Development and integration of a wound cleansing pathway into clinical practice

ABSTRACT

Wound bed preparation has come into sharper focus over the past decade, with strategies identified to improve wound condition. This article focuses on implementing a wound cleansing policy and measuring, through audits, how this change affected rates of wound infection. From 2016 onwards, the Skin Integrity Team at Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust took steps to revise and improve wound care practices. This resulted in the introduction of a wound cleansing pathway incorporating a surfactant-based cleanser in place of saline, with subsequent staff training and other changes made to practice. This study details the steps taken to implement the new pathway, which brought a reduction in wound infections of 84.3% between 2017 and 2019.

Keywords: Wound bed preparation ■ Wound cleansing ■ Wound infection ■ Prontosan ■ Biofilm ■ Clinical

Unwarranted variation in care has been a key topic for NHS England since the publication of the Carter (2016) report 5 years ago. Work by Guest et al (2015) highlighted the burden of wound care and these themes continue to be a focus at national level as part of the National Wound Care Strategy Programme (https://www.nationalwoundcarestrategy.net).

Wound bed preparation has become a foundation of chronic wound management (European Wound Management Association, 2004; Dowsett and Newton, 2005), with active wound cleansing recognised as one of the fundamental elements of a multi-stage approach to achieving an improved clinical outcome (World Union of Wound Healing Societies 2016). Alongside wound cleansing, wound bed preparation relies heavily on debridement to remove undesirable tissue and disrupt the microbial burden that may predispose to the formation of a biofilm and result in the development of a wound infection. The debridement process can be positively assisted by the use of an appropriate wound cleansing solution that contains both polyhexanide and betaine. A gel containing polyhexanide and betaine active ingredients can be used between dressing changes to prevent reformation (Valenzuela and Perucho, 2008; Ricci, 2018).

In 2016, the Skin Integrity Team at Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust (DBTHFT) was formed. A review of treatment within the complex wound clinic was undertaken and this identified that an increasing number of patients attending the clinic had a wound infection. Inconsistencies and variability in wound care within the clinic were noted: prior to the formation of the Skin Integrity Team there had been no wound bed preparation and therefore no cleansing of wounds within the clinics prior to 2016. The team began the process of improving practice with the aim of addressing the high infection rate.

Research

As part of the drive to improve practice in the clinic, the Skin Integrity Team attended the Wounds UK symposium, Taking Wound Cleansing Seriously to Minimise Risk, in 2016, facilitated by one of the authors (MC). The symposium included a presentation of an outline of the current evidence and the role of an 'active cleanser' as an integral part of the wound bed preparation process (Collier and Hofer, 2017). At the time of attending the conference, saline was being used as the primary wound cleansing agent at DBTHFT.

In light of the evidence presented, a decision was made to prioritise wound bed preparation and implement an active cleanser for hard-to-heal wounds. After internal discussions, it was agreed at a local level that hard-to-heal wounds would be classified as those of over 21 days in duration. Previous work has reported that hard-to-heal wounds have a high prevalence of biofilm (Malone et al, 2017) and the presence of biofilm within the wound margins is increasingly being accepted as one of the main reasons for delayed healing (Fletcher and Bradbury, 2011).

The Skin Integrity Team started in its new role by introducing the use of saline for wound cleansing, which was remained the practice up until the pilot of an alternative solution described in this article.

Methods

The Skin Integrity Team reviewed the recent wound cleansing literature available up to 2016. Based on the available evidence and reviewed at the time by the two of the authors of this article (TV and KM), the wound cleansing solution selected for use in a pilot clinical evaluation was Prontosan Wound Irrigation Solution, in which the active ingredients are polyhexamethylene biguanide 0.1% (polyhexanide or PHMB),

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Table 1. Wound bed preparation cleanser pilot evaluation results

Wound type	Patient gender and age	Duration of wound initially	Wound size at start	Wound size reduction	Observation period
Amputation	M, 65	13 months	30 cm^2	73%	13 weeks
Abdominal	F, 52	23 months	10 cm^2	40%	13 weeks
Spine	F, 61	27 months	6 cm^2	62%	6 weeks
Leg	F, 78	25 months	2 cm^2	79%	10 weeks

and betaine surfactant 0.1%. Collier and Hofer (2017) reported that, in combination, these two ingredients work to provide a mechanical desloughing effect: betaine disrupts the biofilm and cleanses slough and debris (betaine micelles lift and hold debris), while the PHMB has an adjuvant antimicrobial effect. It should be noted that other wound cleansing solutions were considered as part of clinical decision-making. The clinical review of the literature undertaken by two of the authors (TV and KM) also highlighted the following:

- PHMB and betaine solution has a significantly higher efficacy compared with normal saline solution in reducing inflammatory signs and accelerating the healing of vascular leg ulcers and pressure ulcers (Bellingeri et al, 2016)
- Wounds cleansed with PHMB and betaine healed 4 weeks faster than those cleansed with saline (Andriessen and Eberlein, 2008)
- Improvements in wound odour and reduction in pain have been noted (Valenzuela and Perucho, 2008; Durante et al, 2014)
- Infection rates have been observed as reducing from 40% to 3% following the introduction of a wound cleansing solution containing PHMB and betaine to manage diabetic foot ulcers, pressure ulcers and leg ulcers in outpatient clinics (Möller et al, 2008).

