



Chronic wounds: advanced wound dressings and antimicrobial dressings

Evidence summary

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Key points from the evidence

The content of this evidence summary was up-to-date in March 2016. See <u>summaries</u> of <u>product characteristics</u> (SPCs), <u>British national formulary</u> (BNF) or the <u>MHRA</u> or <u>NICE</u> websites for up-to-date information.

Overall summary

This evidence summary discusses the best available evidence for advanced wound dressings and antimicrobial dressings for managing common chronic wounds (diabetic foot ulcers, pressure ulcers, venous leg ulcers and infected wounds). It includes evidence and recommendations from national guidance (if available) and the most up-to-date systematic reviews and meta-analyses (search date July 2015).

Dressings should provide the optimal environment for wound healing. For the purposes of

this briefing, advanced dressings are those that do this by simple physical or chemical means, typically by controlling moisture levels (for example, alginate, film, foam, hydrocolloid and hydrogel dressings).

Systematic reviews and meta-analyses have identified little good quality evidence from randomised controlled trials (RCTs) to support the use of advanced or antimicrobial dressings (such as iodine, honey or silver dressings) for chronic wounds. As well as being few in number, many of the RCTs have significant limitations and the evidence is generally of low quality (see evidence is generally of low quality (see evidence is generally of dressings are uncertain and not optimal in terms of informing clinical practice. Further good quality research is needed to improve confidence in the evidence, and would probably change the implications for practice.

The systematic reviews and meta-analyses included in this evidence summary found some low and very low-quality evidence that some advanced dressings (for example, hydrocolloid, hydrogel, film and foam dressings) are more effective than simple conventional dressings (such as basic wound contact or gauze dressings) for treating some wounds. However, many of the conventional dressings used as comparators are no longer routinely recommended for chronic wounds (for example, gauze dressings) and there is generally insufficient evidence to distinguish between different types of advanced dressings. Studies are also lacking on the cost effectiveness of advanced dressings for managing chronic wounds.

Dressing selection should be made after careful clinical assessment of the person's wound, their clinical condition, and their personal experience and preferences. If a specific dressing cannot be adequately justified on clinical grounds, it would seem appropriate for NHS healthcare professionals to routinely choose the least costly dressing of the type that meets the required characteristics appropriate for the type of wound and its stage of healing (for example, size, adhesion, conformability and fluid handling properties). The frequency of dressing change needs to be carefully considered and should be appropriate for the wound and dressing type. Prescribing the minimum quantity of dressings necessary to meet a person's needs can avoid wastage and stockpiling. Silver dressings should be used only when there are clinical signs or symptoms of infection.

Introduction and current guidance

Over the past 20 years, studies have generated much evidence to show that a moist wound environment is essential for wound healing. This has caused a proliferation of

wound dressings with a higher acquisition cost than standard dressings and has left wound care providers confused about when it is appropriate to use these more expensive dressings (Agency for Healthcare Research and Quality 2014).

Advanced wound dressings (for example, alginate, film, foam, hydrocolloid and hydrogel dressings) regulate the wound surface by retaining moisture or absorbing exudate, so protecting the wound base and tissue surrounding the wound. Maintaining a good moisture balance minimises patient discomfort before, during and after dressing changes. Some dressings are used for their antimicrobial properties (for example, iodine, honey and silver dressings). Choice of dressing may change as the nature of the wound base and wound exudate changes. Therefore, the selection of dressings requires training and expertise in wound care (Agency for Healthcare Research and Quality 2014).

The <u>advanced wound dressings section</u> of the BNF provides information on the types and properties of different advanced dressings, and a <u>table</u> that suggests choices of primary dressing depending on the nature of the wound. Factors that should be considered when choosing a dressing include:

- · the stage of wound healing
- amount of exudate
- infection
- odour
- the adhesiveness of a dressing (ease of removal)
- irritation caused by the adhesive
- absorption
- the frequency of dressing changes
- ease of use of the dressing
- amount of pain at dressing changes
- protection of the surrounding skin
- patient preference.

In primary care in England, prescription costs of advanced wound dressings and antimicrobial dressings are over £110 million each year, and other procurement routes add to the total NHS expenditure on these products. The wide range of wound dressings and their associated costs present a challenge for healthcare professionals who are managing wounds. Choice requires knowledge of the safety and clinical and cost effectiveness of a wide range of dressings. However, the clinical evidence supporting the use of wound dressings is less well known and of poorer quality than in many other areas of prescribing.

NICE has issued guidance on <u>preventing and managing pressure ulcers</u> and <u>preventing and managing diabetic foot problems</u>. The Scottish Intercollegiate Guidelines Network (SIGN, <u>accredited by NICE</u>) has issued guidance on the <u>management of chronic venous leg ulcers</u>. Although these guidelines give important recommendations about wound care, they do not make recommendations on specific products. Other chronic wounds considered in this evidence summary are arterial leg ulcers and infected wounds.

Full text of introduction and current guidance.

Evidence review

In most of the systematic reviews and meta-analyses outlined in this evidence summary, the quality of the evidence is rated using the <u>Grading of Recommendations Assessment</u>, <u>Development and Evaluation (GRADE) system</u>:

- high quality: further research is very unlikely to change our confidence in the estimate of effect
- moderate quality: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
- low quality: further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
- very low quality: any estimate of effect is very uncertain.

If atypical methods of assessing quality have been used, this has been noted in the discussions.

Diabetic foot ulcers

- The 2015 NICE guideline on <u>preventing and managing diabetic foot problems</u> found that evidence surrounding different types of dressings for diabetic foot ulcers was generally of low or very low quality and often limited or inconclusive. The guideline recommends wound dressings (type not specified) as an option for managing diabetic foot ulcers, alongside a range of other options provided by a multidisciplinary team. When deciding about wound dressings and other options, the clinical assessment of the wound and the person's preference should be taken into account, and dressings with the lowest acquisition cost appropriate to the clinical circumstances should be used.
- A Cochrane overview (<u>Wu et al. 2015</u>; 17 randomised controlled trials [RCTs], total number of participants unclear) also concluded that there is currently no robust evidence that any advanced dressing type is more effective than basic wound contact dressings for healing foot ulcers in people with diabetes. Few RCTs were available for each comparison and they generally had small numbers of participants. When direct evidence of a difference was reported, the evidence was considered to be low or very low quality. Therefore, the findings are reported to be uncertain and not optimal in terms of informing practice. The authors concluded that practitioners may want to consider the unit cost of dressings, their management properties and the person's preference when choosing dressings.
- See the full evidence review on <u>diabetic foot ulcers</u> for more information.

