# Relevance of a Health Technology Assessment report: antimicrobial wound dressings for diabetic foot chronic wounds with local infection

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### Article points

1. Antimicrobial wound dressings continue to be used by clinicians, despite a lack of evidence to support their use.
2. There are a variety of antimicrobial dressings available with silver, honey and iodine-based preparations the most commonly used in diabetic foot management.
3. Clinicians must have the ability to identify local wound infection in diabetic foot and determine the best method of prevention and treatment.

### Key words

- Consensus recommendations
- Topical antimicrobial wound dressings

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**This article discusses the challenges of implementing recommendations of a recent Health Technology Assessment report highlighting available evidence for the use of antimicrobial wound dressings (AWDs). Despite a lack of clear evidence to support their use, they are routinely used as part of management plans in local diabetic foot wound infection. Therefore, it would suggest that clinical judgement views there is a role for the continued use of AWDs. If so, in the interest of patient safety, there is a need for clear guidance on when to initiate, the duration of use and when to stop. The report provides recommendations that reflect this apparent disparity between theory and practice. The authors seek to stimulate discussion in this challenging area and to explore if there is a place for AWDs or are there alternative methods of preventing and treating local wound infection?**

Healthcare Improvement Scotland produced the Health Technology Assessment (HTA) Report 13 on the use of antimicrobial wound dressings for chronic wounds, which has recently been published (Healthcare Improvement Scotland, 2015). The HTA report provides a great deal of information, which would be impossible to cover in one article. However, for the purposes of this discussion, the HTA recommendations and consensus statements will be highlighted for the attention of *The Diabetic Foot Journal* readership, to open up discussion on this important area.

The overarching research questions addressed in the HTA report were:

- What is the clinical and cost effectiveness of different antimicrobial wound dressings (AWDs) and their safety, compared with other dressings and techniques, for treating localised wound infection in chronic wounds in adults?
- What are the patient and organisational issues associated with the use of different AWDs in adult patients with chronic wounds?

The report was restricted to reviewing *in vivo* studies of chronic diabetic foot ulcers, pressure ulcers, leg ulcers and wounds healing by secondary intention. The three main chronic ulcer types constituted 90% of wounds. *In vitro* studies were excluded, as the focus of the work was on patient outcomes and consideration of the results on *vitro* studies would not remove uncertainties in the findings.

It is not within the remit of this article to discuss the roles of systemic antimicrobials or the multidisciplinary diabetic foot team.

Product choices consisted of AWDs listed in Part 5 of the British National Formulary (2015), which included iodine, silver, honey, polyhexamethlene biguanide (PHMB), dialkylcarbamoyl chloride (DACC) and glucose oxidase/lactoperoxidase.

The main finding from the clinical and cost-effectiveness aspect of the HTA was that there is insufficient clinical evidence to support the use of AWDs to treat local infection in chronic wounds. Despite this, they are currently used for this indication in NHS Scotland. This HTA has highlighted that the approach used varies between and within NHS health boards. There are no clear starting and stopping rules for AWDs, and the range of AWDs available for clinicians to use varies. This inconsistency can be frustrating for

staff, and can be an additional burden to patients. There is a need for a more consistent approach until the clinical evidence becomes more informative.

This view raises a challenge since respondents in the HTA noted that they included the use of AWDs for both compromised and non-comprised perfusion in the management of diabetic foot ulcers.

"Chronic wounds often contain necrotic or sloughy tissue, which can harbour bacteria and act as a barrier to healing," explained Vowden and Vowden (2011). Do the HTA (2015) findings present an argument for greater research into the role of safe and cost-effective alternative methods of reducing bacterial bioburden, which may replace or complement the use of AWDs for diabetic foot ulcers?

In light of this, rather than a major paradigm shift and opting for a 'ban' on the use of AWDs, perhaps the report may well support a view similar to Verheij (2009); namely to identify the small group of patients who really need antibiotic treatment and to explain, reassure and educate the large group of patients who do not.

The issues explored in the Health Technology Assessment Report 13 (Health Improvement Scotland, 2015) were facilitated by means of expert panel views; synthesis of quantitative and qualitative literature; clinician questionnaire; and focus group/patient interviews.

Specialist podiatrists and nurses were included in the HTA expert group. A clinician questionnaire was completed by 263 respondents. The majority of respondents were district nursing staff (31.9%) with podiatrists accounting for 20.5%.