This articles makes reference to infected wounds throughout. All wounds in the complex wound clinic were clinically assessed for signs of infection using the following parameters:

- Erythema
- Local warmth
- Swelling
- Purulent discharge
- Delayed wound healing
- New or increasing pain
- Increasing malodour
- Crepitus.

Clinical confirmation of some or all of these parameters led to a wound swab being taken, determined by local wound assessment policy. Swabbing was undertaken after wound cleansing and, where applicable, wound debridement was then carried out. A 'confirmed infection' indicated positive results from both the clinical assessment and swabbing, while a 'suspected infection' indicated a positive clinical evaluation that was not subsequently confirmed via swabbing.

Pilot clinical evaluation

A pilot clinical evaluation of between 6 and 13 weeks' duration (depending on patient) was undertaken from December 2016 (see *Table 1*). As mentioned above, the formation of the Skin Integrity Team saw the introduction of saline as a cleansing solution for hard-to-heal and 'at-risk' wounds. Complex and difficult wounds showing no signs of progression were identified for inclusion in the pilot: the wounds selected had failed to reduce in size over the preceding 21 days and/or had received repeated rounds of antimicrobial treatments, which was indicative of the presence of biofilm within the wound (Phillips et al, 2010). Four wounds met the criteria of stalled healing (having failed to reduce in size over the preceding 21 days) and repeated rounds of antimicrobial treatments, which are both markers indicative of the presence of biofilm within the wound (Phillips et al, 2010).

The primary measure indicative of improvement selected for the pilot was wound size (cm^2) reduction, as this was well documented and would be a consistently reported variable in all patient types. The four patients with wounds that met the inclusion criteria were recruited for the pilot, with documented verbal consent acquired from each patient prior to commencement of the evaluation.

From December 2016 the practice of wound cleansing with saline was replaced with a PHMB and betaine solution soak at every dressing change, and the four patients were seen at the Trust's complex wound clinic by members of the Skin Integrity Team. The duration of treatment for the four participants was between 6 and 13 weeks. No other procedural changes were implemented during the pilot phase. Patients and clinical outcomes were monitored and recorded for analysis at each clinic appointment.

Pilot clinical evaluation results

The results (*Table 1*) demonstrated a clear (40–73%) reduction in wound size for all four wounds (within 6–13 weeks). The pilot evaluation indicated to the Skin Integrity Team that implementation of a PHMB and betaine cleansing solution, in place of saline, could improve future clinical and patient outcomes. Following the pilot's impressive results, it was agreed to further develop the wound bed preparation theme and develop a new Wound Cleansing Policy within the Trust, including the use of a PHMB and betaine cleanser, which would be rolled out in 2017.

Implementing the policy

In 2017, following the pilot, the Trust developed its Wound Cleansing Policy, with PHMB and betaine solution introduced for wound cleansing for all patients' wounds that met the following criteria:

- Wounds had been present for more than 21 days
- Wounds that were less than 21 days' duration but where a risk of infection/the presence of biofilm were probable, which included patients with:
  - Conditions of hypoxia
  - Poorly controlled diabetes
  - Known history of alcohol or substance abuse
  - Nutritional deficiency
  - Prior to further surgery
  - Contaminated or dirty wounds.

In spring 2017, the Wound Cleansing Policy (*Figure 1*), with an accompanying user guide (*Figure 2*), was implemented across the Trust's complex wound clinics and inpatient hospital

