NICE guidance in real life: Implementation of an evidence-based care pathway within a new wound healing clinic

KEY WORDS

- ➤ Cost effectiveness
- ► Evaluation
- ► NICE guidance
- ▶ Pathways
- ► Quality of life
- ▶ URGOStart treatment range

This article discusses how a community wound healing clinic (WHC) was implemented within one locality in an NHS community healthcare organisation to address key clinical challenges, such as variations in wound care practice and the implementation of evidence-based care. To ensure consistency in care, an evidence-based clinical pathway was introduced, which included the UrgoStart treatment range of dressings that has been recommended for the treatment of diabetic foot ulcers and venous leg ulcers by the National Institute for Health and Clinical Excellence (NICE, 2019a) as it is associated with enhanced wound healing when used in addition to standard care. A standardised referral pathway from the General Practitioner to the WHC was also introduced. In total, 33 patients (34 wounds) with a wide range of wound types and comorbidities were involved in the clinical evaluation. The findings demonstrate real-world outcomes that concur with findings from the CHALLENGE (Meaume et al, 2012) and EXPLORER (Edmonds et al, 2018) randomised controlled trials and are further endorsement of how NICE recommendations translate into tangible improvements when combined with an evidence-based approach.

pproximately 2.2 million people live with a chronic wound in the United Kingdom (Guest et al, 2015; 2016; 2017; 2018), a number which is set to increase year on year. Improving patient outcomes and optimising wound care practice have been identified as key national priorities. A vital step in achieving these objectives is the provision of a co-ordinated, strategic approach in the assessment, treatment and management of wounds (NHS England, 2018).

The increasing number of patients requiring health and social care interventions; additional pressure on nurse caseloads and the broader healthcare service provider; and overuse of ineffective interventions and underuse of evidence-based treatments continue to occur in practice (Gray et al, 2018). Effective, standardised wound care enabled by simple, robust clinical pathways can help to address the variations in practice (Stephen-Haynes, 2013; Atkin et al, 2020).

Patient quality of life (QoL) is impacted by the clinical complexities associated with delayed healing and extended hospital care (MacDonald, 2009). There

are demonstrable negative consequences of living with a wound, including psychological and emotional factors associated with increased pain, reduced mobility and physical impairment (Fearns et al, 2017).

This article describes the implementation and evaluation of an evidence-based treatment pathway within a new wound healing clinic (WHC) introduced to an NHS locality in response to observed clinical and service delivery challenges (*Box 1*) and wound care practice variations.

WOUND HEALING CLINIC IMPLEMENTATION

The WHC was established with the support of the organisation's senior management leads, GP practice leads, clinic staff and the Tissue Viability Lead (JT) and was based on a successful wound healing service model previously introduced locally. The WHC was developed with three key objectives aimed at managing the following challenges:

✤ To ensure timely, holistic assessment and implementation of appropriate treatment plans and

Box 1. Local clinical challenges

- High cost to the NHS
- High cost for patient's QoL
- Clinical outcomes not capturedHigh prevalence of chronic
- wounds (mainly VLU and DFU)Inconsistencies and variations in treatment
- Poor use of clinical evidence
- Perceived lack of time in general practice.

clinical pathways to improve clinical outcomes and patient QoL

- >> To facilitate, where appropriate, supported shared care for patients, carers and family members
- >> To monitor real-world outcomes that reflect high-level clinical evidence and ensure a consistent approach when evaluating new products with a view to support appropriate local wound care formulary decisions.

Elements of the WHC included (1) a new referral pathway; (2) a treatment plan that included the UrgoStart treatment range; and (3) additional staff training.

1. Referral pathway

A referral pathway was developed and implemented to facilitate referrals from the GP practice to the WHC (*Figure 1*). Patients with a non-healing wound present for 2 weeks or longer were referred to the WHC. If the patient was at high risk due to underlying comorbidities, they may be referred sooner. Patient referrals were triaged, and appointments were offered according to wound aetiology and associated risk factors and comorbidities. Patients were not discharged from the WHC until complete healing. Patients with venous leg ulcers (VLUs) required ongoing hosiery maintenance, repeat Ankle–Brachial Pressure Index assessments and limb assessment. The WHC staff recorded all patient data, patient consent and provided patient information and support.

With the support of Urgo Medical, a database to collect wound and patient information was developed for accurate documentation of wound assessment, diagnosis, progression and clinical/patient outcomes. A locally developed unvalidated QoL tool was used on admission and repeated every 2 weeks or sooner if changes were noted in the patient's reported QoL (*Box 2*; Tickle, 2018).