Respondents' clinical activity highlighted that the majority of patients were managed in primary care with 20% attending specialist outpatient

**Table 1. Health Technology Assessment recommendations.**

| | Overall recommendations |
|---|---|
| 1 | The routine use of antimicrobial wound dressings (AWDs) to heal chronic wounds is not recommended |
| 2 | In the absence of sufficient clinical evidence to guide decisions making, NHS Scotland should adopt a consistent approach to guide usage of AWDs in treating localised wound infection in chronic wounds. A national management algorithm should be agreed |
| 3 | When selecting a dressing for people with chronic wounds, alongside holistic clinical assessment, consider the factors of importance to the patient, such as odour, pain/discomfort, leakage and mobility, as well as healing |
| 4 | Having first taken into account patient- and wound specific-factors, the cost of dressings relative to their benefits should guide their use |
| 5 | There is a need for good-quality randomised controlled trials on the use of AWDs to treat localised infection in chronic wounds. The subsequent impact of reduced infection on patient outcomes (for example, healing, improvement in signs and symptoms) also needs to be explored. There is also a need for good-quality economic evaluations. |
| 6 | A national patient leaflet should be developed, which can be used as an aid to support shared decision-making between patients with chronic wounds and healthcare professionals. |
| 7 | There is a need for accessible and evidence-based education and training on the appropriate use of AWDs in chronic wounds |
| 8 | The Therapeutics Branch in the Pharmacy and Medicines Division at Scottish Government would be well placed to take forward the implementation of the recommendations in this HTA. |

**Table 2. Where consensus could not be achieved.**

| Lack of consensus | Links with consensus statements in Table 1 |
|---|---|
| Which types of AWD to use in different wound types. | 2,3,4,7 |
| How long to use AWDs in chronic wounds in which signs and symptoms of infection were improving, but not clearing entirely. | 1, 2, 6,7 |

clinics (i.e. podiatry, diabetic multidisciplinary teams and leg ulcer clinics).

## Discussion

Dressing choice for diabetic foot ulcers can be challenging due to the complexity of wound types (perfusion, tissue type, deformity etc). It is not within the scope of this article to enter into discussion about wound assessment, however, Botros et al (2010) stressed the importance of completing a comprehensive diabetes assessment. Sood et al (2014) also stated that "wound characteristics must be addressed" before choosing a wound dressing.

"Dressing choice will generally change as the wound characteristics change during healing," stated Bergin et al (2012). This may result in variations in practice, dependent on the knowledge base of clinicians and patient choice. However, it is important to ensure products are used appropriately and cost effectively (Jeffcoate et al, 2009). Dressing choice is further complicated since there is "little evidence to support the choice of any one dressing or wound application in preference to any other in attempts to promote healing of chronic ulcers of the foot in diabetic patients" (Apelqvist et al, 2012). If an AWD is considered appropriate, the clinician should be aware that "an antimicrobial dressing may reduce the level of bacteria at the wound surface, but will not eliminate a spreading infection" (Scottish Government, 2014). An active diabetic foot ulcer should, therefore, be referred to the multidisciplinary foot team (NICE, 2015).

One podiatrist noted: "When dealing with high-risk diabetic wounds, which can easily become infected with the risk of amputation (especially if that person has had a previous amputation), there is always the thought at the back of your mind that it's safer to use antimicrobials to prevent infection as the possible consequences will be disastrous" (HTA, 2015). There did not appear to be agreement on what would prompt the process of prescribing AWDs for prophylaxis.

If the assumption is that AWDs will continue to be used, a rationale for use is required to support clinicians in safe practice. Chadwick (2013) suggested that "topical antimicrobials may be beneficial in certain situations", for example, "where there are concerns regarding reduced antibiotic tissue penetration" to reduce the bacterial load. HTA (2015) respondents noted that in treating chronic wounds, they limited their use of AWDs to wounds showing signs and symptoms of infection. Botros et al (2010) recommended that ulcers should be evaluated at each visit for clinical signs of infection with appropriate follow-up microbiology if required.

There is, therefore, a need for education to ensure that signs and symptoms of wound infection in diabetic foot ulcers are clearly understood and this is differentiated and recognised between chronic wound types (European Wound Management Association, 2015, TRIEPodD-UK (2012).

