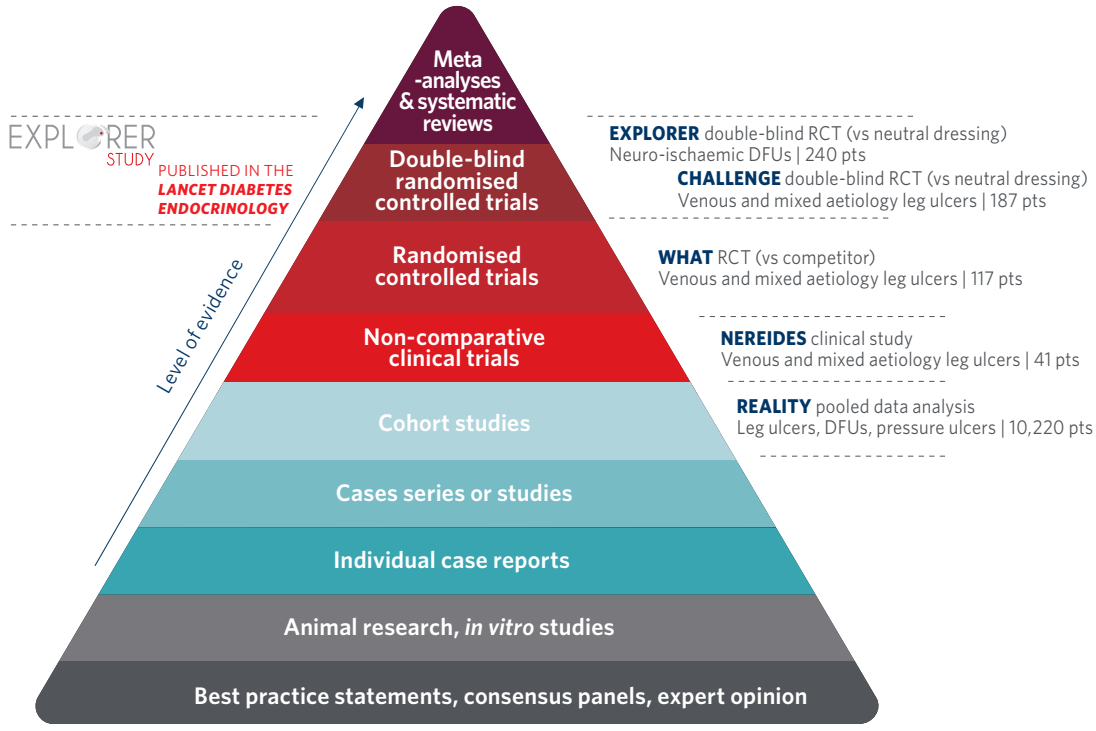


Figure 3: Pyramid of evidence of UrgoStart range of products. DFU=diabetic foot ulcers; Pts=patients; RCT=randomised controlled trial.

The traditional hierarchy of evidence pyramid demonstrates the strength of research (Sackett et al, 1996). Systematic reviews and RCTs are considered the best available evidence to determine treatment efficacy. Patient and clinician experience can also be evidenced by qualitative data collected in a cohort study or case series.

EXPLORER (Edmonds et al, 2018); **CHALLENGE** (Meaume et al, 2012); **WHAT** (Schmutz et al, 2008); **NEREIDES** (Sigal et al, 2017); **REALITY** (Münter et al, 2017).

TLC-NOSF local treatment is incorporated into a range of innovative wound dressings, indicated for DFUs, as well as leg ulcers and pressure ulcers. The treatment is composed of a lipido-colloid TLC-NOSF Healing Matrix (NOSF* impregnated in a TLC healing matrix). The TLC-NOSF Healing Matrix when in contact with wound exudate forms a lipido-colloid gel, which creates and maintains a moist environment conducive for healing. The TLC-NOSF Healing Matrix acts locally in the wound on two key factors significantly impairing wound healing: inhibition of excess matrix metalloproteinases (MMPs; White et al, 2015), and restoration of neovascularisation by reactivating vascular cells' proliferation and migration (White et al, 2015; Edmonds et al, 2018) (Figure 4A & 4B).