Pressure ulcers

- The NICE guideline on preventing and managing pressure ulcers found that, overall, the quality of clinical evidence for wound dressings was low to very low because most of the studies had very serious limitations. No recommendations could be made about using specific types of dressings, except that gauze dressings should not be used for pressure ulcers. The NICE guideline development group emphasised that the effectiveness of each dressing would depend on the type of pressure ulcer and, therefore, chose to recommend a dressing that promotes the optimum healing environment, rather than a specific type of dressing. NICE advises that clinicians should discuss the type of dressing with the person with the pressure ulcer and, if appropriate, their family or carers, taking into account the person's pain and tolerance, the position of the ulcer, the amount of exudate and the frequency of dressing change. A dressing that promotes a warm, moist wound healing environment should be considered for grade 2, 3 and 4 pressure ulcers.
- Two Cochrane reviews on advanced wound dressings for **treating** pressure ulcers have been published. The first review (<u>Dumville et al. 2015a</u>) (11 RCTs, n=523) found there was no evidence of a difference between hydrogel and other dressings in terms of complete wound healing or adverse events (low- or very low-quality evidence). The second review (<u>Dumville et al. 2015b</u>) (6 RCTs, n=336) found no evidence of a difference between alginate dressings and alternative treatments in complete wound healing (very low-quality evidence). The RCTs included in both Cochrane reviews were small and considered to be <u>statistically underpowered</u> to detect treatment differences, should they exist. Also, they had short follow-up times (3 to 12 weeks) and were at risk of <u>bias</u>. The implications for practice are therefore unclear. The authors noted that healthcare professionals may wish to consider other characteristics such as costs and wound management properties when choosing between dressings.

- A meta-analysis by <u>Huang et al. (2015)</u> (35 RCTs or quasi-RCTs, n=5,401) on dressings for preventing pressure ulcers found that compared with standard care alone, the risk of developing pressure ulcers was reduced in people who used hydrocolloid dressings, foam and film dressings. Fewer people in the foam dressings group developed pressure ulcers compared with the hydrocolloid dressings group. However, although the authors stated that the methodological quality of the included studies was assessed using the Cochrane Collaboration tool and the risk of bias is reported, the quality of the evidence is not graded. They noted that the included trials have many limitations and stressed that dressings do not replace best practices, such as turning and repositioning, skin care, good nutrition and continence management. In people who are at risk of pressure ulcers, NICE guidance on <u>preventing and managing pressure ulcers</u> recommends repositioning, ensuring nutrition and hydration are adequate, using pressure redistribution devices and considering barrier creams for preventing pressure ulcers.
- See the full evidence review on pressure ulcers for more information.

Venous leg ulcers

- SIGN guidance on the <u>management of chronic venous leg ulcers</u> (published in 2010; <u>accredited by NICE</u>) advises that simple non-adherent dressings and high compression multicomponent bandaging should be used for treating venous leg ulcers. Silver and honey dressings should not be used routinely. Graduated compression hosiery is recommended to prevent recurrence of venous leg ulcers. The evidence that the SIGN recommendations were based on is updated by the evidence outlined below.
- Three Cochrane reviews have considered wound dressings for healing venous leg ulcers. The first review (O'Meara et al. 2015) (5 RCTs, n=295) found no differences between different alginate dressings, or between alginate dressings and hydrocolloid dressings, or alginate dressings and non-adherent dressings. The second review (O'Meara and Martyn-St James 2013) (12 RCTs, n=1,023) found no differences between foam dressings and a variety of other primary wound contact dressings when applied beneath compression systems. The RCTs included in these 2 Cochrane reviews were considered at high or unclear risk of bias and the quality of the evidence was generally reported to be low or very low quality. The authors concluded that good-quality evidence from well-designed RCTs is needed before definitive conclusions about the efficacy of alginate or foam dressings for managing venous leg ulcers can be drawn and recommendations about their use can be made.

- No trials were identified comparing different dressings for relieving pain in venous leg ulceration in the third Cochrane review (Briggs et al. 2012). Foam dressings containing ibuprofen (2 RCTs, n=470) did appear to provide pain relief for some people with painful venous leg ulcers compared with best practice or non-medicated foam dressings. However, the authors of the Cochrane review noted that the studies have methodological limitations that make interpreting the evidence difficult. Also, the release of ibuprofen into the wound bed depends on the presence of wound exudate and therefore these dressings are not suitable for people with venous leg ulcers that have low levels of, or no, exudate.
- The Agency for Healthcare Research and Quality (2014) (AHRQ) in the USA considered the benefits and harms of dressings that regulate wound moisture in people with chronic venous leg ulcers. In terms of the proportion of ulcers healed, no differences were found between the groups for comparisons including advanced wound dressings (film, alginate and antimicrobial dressings, including silver dressings). Definitive conclusions could not be drawn for many comparisons because of limitations in study quality, imprecise estimates and heterogeneity in study designs. Also, conclusions about the effects of advanced wound dressings on pain or quality of life could not be made due to inconsistent reporting of these outcomes. The AHRQ stated that there was a general lack of well-designed, well-controlled studies, as well as lack of a standard case definition, or approaches to managing confounders and interactions. For advanced wound dressings, there was no impact on wound healing when compared with compression therapy alone.
- A meta-analysis of 2 RCTs (n=255) of silver dressings for venous leg ulcers by Greer et al. (2013), which were assessed as fair quality by the authors, found that there was no difference between silver dressings and non-silver dressings. A second study by Leaper et al. (2013) (4 RCTs, n=1,055) found that, compared with control (foam or alginate dressings, or local best practice including passive and non-antimicrobial dressings), a specific brand of silver dressings reduced ulcer area over 4 weeks in people with hard-to-heal venous leg ulcers. However, this meta-analysis has many limitations that affect its interpretation. For example, it did not report the quality of the evidence or assess the risk of bias, complete data were not reported for all outcomes, only 1 brand of silver dressing was assessed and, as well as sponsoring the study, the manufacturer of that brand of dressing was involved in authoring the paper.