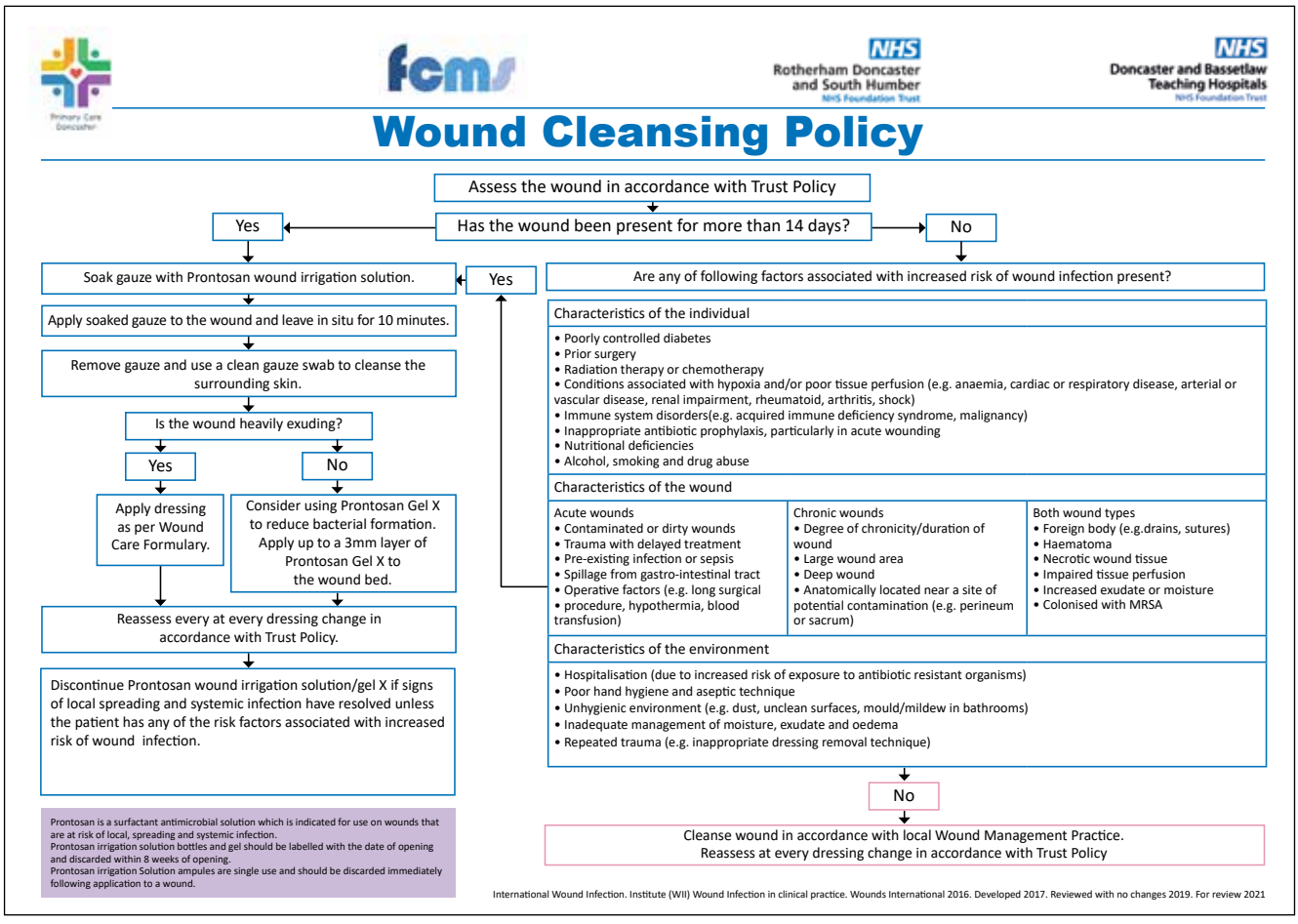

Figure 1. Wound Cleansing Policy, 2021

wards, as well as in the community setting, which included its adoption by both district and practice nurses. Inclusion of all local logos on the documentation was a considered a positive step to promote adherence to the policy. Compliance with the new policy was 100% in the complex wound clinic. However, the Skin Integrity Team was unable to quantify compliance data for the Trust's inpatient areas or for wounds cared for in community settings.

Review and annual auditing

Six months following the introduction of the Wound Cleansing Policy, the Skin Integrity Team undertook an audit to determine the policy's effectiveness. A 4-week period was allocated for completion of the audit: between 23 October and 19 November 2017 data were collected for 261 patients attending the Trust's complex wound clinics.

The following primary outcomes were recorded as part of the audit: data on clinical signs of local, spreading and/or systemic infection (which would trigger the need to take a swab). If a swab returned positive for wound-bed anaerobic and/or aerobic bacteria, the wound was recorded as a confirmed infection (*Figure 3*).

The 2017 audit recorded 261 patients and showed that 10.3% of wounds (27/261) were swabbed due to suspected spreading and/or systemic wound infection. Overall, 7.3% of wounds (19/261) had a confirmed wound bed anaerobic/aerobic bacterial infection, by return of a positive wound swab. Of these, *Staphylococcus aureus* accounted for more than half (57.9%; 11/19) the infections. *Figure 4* shows the details of microbial breakdown per audit year.

Embedding the policy and 2018 audit

This year was identified as one of consolidation, allowing for the Wound Cleansing Policy to be fully embedded in all healthcare settings and to facilitate the monitoring of the longer term impact of the policy; no other changes to clinical practice were made during the year. The original wound cleansing audit was repeated in the complex wound clinic between 22 October and 18 November 2018, the equivalent 4-week period to the previous year, to minimise potentially confounding factors associated with certain times of the year.

A total of 236 wounds were recorded during the audit, with the results showing that 3.8% of wounds (9/236) were suspected of a spreading and/or systemic wound infection. Overall, 3.4% of wounds (8/236) were confirmed as infected by return of a positive wound swab. Again, *S.aureus* accounted for more than half (62.5%; 5/8) the infections (*Figure 4*). The wound infection rate in 2018 demonstrated a 47% decrease in compared with the previous year, supporting the introduction and full implementation of the Wound Cleansing Policy using the PHMB and betaine solution.

