Development and implementation of a biofilm pathway for chronic wounds

KEY WORDS
- Biofilm formation
- Biofilm pathway
- Topical antimicrobials
- Wound healing

Biofilm formation is rapid and invisible; a systematic approach to treatment that allows antimicrobials to be effective while preventing biofilm reformation is required. The three-step Leicestershire Partnership NHS Trust biofilm pathway was developed to provide a structured approach to chronic wound management. The pathway was developed with industry support. Community nurses were provided with education and printed resources. Patients are initially referred to the tissue viability team for assessment and then issued with a patient passport and managed by the community nurses. Treatment can be stepped up or down depending on clinical presentation. Initial clinical results have proven very positive and are supported by patient testimonials.

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Awareness within healthcare of biofilm formation and its impact on wound healing has risen exponentially in the past 3 years as studies have been published and the industry has marketed products aimed at disrupting/preventing biofilms. The formation of a biofilm is both rapid and invisible. Treatment needs to be structured to ensure a systematic approach that not only allows topical antimicrobials to be effective but also prevents biofilm reformation. This article reflects on the development and implementation of a biofilm pathway in a combined mental health and community nursing NHS Trust. It discusses the clinical rationales, methodology and ongoing challenges.

Biofilms are found in many areas of life such as on teeth, bacon and in open wounds (Bourdillon, 2016; Wounds UK, 2017). They can be bacterial or fungal, and although most can develop into a biofilm (Parsons and Metcalf, 2014) not all have the capability to do so (White et al, 2012; Edwards-Jones, 2017). Studies in the past 7 years have focused on the prevalence of biofilms in chronic wounds, with results varying from >78% (Malone et al, 2017) to >90% (Attinger and Wolcott, 2012). The 2017 Wounds UK Best Practice Statement on biofilms asserts that all chronic wounds have a biofilm but that its presence does not necessarily prevent these wounds from healing. The sometimes, indiscriminate use of topical antimicrobials in the community with no recorded clinical rationale is a concern here. Mahoney (2015a) audited electronic patient records and found indiscriminate antimicrobial use to be a factor in 44% of community nursing patients, supporting the assertion that traditional practices challenge the implementation of evidence-based practice (Collier and Hofer, 2017). The test for community nursing is recognising not only the polymicrobial nature of chronic wounds (Thomson et al, 2010) but also that, where a biofilm has formed, standard treatment with topical antimicrobials will be ineffective (Mahoney, 2015a). According to the Royal College of Nursing, however, declining numbers of district and community nurses (Glaspar, 2017) mean that the knowledge and skills needed to provide high quality wound care are in short supply (Newton, 2017).

The NHS is charged with increasing productivity, clinical- and cost-effectiveness in an environment of decreased real-term funding (Ousey and Bielby, 2011). Research carried out by Guest et al (2015) into the burden of wound care on the NHS found that chronic wounds cost the NHS £4.5 billion–£5.1 billion in 2012–13.

Table 1. Stages of biofilm development

Stage	Action	Result
Initial attachment	Planktonic bacteria attach to each other or a surface to form micro-colonies	Attachment is weak and reversible
Irreversible attachment	2–4 hours after initial attachment bacteria multiply, firmly attach to the surface and begin to secrete extracellular polymeric substance (EPS)	▸▸ Active debridement is required to break attachment ▸▸ Polysaccharides, lipids and proteins are available to 'feed' the bacteria
Maturation	After 6–12 hours, tolerance to antibiotics and topical antimicrobials increases and the EPS matures	▸▸ Host recognition of the biofilm, but EPS provides a protective barrier, impeding immune response. ▸▸ Tissue destruction due to excess neutrophils and pro-inflammatory cytokines at the site
	After 24–48 hours, the EPS is fully mature. There is gene sharing to protect the biofilm, conferring antibiotic resistance. Water channels form and microbes begin to multiply	▸▸ Chronicity in the wound. No healing progression ▸▸ Increased capillary permeability and inflammation can cause fibrin slough to develop; the wound becomes shiny in appearance.
	Slowed metabolism	Antibiotics requiring bacterial growth and metabolic activity to work become ineffective
Dispersion	The biofilm begins to spread to other sites through the release of free-floating planktonic cells	Satellite areas develop a biofilm and become chronic wounds

It was against this background that the Leicestershire Partnership NHS Trust (LPT) biofilm pathway was developed. The pathway's aim is to provide a structured approach allowing nurses to step up or step down treatment according to clinical presentation. It also offers the patient an opportunity to not only maintain control over his or her wound care, but also provide self-care where appropriate.