- Economic modelling of data from 1 of the RCTs in the meta-analyses (the VULCAN trial [Michaels et al. 2009], n=213) found that silver dressings were associated with an incremental cost of £97.85 compared with control dressings when used for treating venous leg ulcers. The additional cost of silver dressings was partly due to an increased cost of dressings, but also due to a greater number of dressing changes in the silver dressings group. Although it was a pragmatic, publicly funded, well-designed RCT that reflected standard practice at the time it was undertaken, this study (and its cost-effectiveness analysis) has been criticised for its relevance and generalisation to everyday clinical care; for example, participants did not necessarily have wounds that were infected or were at high risk of becoming infected (Gottrup and Apelqvist 2010).
- A more recent study by <u>Jemec et al. (2014)</u> used data from the meta-analysis by <u>Leaper et al. (2013)</u> and estimated that the initial 4 weeks' treatment in primary care was about £90 more expensive for the group treated with silver dressings compared with non-silver dressings. However, because of a shorter time to wound healing and less need for referral for specialist care, the average total treatment cost per person was about £140 lower for silver dressings compared with non-silver dressings. It is unclear how the outcome time to wound healing was obtained from the outcomes presented by <u>Leaper et al. (2013)</u> (primarily reduced ulcer area). Also, the limitations of the study by <u>Leaper et al. (2013)</u> subsequently limit the quality of the cost-effectiveness analysis and affect its application to practice.
- See the full evidence review on venous leg ulcers for more information.

Arterial leg ulcers

- A Cochrane review (<u>Forster and Pagnamenta 2015</u>) found no studies on wound dressings that met the inclusion criteria.
- See the full evidence review on <u>arterial leg ulcers</u> for more information.

Infected wounds

- A meta-analysis by <u>Carter et al. (2010)</u> (10 RCTs, n=1,356) found no difference between silver dressings and control dressings in complete healing of leg wounds and ulcers, although reduction in wound size was greater with silver dressings in the short term. Measures of infection were not assessed. Although they noted that all of the RCTs on silver dressings had quality or bias issues, none were considered by the authors to be poor quality. However, this study assessed the quality of the evidence using an atypical approach. Also, the included RCTs had many limitations, including lack of blinding or allocation concealment, use of inappropriate analyses, incomplete reporting, lack of generalisability to real world populations, differences in baseline characteristics and loss of patients to follow-up.
- A Cochrane review (<u>Storm-Versloot et al. 2010</u>) on topical silver products (dressings or creams) for preventing wound infection identified 26 RCTs (n=2,066), 20 of which considered burns. Most of the trials were small and of poor quality, with many demonstrating a high or uncertain risk of bias. The authors considered that there was insufficient evidence to support the use of silver dressings or creams because, generally, they did not promote wound healing or prevent wound infections.
- A Cochrane review by <u>Jull et al. (2015)</u> concluded that honey appeared to heal partial thickness burns (2 RCTs, n=992: high-quality evidence) and infected post-operative wounds (1 RCT, n=50: moderate-quality evidence) more quickly than comparators. However, the comparators used may not be relevant to current practice (for example, paraffin gauze, sterile linen and gauze), reducing the relevance and generalisability of the results. Evidence for differences in the effects of honey and comparators when used for other wounds is of low or very low quality and does not form a robust basis for decision-making.
- A systematic review (<u>Vermeulen et al. 2010</u>) (27 RCTs, number of participants not reported) found that most RCTs showed no substantial differences in beneficial or adverse effects between iodine (mainly povidone or cadexomer iodine) and comparators when used for chronic and acute wounds, burn wounds, pressure sores and skin grafts. Overall, trial quality was limited. The authors concluded that iodine does not appear to be inferior to other antiseptic agents and does not impair wound healing. However, there is a need for high-quality RCTs addressing the effectiveness and safety of iodine to treat or prevent wound infection, in order to clearly determine its place in present-day wound care.
- See the full evidence review on infected wounds for more information.

Evidence strengths and limitations

- Dressings are generally classified as medical devices. The quality of the evidence required for approval of medical devices is generally lower than that required for medicines. This is reflected in the poor quality of many of the RCTs in this area.
- Few RCTs were available for many of the comparisons considered in the systematic reviews and meta-analyses. Limitations of the RCTs include poor design and reporting, high risk of bias, small sample sizes and imprecision, lack of blinding, use of inappropriate comparators, lack of clinically relevant outcomes and insufficient follow-up.
- The limitations of the RCTs, and subsequently the systematic reviews and meta-analyses based on those RCTs, means that good-quality evidence is available for few analyses of advanced wound dressings for managing chronic wounds. Overall, the clinical evidence is generally uncertain and not optimal in terms of informing clinical practice. Further good quality research is needed to improve confidence in the evidence, and is likely to change the existing evidence. Studies are also lacking on the cost effectiveness of advanced dressings for managing chronic wounds.
- See the full evidence review on <u>evidence strengths and limitations</u> for more information.

Full text of evidence review.

Context

Although representing only 1 route by which dressings are procured within the NHS, the prescription costs of advanced wound dressings and antimicrobial dressings in primary care in England were over £110 million in the year to August 2015 (based on British National Formulary [BNF] volume 69 sections at presentation level; personal communication: NHS Business Services Authority 2015). There is considerable variation in the cost of dressings both between categories of dressings and within each category. For example, silver dressings accounted for about 9% of items supplied on prescription, but in view of their relatively high cost were associated with over 18% (£20.5 million) of the total cost of advanced wound dressings.

Full text of context.

Estimated impact for the NHS

A large number of wound dressings are available with a wide range of physical performance characteristics (such as size, adhesion, conformability and fluid-handling properties). Although laboratory characterisation tests provide a means of comparing the performance characteristics of dressings, they cannot always predict how they will perform in the clinical situation, particularly in terms of healing.

Prescribers' ability to choose wound dressings on the basis of clinical evidence is hindered by the relative lack of robust clinical- or cost-effectiveness evidence, as highlighted in numerous systematic reviews. There is some limited evidence that some advanced dressings are more clinically effective than simple conventional dressings for treating some wounds. For example, systematic reviews and meta-analyses found:

- hydrogel dressings were more effective than basic wound contact dressings for complete healing of diabetic foot ulcers (low-quality evidence), as were foam dressings (very low-quality evidence)
- hydrocolloid and polyurethane film dressings were more effective than gauze dressings in terms of the proportion of pressure ulcers completely healed (low-quality evidence).

However, many of the conventional dressings used as comparators are no longer routinely recommended for chronic wounds (for example, gauze dressings) and there is generally insufficient evidence to distinguish between advanced dressings.