2. Treatment plan incorporating the UrgoStart treatment range of dressings

The National Wound Care Strategy Programme (NWCSP) is committed to ensuring patients receive high-quality wound care services that include evidence-based, cost-effective treatment to reduce time to healing and improve healing rates and QoL (Adderley, 2018). In agreement with the local Medicines Management Team, a wound treatment evaluation was undertaken using the UrgoStart treatment range of dressings. It has previously been established that an evaluation of the patients' response to the UrgoStart treatment range and how clinicians manage implementation locally would be beneficial (Milne and Tariq, 2020). A clinical pathway was developed and supported the appropriate



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Box 2. Tickle Quality of Life tool (published with permission of Joy Tickle [2018])

The Tickle Quality of Life (QoL) tool encourages open dialogue between the clinician and patient to gain a deeper understanding of the impact of the wound on the patient's life. The tool has 10 questions and each answer is allocated a score between 0-10 (0=no impact on quality of life, 10=greatest negative impact on quality of life). The minimum score is 0, and the maximum score is 100.

The patient's responses assist the clinician to measure the impact of the wound on the patient's QoL and to develop and implement a treatment plan that helps to improve the areas affecting the patient's QoL.

- 1. Does your wound/condition make you unhappy?
- 2. Does the wound/condition cause trouble with your day to day activities?
- 3. Does it affect your image or how you look?

4. Does the length of time you have had the wound cause you anxiety and frustration?

- 5. Does the wound/condition make it difficult to move about/mobilise?
- 6. Does your wound/condition make you more dependent on others?
- 7. Is the wound affecting you financially?
- 8. Does the wound/condition make it difficult to climb the stairs?
- 9. Does the wound /condition make you feel isolated or has led to isolation?
- 10. Does the wound /condition make it difficult to wear the clothing and footwear you would like?

implementation of the treatment range (Stephen-Haynes, 2013; Seaton et al, 2020). An evidence-based, individualised care plan for each patient was provided in accordance with the newly implemented treatment pathway (*Figure 2*).

The clinical efficacy of the UrgoStart treatment range is supported by several randomised controlled trials (RCTs) and real-world outcomes (e.g. WHAT study [Schmutz et al, 2008]; CHALLENGE study [Meaume et al, 2012]; REALITY [Münter et al, 2017]; EXPLORER study [Edmonds et al, 2018]). The UrgoStart treatment range has been endorsed by the National Institute for Health and Clinical Excellence (NICE) for its benefits in treating leg ulcers, diabetic foot ulcers (DFUs) and pressure ulcers, including healing wounds sooner, improving patient QoL, and realising potential savings to the NHS at approximately £541 per patient per year with



Figure 2. The UrgoStart treatment range pathway

Tickle J (2018) Tickle Quality of Life Tool (unpublished)

a chronic VLU and £342 per patient per year with a DFU (Meaume et al, 2012; 2017; Edmonds et al, 2018; Münter et al, 2017; NICE, 2019a; 2019b).

3. Staff training

The WHC staff received additional training supported by the Tissue Viability Lead (JT). Clinical competencies were developed and assessed for each member of staff, including wound and limb assessment and management to ensure consist care was provided.

MEASURING OUTCOMES OF THE WHC

Prior to the implementation of the WHC, there was no coding for patients with wounds who attended the GP practice. Furthermore, some patients had no diagnosis of wound aetiology and there was limited wound outcome measures with multiple treatment variations; these local challenges have also been reported as national challenges (Guest et al, 2015). From day 1 of WHC implementation, a clinical tracker was introduced that captured the following data for each patient admitted to the WHC:

- 1. Age/gender
- 2. Existing comorbidities
- 3. Wound aetiology
- 4. Duration of the wound
- 5. Wound treatments
- 6. Wound size and depth
- 7. QoL score (using the Tickle QoL tool).

RESULTS

Patients

In total, 33 patients with 34 wounds were monitored over a 3-month period between 30 September 2019 and 8 January 2020. Wounds included VLUs (17), mixed aetiology leg ulcers (3), arterial leg ulcers (1), DFUs (3), pressure ulcers (2) and other types of wounds (8) including trauma wounds, graft sites and post-operative abdominal wounds. Wound durations ranged from less than 1 week (described as a new wound) to over a year (described as a longterm wound) There was a wide range of patient comorbidities among the patients (*Figure 3*).

Treatment

The evaluation included wound aetiologies that were not necessarily supported by the NICE (2019a) guidance; however, all the wounds and patients were deemed clinically suitable for the treatment. All the wounds were treated with the UrgoStart treatment range along with normal standard of care, which included appropriate compression therapy, offloading, pressure relief and pain management. A total of 18 wounds were initially treated with UrgoStart Plus Pad (53%), nine wounds were treated with UrgoStart Contact (26%) and seven wounds were treated with UrgoStart Plus Border (21%) (Figure 4). The choice of dressing was dependent on the status of the wound bed and type of wound. UrgoStart Plus can be used from day 1 to complete healing and is suitable for sloughy wounds, while UrgoStart Contact is used as a contact layer for superficial wounds with minimal slough and cavity wounds. The non-bordered version of UrgoStart Plus Pad is suitable for use under compression and retention bandages.

Wound healing

Of the 34 wounds included in this evaluation, 33 wounds healed completely within 12 weeks, and one wound healed at 16 weeks (*Figure 5*). There was a 45% reduction in average wound surface area between week 2 and week 4, and a 57% reduction between week 4 and 6 (*Figure 6*). A VLU or pressure ulcer that has not reduced in area by 40% (or by 50% for a DFU) after 4 weeks of optimal treatment is unlikely to heal; therefore, the percentage reduction in wound area after 4 weeks of optimal treatment may provide a useful indicator for progression of healing (Kantor and Margolis, 2000; Snyder et al, 2010).