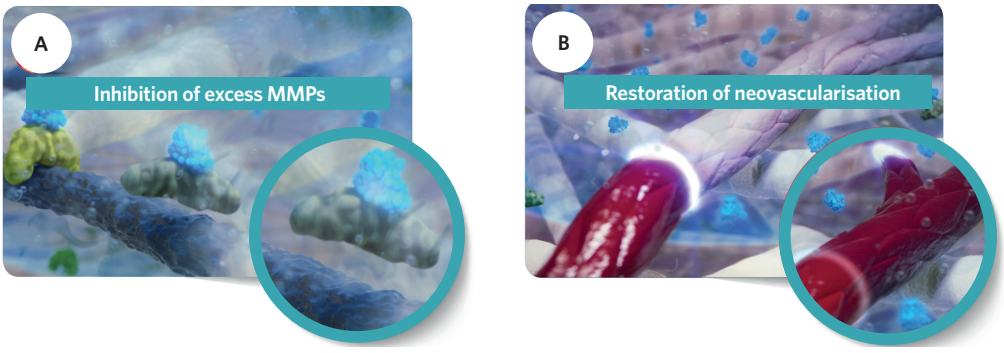


Figure 4: The TLC-NOSF mode of action: inhibition of excess matrix metalloproteinases (MMPs) and interaction with growth factors, particularly those acting on vascular cells to induce neovascularisation

*NOSF (Nano OligoSaccharide Factor) = KSOS (potassium sucrose octasulfate)

STANDARD OF CARE EXPLAINED

Graham Bowen, Clinical Lead for Podiatry, Adelaide Health Centre, Western Community Hospital, Southampton
Helena Meally, Hospital Podiatrist, Leeds Teaching Hospitals Trust

Standard care for DFU management should begin with a thorough holistic assessment of the patient and wound by a competent healthcare professional following a structured, formalised process. After wound assessment and wound bed preparation (including cleansing and debridement), treatment of infection, exudate management and periwound skin care, and management of aetiology and comorbidities, such as ischaemia (Schultz et al, 2003; Harries et al, 2016), the patient and wound should be assessed regularly every 4 weeks (Frykberg & Banks, 2016).

When treating and managing DFUs, there are five key objectives (World Union of Wound Healing Societies [WUWHS], 2016):

- To prevent DFUs and create ulcer-free days
- To reduce healing time and lead to ulcer remission
- To achieve limb salvage
- To increase quality of life
- To decrease mortality (NDFA, 2018).

Early, prompt referral and assessment by an expert MDFT is also key to improving patient and clinical outcomes (WUWHS, 2016). Despite this and the objectives set by the WUWHS (2016), a recent study of the management of newly diagnosed DFUs over a 12-month period from the THIN (primary care based) database reported that only 22% were referred to a specialist DFU clinic (Guest et al, 2018).

During the 12-month period, only 5% of patients were provided with offloading or podiatry referral; 45% were given a systemic antimicrobial at diagnosis despite only 14% having documented infection; and only 13% had a classification of vascular status (Guest et al, 2018).

At 12 months, 35% of DFUs had healed, 48% remained unhealed and 17% had received an amputation at a cost per patient of £2140, £8800 and £16,900 respectively. In total, 73% of the total NHS cost of managing a DFU was incurred in community care, while 65% of the cost of managing an amputated wound was incurred in secondary care (Guest et al, 2018).

There is a huge potential to improve clinical outcomes for patients with DFUs. Determining the key pillars of standard of care will contribute to improving the healing rates and reducing healing times of DFUs.

ADDING EVIDENCE-BASED LOCAL TREATMENT TO STANDARD OF CARE

Graham Bowen, Clinical Lead for Podiatry, Adelaide Health Centre, Western Community Hospital, Southampton
Helena Meally, Hospital Podiatrist, Leeds Teaching Hospitals Trust

To achieve the objectives of DFU care (WUWHS, 2016), the Expert Panel agreed the following pillars of DFU standard of care. According to recent guidelines and systematic reviews, the evidence to support the adoption of any particular intervention in the management of DFU is poor. The use of evidence-based research may help to achieve more consistent treatment (Ubbink et al, 2015). The EXPLORER study has provided support that a robust evidence base can improve outcomes. As such the Expert Panel recommend including an additional pillar of **evidence-based local wound care** (Figure 5).

Offloading

- Patients should be educated to minimise standing and walking
- Reduction of pressure is essential for ulcer protection and healing
- Offer non-removable casting to offload plantar neuropathic, non-ischaemic, uninfected forefoot and midfoot DFUs
- Offer an alternative offloading device until casting can be provided (NICE, 2015)
- Regular follow-up should be undertaken to ensure clinical effectiveness and concordance.