Dressing selection should be made after careful clinical assessment of the person's wound, their clinical condition, and their personal experience and preferences. If a specific dressing cannot be adequately justified on clinical grounds, it would seem appropriate for NHS health professionals to routinely choose the least costly dressing of the type that meets the required characteristics appropriate for the type of wound and its stage of healing (for example, size, adhesion, conformability and fluid handling properties). The frequency of dressing change needs to be carefully considered and should be appropriate for the wound and dressing type. Patients should be assessed regularly. Prescribing the minimum quantity of dressings necessary to meet a person's needs can avoid wastage and stockpiling.

The <u>silver dressings section</u> of the BNF states that antimicrobial dressings containing silvershould be used only when clinical signs or symptoms of infection are present. Silver

ions exert an antimicrobial effect in the presence of wound exudate; therefore, the volume of wound exudate as well as the presence of infection should be considered when selecting a silver dressing. Local protocols may be useful to help clinicians decide when silver dressings should be used.

In view of the multitude of dressings available, the absence of good-quality evidence for national guidelines to base specific recommendations on, and recognising financial constraints, local formularies provide a means of rationalising choice of dressings. Educational programmes can help to ensure that use of formulary wound dressings is optimised.

Full text of estimated impact for the NHS.

About this evidence summary: medicines and prescribing briefing

'Evidence summaries: medicines and prescribing briefings' aim to review the evidence for the clinical effectiveness of medicines within a therapeutic class or indication to provide advice on the relative position of each medicine as a therapeutic option. This will assist localities in their planning on medicines optimisation priorities as well as providing individual prescribers with information to help informed decision making. The strengths and weaknesses of the relevant evidence are critically reviewed to provide useful information, but this evidence summary: medicines and prescribing briefing is not NICE guidance.

Full evidence summary: medicines and prescribing briefing

Introduction and current guidance

Choosing the most appropriate dressing for a wound requires knowledge of the safety and the clinical and cost effectiveness of a range of dressings. It also requires careful clinical assessment of the person's wound, their clinical condition and comorbidities, and personal circumstances and preferences. Noting that dressings are also procured by other routes, prescribing of advanced wound dressings and antimicrobial dressings accounts for about £110 million per year in primary care in England, with more than £20 million spent on silver dressings alone. However, the clinical evidence supporting the use of wound dressings is

less well known and of poorer quality than in many other areas of prescribing. This evidence summary considers the best available evidence for using advanced wound dressings and antimicrobial dressings for treating chronic wounds in primary care, and considers the implications for dressing choice.

Dressings should provide the optimal environment for wound healing. For the purposes of this briefing, advanced dressings are those that do this by simple physical or chemical means, typically by controlling moisture levels (see below and the <u>advanced wound dressings section</u> of the British National Formulary [BNF]). Antimicrobial agents, such as iodine, honey or silver are incorporated in advanced and basic wound contact dressings (see the <u>antimicrobial dressings section</u> of the BNF), which are both considered in this briefing. Use of specialised dressings, which aid wound healing by means of physiologically active components (for example, growth factors, collagen or hyaluronic acid) or with more complex adjunct therapies (such as topical negative pressure and electrical stimulation), are outside the scope of the publication. Other types of topical treatments such as ointments and larvae are also excluded.

Commonly used advanced dressings include (<u>Dumville et al. 2015b</u>):

- Alginate dressings, which are highly absorbent. The alginate forms a gel when in contact with the wound surface, which can be lifted off at dressing removal or rinsed away with sterile saline. Bonding to a secondary viscose pad increases absorbency.
- **Film dressings**, which are permeable to water vapour and oxygen but not to water or micro-organisms.
- **Foam dressings**, which normally contain hydrophilic polyurethane foam and are designed to absorb wound exudate and maintain a moist wound surface. Some foam dressings include additional absorbent materials, whereas others are silicone-coated for non-traumatic removal.
- Hydrocolloid dressings, which are occlusive and usually composed of a hydrocolloid matrix bonded onto a vapour-permeable film or foam backing. This matrix forms a gel that provides a moist environment when in contact with the wound surface.
 Hydrofibre alternatives have been developed that resemble alginates, are not occlusive and are more absorbent than standard hydrocolloid dressings.
- Hydrogel dressings, which consist of cross-linked insoluble polymers and up to 96% water. They are designed to absorb wound exudate or to rehydrate a wound, depending on wound moisture levels.

See the <u>advanced wound dressings section</u> of the BNF for more information on the types and properties of different advanced dressings, and a <u>table</u> that suggests choices of primary dressing depending on the nature of the wound.

This briefing primarily considers chronic wounds that have not followed the expected pattern of healing (inflammation, granulation and vascularisation, and epithelialisation and wound contraction) in a timely manner, generally because of vascular insufficiency or neuropathy. These commonly include diabetic foot ulcers, pressure ulcers, venous leg ulcers and infected wounds. Arterial leg ulcers are also considered. Use of dressings for acute wounds and traumatic or surgical wounds is outside the scope, as is cleaning or debriding wounds.

People with chronic wounds are usually cared for by nurses in their homes, GP practices, community-based clinics or in residential care. Therefore, this briefing considers the management of chronic wounds in primary care. Supply arrangements for dressings are not considered in the evidence summary.

NICE has issued guidance on <u>preventing and managing pressure ulcers</u> and <u>preventing and managing diabetic foot problems</u>, and a quality standard on <u>pressure ulcers</u>.

The Scottish Intercollegiate Guidelines Network (SIGN, <u>accredited by NICE</u>) has issued guidance on the <u>management of chronic venous leg ulcers</u>. Healthcare Improvement Scotland has produced a best practice statement on the <u>prevention and management of pressure ulcers</u>.

More information on managing chronic wounds is available in NICE clinical knowledge summaries on venous leg ulcers and type 2 diabetes (managing foot problems).

A NICE key therapeutic topic on <u>wound care products</u> (NICE advice KTT14) supports medicines optimisation in this area but is not formal NICE guidance. This key therapeutic topic will be updated following the publication of this evidence summary.

Wounds UK have issued various <u>best practice statements</u> on wound management, but the quality of the evidence and processes used to produce them is unclear.

Evidence review

This evidence review includes the best available evidence for advanced wound dressings

and antimicrobial dressings for managing common chronic wounds in primary care (search date July 2015). It outlines evidence from national guidance (if available) and the most up-to-date systematic reviews and meta-analyses published since that guidance.

