Taking wound cleansing seriously to minimise risk

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This article is based on a symposium held at the Wounds UK annual conference in Harrogate on 14th November 2016. The symposium consisted of presentations by two speakers: Mark Collier (Nurse Consultant, Tissue Viability, United Lincolnshire Hospitals NHS Trust) providing practical information and guidance based on his experience of using Prontosan® (B Braun) in practice; and Pamela Hofer (Medical and Scientific Affairs, B Braun) outlining scientific evidence for the product.

MINIMISING THE RISK OF HEALTHCARE-ASSOCIATED INFECTION

Rates of healthcare-associated infection (HCAI) are rising (National Institute for Health and Care Excellence [NICE], 2011). In practice, part of the issue is due to the fact that HCAIs are often incorrectly identified by healthcare staff and patients alike, as symptoms may only appear after the patient's discharge from hospital. Therefore, rates of HCAI are habitually underestimated; NICE estimates the rate at 20% (NICE, 2011), but anecdotal evidence suggests that the reality in practice would be closer to 30–40%.

These statistics indicate that a new approach is necessary. A new pathway incorporating a structured wound cleansing regimen has been developed and is now in use in the United Lincolnshire Hospitals NHS Trust (ULHT), which has helped in building evidence of improving HCAI rates (Collier, 2016).

The vision is to provide gold-standard, patient-centred care. While all healthcare professionals strive to give excellent care, delivered with compassion and respect,there are still improvements that can be made in achieving this in practice, so it is important always to strive for the ideal. If a structured wound cleansing pathway may help, it should be considered as part of the care provided (Collier, 2016).

EVIDENCE-BASED PRACTICE

Nursing continues to be a discipline 'based on tradition' and it can be a challenge to change to a more evidence-based practice. The tradition in wound cleansing is to use saline or water; however, evidence now exists for newer, more effective cleansing agents that are safe and easy to use (International Wound Infection Institute [IWII], 2016).

Cost of treatment has been found to be 3.6 times more expensive than prevention (Santamaria et al, 2013), so all actions/interventions should be considered with this cost-effectiveness in mind. Prevention *versus* treatment costs are widely discussed in the area of pressure ulcers, but this could (and should) also be applied to infection. See *Figure 1* for more detailed information on the rationale for using wound cleansing treatments.

WOUND CLEANSING AND BIOFILMS

It is now acknowledged that: 'The prevention and management of biofilms in chronic wounds is rapidly becoming a primary objective of wound care, with the presence of biofilm acknowledged as a leading cause of delayed wound healing' (World Union of Wound Healing Societies, 2016).

Current evidence suggests that biofilms cannot necessarily be prevented with one wound cleansing product, but wound cleansing as a practice may affect and improve biofilm prevention and treatment. Over 90% of wounds are estimated to have a biofilm, according to statistics (Attinger and Wolcott, 2012), and the cycle of biofilm has been found to delay healing (*Figure 2*). Good assessment and treatment and, particularly, early intervention should help to improve these figures; biofilms are not, as may be assumed, 'indestructible' — a combination of factors should be able to help prevent biofilm formation and reformation.

A NEW APPROACH

NICE guidance on surgical site infections (SSIs) has been developed, which takes into account that discharging patients from hospital too early may be affecting rates of infection and how SSIs are recognised and subsequently