Metabolic control/holistic management

- Metabolic approach requires optimisation of glycaemic control, malnutrition and oedema (if present)
- Optimal management of relevant comorbidities (including mental health) is mandatory.

Assessment of infection

- When there are local signs of infection, empirical antibiotic therapy should be administered (refer to local antibiotic guidelines) and an antimicrobial dressing (such as UrgoClean Ag) applied if appropriate for the patient and wound
- Removal of any necrotic or non-viable tissue following comprehensive assessment of infection severity and foot perfusion is required.

Assessment of perfusion/ischaemia

- When a neuro-ischaemic or ischaemic DFU (absence of palpable pulses and/or multiphasic handheld Doppler signal) does not show signs of healing, revascularisation should be considered
- If ABPI is <0.5 and/or toe pressure is <30 mmHg then refer urgently to vascular services.

Evidence-based local wound care

- Frequent DFU assessment, debridement and redressing should be undertaken based on the DFU presentation
- Dressing selection is based on the DFU findings, ulcer bed, exudate level, size, depth and local pain
- To promote wound progression, and, in particular in the case of neuro-ischaemic DFUs, consider dressings with TLC-NOSF (Edmonds et al, 2018).

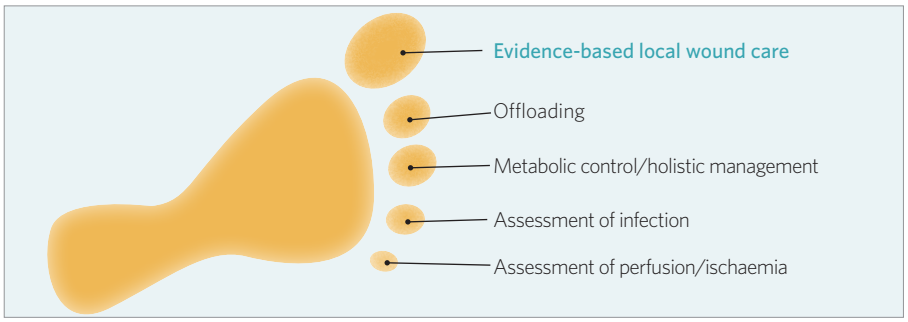


Figure 5: The pillars of DFU standard of care with the addition of evidence-based local wound care

DEVELOPMENT OF THE DFU PATHWAY

Michelle Goodeve, Diabetes Specialist Podiatrist, Provide CIC
Chris Manu, Consultant Diabetologist and Diabetes Foot Medicine, King's College Hospital NHS Foundation Trust

Over recent years, due to the demonstrated improvements in clinical outcomes, there has been an increase in the number of MDFT or specialist centres. However, even when referral to multidisciplinary clinics is available, late referral can still be a service delivery challenge.

A clear and simple pathway that is easy for clinicians working with patients with DFUs would contribute to addressing the challenge of late referral. A fast-track pathway for DFUs was developed in collaboration with senior members of the D-FootTeam and the International Diabetes Foot Care Group (IDFCC), a group of young academic from five European countries working in diabetes foot care. The project also had an unrestricted grant from the URGO Medical Foundation.

The DFU pathway (page 8) aims to help identify the patients most at risk of complications by adopting a holistic approach to the patient's initial assessment. Patients are fast-tracked into three levels of care:

- **Severely complicated ulceration** needing urgent immediate hospitalisation
- **Complicated ulceration** needing referral to specialist foot care team within 1 day
- A **non-complicated ulceration** that can be monitored by the local healthcare professional, but fast-tracked to foot protection team (FPT)/MDFT care promptly according to local guidelines/pathway.

SINBAD Classification

Louise Mitchell, Clinical Specialist Podiatrist, Birmingham Community Healthcare NHS Trust

To ensure holistic assessment and treatment of DFUs, the wound should be classified according to a validated clinical tool (Frykberg & Banks, 2016; WUWHS, 2016). A classification system should encompass all the variables that contribute to wound severity and outcome. SINBAD is a simple DFU classification system that grades ulcers according to Site, Ischaemia, Neuropathy, Bacterial Infection, Area and Depth. The SINBAD Classification works as a prompt for medical history and provides a standardised approach that is reproducible from baseline to complete healing (Ince, 2008). Advocated by NICE (2015) and used by the NDFA, the SINBAD Classification System can identify improvement or deterioration of DFU in the planning and monitoring of treatment, and in predicting outcome. It also provides a communication aid between practitioners for the purpose of referral. The DFU pathway incorporates the SINBAD Classification.