During the 2018 audit the Skin Integrity Team had access to a fluorescent imaging device, which enables a visualisation of bioburden. It enables the identification of bacterial loads of

Prontosan Wound Irrigation Solution User Guide

Does the wound meet the criteria set within the Wound Cleansing Policy

No

Cleanse wound in accordance with local Wound Management Practice.

Reassess at every dressing change in accordance with Trust Policy.

Yes

❶ Soak gauze with Prontosan Wound Irrigation Solution.

❷ Apply soaked guaze to the wound and leave in situ for 10 minutes.

❸ Remove gauze and use a clean gauze to cleanse the surrounding skin.

❹ Is the wound heavily exuding?

Yes

Apply dressing as per Wound Care Formulary.

No

Consider using Prontosan Gel X to reduce bacterial formation. Apply up to a 3mm layer of Prontosan Gel X to the wound bed.

❺ Reassess the wound at every dressing change in accordance with the Trust Plolicy

❻ Discontinue Prontosan Wound Irrigation Solution/Prontosan Gel X if signs of local spreading and systemic infection have resolved unless the patient has any of the risk factors associated with increased risk of wound infection.

Prontosan is a surfactant antimicrobial solution which is indicated for use on wounds that are at risk of local, spreading and systemic infection.

Prontosan irrigation solution bottles and gel should be labelled with the patients identification details, date of opening and discarded within eight weeks of opening.

Prontosan irrigation Solution ampules are single use and should be discarded immediately following

International Wound Infection. Institute (WII) Wound Infection in clinical practice. Wounds International 2016. Review Feb 2019.

Product Description	Size	Pack Size	Product Code	PIP Code	NHS Supply Chain Code
Prontosan Solution	40ml ampoule 350ml bottle 1000ml bottle	24 10 10	400484 400403 400240	374-5940 324-8572 402-8551	ELY424 ELY248 ELY617
Prontosan Solution with Adapter	1000ml bottle	10	400446	402-8544	ELY618
Prontosan GEL X	50g tube 250g tube	20 20	400517 400508	378-1796 367-8612	ELZ542 ELZ396

IInternational Wound Infection. Institute (WII) Wound Infection in clinical practice. Wounds International 2016. Developed 2017. Reviewed with no changes 2019. For review 2021

Figure 2. Wound cleansing user guide, 2021

more than 104 colony-forming units per gram at tissue depths of up to 0.8 mm: the device shows Gram-negative species as fluorescent red and Gram-positive species as green.

Four patients were selected for additional visual assessment using the device to further clarify the effectiveness of the Wound Cleansing Policy. Images of the patients' wounds were made before and after the wounds were treated with wound cleansing soaks and pre- and post-debridement. The visualisation of the bioburden allowed the Skin Integrity Team to tailor debridement to the needs of each patient's wound. As a result, members of the Skin Integrity Team were also able to provide colleagues within the team with information about the areas identified in the images as showing the presence of increased bioburden. The device proved to be a useful assessment tool, because it enabled practitioners to focus their debridement techniques more appropriately.

The case study (*Figure 6*) illustrates the use of fluorescent imaging technology in the case of a patient who had a wound on an amputation site. This technology was helpful in the treatment process because it enables targeted debridement to be undertaken in areas that may have appeared clean to the naked eye. For example, *Figure 6* shows the bacterial burden both on and below the intact skin. The use of the technology facilitated targeted debridement and subsequent reduction in the bacterial burden.

Case study

A fluorescent imaging device, which enables the visualisation of the bioburden within a wound bed, was available for use alongside the Wound Cleansing Policy. A small group of patients was selected for assessment using the device, and their informed consent was obtained and documented.

The fluorescing images in *Figure 6* illustrate the condition of an amputation wound pre- and post-treatment in a patient who attended a complex wound clinic twice a week for holistic wound care assessment and interventions, which included cleansing and debridement. The imaging shows how the use of Prontosan soak and wound debridement led to a reduction in bacterial burden in the wound.

Increased wound fluorescence was observed following the use of the PHMB and betaine soak. The change was interpreted as due to the surfactant action of betaine, which breaks down biofilm and releases the bacteria present deeper in the wound bed, enabling removal of devitalised tissue using a debridement pad. The fluorescence can also facilitate targeted debridement in areas that may have appeared visually clean to the naked eye.

Training and 2019 audit

Throughout 2019, the Skin Integrity Team worked as part of the wider health community to support a shared care approach for the patients of Doncaster. This included running a dedicated training event for local practice nurses. In February, a training workshop was developed and piloted with 50 practice nursing staff, to assist their continuing professional development and to further promote evidence-based practice.