WHAT IS A BIOFILM AND WHY IS IT A PROBLEM?

Biofilms are usually described as polymicrobial communities (Parsons and Metcalf, 2014; International Wound Infection Institute, 2016); however, a biofilm can also form from a single pathogen (Edwards-Jones, 2017). Biofilm development can be broken down into four stages (*Table 1).* Planktonic bacteria communicate with each other through cell-to-cell signalling (quorum sensing). This is not essential for a biofilm to form, however, and when quorum sensing is no longer useful in fooling the body's immune system the bacteria suppress it (Edwards-Jones, 2017).

Biofilm visibility has been an area of debate among clinicians. Biofilms are, by nature, microscopic and invisible to the naked eye (White et al, 2012; Bourdillon, 2016). White et al (2012) asserted that the 'slime' often cited by clinicians was "not accepted as evidence of a biofilm" and White et al (2012) noted that biofilms should not be confused with a 'pseudomembrane' of fibrin debris, neutrophils and bacteria that presents as a "thin, adherent, grey-white exudative layer" that can be removed from the surface. This pseudomembrane is often confused with biofilm presence and clinicians need to take a whole-system approach to identify whether a biofilm is likely to be present (*Box 1).*

The ability to recognise infection is an essential component of all nurses' clinical wound care skills. Traditionally the presence of infection is determined is through observation of the wound, its behaviour, characteristics and progress. The difficulty with biofilms is that they do not necessarily exhibit classic signs of infection and may actually be asymptomatic (European Wound Management Association, 2009). Although a wound swab may be indicated

Box 1. Biofilm indicators

- Poor-quality granulation, i.e. friable, dark
- Increasing exudate
- Increasing malodour
- Recurring infection after completion of antibiotic course
- Polymicrobial-negative wound swabs
- No healing progression despite patient optimisation and appropriate treatment
- Not resolved with a topical antimicrobial course
- Recurring slough
- Low-level chronic inflammation

with some infections to confirm bacterial load (White and Cutting, 2008), biofilms are not free-floating and therefore cannot be picked up through wound swabbing (Mahoney, 2015a). The lack of a positive swab in the presence of an optimally-treated non-healing chronic wound is one indicator that a biofilm may be present (*Box 1).*

Biofilm infection can persist for extensive periods of time (Dowsett, 2013), with chronic wounds providing the optimum environment for pathogens to attach and multiply (Bourdillon, 2016). Chronic wounds have a well-documented negative impact on patient quality of life (Green and Lester, 2009; International Consensus, 2012). Effective decision-making and good clinical assessment in wound care are essential to ensure a rapid, accurate, response to infection and to prevent chronicity (Mahoney, 2015a). Such prompt action also reduces healthcare costs.

In 2013, Glaspar stated that the challenges of an ageing population would not be met in the community due to the falling numbers of district nurses. The decreasing number of district nurses — a reduction of 44% between 2010 and 2017 (Glaspar, 2017) — has had a direct impact on preventative care and the recognition of chronicity causation. Dowsett (2013) highlighted a 'failure' in the identification and treatment of chronic wounds because the underlying cause is often not being addressed. Patients with chronic wounds would traditionally have been on a district nurse caseload and it is the expertise of these nurses that is needed to address the prevalence of biofilms in chronic wounds through robust, holistic assessment and review.

PATHWAY DEVELOPMENT AND IMPLEMENTATION

Publication of the report by Guest et al (2015) and recognition of the challenges posed by decreasing numbers of community nurses in the face of rising numbers of chronic wounds led the author to research and develop the LPT biofilm pathway. A review of best practice and recent publications on biofilms identified: the specific actions needed to disrupt attachment, interrupt intercellular communication and prevent reformation; to cleanse and debride; and the need to treat the wound using a topical antimicrobial (Mahoney, 2015b; Swanson et al, 2016; Collier and Hofer, 2017).

Antimicrobial selection

Many chronic wounds have been subject to extended antimicrobial use, which can have a negative effect on tissue due to non-selectivity (Mahoney, 2015a). Phillips et al (2010) reported that standard antimicrobials such as silver, honey, polyhexamethylene biguanide (PHMB) and iodine were all effective when used after debridement in biofilm-based wound care. It was therefore considered important when developing the biofilm pathway to include a non-toxic antimicrobial that could be used in the longer term for patients assessed and reviewed as needing it, e.g. patients with comorbidities that increase their biofilm/infection risk either through poor oxygenation to the site or poor nutrition (Parsons and Metcalf, 2014).