Box 2: Take-away messages on SINBAD classification

- Advocated by NICE (2015) and used by the National Diabetic Foot Care Audit
- Aids improved record-keeping and communication
- Includes essential standards of ulcer assessment

DFU pathway for Scotland

Duncan Stang, Podiatrist and National Diabetes Foot Co-ordinator, NHS Lanarkshire

The DFU pathway follows the ethos of care outlined in the *Diabetic Foot Risk Stratification and Triage* developed by the Scottish Diabetes Foot Action Group (SIGN, 2017), and has been adapted for use in Scotland (page 9). The main change to the pathway is to substitute the SINBAD Classification system for the Texas Foot Ulcer Classification System, which is used in Scotland and included in the Scottish Care Information Diabetes (SCI-Diabetes) ulcer management system – the system to record diabetes foot ulceration in Scotland.

DFU pathway for Wales – under consultation

Scott Cawley, National Diabetic Foot Co-ordinator for Wales

The principles of the DFU pathway direct care to the person or team with the necessary competency to manage the wound in a timely manner. In Wales, there is an integrated foot service with a single point of contact in most areas. Some members of the MDFT are also part of the FPT, facilitating a link and a step-up and step-down approach between teams. Wales will be looking to build on the principles of this document to develop a pathway reflecting the integrated services in Wales.

PATHWAY FOR DIABETIC FOOT ULCERATION

AT FIRST PRESENTATION

Endorsed by D-Foot International and the International Diabetic Foot Care Group

High risk co-morbidities

- Heart failure
- End stage renal disease
- Depression

Holistic approach

- Medical/social history
- Clinical examination
- Laboratory investigations

Key documents:

- NICE (2015) NG 19
- National Diabetes Foot Audit (NDFA) www.content.digital.nhs.uk/footcare

ASSESSMENT OF THE DIABETIC FOOT ULCER (RAG)

Palpable pulses No clinical signs of infection as per IDSA guidelines for infection* SINBAD 0-2 moderate DFU	Non-palpable pulses/infection*/ end stage renal disease/active heart failure SINBAD 3-6 severe DFU	Abscess spreading/wet gangrene Fever or other signs of sepsis
NON-COMPLICATED DFU	COMPLICATED DFU	SEVERELY COMPLICATED DFU
Referral to FPT and MDFT See your local guidelines/pathway	Referral to MDFT immediately (within 1 working day) as per your local guidelines/pathway	Refer immediately for hospitalisation (as per your local guidelines/pathway)
Standard of Care	Standard of Care	Once stabilised/procedure completed/on discharge, refer back to MDFT and/or FPT as per local guidelines/pathway
4 weeks of treatment Expect 50% reduction in ulcer size within 4 weeks. If not, treat as indicated by SINBAD		
Regular reassessment and appropriate follow up. Consider adding TLC-NOSF dressing to your standard of care.	Regular reassessment and appropriate follow up. Consider adding TLC-NOSF dressing to your standard of care.	Regular reassessment and appropriate follow up. Consider adding TLC-NOSF dressing to your standard of care.

GOAL: Create ulcer-free days/give ulcer remission/limb salvage/improve quality of life/decrease mortality (NDFA)

STANDARD OF CARE – IN ORDER OF NEED

OFFLOADING: Patients should be educated to minimise standing and walking. Reduction of pressure is essential for ulcer protection and healing. Offer nonremovable casting to offload plantar neuropathic, non-ischaemic, uninfected forefoot and midfoot diabetic ulcers. Offer an alternative offloading device until casting can be provided (NG19; NICE, 2015). Regular follow up should be undertaken to ensure clinical effectiveness and concordance.

METABOLIC CONTROL/HOLISTIC MANAGEMENT: Metabolic approach requires optimisation of glycaemic control, malnutrition and oedema (if present). Optimal management of relevant co-morbidities (including mental health) is mandatory.

INFECTION*: When there are local signs of infection, empirical antibiotic therapy should be administered (refer to your local antibiotic guidelines). Removal of any necrotic or non-viable tissue following comprehensive assessment of infection severity and foot perfusion is required.