Pre-training assessments were conducted with the practice nurses to gain an understanding of their existing knowledge around wound cleansing, including on topics such as biofilms, wound infection and TIMERS (Atkin and Tettelbach, 2019),

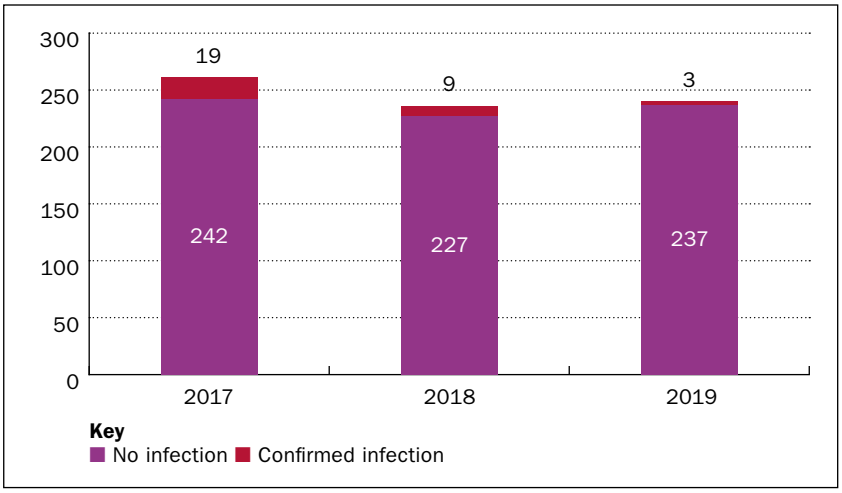

Figure 3. Number of confirmed infected and non-infected wounds recorded during the 4-week annual audits conducted between 2017 and 2019

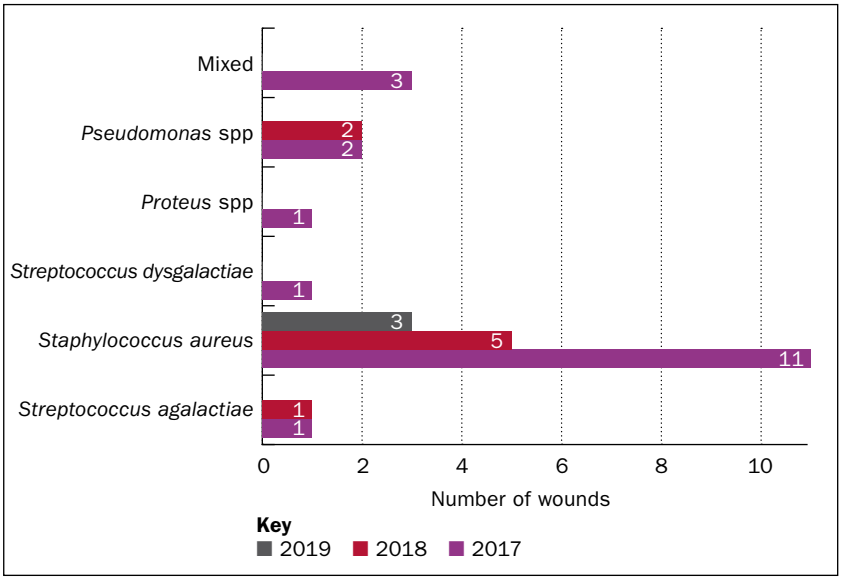

Figure 4. Number of positive swabs by microbial species recorded during the 4-week annual audits conducted between 2017 and 2019

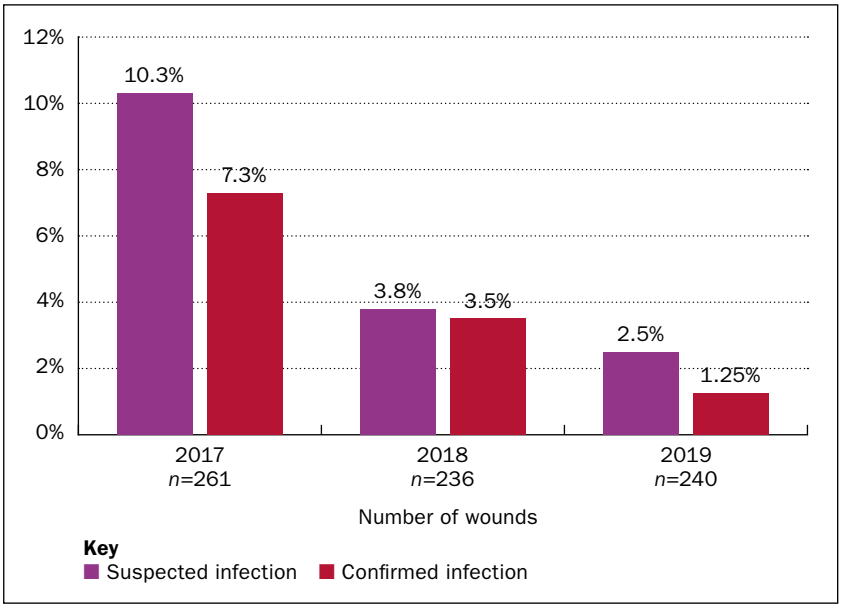

Figure 5. Suspected and confirmed infections as a percentage of the total number of wounds recorded during the 4-week annual audits conducted between 2017 and 2019