PHMB is an antimicrobial compound that has a non-toxic effect on tissue. PHMB surfactant begins disturbing the biofilm immediately and soak times can be adjusted according to clinical presentation (Collier and Hofer, 2017). Dowsett (2013) recommends "vigorous cleansing for removal and prevention". Within the biofilm lifecycle, PHMB surfactant also impedes biofilm attachment and maturation (Mahoney, 2015a) For these reasons, and due to its availability on the LPT formulary, the author included Prontosan® Wound Irrigation Solution and Prontosan® Wound Gel X in the pathway (Bradbury and Fletcher, 2011).

Debridement selection

Debridement needs to be both frequent and repeated over a minimum of 2 weeks, and sometimes longer (Dowsett, 2013; Mahoney, 2015b). For debridement at the wound bed, Debrisoft® Cleaning Pad and Lolly were included. These products were selected as although other methods of debridement may be more effective, i.e. sharp or hydrosurgery, these options are not available to community

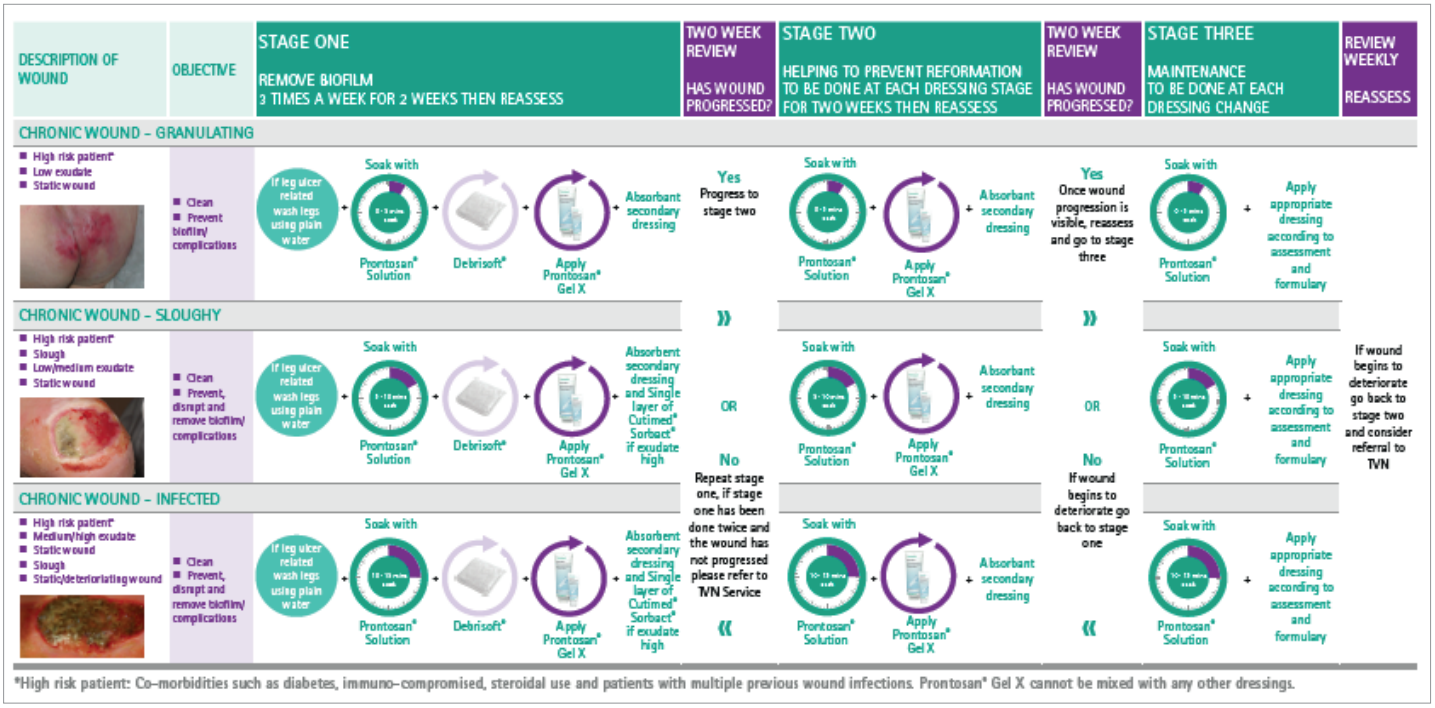


Figure 1. The Leicestershire Partnership NHS Trust biofilm pathway

nurses and the pathway needed to be realistic and available to all who needed it.