ASSESSMENT OF PERFUSION: When a neuro-ischaemic or ischaemic DFU (absence of palpable pulses and/or multiphasic handheld Doppler signal) does not show signs of healing, revascularisation should be considered. If ABPI is <0.5 and/or toe pressure is <30mmHg then refer urgently to vascular services.

LOCAL WOUND CARE: Frequent DFU inspection/assessment, debridement and redressing should be undertaken based on the DFU presentation. Dressing selection is based on the DFU findings, ulcer bed, exudate level, size, depth and local pain. To promote wound progression and in particular in the case of neuro ischaemic DFU, consider dressings with Lipido-Colloid Technology with Nano-Oligo Saccharide Factor (TLC-NOSF) (Edmonds et al, 2018).

IDSA

The IWGDF and the Infectious Disease Society of America (IDSA) have developed validated clinical criteria for recognising and classifying diabetic foot infection (Lipsky et al, 2015)	Grade/severity
No clinical signs of infection	Grade 1/Uninfected
Superficial tissue lesion with at least two of the following signs: — Local warmth — Erythema >0.5–2cm around the ulcer — Local tenderness/pain — Local swelling/induration — Purulent discharge Other causes of inflammation of the skin must be excluded	Grade 2/Mild
Erythema >2cm and one of the findings above or: — Infection involving structures beneath the skin/ subcutaneous tissues (eg deep abscess, lymphangitis, osteomyelitis, septic arthritis or fasciitis) — No systemic inflammatory response (see Grade 4)	Grade 3/Moderate
Presence of systemic signs with at least two of the following: — Temperature >39°C or <36°C — Pulse >90bpm — Respiratory rate >20/min — $PaCO_2$ <32mmHg — White cell count 12,000mm^3 or <4,000mm^3 — 10% immature leukocytes	Grade 4/Severe

SINBAD

SINBAD	0	1	Score
Site	Forefoot	Rearfoot	0/1
Ischaemia	At least one Pedal pulse	Clinical evidence of reduced blood supply	0/1
Neuropathy	Intact	Not intact 8/10 and less	0/1
Bacterial Load	None	Present	0/1
Area	Ulcer < 1cm^2	>1cm^2	0/1
Depth	Texas 0 or 1	Texas 2 or 3	0/1

SINBAD score	Time to Heal
0-2 (Moderate)	Up to 77 days
3-6 (Severe)	Range 126–577 days

*IDSA Infectious Disease Society of America.

Bowen G, Russell D, Allam J et al. DFU pathway adapted from D-Foot Team and the International Diabetes Foot Care Group (2018)

SCOTTISH PATHWAY FOR DIABETIC FOOT ULCERATION

AT FIRST PRESENTATION

Endorsed by D-Foot International and the International Diabetic Foot Care Group

High risk co-morbidities

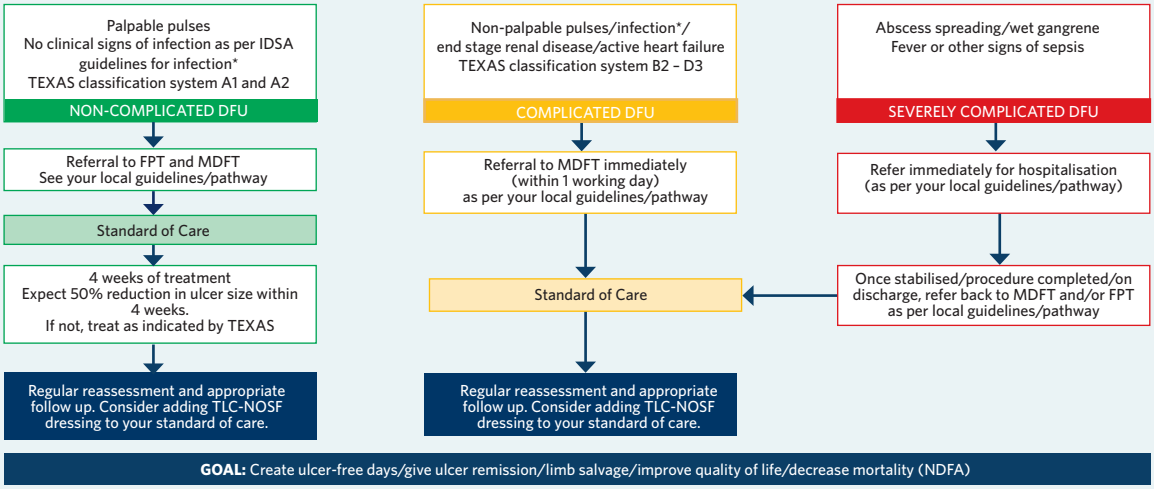
- Heart failure
- End stage renal disease
- Depression