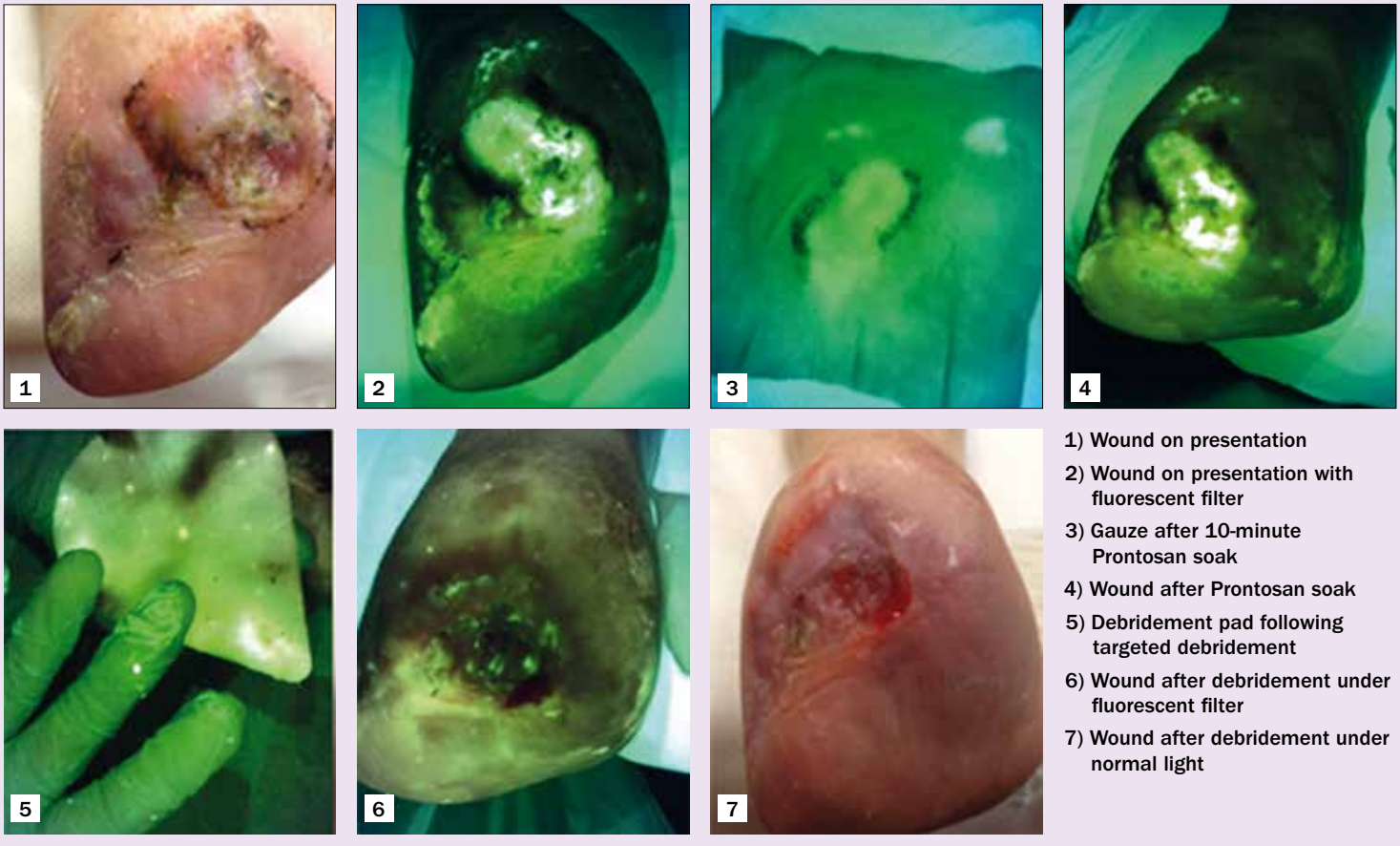

Figure 6. The use of a fluorescent imaging device to visualise a patient's wound bioburden at different stages of management

which represents:

- T for tissue: non-viable or deficient
- I for infection/inflammation
- M for moisture imbalance
- E for edge of wound, non-advancing or undermined
- R for regeneration/repair of tissue
- S for social factors that affect the trajectory of wound healing.

Following the training, the Skin Integrity Team assessed the impact and relevance of the session. The average pre-training assessment score was 27% (range 10–50%), rising to 84% (range 63–100%) post-training. This demonstrated that the training had achieved its objectives of updating nurses' knowledge and that it was of clinical relevance and value to community staff. Analysis of feedback after the initial events highlighted that a prescriptive pathway was clinically relevant, encouraging evidenced-based practice in the management of wound care patients. It was anticipated that improved outcomes would be observed in future. The feedback also showed that the pathway was appreciated by all staff involved.