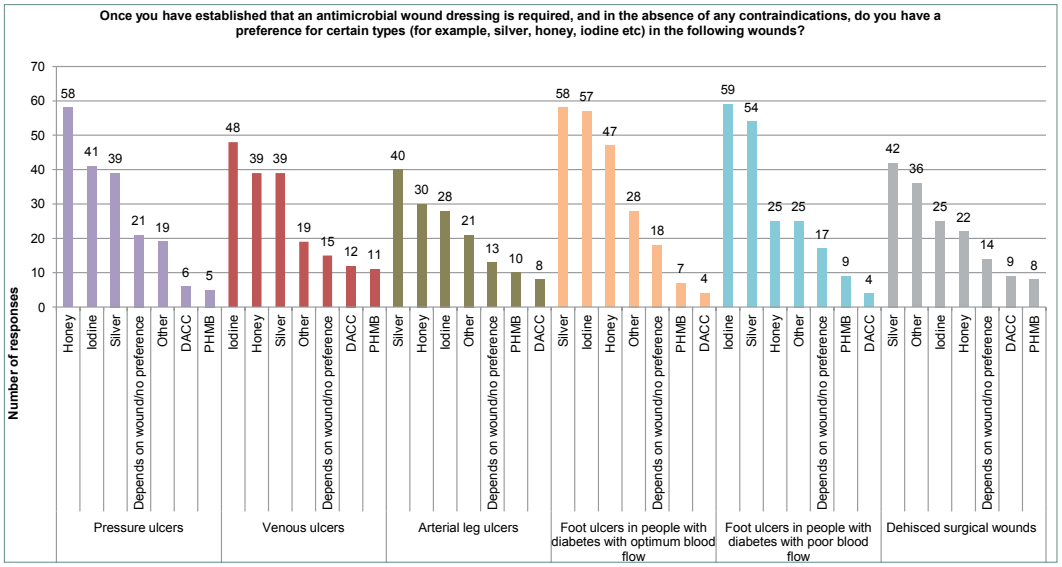


*Figure 1. Once you have established that an AWD is required, do you have a preference for certain types? (Healthcare Improvement Scotland, 2015).*

Duration of treatment, number of interventions and volume required should be taken into account for safe prescribing. This will prevent ongoing use of an AWD when not required, or the risk of potential side effects, which can result in delayed healing or desiccation to underlying structures, such as tendon and bone. This is an area that requires greater discussion.

This journal's readership will be familiar with the much quoted 'Vulcan study' on the use of silver dressings on leg ulcers (Michaels et al, 2009). There was some debate that the study "did not use silver as recommended" (Leaper and Drake, 2011). There are a number of reviews on the use of silver dressings that have highlighted the lack of robust evidence to support their routine use (Botros et al, 2010; Storm-Versloot et al, 2010; Game et al, 2012; Health Improvement Scotland, 2012).

The Vulcan Study demonstrated that there is "little to be gained in using AWDs on wounds with no signs of clinical infection" (Scottish Government, 2014). Avoiding the use of silver may increase the chance of the clinician migrating to routine use of other types of AWDs. One podiatrist noted: 'I feel that silver dressings when used appropriately can be very useful in diabetic foot ulcers. It is very unfortunate that there is very little evidence for their use, therefore, their use is restricted.' (HTA 2015)

Clinicians' responses from the report questionnaire noted that for diabetic foot ulcers — irrespective of compromised perfusion or not — iodine, silver and honey were most frequently chosen (*Figure 1*). This demonstrates that the respondents in this study continue to use AWDs, in the management of the diabetic foot ulcers.

## Recommendations

The recommendations, consensus and non-consensus statements provide opportunities for discussion and collaborative working across all specialties to support cost-effective, safe, patient-centred care. The eight recommendations (*Table 1*) are relevant to all chronic wound ulcers. Greater detail regarding the literature review on diabetic foot ulcers and consensus statements are available in the HTA (2015).

### Statements where consensus was reached

Consensus was reached that AWDs should be avoided in the absence of signs of clinical infection. Internationally recognised tools, such as Wound Bed Preparation and TIME, support a consistent systematic approach to wound assessment (Falanga, 2001; Schultz and Dowsett 2012; Ousey and Atkin, 2013). Stratifying chronic wounds with use of grading tools to promote a common language and inform care pathways is recommended. NICE (2015) has recommended the use of grading tools, such as SINBAD or TEXAS, for diabetic foot.

### Where consensus could not be reached

There were two main themes where consensus could not be reached (*Table 2*). This demonstrated overall, that there is consensus on clinicians' perception on what we should

do, but conversely there was a lack of consensus on the detail of how to do it, in terms of which product should be used, when and for how long. This provides an opportunity to identify where consensus statements can be developed to provide a focus for further research and team work.