Financial considerations

To be effective, the pathway needed to align with the known lifecycle of a biofilm (*Table 1)*, follow a clear structure and be accessible to staff wanting to commence a patient on it (Edwards-Jones, 2017). In addition to these factors, support tools and an education programme would be needed for implementation.

Many NHS Trusts are facing financial challenges. Working in partnership with industry provides access to the educational resources industry can provide. In turn, inclusion in the wound care formulary increases product use. Joint working therefore benefits both parties and is invaluable in improving patient outcomes (Ousey and Bielby, 2011). Industry and NHS codes of practice advocate transparency in all interactions and this is particularly important in wound care, where formulary inclusion can generate significant business. The 2015 Nursing & Midwifery Council code of conduct requires that any decisions made are not unduly influenced by commercial offers. All products included in the LPT biofilm pathway were already on formulary, therefore there was no conflict of interest or undue commercial influence in the decisions taken.

The pathway

The LPT biofilm pathway takes the patient through three stages of healing, with a review every 2 weeks (*Figure 1)*. It advises on PHMB soak times in line with presentation, the addition of a dialkylcarbamoyl chloride (DACC) sheet for highly exuding wounds, and when to refer a patient to the tissue viability nurse.

Early trials of the pathway delivered immediate results (*Figure 2)*, and it was presented to district nurses for their feedback prior to implementation. An error made at this time was allowing stage 1 debridement to be performed two to three times a week instead of three times a week. This leeway was instigated in response to district nurses' concerns that they were finding it difficult to cover visits, that bank/agency nurse use was high and they could not increase the number of visits for those in compression. Although one patient still progressed with twice weekly visits, they did not advance beyond stage 1. This led to less cost-effective treatment when compared to implementing the pathway as a whole. From this experience, the district nursing teams have learnt that in order to

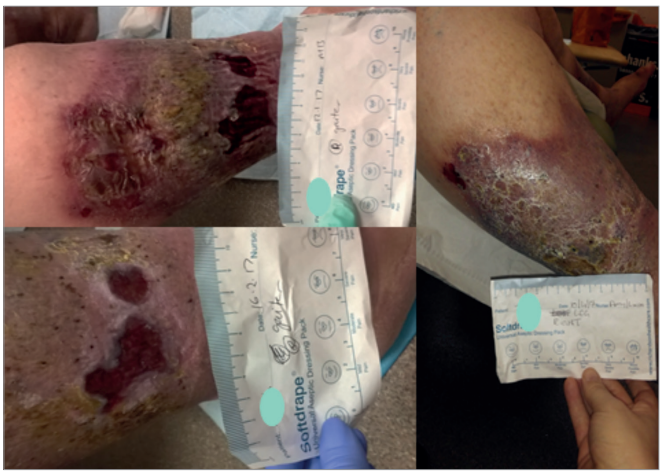
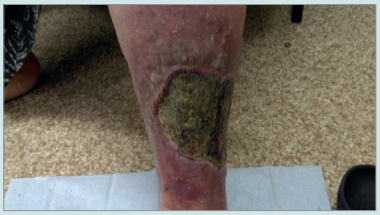
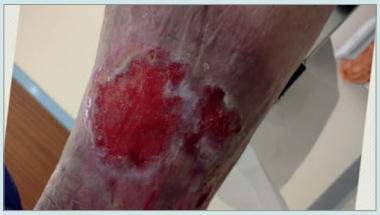


Figure 2. Trials of the pathway were successful, with rapid results

Box 2. Case study: Patient with a non-healing leg ulcer



March 2017: started on pathway
Non-healing
Size: 12 cm × 7 cm; depth: 2–3 mm



November 2017
Stage 3 healing
Size: 4.7 cm × 3.0 cm

Patient characteristics and case history

- Female, age 50
- Non-healing leg ulcer of 5 years' duration
- Patient would only attend the clinic two times per week, so her wound remained at stage 1 for longer than ideal, although healing did progress
- Ulcer was superficial with 100% granulation in November 2017
- In March 2018, the wound had almost healed

Patient perspective

"I was in constant pain, which meant I had to take lots of pain killers – all different types. These made me feel tired all the time and never really took all the pain away. I became less mobile and this effected my walking. I was always getting antibiotics, which also made me feel sick. My legs were constantly wet and leaking and really smelt bad. It was embarrassing. It used to stress me out because I was always having to ring the nurses up, it took ages to get through and when I did see a nurse I felt guilty because I felt like it was my fault, I was holding them up and making them really busy. My dad was getting really worried because it was taking so long.