In July 2019, an updated training programme was launched and continued to be delivered into 2020 to practice nurses. Among other topics, the programme covered the pathways in place for the relevant local area. The programme's learning objectives included refreshing and updating clinicians' knowledge of the anatomy and physiology of the skin, the wound healing processes, wound infection, barriers to healing, the evidence base relevant to wound cleansing and wound assessment, and the latest formulary dressing choices, in line with local pathways. The training events lasted one working day and incorporated presentations and discussions facilitated by members of the Skin Integrity Team.

Recent guidance from National Wound Care Strategy Programme (2020) states that wounds should be assessed within 14 days of presentation, prompting the decision that all wounds with a longer duration than 14 days would be treated with the PHMB and betaine soak as per the updated Wound Cleansing Pathway.

As in previous years, an audit was repeated in the complex wound clinic over an equivalent 4-week period between 21 October and 17 November 2019. It included 240 patients, with 2.5% of wounds (6/240) suspected of wound infection, of which 1.25% (3/240) had a confirmed infection. *S. aureus* accounted for all infections (3/3) (*Figure 4*). The wound infection rate in 2019 demonstrated a 66% decrease compared the previous year and an 84.3% reduction from 2017 (*Figure 5*).

Updated policy and 2020 audit

Most recently, the wound care policy has been updated again after a successful trial to include the use of the Prontosan Debridement Pad to support the removal of slough and further cleanse hard-to-heal wounds, replacing the previously used monofilament pad. The updated Wound Cleansing Policy is illustrated in *Figure 1*.

The 2020 audit was conducted between 19 October and 13 November 2020 but, due to the temporary changes to

practice due to COVID-19, just 78 patients were included in the complex wound clinic over this period. This was a 67% decrease on the previous year, but infection rates were comparable with the 2019 data at 1.2% (one non-concordant patient was excluded). The exceptional circumstances of this year, and the subsequent effect on clinic attendances, mean that no further audit data have been included for comparison.

Discussion

Nationally reported infection rates vary for the types of hard-to-heal wound treated in the Skin Integrity Team's complex wound clinic: venous leg ulcer infection rates at presentation have been reported as being 12–30% (Guest et al, 2018a). In the case of diabetic foot ulcers, infection rates have been reported in the range 14–45% (Guest et al, 2018b), with 35% of pressure ulcers identified as developing an infection (Guest et al, 2018c).

An audit undertaken at another UK complex wound clinic (Price et al , 2019) reported wound infection rates among patients prescribed antibiotics over a 3-year period: prescription of an antibiotic was reported in 9.3% of patient encounters (270), with antimicrobial prescription reported in 33% (151). Of the 36 patients included in the audit, there were 29 instances of a confirmed infection, because 4 of the 25 patients required antibiotics on more than one occasion (Price et al, 2019).

The Doncaster Skin Integrity Team's initial move from using saline to Prontosan solution for wound cleansing, which began in early 2017, was positively evidenced by the low wound infection rate of 7.3% noted later in the year, with complete implementation leading to a further reduction in infection of 3.8% for 2018 over the audit period. In 2019, a number of initiatives (see *Figure* 7 for project timeline), including the introduction of a supported shared care approach, resulted in a further reduction in wound infection, with a reported rate of 1.3%, which continued into 2020 despite the challenging nature of wound care over the pandemic year.

Overall, between 2017 and 2019 a 84.3% reduction in infection rates was achieved as a result of the Skin Integrity Team's strategy of developing an evidence-based wound cleansing policy and disseminating it to the wider clinical area supported by a tailored training programme. The programme was developed by the Doncaster Skin Integrity Team for practice nurses and covered the concepts of wound bed preparation, biofilm management and effective dressing selection.

The findings of the audits, undertaken after the implementation of the use of a PHMB and betaine wound cleanser, are consistent with results reported previously in the literature (Andriessen and Eberlein, 2008; Valenzuela and Perucho, 2008; Fletcher and Bradbury, 2011; Halim et al, 2012; Bellingeri et al, 2016; Collier and Hofer, 2017; B.Braun Medical, 2021). A randomised controlled trial (RCT) comparing patients with venous leg ulcers cleansed with PHMB (n=143) and betaine with patients receiving standard care with saline (n=146) demonstrated the superior action of the former. Its use improved wound condition and reduced signs of inflammation over 28 days (Bellingeri et al, 2016). A retrospective analysis of 953 patients whose wounds were cleansed with PHMB and betaine in place of saline