### Challenges of making appropriate product choices

A wide range of AWDs are available, with each category having different levels of antimicrobial activity. Since the clinician is either prescribing or influencing a prescribing decision, it is essential that there is an understanding of the actions of the antimicrobial agent (Gottrup et al, 2013). The rationale why a particular clinician chooses to use an AWD in preference to an alternative method of reducing bacterial bioburden (e.g. debridement) should be consistent and clear, regardless of the patient environment or circumstances.

All AWDs, including the 'preferred' choices, iodine, silver and honey (*Figure 1*), have many presentations with base or 'carrier', such as a gel, foams or alginate. A clinical decision is, therefore, required to establish which presentation will be the most effective, to maximise interaction at the wound bed and manage different levels of exudate or manage odour or pain (Wounds UK, 2011) with "specific products chosen to reflect the overall treatment of the wound" (Wound Care Alliance, 2011).

Conversely, it is also crucial to ensure application of a product does not contribute to pain, odour and exudate due to the carrier or active antimicrobial. These factors were also highlighted in the patient issues section of the HTA. These can have a major impact on patients' wellbeing, if left uncontrolled.

The presence of slough, necrosis, exudate and tracking channels on the wound also have to be taken into account when a dressing choice is being made.

Some AWDs have the ability to debride the wound, as well as manage different levels of exudate. A sound rationale for choice of debridement "can be generated via the diagnosis of different kinds of tissue types and bioburden which cover the wound bed, the state of the wound edges and the periwound skin" (Strohall et al, 2013).

"There are a number of techniques for actively debriding a wound," according to Wounds UK (2013). Respondents in the study questionnaire gave examples of Debrisoft® (Activa Healthcare), Versajet® (Smith & Nephew) and superabsorbers, which they used as alternatives to AWDs. It is essential that the most suitable choice of debridement is made for a particular wound, and the clinician has the competency skills to carry out the procedure (TRIEPodD-UK, 2012)

### Duration of product use

The HTA identified consensus on "2-week" challenges of AWDs when a decision is made to commence. This should not be interpreted to mean that only 2 weeks is permitted when using an AWD, but rather "if used, there should be regular review of the efficacy of an antimicrobial wound dressing and it should be stopped after 2 weeks if there is limited or no benefit" (Scottish Government, 2014). The HTA (2015) concurred with this view, with a consensus on discontinuing AWDs if symptoms of localised infection had been resolved; continuing for a further 2 weeks if symptoms are resolving; and a review management plan if symptoms were static or deteriorating.

## Conclusion

The HTA produced both evidence-based and consensus recommendations to support best practice when AWDs are being considered. This also highlighted the need for robust research, as well as consideration of other factors that affect patient wellbeing when choosing a product.

Comments by some report respondents included the view that there was "overuse" and "inappropriate use" of AWDs. No clinician intentionally sets out to cause harm, however, variations in practice may indicate differences in views between healthcare professionals as to what is an appropriate treatment.

An algorithm or pathway, suitable for all chronic wound types, on the management of local wound infection, has been included as a consensus recommendation. An agreed

framework could help inform content of local wound formularies and identify necessary requirements if there are any gaps in delivery of education or organisational changes.

The HTA report provides an opportunity to clarify 'appropriate use' and provide robust guidance on the use of AWDs and alternative products to reduce the bacterial bioburden. ■


Apelqvist J (2012) Diagnostics and treatment of the diabetic foot. *Endocrine* **41**: 384–97

Bergin SM, Gurr JM, Allard BP et al (2012) Australian Diabetes Foot Network: management of diabetes-related foot ulceration – a clinical update. *Med J Aus* **197**: 226–9

Botros M, Goetti K, Parsons L et al (2010) Best practice recommendations for the prevention, diagnosis and treatment of diabetic foot ulcers: update 2010. *Wound Care Canada* **8**: 6–70

Chadwick et al (2013) *Guidelines: Wound Management in Diabetic Foot Ulcers*. Wounds International. Available at: www.woundsinternational.com

Chadwick P (2013) *International Case Series: Using Askina® Calgitrol® Paste in the Treatment of Diabetic Foot Infection: Case Studies*. London: Wounds International. Available at: http://www.woundsinternational.com

Falanga V. Introducing the concept of wound bed preparation (2001) *Int Forum Wound Care* **16**: 1–4