In most of the systematic reviews, the quality of the evidence is rated using the <u>Grading of Recommendations Assessment</u>, <u>Development and Evaluation (GRADE) system</u>:

- high quality: further research is very unlikely to change our confidence in the estimate of effect
- moderate quality: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
- low quality: further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
- very low quality: any estimate of effect is very uncertain.

When atypical methods of assessing quality have been used, this has been noted in the discussions.

Little evidence on the cost effectiveness of wound dressings in the UK was identified in the searches performed for the evidence summary, but is included when possible.

Diabetic foot ulcers

The risk of foot problems is increased in people with diabetes, largely because of diabetic neuropathy and peripheral arterial disease. It is estimated that 10% of people with diabetes will have a diabetic foot ulcer at some point in their lives. Diabetes is the most common cause of non-traumatic limb amputation, with diabetic foot ulcers preceding more than 80% of amputations in people with diabetes. Mortality rates after diabetic foot ulceration and amputation are high, with up to 70% of people dying within 5 years of having an amputation and around 50% dying within 5 years of developing a diabetic foot ulcer (NICE guideline on preventing and managing diabetic foot problems).

Foot problems in people with diabetes have a significant financial impact on the NHS through primary care, community care, outpatient costs, increased bed occupancy and prolonged stays in hospital. A report published in 2012 by NHS Diabetes estimated that around £650 million (or £1 in every £150 the NHS spends) is spent on foot ulcers or

amputations each year (NICE guideline on preventing and managing diabetic foot problems).

The 2015 NICE guideline on <u>preventing and managing diabetic foot problems</u> recommends that people with diabetic foot problems should be referred to the multidisciplinary foot care service. Wound dressings (type not specified) are an option for managing diabetic foot ulcers alongside offloading (use of a plaster case to remove pressure from the ulcer), control of foot infection, control of ischaemia and wound debridement. When deciding about wound dressings and offloading, the clinical assessment of the wound and the person's preference should be taken into account, and dressings or devices with the lowest acquisition cost appropriate to the clinical circumstances should be used.

Evidence from the full NICE guideline: <u>Diabetic foot problems</u>

Alginate dressings versus foam dressings: 1 low-quality <u>randomised controlled trial</u> (RCT: n=60) found there was no statistically significant difference between complete ulcer healing at 8 weeks for diabetic foot ulcers treated with an alginate dressing or a foam dressing.

Hydrofibre dressings versus saline gauze dressings: 2 very low-quality RCTs (n=51) found there was no statistically significant difference between ulcer healing, the number of adverse events or the number of complications for diabetic foot ulcers treated with a hydrofibre dressing or a saline gauze dressing.

One very low-quality RCT (n=20) found diabetic foot ulcers treated with a hydrofibre dressing healed significantly faster than those treated with a saline gauze dressing (mean healing time 127 days compared with 234 days, \underline{p} <0.001).

Hydrocolloid dressings versus alginate dressings: 1 low-quality RCT (n=134) found there was no statistically significant difference between ulcer healing, ulcer healing time, number of adverse events or number of complications for diabetic foot ulcers treated with a hydrocolloid dressing or a calcium alginate dressing.

Hydroactive dressings versus hydrophilic dressings: 1 very low-quality RCT (n=40) found there was no statistically significant difference between ulcer healing time or the change in ulcer size for diabetic foot ulcers treated with a hydroactive dressing or a hydrophilic dressing.

Other dressings: 1 moderate-quality RCT (n=229) found there was no statistically significant difference between ulcer healing, healing time, number of amputations, adverse events or complications for diabetic foot ulcers treated with a hydrofibre dressing, iodine-impregnated dressing or a non-adherent dressing.

One moderate- to low-quality RCT (n=50) found there was no statistically significant difference between adverse events and ulcer cure rates for people treated with soft silicone dressing or a Vaseline gauze dressing over 12 weeks.

See the diabetic foot problems, appendix F and appendix I for more details.

Conclusion: The guideline development group concluded that evidence surrounding different types of dressings for diabetic foot ulcers was often limited or inconclusive. The group proposed that more RCTs should be undertaken to monitor and evaluate the cure rates of foot ulcers resulting from diabetes, rates and extent of amputation (major or minor), health-related quality of life, adverse events and hospital admission rates and length of stay. However, alternative methodologies may also be considered in the case of treating a complex wound.

The guideline development group considered that patient decisions, dressing availability, wound severity and factors such as infection control were all issues that contribute to decisions about the choice of dressing. It therefore considered it was inappropriate to recommend specific types of dressing. The group did however acknowledge that the lowest cost dressings may not necessarily be the most appropriate dressings for patient needs and therefore reflected this in the recommendations.

Cochrane overview: Dressings for treating foot ulcers in people with diabetes

This Cochrane overview (<u>Wu et al. 2015</u>) summarised data from 13 <u>systematic reviews</u> of 17 RCTs looking at the effectiveness of dressings for healing foot ulcers in people with diabetes. Collectively, the trials compared 10 types of dressings with each other, making a total of 37 comparisons (11 supported by direct data and 26 supported by indirect data only). All the included reviews were considered to be of moderate to high quality.

For comparisons informed in part by direct data, the reviews reported no clear evidence of a difference between the following dressings in terms of wound healing:

- basic wound contact dressings compared with alginate dressings (2 RCTs, n=114: moderate-quality evidence)
- basic wound contact dressings compared with hydrofibre dressings (2 RCTs, n=229: moderate-quality evidence)
- basic wound contact dressings compared with iodine-impregnated dressings (1 RCT, n=214: moderate-quality evidence)
- foam dressings compared with hydrocolloid dressings (1 RCT, n=40: low-quality evidence)
- iodine-impregnated dressings compared with hydrofibre dressings (1 RCT, n=211: moderate-quality evidence)
- alginate dressings compared with silver hydrofibre dressings (1 RCT, n=134: moderate-quality evidence).

Hydrogel dressings were found to be statistically significantly more effective than basic wound contact dressings for complete wound healing (3 RCTs, n=198: direct data, relative risk [RR] 1.80, 95% confidence interval [CI] 1.27 to 2.56: low-quality evidence), as were foam dressings (2 RCTs, n=49: direct and indirect data, odds ratio [OR] 4.32, 95% CI 1.56 to 9.85: very low-quality evidence). Foam dressings were more effective than alginate dressings (2 RCTs, n=50: direct and indirect data, OR 3.61, 95% CI 1.30 to 8.30: very low-quality evidence).