"Since starting the biofilm pathway my leg has got better. I have virtually no pain now. I have come off a lot of the pain relief, so I don't feel as tired anymore. I don't need any more antibiotics. I don't feel stressed because I don't need to ring the nurses. I don't get the guilt now. I go to clinic at set times for set periods of time, the nurses know what to do, and the care is consistent.

"I like having my own dressings and passport to bring to clinic. I know I've got everything we need. The smell is gone and my leg doesn't leak any more. Its nearly healed. I'm able to go out with my dog now and I'm not embarrassed when I see my friends."

heal patients and reduce their caseload, there needs to be an initial investment in increased visits to ensure the debridement stage is completed effectively.

Weekly education on the pathway was provided to community nurses between August and December 2017. The presentation took them through what a biofilm was and why it was contributing to the non-healing wounds on their caseload. Training also provided an opportunity to share patient case studies and discuss progression to healing (*Box 2* and *3).*

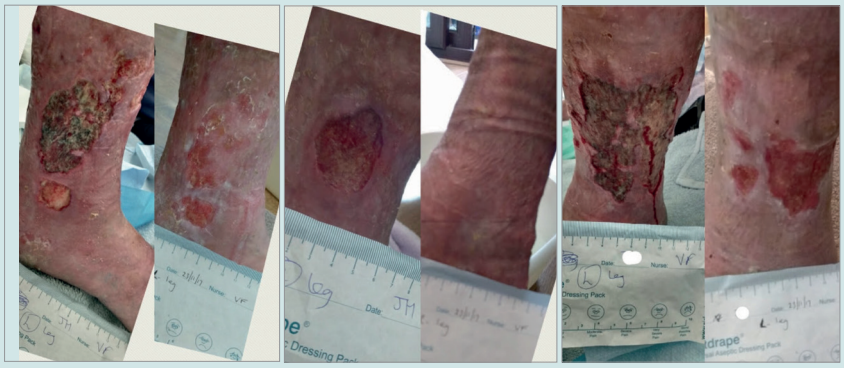
Resources for the pathway were given out at the study events and included an A6 pocket guide, A3 laminate for bases and biofilm passports for patients (*Figure 3*); these were all provided by B. Braun and L&R Healthcare. The patient passports are an essential component of the pathway, promoting concordance and continuity through clinicians actively engaging patients in the treatment regimens (Dowsett, 2013; Ettridge, 2017). The passport provides initial information on what a biofilm is and what treatment involves. Subsequent pages are dedicated to each stage so that clinicians can record their interventions and reviews.

To ensure accurate allocation to the pathway and to support the teams, patients considered for the pathway were referred to the tissue viability team. Although this has limited the number of patients allocated to the pathway, it has been required to ensure that the management of any underlying conditions has been optimised and that treatment rationales are fully explained to the patient to improve concordance (International Consensus, 2012). It also allows the tissue viability team to confirm that products and the passport are in place and there is a commitment to ensuring the patient receives three visits a week for the duration of stage 1 (this can be 2–4 weeks, depending on clinical presentation and comorbidities). It is imperative that patients understand that a missed visit during these weeks will allow the biofilm to reform and gain a more tenacious attachment.

CHALLENGES

The main challenge has been clinicians who have not attended the training recording that

Box 3. Case study: Patient with bilateral leg ulcers



September 2017: Patient started on pathway

December 2017: Right leg healed

December 2017: Left leg in stage 3 healing

Patient characteristics and case history

- Male, age 77
- Bilateral leg ulcers for 2+ years
- Right leg ulcer: 3.6 cm × 3.4 cm
- Left leg ulcer: circumferential and irregular shaped
- Started on biofilm pathway on 18 September 2017
- Received three home visits per week while at stage 1 healing
- Right leg took approximately 2 months to heal
- Left leg continues on stage 3 healing and consists of two ulcers measuring approximately 1 cm × 1 cm on the outer leg and 4 cm × 1 cm on the rear. Both ulcers have 100% granulation
- Patient now in hosiery

Patient perspective

"I had these ulcers for over 2 years and they wouldn't heal. I had cellulitis two times and ended up in hospital having really strong antibiotics that had to be put into my veins. I then had to have the nurses come to my home to give them to me. The pain was constant – it kept me awake at night. My wife was worried and felt helpless that she could not help me. I stopped going to visit my grandchildren due to the fear of them catching my legs because of the pain. I was also embarrassed of the smell. I remember one Christmas when the family got together, I didn't want to be there. I sat at the back of the room because I was so worried about the smell. I remember wrapping the bandages up with cling film to try and disguise it. I never went again after that. I became socially isolated.