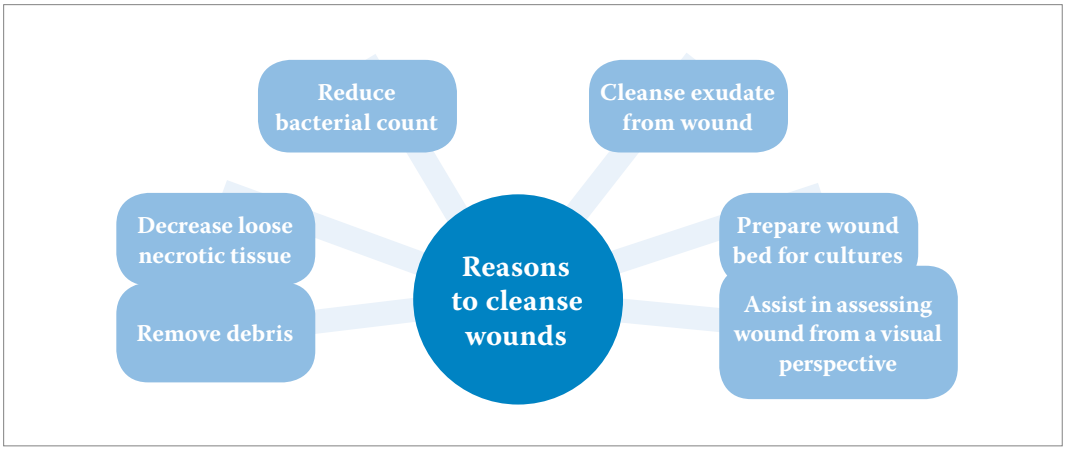

Figure 1. Rationale for cleansing wounds

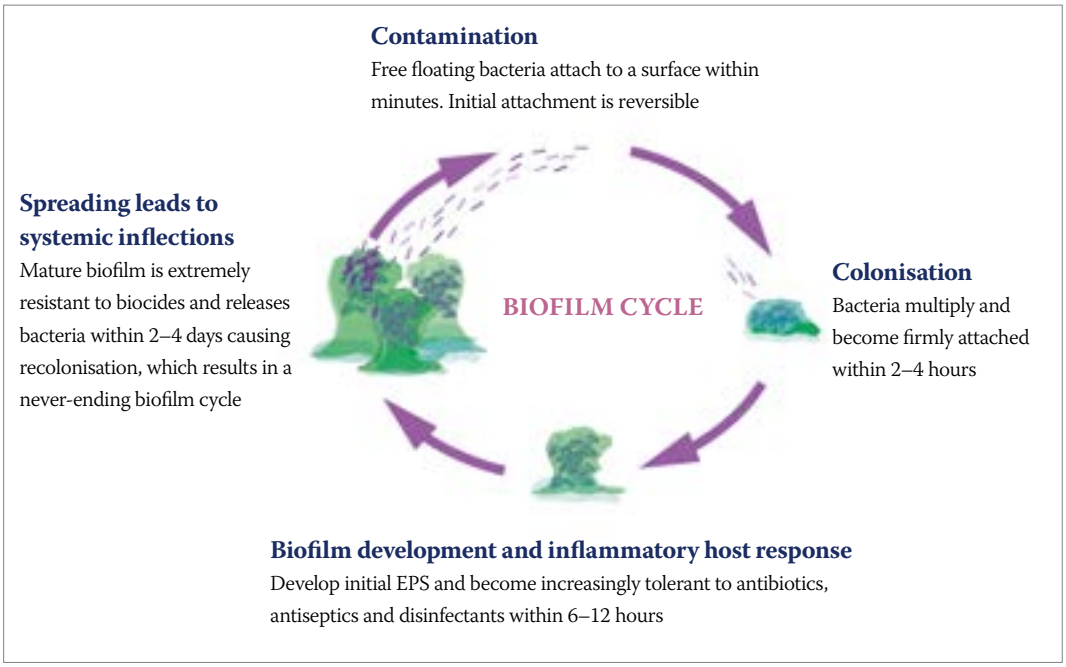

Figure 2. Biofilm cycle

managed (NICE, 2008). While patients should be discharged as soon as possible, it is important to acknowledge that in reality some are discharged too early and should be kept in an acute setting for longer — for reasons that include monitoring for possible infection.

With this in mind, it is also important to look at cleansing solutions as a possible means of preventing infection and lowering rates so this becomes less of an ongoing problem.

In developing new wound cleansing protocol at ULHT, Prontosan was found to have the widest range of efficacy to clean contaminated wounds (*Box 1*). While the main consideration was clinical benefit in practice, cost information was also considered as part of the review of products that resulted in Prontosan being selected as the product of choice in this protocol.

Therefore it was decided that Prontosan was the product that should be used as part of the wound cleansing pathway (Collier, 2016) based on the results from wound swabs (*Table 1*) and a the use of a consistent swabbing technique (*Box 2*). The early benefits to the new pathway at ULHT have been recognised and are ongoing (Collier, 2016).

PRONTOSAN IN PRACTICE

The properties of Prontosan that made it suitable

The symposium and report were supported by B Braun.

Box 1. ULHT protocol for the consideration of any wound management product for formulary inclusion

- Nurse Consultant reviews laboratory evidence for product under consideration
- Comparative clinical evidence is reviewed/ considered
- A further comprehensive literature search is undertaken
- A targeted clinical in-house evaluation is undertaken on behalf of the Trust (minimum 10 – maximum 20 patients)
- Results of all of the above are reviewed by the ULHT formulary review panel
- Specific cost-effectiveness information reviewed
- Cost pressure to Trust if product included on formulary considered with Procurement nurse adviser

Box 2. Wound swabbing techniques

Dry swab, e.g. wounds, leg ulcers:

- Remove swab and carriage tube from packaging
- Lightly run swab over wound
- Remove bung from carriage medium tube. Place swab into carriage medium tube and click closed
- Apply computer-generated label to outer case and place in transportation bag
- Apply any biohazard sticker to outer bag as required. Send to laboratory for analysis

Wet swab: e.g. MRSA, dry wounds:

- Remove swab and carriage tube from packaging
- Remove bung from carriage medium tube and dip swab into the carriage medium and remove
- Lightly run over area to be swabbed or place in nares of nose and run swab around inner area
- Place swab into carriage medium tube and click closed
- Apply computer-generated label to outer case and place in transportation bag
- Apply any biohazard sticker to outer bag as required. Send to laboratory for analysis

for use in the wound cleansing pathway included:

- Excellent skin tolerance
- Non toxic, non irritant
- Hypoallergenic
- No known resistance
- Suitable for long-term use, not absorbed
- No inhibition of granulation tissue, unlike antiseptics
- Efficacy in preventing and treating biofilm.