Holistic approach

- Medical/social history
- Clinical examination
- Laboratory investigations

Key documents:
- NICE (2015) NG 19
- National Diabetes Foot Audit (NDFA) www.content.digital.nhs.uk/footcare

ASSESSMENT OF THE DIABETIC FOOT ULCER (RAG)



GOAL: Create ulcer-free days/give ulcer remission/limb salvage/improve quality of life/decrease mortality (NDFA)

STANDARD OF CARE

NON-COMPLICATED DFU

OFFLOADING: Patients should be educated to minimise standing and walking. Reduction of pressure is essential for ulcer protection and healing. Offer nonremovable casting to offload plantar neuropathic, non-ischaemic, uninfected forefoot and midfoot diabetic ulcers. Offer an alternative offloading device until casting can be provided (NG19; NICE, 2015). Regular follow up should be undertaken to ensure clinical effectiveness and concordance.

METABOLIC CONTROL / HOLISTIC MANAGEMENT: Metabolic approach requires optimisation of glycaemic control, malnutrition and oedema (if present). Optimal management of relevant co-morbidities (including mental health) is mandatory.

INFECTION AND ASSESSMENT OF PERFUSION

ASSESSMENT OF PERFUSION: When a neuro-ischaemic or ischaemic DFU (absence of palpable pulses and/or multiphasic handheld Doppler signal) does not show signs of healing, revascularisation should be considered. If ABPI is <0.5 and/or toe pressure is <30mmHg then refer urgently to vascular services.

INFECTION*: When there are local signs of infection, empirical antibiotic therapy should be administered (refer to your local antibiotic guidelines). Removal of any necrotic or non-viable tissue following comprehensive assessment of infection severity and foot perfusion is required.

LOCAL WOUND CARE: Frequent DFU inspection/assessment, debridement and redressing should be undertaken based on the DFU presentation. Dressing selection is based on the DFU findings, ulcer bed, exudate level, size, depth and local pain. To promote wound progression and in particular in the case of neuro-ischaemic DFU, consider dressings with Lipido-Colloid Technology with Nano-Oligo Saccharide Factor (TLC-NOSF) (Edmonds et al, 2018).

IDSA

The IWGDF and the Infectious Disease Society of America (IDSA) have developed validated clinical criteria for recognising and classifying diabetic foot infection (Lipsky et al, 2015)	Grade/severity
No clinical signs of infection	Grade 1/Uninfected
Superficial tissue lesion with at least two of the following signs: — Local warmth — Erythema >0.5–2cm around the ulcer — Local tenderness/pain — Local swelling/induration — Purulent discharge Other causes of inflammation of the skin must be excluded	Grade 2/Mild
Erythema >2cm and one of the findings above or: — Infection involving structures beneath the skin/subcutaneous tissues (eg deep abscess, lymphangitis, osteomyelitis, septic arthritis or fasciitis) — No systemic inflammatory response (see Grade 4)	Grade 3/Moderate
Presence of systemic signs with at least two of the following: — Temperature >39°C or <36°C — Pulse >90bpm — Respiratory rate >20/min — $PaCO_2$ <32mmHg — White cell count 12,000mm^3 or <4,000mm^3 — 10% immature leukocytes	Grade 4/Severe

TEXAS CLASSIFICATION SYSTEM

	GRADE			
STAGE	0	1	2	3
A	Pre or postulerative lesion completely epithelised	Superficial wound not involving tendon, capsule or bone	Wound penetrating to tendon or capsule	Wound penetrating to bone or joint
B	With infection	With infection	With infection	With infection
C	With ischaemia	With ischaemia	With ischaemia	With ischaemia
D	Infection and ischaemia	Infection and ischaemia	Infection and ischaemia	Infection and ischaemia

*IDSA Infectious Disease Society of America

Bowen G, Russell D, Allam J et al. DFU pathway adapted from D-Foot Team and the International Diabetes Foot Care Group (2018)