Game FL, Hinchliffe RJ, Apelqvist J et al (2012) A systematic review of interventions to enhance the healing of chronic ulcers of the foot in diabetes. *Diabetes Metab Res Rev* **28**: 119–41

European Wound Management Association (2005). *Position Document: Identifying Criteria for Wound Infection*. London: MEP Ltd. Available at: http://bit.ly/2cpgTS2 (accessed 19.09.2016)

Gottrup F, Apelqvist J, Bjansholt T et al (2013) EWMA document: Antimicrobials and non-healing wounds. Evidence, controversies and suggestions. *J Wound* **22**: S1–S92

Healthcare Improvement Scotland (2013) *Are Silver Dressings Clinically Effective and Cost Effective for the Healing of Infected Wounds and the Prevention of Wound Infection Relative to Other Types of Dressing? Technologies Scoping Report 12*. Available at: http://www.healthcareimprovementscotland.org/our_work/technologies_and_medicines/shtg_scoping_reports/technologies_scoping_report_12.aspx (accessed 19.09.2016)

Haesler E (2014) National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers: Quick Reference Guide. Accessed: http://www.npuap.org/wp-content/uploads/2014/08/Updated-10-16-14-Quick-Reference-Guide-DIGITAL-NPUAP-EPUAP-PPPIA-16Oct2014.pdf

Healthcare Improvement Scotland (2015) *Antimicrobial Wound Dressings (AWDs) for Chronic Wounds. Health Technology Assessment Report 13*. Available at: http://www.healthcareimprovementscotland.org/ (accessed 19.09.2016)

Jeffcoate WJ, Price PE, Phillips CJ et al (2009) Preparations in the management of chronic ulceration of the foot in diabetes. *Health Technol Assess* **13**: 54, 1–86, iii–iv. Available at: http://www.journalslibrary.nihr.ac.uk/__data/assets/pdf_file/0006/64626/FullReport-hta13540.pdf

Leaper D, Drake R (2011) Should one size fit all? An overview and critique of the VULCAN study on silver dressings. *Int Wound J* **8**: 1–4

Michaels JA, Campbell B, King B et al (2009) Randomized controlled trial and cost-effectiveness analysis of silver-donating antimicrobial dressings for venous leg ulcers (VULCAN trial). *Br J Surg* **96**: 1147–56

NICE Guideline (2015) Diabetic foot problems: prevention and management. Available at: www.nice.org.uk/guidance/ng19 (accessed 19.09.2016)

Ousey K, Atkin L (2013) Optimisng the patient journey made easy. Wounds UK **9**: 1–6

Schultz G, Dowsett C (2012) Technology Update: wound bed preparation revisited. *Wounds International* **3**: 25–9

Scottish Government (2014) National therapeutic Indicators 2014/15. Therapeutic Branch. Available at: http://www.sehd.scot.nhs.uk/publications/DC20141201nti.pdf (accessed 19.09.2016)

Sood et al (2014) Wound dressings and comparative effectiveness data. *Advanced Wound Care* **3**: 511–29

Storm-Versloot MN, et al (2010). Topical silver for preventing wound infection. *Cochrane Database Systematic Review* **17**: CD006478.

Strohal R, Apelqvist J, Dissemond J et al (2013) EWMA Document: Debridement. *Journal Wound Care* **22**: S1–S52

TRIEPodD-UK (2012) *Podiatry Competency Framework for Integrated Diabetic Foot Care: A User's Guide*. Available at: http://www.diabetesonthenet.com/media/fduk/TRIEPodD-UL_compframe.pdf (accessed 21.07.2016)

Vowden K, Vowden P (2011) *Debridement Made Easy*. Wounds UK. Available: http://www.wounds-uk.com/pdf/content_10133.pdf (accessed 19.09.2016)

Wound Care Alliance (2011) *Best Practice Statement: The Use of Topical Antiseptic/antimicrobial Agents in Wound Management*. 2nd edition. Wounds UK, London. Available at: http://bit.ly/2de2t9i (accessed 19.09.2016)

Wounds UK (2013) *Effective Debridement in a Changing NHS: A UK Consensus*. Wounds UK, London. Available at: www.wounds-uk.com

Verheij TJM (2009) The antibiotic revolution should be more focused. *Br J Gen Pract* **59**: 716–7. Available at: www.ncbi.nlm.nih.gov/pmc/articles/PMC2751913