The main component of Prontosan in terms of its clinical efficacy is that it combines the active ingredients of polyhexamethylene biguanide (Polyhexanide or PHMB) and betaine (*Figure 3*).

Polyhexanide is a highly effective broad spectrum antimicrobial that has been found to reduce bioburden and promote healing (Wounds UK, 2016). It is active against gram negative and gram positive bacteria, fungi and yeast (including MRSA and Pseudomonas aeruginosa). Polyhexanide has been in general use for about 60 years; it has demonstrated good clinical safety data with minimal toxicity and no evidence of resistance. Polyhexanide is not absorbed by human cells and tissue, therefore it cannot interfere with the metabolism of the body.

Betaine is a gentle, effective surfactant (detergent), which is able to penetrate and remove biofilm and wound debris (IWII, 2016). The Betaine molecule reduces surface tension to support softening, loosening and detaching of debris and biofilm; once removed, the debris and biofilm are held in the solution, preventing recontamination.

SUSTAINING IMPROVEMENT

The pathway resulted in significant improvements in HCAI/SSI rates at ULHT (*Table 1*). As well as using the wound cleansing solution, if a patient had a history of repeated infection, a protocol was also developed of giving the patient Prontosan gel for continued use after discharge where appropriate. This was found to help patients manage their own care, and was more cost-effective than potential infection and readmission into the hospital setting.

The key to success in implementing the new pathway was not only achieving, but crucially also sustaining, the changes made. At ULHT, it was vital to introduce this as part of the organisational framework and culture. This approach consisted of:

Organisation

- Ensure 'change' fits with culture and stated goals
- Implement the infrastructure to support change

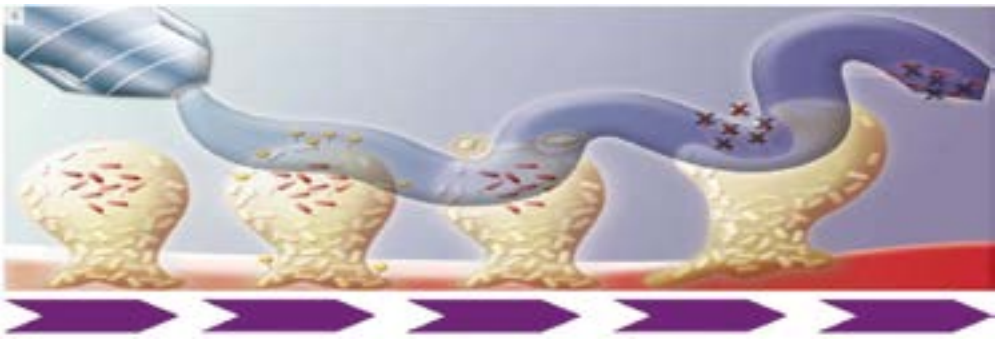

Figure 3. Mode of action of polyhexanide as adjuvant antimicrobial

Table 1. HCAI/SSI rates at ULHT (Collier, 2016)

Organisms	Aug 2012 – Nov 2013	June 2015 – Sept 2016	June 2015 – Sept 2016
Other organisms	33	0	-100%
Enterococcus	6	5	-17%
Staphylococcus aureus (MRSA)	31	23	-26%
Escherichia coli/ vulneris	52	6	-88%
Pseudomonas	68	2	-97%
Anaerobic organism	51	4	-98%
Staphylococcus (excluding *MRSA*)	221	6	-97%
Enterobactor	23	1	-96%
Streptococcus	42	2	-95%
Yeast (undifferentiated)	17	0	-100%
Total	**544**	**49**	**-92%**

Process

- Monitor progress
- Identify benefits beyond patients
- Ensure credibility of evidence
- Promote adaptability of both individuals and organisation

Staff

- Involve all staff with the initiative/change
- Stimulate/support positive attitudes
- Motivate individuals
- Involve all, including senior management and clinical leaders
- Provide dedicated training sessions

On a practical level, successful changes were maintained by:

- Promoting evidence-based and cost-effective wound management and infection prevention practices
- Promoting 'high quality care for all'
- Promoting an integrated approach, involving all members of the MDT
- Educate practitioners/managers/all disciplines/patients
- Continuing to review practice/new evidence

The overall key objective was to provide 'high quality care for all'. It was noted that the reduction in infection rates was not solely attributed to the use of Prontosan. The initiation of the full protocol of infection monitoring and prevention contributed to the improved situation, which included the use of Prontosan. However, it is worth noting that these results were found to be 'very impressive' in all areas. MRSA was still found to be a problem overall, but even here rates were significantly reduced (*Table 1*).