Conclusion: The Cochrane review concluded that there is currently no robust evidence that any advanced dressing type is more effective than basic wound contact dressings for healing foot ulcers in people with diabetes. The authors noted that there is imprecision around the estimates for all the comparisons because few RCTs were available and these trials generally had small numbers of participants. Also, in the 3 comparisons in which direct evidence of a difference was reported, the evidence was considered to be low or very low quality. Therefore, the findings are reported to be uncertain and not optimal in terms of informing practice.

It has been suggested that different dressings may be more appropriate for specific wound states or stages of healing, implying that complete healing may not be an appropriate treatment aim for all interventions. For example, foam and alginate products may be used to manage periods of heavy exudate, while antimicrobial dressings may help to resolve infection (see the <u>wound management products section</u> of the BNF). Most of

the RCTs discussed in the Cochrane review focused on wound healing as the primary outcome and presented relatively few data on secondary outcomes. The authors noted that more research is needed on benefits that may be achieved with different types of dressings and how additional outcomes of importance to decision-makers (including service users) such as exudate management, resolution of infection and adverse effects may best be measured. They concluded that practitioners may want to consider the unit cost of dressings, their management properties and the person's preference when choosing dressings.

Pressure ulcers

Pressure ulcers are caused when an area of skin and the tissues below are damaged as a result of being placed under sufficient pressure to impair blood supply. They represent a major burden of sickness and reduced quality of life for people with pressure ulcers and their carers. New pressure ulcers are estimated to occur in 4–10% of patients admitted to hospitals in the UK, with the precise rate depending on case mix. The rate is unknown in the community and care homes (NICE guideline on pressure ulcers scope).

The NICE guideline on <u>preventing and managing pressure ulcers</u> covers identification, risk assessment, prevention and treatment. Recommendations for treating pressure ulcers include wound care, adjunctive therapies and support surfaces.

According to NICE, clinicians should discuss the type of dressing with the person with the pressure ulcer and, if appropriate, their family or carers, taking into account the person's pain and tolerance, the position of the ulcer, the amount of exudate and the frequency of dressing change. A dressing that promotes a warm, moist wound healing environment should be considered for grade 2, 3 and 4 pressure ulcers. Topical antimicrobial dressings should be considered for neonates, infants, children and young people when clinically indicated; for example, if there is spreading cellulitis. Gauze dressings should not be used in adults or children. Iodine dressings should not be used in neonates.

This evidence summary focuses on the use of wound dressings to manage pressure ulcers in adults because they make up the majority of cases in primary care.

Evidence from the full NICE guideline: Management of pressure ulcers

Hydrocolloid dressings versus gauze dressings: In 4 RCTs (273 ulcers), hydrocolloid dressings were found to be statistically significantly more effective than gauze dressings

in terms of the proportion of pressure ulcers completely healed (RR 2.53, 95% CI 1.70 to 3.78: low-quality evidence). Benefits appeared to be more pronounced in people with spinal cord injury than in the general population. Gauze dressings caused significantly more harm than hydrocolloid dressings in terms of skin irritation (1 RCT, 100 ulcers: OR 0.11, 95% CI 0.03 to 0.44: low-quality evidence), pain at dressing removal (1 RCT, 34 ulcers: OR 0.09, 95% CI 0.02 to 0.45: low-quality evidence) and discomfort (1 RCT, 34 ulcers: OR 0.07, 95% CI 0.02 to 0.32: low-quality evidence). Mortality was statistically significantly higher in the gauze dressings group (3 RCTs, 156 ulcers: RR 0.24, 95% CI 0.07 to 0.89: very low-quality evidence).

Hydrocolloid dressings versus foam dressings: There was no statistically significant difference between hydrocolloid dressings and foam dressings for the proportion of people whose ulcers were completely healed (3 RCTs, 157 ulcers: very low-quality evidence), mortality (1 RCT, 60 ulcers: very low-quality evidence) or adverse events (2 RCTs, 100 ulcers: very low-quality evidence).

Hydrocolloid dressings versus polyurethane film dressings: There was no statistically significant difference between hydrocolloid dressings and polyurethane film dressings for ulcer healing outcomes (very low-quality evidence). Mean comfort and odour scores were marginally better in the polyurethane dressings group (1 RCT, 72 ulcers: mean differences –0.20, 95% CI –0.33 to –0.07 and –0.40, 95% CI –0.64 to –0.16 respectively: very low-quality evidence).

Hydrocolloid dressings versus hydrogel dressings: Hydrogel dressings were statistically significantly more effective than hydrocolloid dressings for the proportion of pressure ulcers completely healed in 1 RCT (129 ulcers: RR 0.46, 95% Cl 0.25 to 0.84: very low-quality evidence). The guideline development group discussed that in clinical practice hydrogel dressings and hydrocolloid dressings were not necessarily an appropriate comparison because there would be different clinical indications for each dressing.

Hydrocolloid dressings versus alginate dressings: In 1 RCT (110 ulcers), there was no statistically significantly difference between hydrocolloid and alginate dressings for the proportion of people whose ulcers were 40% healed (very low-quality evidence). However, the mean percentage reduction in ulcer area was higher in the alginate group (mean difference –26.50%, 95% CI –42.38% to –10.62%: low-quality evidence). The guideline development group considered that comparing alginate dressings with hydrocolloid dressings was not a relevant comparison because they are used in clinical practice for different clinical indications.

Foam dressings versus gauze dressings: In 2 RCTs (74 ulcers), there was no statistically significant difference between gauze and foam dressings in terms of the proportion of people whose ulcers were completely healed and reduced mortality (very low-quality evidence).

Foam dressings versus hydrogel dressings: In people undergoing palliative care, there were no statistically significant differences between foam and hydrogel dressings in terms of the proportion of ulcers completely healed (1 RCT, 38 ulcers: very low-quality evidence) and most other outcomes assessed (very low-quality evidence).

Polyurethane film dressings versus gauze dressings: Polyurethane film dressings were statistically significantly more effective than gauze dressings for the proportion of pressure ulcers completely healed (2 RCTs, 53 ulcers: OR 0.08, 95% CI 0.02 to 0.31: low-quality evidence).