GLOSSARY FOR DFU PATHWAYS

Active heart failure: Patient on current treatment for heart failure (e.g. patients with known structural heart disease and shortness of breath and fatigue, reduced exercise tolerance).
Concordance: A negotiated, shared agreement between clinician and patient concerning treatment regimen(s), outcomes, and behaviours; a more cooperative relationship than those based on issues of compliance and non-compliance.
Debridement: Removal of devitalised tissue, to promote an optimal environment for healing. This can include surgical, sharp, autolytic, mechanical, chemical, enzymatic.
Depression: Patient on medical therapy for depression or depression symptoms which include feeling sad or having a depressed mood, loss of interest or pleasure in activities once enjoyed, changes in appetite (weight loss or gain unrelated to dieting), trouble sleeping or sleeping too much, loss of energy or increased fatigue, increase in purposeless physical activity (e.g., hand-wringing or pacing) or slowed movements and speech (actions observable by others), feeling worthless or guilty, difficulty thinking, concentrating or making decisions, thoughts of death or suicide. The symptoms must last at least two weeks for a diagnosis of depression. Depression is associated with increased mortality in patients with DFU.
Diabetic Foot Clinic: Diabetic Foot Centre that provides outpatient and preferably inpatient care with a multidisciplinary team composed of diabetologist, podiatrist or specialist nurse and a surgeon, preferably with skills of revascularisation and good knowledge of surgery of deep foot infections with a 24-hour urgency service.
End stage renal disease: Patient on renal replacement (i.e peritoneal dialysis or haemodialysis).
FPT: Foot Protection Team.
Gangrene: Death of tissue due to insufficient blood supply. Without infection this generally results in dry and black tissue, frequently called dry gangrene; when the tissue is infected, with accompanying putrefaction and surround cellulitis, it is often called wet gangrene.
Granulation: This is a light red, soft, moist and granular new connective tissue that appears on the surface of an ulcer during the healing process.
Infection: See IDSA chart (Lipsky et al, 2015).
MDFT: Multidisciplinary Foot Team.
Necrosis: Dead or devitalised tissue.
Neuro-ischaemia: The combined effect of diabetic neuropathy and ischaemia, whereby macrovascular disease and, in some instances, microvascular dysfunction impair perfusion in a diabetic foot.
RAG: Red/Amber/Green to signal status/severity.
Signs of re-epithelialisation: Appearance of new epithelium tissue covering the wound with reduction of ulcer surface.
SINBAD: A DFU classification system that grades ulcers according to Site, Ischaemia, Neuropathy, Bacterial Infection, Area and Depth (Ince, 2008). This can help in the planning and monitoring of treatment and in predicting outcome.
TEXAS: The University of Texas wound classification system is a simple method for describing a diabetic foot lesion. It correlates with the risk of amputation and the chance for ulcer healing (Lavery et al, 1996).

TLC-NOSF TREATMENT IN PRACTICE

Figure 6. Right first metatarsal phalangeal joint ulcer that had been present for 6 months

Figure 7. UrgoStart commenced once infection was resolved in September 2017

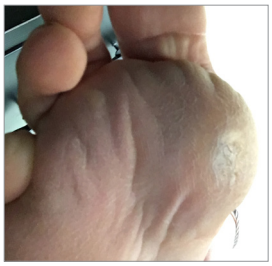


Figure 8. 23 February 2018: wound completely re-epithelialised

"...I want to get this thing healed as quickly as possible. It has gone on long enough"

Tim, a patient with a DFU

Right first metatarsal phalangeal joint DFU caused by new shoes in Summer 2016

Michele Goodeve, Diabetes Specialist Podiatrist, Provide CIC

Tim was discharged from ICU following IV antibiotics to resolve the infection and sepsis. The DFU had been static for months (Figure 6) even before the sepsis episode, potentially indicating an increased level of MMPs. The wound bed comprised mostly granulation tissue and less than 30% slough.

The MDFT selected the UrgoStart (TLC-NOSF) range based on the results of the EXPLORER study, which showed a statistically significant improvement in healing rates compared to the control dressing (Edmonds et al, 2018). It was thought that UrgoStart would not only improve the healing outcome but also the patient's experience. There were no clinical signs of infection, which was confirmed by a wound swab. UrgoStart was commenced on 25 September 2017 to inhibit proteases activity and reduce healing time (Figure 7; Raffetto, 2014; Edmonds et al, 2018).

The ulcer was sharp debrided, cleansed with saline and UrgoStart non-adhesive foam dressing was applied and secured with a bandage. Tim was advised to wear a pneumatic walking brace with total contact insole to offload the foot (NICE, 2015).