"I became frustrated as they [the Trust] would send agency nurses and I was never sure if anyone was going to come. I was constantly ringing up. I felt guilty that I was having to keep having nurses come – I know how busy they are. I was frustrated because the ulcers were not healing, nothing was moving forward. There was no continuity with dressings: one nurse would use one thing and another would use something else. I lost faith in the nurses.

"Then the tissue viability nurse came and put this plan into place to start the biofilm pathway. She put my mind at rest. We started the pathway and things started to change. I could see it working. I felt like there was light at the end of the tunnel. The smell soon went. I felt like I was back in control. My right leg has healed really fast. I can put shoes on again because I'm in hosiery. Even wearing trousers again without the bandages sticking. I'm more mobile again. My left leg is nearly healed.

"I've learnt a lot about this pathway and I see other people in bandages and feel like I'm one of the lucky ones. It's like a huge weight lifted off my shoulders."

they have started a patient on the pathway when they have not got the passport or Debrisoft. The reasons for this are twofold: first, the success of other patients who have healed on the pathway; and second, that access to Debrisoft in LPT is only via the tissue viability team. This latter reason is because of previous misuse in LPT and the budget for wound care being held by the Clinical Commissioning Groups. To resolve these issues, the complex care lead in each team now verbally reviews each pathway patient at the start of the week to ensure that the correct process is being followed. The monitoring has only recently been implemented across the teams and it is not clear yet whether it has been successful across LPT.

The Kings Fund (2016) has identified that the fall in community nursing numbers is having an impact on patient visits and continuity of care. This is reflected in the reliance on bank and agency nursing staff in LPT community nursing teams. In combination with visits being postponed, the lack of regular nurses has been an additional barrier to successful implementation of the pathway.

A further obstacle to success has been clinicians not debriding effectively with the Debrisoft, leading to wounds remaining at stage 1 healing for extended periods of time. On investigation, the tissue viability nurse supporting implementation found that clinicians were concerned they would cause the patient pain or were uncomfortable with causing the wound to bleed. Bleeding on debridement is likely due to the friable granulation often associated with biofilms and demonstrates a gap in some clinicians' knowledge. To address this, the company representative for Debrisoft (L&R Healthcare) has been asked to visit community nurse bases and discuss patients using Debrisoft to maintain control of their own pain levels as well as to explain that tissue may bleed as a result of the biofilm.

FUTURE WORK

Prior to publication of the Best Practice Statement on biofilm management (Wounds UK, 2017) there did not appear to be a consistent approach to treating biofilms despite an increasing awareness of the need to debride and kill the pathogens. The financial limitations currently placed on services has led to difficulties in providing therapies that

Figure 3. Patients each received a biofilm pathway passport

are both cost- and clinically-effective (Newton, 2017). This is reflected in the restricted access to Debrisoft in LPT, where consideration needs to be given to a spend-to-save model to ensure all patients who need this treatment are able to access it.

CONCLUSION

Biofilm-based wound care is aimed at providing clinicians with a proven strategy to disrupt, kill and prevent the reformation of microorganisms that are preventing a wound from healing (Parsons and Metcalf, 2014; Wounds UK, 2017). Although a 'shiny' surface may be present with a biofilm, it is not a definitive indicator and clinicians need to be aware that such an appearance can be generated by different pathogens (White et al, 2012; Swanson et al, 2016). The development of a clear pathway to support clinicians in their decision making is essential (Parsons and Metcalf, 2014). Once implemented, it can provide clear evidence of quality improvement and measurable outcomes; these are essential in demonstrating the efficacy of interventions (Dowsett, 2013). The challenges lie with workforce pressures, declining numbers of nurses, negative staff wellbeing and an increasingly task-oriented approach (Kings Fund, 2016; Glaspar, 2017). Joint working with industry allows external expertise to be drawn on for pathway implementation and, as a result, improved patient outcomes (Ousey and Bielby, 2011).

The development of the LPT biofilm pathway has provided community nurses with a tool to improve patient quality of life through reducing exudate, odour and — where there are no insurmountable barriers — healing. It remains essential for the patient to have a holistic assessment and for factors delaying healing to be addressed. Patient testimonials provide the impetus to address the challenges faced. WUK

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