Hydrogel dressings versus gauze dressings: No statistically significant differences were found between hydrogel and gauze dressings (very low-quality evidence).

Alginate dressings versus silver-containing alginate dressings: There were no statistically significant differences between alginate and silver-containing alginate dressings (very low-quality evidence).

See the pressure ulcers, <u>appendix I and appendix G</u> for more information on the evidence to support the use of wound dressings for managing pressure ulcers in adults and children.

Economic analyses: The NICE guideline development group considered 3 economic analyses that included gauze dressings. None of these studies found gauze dressings to be cost effective. Comparators included alginate, hydroactive dressings and hydrocolloid dressings.

Regarding other dressings, 11 economic studies were considered but the guideline development group did not consider that the economic evidence was strong enough to identify a cost-effective type of dressing. They considered unit costs relevant to the UK, but noted that the major resource implications come from the frequency that each dressing requires changing. This is likely to depend on a range of factors, such as location of the ulcer, the amount of exudate and patient acceptability. The frequency of dressing change can also have a substantial impact on quality of life.

Conclusion: Overall, the quality of clinical evidence was graded low to very low. Most of the studies had very serious limitations. In the studies that found a clinical effect, most of the results had serious to very serious imprecision, indicating high uncertainty in the results. The guideline development group noted that there were some problems with the comparisons in studies, such as non-clinically relevant comparisons and dressings not used in current UK clinical practice.

The guideline development group found there was little clinical benefit of gauze dressings and these are not recommended for pressure ulcers. There are adverse events associated with gauze dressings that the guideline development group identified as important, such as increased pain at dressing removal, skin irritation and discomfort.

The guideline development group did not consider that the evidence allowed for a recommendation to be made about the use of a specific type of dressing. This was because of the lack and quality of evidence, as well as the importance of considering the function of the dressing and specific patient factors. The group emphasised that the effectiveness of each dressing would depend on the type of pressure ulcer and, therefore, chose to recommend a dressing that promotes the optimum healing environment, rather than a specific type of dressing.

The guideline development group considered it was important to take into account the following factors when choosing a dressing:

- the adhesiveness of a dressing (ease of removal)
- · the nature of the wound
- ease of use of the dressing
- · amount of exudate
- amount of pain at dressing changes
- protection of the surrounding skin
- irritation caused by the adhesive
- infection
- odour

absorption.

In addition, it was noted that a wound can deteriorate because of dressing changes and this is a specific issue with regards to sacral ulcers that are likely to become frequently soiled. The frequency of dressing changes was also noted to affect the healing of a wound, and can be detrimental to the effectiveness of the dressing.

Cochrane review: Hydrogel dressings for treating pressure ulcers

This Cochrane review (<u>Dumville et al. 2015a</u>) included 11 RCTs (n=523), including 3 that were not in the NICE guideline on <u>pressure ulcers</u>. The RCTs compared hydrogel dressings with 6 different comparators, including basic wound contact dressings, hydrocolloid dressings, other hydrogel dressings and foam dressings. However, the trials were poorly reported so only limited data were available for analysis and no meta-analyses could be performed.

When data were available, there was no evidence of a statistically significant difference between hydrogel and alternative dressings in terms of complete wound healing (the primary outcome) or adverse events (low- or very low-quality evidence).

The included RCTs were small (n=10 to n=143). Therefore, they were considered to be <u>statistically underpowered</u> to detect treatment differences, if they existed, and the findings were imprecise. In addition, the trials had short follow-up times (3 to 12 weeks) and were at high or unclear risk of <u>bias</u>.

Conclusions: The authors concluded that the systematic review did not find reliable evidence that hydrogel dressings either increase or decrease the healing of pressure ulcers compared with other dressings. They noted that practitioners may therefore elect to consider other characteristics such as costs and symptom management properties when choosing between dressings.

Cochrane review: Alginate dressings for pressure ulcers

This Cochrane review (<u>Dumville et al. 2015b</u>) included 6 RCTs (n=336), including 3 that were not in the NICE guideline on <u>pressure ulcers</u>. The RCTs compared alginate dressings with 6 other interventions, including hydrocolloid dressings and silver-containing alginate dressings. Overall, the body of literature was very limited: each comparison was informed by only 1 RCT.

Few data were available for the primary outcome, complete wound healing: 1 small RCT (n=36) found no evidence of a statistically significant difference between 2 brands of alginate dressings (very low-quality evidence). One study (n=110: also discussed in NICE's full guideline on pressure ulcers, see earlier for details) reported a statistically significant reduction in ulcer area and the mean number of dressing changes with alginate dressings followed by hydrocolloid dressings compared with hydrocolloid dressings alone (very low-quality evidence). There was no evidence of a difference between the groups in any other secondary outcomes reported, including adverse events and wound infection.

The RCTs included in the Cochrane review were small and considered to be underpowered to detect differences between the dressings, if they existed. Follow-up times were short (4 to 8 weeks in 5 RCTs and unclear in the sixth RCT) and the evidence was of low or very low-quality and at risk of bias. The authors also noted that there may be comparisons that are important to decision-makers for which trials have not been conducted.

Conclusions: The authors concluded that the relative effects of alginate dressings compared with alternative treatments are unclear. Decision-makers may wish to consider aspects such as cost of dressings and the wound management properties offered by each dressing type, for example, exudate management.

Meta-analysis: Dressings for preventing pressure ulcers

This meta-analysis (<u>Huang et al. 2015</u>) included 35 RCTs or quasi-RCTs (n=5,401), 30 of which compared the number or incidence of pressure ulcers in people receiving standard care plus dressings with those in people receiving standard care alone. The other 5 trials compared dressings without a control group and were analysed separately.

Compared with standard care alone, the risk of developing pressure ulcers was statistically significantly reduced in people who used hydrocolloid dressings (7 trials, n=494: RR 0.20, 95% CI 0.12 to 0.36, p<0.001), foam dressings (11 trials, n=2,090: RR 0.17, 95% CI 0.12 to 0.26, p<0.001) and film dressings (3 trials, n=307: RR 0.50, 95% CI 0.32 to 0.76, p=0.001). Statistically significantly fewer people in the foam dressings group developed pressure ulcers compared with the hydrocolloid dressings group (4 RCTs, n=467: RR 0.16, 95% CI 0.07 to 0.38, p<0.001).