Tim was assessed on a weekly basis and the wound began to reduce in size; after 1 week of using UrgoStart as part of a holistic management regimen, there was a 1mm reduction in width, a 2mm reduction in length and the depth of the ulcer had reduced. The periwound and surrounding skin looked healthier, and there was an increase in granulation tissue at the wound bed. UrgoStart had a longer wear time compared to the previous regimen of absorbent dressings and padding, which had required changing every 2–3 days. Therefore, there was a reduction in clinical time and clinic visits for the patient.

Final comments

After 66 days of using UrgoStart, the wound had completely healed (Figure 8). Evidence-based research had been lacking in local diabetic foot care, but implementing a care plan with relevant evidence as part of the holistic approach is key to improving patient outcomes. Patients should be encouraged to partner the clinician in the management of their condition and play a more active role in decision-making regarding diabetic foot ulceration and their care.

Tim's perspective in his own words

Before starting treatment with UrgoStart, I was in a dark place. The DFU was not healing, and for 3 and a half months I had thought it would be easier to have an amputation so that I could, at last, start some form of recovery.

Once treatment with UrgoStart was commenced, no extra padding was required, so I was soon able to return to my daily activities. I still had to offload and keep the wound dry, but I was able to change the dressing myself, which meant I didn't have to attend so many hospital appointments. The appearance and the smell of the wound improved, which was a real positive and made a huge difference to my relationship with my partner. The healing wound provided an upbeat change to my life, allowing me to go back to my daily activities and continue the things I love to do.

TLC-NOSF TREATMENT IN PRACTICE

Figure 9. Ulcers present for approximately 3 days

Figure 10. 1 week from baseline

Figure 11. 2 weeks from baseline

UrgoStart Plus (TLC-NOSF) used for multiple ulcerations caused by casted device

Louise Mitchell, Clinical Specialist Podiatrist, Birmingham Community Healthcare NHS Foundation Trust

This is a 57-year-old male with poorly controlled type 2 diabetes, which has led to profound neuropathy with marked muscle wastage to lower limbs and feet. He has a history of DFUs affecting both feet, and all the toes of his left foot have been amputated.

The patient had a metatarsal phalangeal joint ulcer on the left foot and was under the care of the MDFT. A casted device had been made to provide pressure relief, which had unknowingly rubbed, causing three areas of superficial ulceration to the lateral and dorsal aspects of the left ankle. The wounds had been present for approximately 3 days before identification at clinic (Figure 9). The three ulcers measured 5mm x 4mm; 8.5mm x 5.5mm; and 4mm x 3mm. All wound bases were sloughy, with inflammation at the edges and peri-wound area. There were no clinical signs of infection.

UrgoStart Plus, part of the UrgoStart range (TLC-NOSF), was selected to reduce healing time (Münter et al, 2017). At presentation the exudate levels were low, so a low-absorbent dressing was chosen to secure UrgoStart Plus, as the patient was required to continue wearing a slipper cast. The cast was modified and re-edged prior to reapplication. The patient was advised to keep the dressing dry and *in situ* until their next appointment.

Within the first week, the wounds had reduced in size (Figure 10). The patient complained of itching but there was no rash or reaction noted. By the second week, the wounds had healed (Figure 11).

Final comments

Over the short time of using UrgoStart Plus, application and removal were straightforward, and the care regimen was efficient at resolving the slough and moving the ulcers to complete healing. The patient was impressed at how quickly the wounds healed after his previous experience of long episodes of intermittent chronic ulceration. The clinician commented that UrgoStart Plus should be considered as a first-line dressing in the management of a wound for patients whose comorbidities predict impeded healing.

Summary

Graham Bowen, Clinical Lead for Podiatry, Adelaide Health Centre, Western Community Hospital, Southampton

Evidence-based local wound care should be integral to standard care in the management of DFUs.

The results of EXPLORER study, the first RCT conducted on neuro-ischaemic DFUs, provide clinicians with a robust evidence base to support use of TLC-NOSF dressings in clinical practice, and demonstrates a therapeutic procedure that should be considered part of the standard of care.

The positive effect of TLC-NOSF suggests that use of a TLC-NOSF dressing is likely to be cost-effective in terms of improved healing rates, reduced healing time and reduced dressing changes. An evidence-based multidisciplinary management approach to DFUs will increase the potential for improved quality of life and patients' confidence in their treatment.

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