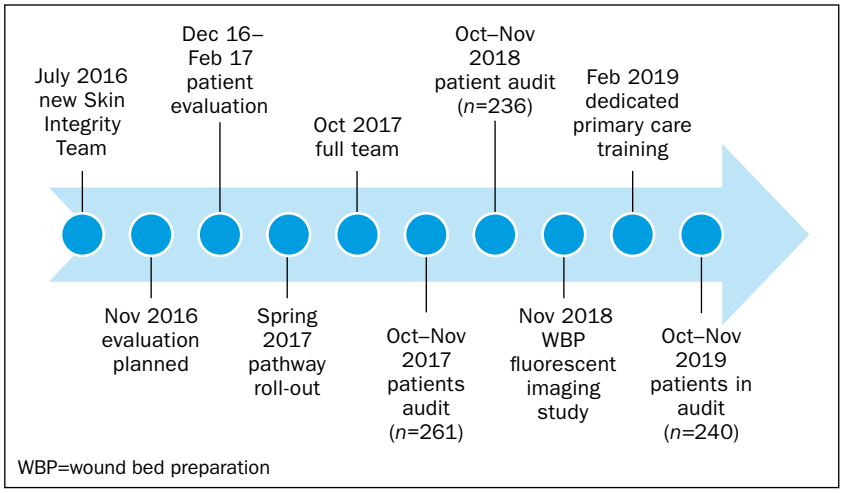

Figure 7. Timeline of the project up to the 2019 audit, with auditing continuing as part of standard practice

demonstrated a cut in infection rates from 40% to 3% over 15 months, with reduced use of antibiotics and improved wound healing (B.Braun Medical, 2021).

A retrospective cohort analysis of venous leg ulcer patients of whom 59 received soaks with PHMB and betaine solution and 53 were treated with saline reported that healing was a mean 4 weeks faster in the PHMB and betaine group. The infection rate was 3% over the 6 months of observation compared with 17% in the saline group (Andriessen and Eberlein, 2008). A study by Collier and Hofer (2017), looking at wide-scale adoption of cleansing with PHMB and betaine in a UK Trust, recorded clinical signs of local, spreading and/or systemic infection (confirmed by a positive wound swab) before and after implementation of a wound cleansing pathway. The results showed that, compared with the 16 months prior to implementation of the pathway, the post-implementation regimen achieved a 92% reduction in infection rates over 3 years.

Finally, an RCT undertaken by Valenzuela and Perucho (2008) tracked wound bed condition and wound size in 142 chronic wounds for 2 weeks. The wounds in one group of patients were cleansed with PHMB and betaine solution, while control group wounds were treated with neutral hydrogel. The study group showed improvements in wound condition, with reduced slough, improved granulation tissue, reduction in surface area and reduced bioburden compared with the controls.

Limitations

Although this study describes a clear reduction in wound infection rates, it is not possible to rank, in terms of importance, the factors responsible. This is due to the fact that several improvements to the wound care pathway were introduced across the course of the study. These included the introduction of PHMB and betaine wound cleanser and an education programme. Indeed, the improvements noted in this article could have been the result of a combination of factors. This highlights the importance of taking a multifaceted approach to wound care

In addition, baseline data (before the introduction of wound cleansing with any solution or product) for 2016 were unavailable for comparison.

KEY POINTS

- Wound cleansing and debridement are fundamental elements of wound bed preparation
- Implementation of a wound cleansing pathway reduced infection rates and showed that wound cleansing can reduce the risk of a wound bed infection at each dressing change for hard-to-heal wounds
- Regular auditing provided a useful tool to aid service improvement

Conclusion

Patient safety is at the centre of all healthcare interventions, so that healthcare providers must demonstrate the use of an evidence-based, cost-effective and efficient rationale for the choice of specific care pathways for individual patient groups (NHS England and NHS Improvement, 2021).

The World Health Organization (1988) states that 'professionals who actively bring the skills of different individuals together, with the aim of clearly addressing the healthcare needs of patients and the community, will strengthen the health system and lead to enhanced clinical and health related outcomes'.

In the first year of the new wound cleansing pathway, the 2017 audit confirmed a wound infection rate of 7.6%, which was below reported national averages. This was well received by the team, who continue to strive for further improvements. The 3-year period under review showed an 84.3% reduction in wound infection, which was in line with the results reported by Collier and Hofer (2017). This was the principal research identified as a pathway that could bring about a reduction in wound infection and that helped stimulate the initiation and development of the pathway at Doncaster. The study has demonstrated that ongoing monitoring, coupled with standardisation of care, can bring further incremental improvements in infection rates. This also needs to be supported with training and inclusive pathway development.

The Skin Integrity Team will continue to implement continuous monitoring and strive for improvement in patient wound care, with annual audit forming a part of the core service facilitated by the team. **BJN**

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CPD reflective questions

- Consider why wound bed preparation key to facilitating wound healing?
- Think about the factors that need to be considered when identifying whether a patient's wound requires the application of wound cleanser and debridement?
- Reflect on how encouraging the application of evidenced-based practice in wound care management benefits the patient and the wound healing process

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