Exudate and peri-wound skin

There was a reduction in the reported exudate levels of the wounds over the evaluation period (Figure 7). After 6 weeks, there were no wounds reported with high exudate, by week 12 there were no wounds reported with moderate exudate, and, by week 16, all wounds were free from exudate; an important factor considering the existing comorbidities of the patients which included chronic venous hypertension, and lymphoedema. Unmanaged exudate can be detrimental to the peri-wound and increase the risk of excoriation and maceration. Initially at week 2, there were five wounds with macerated peri-wound skin; by week 6, there were no reports of macerated skin (Figure 8). It should be noted that exudate levels may initially rise in the debriding and proliferative phases of healing before reducing as healing progresses.



Patient QoL

QoL scores were recorded for all patients (n=33) at admission to the WHC and at discharge when care was complete. The mean average QoL score on admission was 20.75 (5-42) and on discharge was

2.93 (0–21) illustrating an 85% improvement in QoL before and after wound healing *(Figure 9)*.

Wound pain scores were recorded at each visit and a gradual reduction was observed as healing progressed. On a scale of 0-10 (0=no pain, 10=extreme



pain), the mean average pain score reduced from 3.6 at week 2 to 0.9 by week 6 (*Figure 10*).

DISCUSSION

While there is no consensus for the duration of chronic wounds, chronic wounds are generally described as those that have not healed within 1 month (Kyaw et al, 2018) and are usually accompanied by one or more patient comorbidities that impact on healing. Chronic wounds present a significant economic burden to healthcare providers globally and also reduce QoL outcomes (Lo et al, 2020). Costs attributed to managing wounds include hospital inpatient stays, outpatient care, community, practice and specialist nurse visits, GP visits, diagnostics, prescriptions and wound dressings. In 2012, the cost associated with wound management in the UK was estimated at £4.5-5.1 billion (Guest et al, 2017) and in the United States of America estimates suggest 8.2 million Medicare beneficiaries had at least one type of wound, ranging from USD\$28.1-96.8 billion in 2014 (Nussbaum et al, 2018). In the UK, VLU treatment has been estimated to cost £300-600 million per year, equating to approximately 1% of the national healthcare budget (Nelson et al, 2014). The cost to manage an unhealed VLU over 1 year is 4.5 times higher than to manage a healed VLU (£13500 versus £3000 respectively; Guest et al, 2017). If the rate of wound healing increased by an additional 1% per annum, the annual prevalence would start to decrease (Guest et al, 2017).

The implementation of a referral pathway and a standardised, evidence-based clinical pathway to the WHC resulted in a number of positive clinical and economic outcomes, most significantly improved and timely wound healing. This was demonstrated by a reduction in wound area by week 6. This simplified approach ultimately led to all patients in the evaluation achieving complete healing.

This local evaluation has demonstrated that a coordinated holistic management approach can improve wound and patient outcomes. The majority of wounds (n=12) healed within 6 weeks. The ability to effectively improve healing times and outcomes will positively affect cost savings and improve patients' QoL outcomes

Guest et al (2017) highlight in the UK healing rates or venous leg ulceration at 12 months is only 47%. The NWCSP state that higher healing rates for leg ulceration could be achieved by commissioning equitable and accessible services, which would reduce unwarranted variation of care, increase the use of evidence-based care and discourage the overuse of therapies.

The rationale for developing the WHC was to promote timely and consistent care. It is important that any pathway introduced should be aligned with the aims of the NWCSP to improve patient outcomes (Adderley, 2018). This simple pathway based on robust clinical evidence can be implemented in a wide range of healthcare settings and used by a range of staff supported by appropriate training. **Declaration of Interest** The publication of this article is supported by Urgo Medical.

CONCLUSION

A WHC was set up locally to provide a co-ordinated and strategic approach to the assessment, treatment and management of wounds. The approach included the implementation of the UrgoStart treatment range for first-line use for local wound treatment. Using the referral pathway and treatment pathway resulted in complete healing of all 34 wounds in the evaluation by 16 weeks and there were observed improvements in QoL.

In addition to NICE guidance, local real-world evidence is vital to illustrate the need to introduce wound care dressing technologies that have a strong evidence base to clinicians, patients, carers and the wider health care organisation of (Milne and Tariq, 2020). In tandem, clinicians also need to possess the skills, confidence, knowledge and competence to enable accurate and timely clinical decision-making. Reducing variation in practice and getting it right first time will make best use of limited health care resources.

As we move to a future of more integrated care through the new integrated care system (ICS) structure of the NHS, wound care has a significant part to play in nursing closer to home, enhancing outcomes and reducing unwarranted variation in care. As hypothesised in the original "Burden of Wound Care" paper by Guest et al (2015), a focus on improving healing will be the best sustainable means of improving care and patient's QoL, both of which are demonstrated throughout this article.

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