Table 2. Antimicrobial activity of Prontosan in vitro (Koburger et al, 2007)			
Test organism	Exposure time (min)	Concentration (%)/log reduction, unloaded	Concentration (%)/log reduction, unloaded
S. Aureus	1 1 5 10	0.05/>6 0.05/>6 0.05/>6	0.05/>3.2 0.1/>6 0.05/4.5 0.05/6
E. Coli	1 5	0.05/5.9 0.05/>6	0.05/>4.9 0.05/>6
E. Hirae	1 5	0.05/3.6 0.05/>6	0.05/3.4 0.05/>6
P. aeruginosa	1 5	0.05/>6 0.05/>6	0.05/>6 0.05/>6
C. albican	1 5	0.05/>5 0.05/>5	0.05/3.7 0.05/>5

CLINICAL EVIDENCE FOR PRONTOSAN

The essential element of Prontosan as a wound irrigation solution is that it combines Betaine and Polyhexanide, which in tandem have been clinically proved to be more effective in removal of biofilm than traditional cleansing with saline (Bellingeri et al, 2016).

As indicated in *Table 2*, Prontosan has comparable values to other products, however, it does not always achieve a log reduction from >5, which is fine as it is classified as a medical device and not as an antiseptic. Mechanical rinsing is a main factor to clean contamination and colonisation in acute wounds.

López-Rojas et al (2016) have demonstrated the efficacy of Prontosan and stated that the bactericidal activity occures within a much shorter period of time then recommended by the manufacturer. Using in vitro data to define and treat chronic wounds may lead to a suboptimal treatment concept. Prontosan does have clinical evidence to prove the efficacy in wound bed preparation.

A randomised controlled trial (RCT; Bellingeri et al, 2016) involved six centres in Italy, where patients were treated for 28 days and assessed at four time points during the treatment duration. Patients in two groups were treated either with Polyhexanide solution or saline. The results of the study support the superiority of Prontosan compared to Saline. Prontosan did achieve significant better results in wound bed preparation by reducing the inflammatory signs and accelerated healing in venous leg ulcers and pressuer ulcers.

Pain was assessed as a secondary outcome of the RCT. No significant difference in pain levels was observed, but the starting scores were low (3 on the pain scale of 1 to 10). No adverse events were reported over the course of the RCT.

SOAKING TIME: DOES IT MATTER?

This RCT and further evidence in the 10 years since Prontosan has been developed have provided more information on the product's efficacy time. The original instructions for use for the product started as 'a pragmatic approach' based on chemical principles to clean encrusted surfaces rather than practical experience. However, the data presented and further available evidence show that the soaking time is depending on the wound type and the goal of treatment.

It has been shown that in terms of timing recommendations, it is important to look at both the patient and the wound, to assess individually and then use the appropriate pathway in order to meet specific treatment goals (see *Figure 4* for further guidance), depending on whether Prontosan is needed solely to cleanse the wound or to soften slough, disrupt potential biofilm or remove debris.

In choosing the treatment pathway, it is also helpful to remember that Prontosan gel can be

DESCRIPTION OF WOUND	OBJECTIVE	HOW TO USE
ACUTE WOUND – SURGICAL PRIMARY AND SECONDARY INTENTION HEALING		Rinse with solution
• High risk patient* • No slough • Minimal exudate 	• Cleans • Prevents biofilm/ complications	
ACUTE WOUND, e.g. trauma		Soak with solution
• Debris • Haematoma 	• Cleans • Prevents biofilm/ complications	
CHRONIC WOUND — GRANULATING		Soak with solution Consider GelX
• High risk patient* • Low exudate 	• Cleans • Prevents biofilm/ complications	 
CHRONIC WOUND		Soak with solution Apply GelX
• Light slough • Low exudate 	• Cleans • Prevents, disrupts and removes biofilm/ complications	 
CHRONIC WOUND — CRITICALLY COLONISED/INFECTED		Soak with solution Apply GelX
• Medium/high exudate • Static wound • Slough 	• Cleans • Prevents, disrupts and removes biofilm/ complications	 

Figure 4. Timing guidance for using Prontosan on a variety of wounds.

used after wound bed preparation as a barrier for the clean wound. WUK

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