The included trials have limitations. For example, a number were sponsored by manufacturers, variables (age, comorbidities, medications, length of stay, resources and the extent that best practice to prevent pressure ulcers was implemented) were often not

controlled, and it is unclear whether participants in the dressing and control groups were at similar risk of developing pressure ulcers. Also, study durations and follow-ups were short, meaning the number of pressure ulcers developed may have been underestimated. Pressure ulcers commonly occur on the sacrum, coccyx and heels, and these are the most challenging areas to protect because dressings tend to slip, bunch up or get soiled. However, they were not evaluated in the studies.

Conclusions: Hydrocolloid, film and foam dressings were found to prevent pressure ulcers compared with standard care. However, although the authors stated that the methodological quality of the included studies was assessed using the Cochrane Collaboration tool and the risk of bias is reported, the quality of the evidence is not graded. Also, the authors noted that dressings do not replace best practices, such as turning and repositioning, skin care, good nutrition and continence management. In people who are at risk of pressure ulcers, NICE guidance on preventing and managing pressure ulcers recommends repositioning, ensuring nutrition and hydration are adequate, using pressure redistribution devices and considering barrier creams for preventing pressure ulcers.

Venous leg ulcers

A leg ulcer has been defined as 'the loss of skin below the knee on the leg or foot, which takes more than 6 weeks to heal'. Venous leg ulcers are caused by sustained venous hypertension, which results from chronic venous insufficiency or an impaired calf muscle pump. Risk factors include obesity, immobility, varicose veins and deep vein thrombosis. Venous leg ulcers are a common, chronic, recurring condition. Venous ulcers represent 80–85% of all leg ulcers and 60–80% of leg ulcers have a venous component. The prevalence of chronic venous leg ulcers is estimated to be 1–3 per 1,000 of the UK population and increases with age, rising to 20 per 1,000 in people over 80 years of age. Complications include immobility due to pain, infection, negative impacts on daily life and functioning, osteomyelitis and septicaemia (NICE clinical knowledge summary: Venous leg ulcers).

Based on 2001 prices and in the context of a trial in a specialist leg ulcer clinic, the cost of treating 1 ulcer was estimated to be about £1,300 to £1,500 (SIGN guideline: Management of chronic venous leg ulcers).

SIGN guidance on the <u>management of chronic venous leg ulcers</u> (published in 2010; accredited by NICE) provides evidence-based recommendations on the assessment and

treatment of venous leg ulcers, and prevention of recurrence. SIGN advises that simple non-adherent dressings and high compression multicomponent bandaging should be used for treating venous leg ulcers. Silver and honey dressings should not be used routinely. Graduated compression hosiery is recommended to prevent recurrence of venous leg ulcers.

Evidence from the full SIGN guideline: Management of chronic venous leg ulcers

In the SIGN guideline, recommendations on non-adherent dressings and compression bandaging are based on a 2006 Cochrane review (Palfreyman et al. 2006) that has now been superseded by the Cochrane reviews below. The 2006 Cochrane review identified 42 RCTs (n=3,001) in which simple non-adherent dressings were compared with hydrocolloid (9 RCTs, n=928), hydrogel (2 RCTs, n=134) and foam dressings (3 RCTs, n=253). The evidence found did not suggest that hydrocolloid dressings are more effective than simple non-adherent dressings used beneath compression bandages. There was insufficient evidence for other comparisons. No evidence was identified on the effectiveness of different dressings in people unable to tolerate multilayer compression bandaging.

Recommendations on silver dressings are based on a Cochrane review (<u>Vermeulen et al. 2007</u>) and the later <u>VULCAN trial</u> (Michaels et al. 2009). The Cochrane review included 3 RCTs (n=847) comparing silver dressings with foam or alginate dressings, or best practice for treating infected wounds (not only venous leg ulcers). Two RCTs (n=129 and n=99) showed no difference between products and 1 reported statistically significantly faster healing rates but did not report complete healing (n=619). All 3 RCTs were small and of short duration. They could not be combined in a meta-analysis because they considered different wounds, dressings and end points.

<u>VULCAN</u> (n=213) was a pragmatic, publicly funded RCT, which compared a range of silver dressings with a range of non-adherent dressings (in addition to standard compression) and found no statistically significant differences in median time to complete healing or healing rates at 3, 6 and 12 months. See below for more information on this study.

Conclusion: SIGN concluded that simple non-adherent dressings are recommended in the management of venous leg ulcers; silver dressings are not.

Cochrane review: Alginate dressings for venous leg ulcers

This Cochrane review (O'Meara et al. 2015) included 5 RCTs (n=295). One RCT compared different alginate dressings (n=20), 3 compared alginate and hydrocolloid dressings (n=215), and 1 compared alginate and simple non-adherent dressings (n=60). No statistically significant differences were found between the groups for any comparison, for any healing outcome. Adverse event profiles were generally similar between treatment groups. The overall risk of bias was high for 2 RCTs and unclear for 3 RCTs and the quality of the evidence was reported to be very low.

Conclusions: The authors concluded that there is no evidence to suggest that there are any differences in terms of wound healing between different alginate dressings, or between alginate dressings and hydrocolloid dressings, or alginate dressings and non-adherent dressings. Good-quality evidence is required from well-designed RCTs before any definitive conclusions regarding the efficacy of alginate dressings (or other dressings included in the Cochrane review) for managing venous leg ulcers can be drawn and recommendations about their use can be made.

Cochrane review: Foam dressings for venous leg ulcers

This Cochrane review (O'Meara and Martyn-St James 2013) included 12 RCTs (n=1,023) reporting 14 comparisons. No statistically significant differences were found between:

- hydrocellular foam dressings and polyurethane foam dressings in healing outcomes (3 RCTs, n=292)
- foam dressings and hydrocolloid dressings in the proportion of ulcers healed at 12–16 weeks (5 RCTs, n=418)
- foam dressings and paraffin gauze dressings (2 RCTs, n=72), hydrocapillary dressings (1 RCT, n=97), knitted viscose dressings (1 RCT, n=132) or protease modulating matrix (1 RCT, n=12) in healing outcomes
- hydrocellular foam dressings and polyurethane foam dressings (1 RCT, n=156), or foam dressings and hydrocapillary (1 RCT, n=97), hydrocolloid (1 RCT, n=107) or knitted viscose dressings (1 RCT, n=132) in adverse effects.

Six RCTs were considered to be at overall high risk of bias, and the remaining 6 RCTs were considered to be at overall unclear risk of bias. The evidence was generally of low quality. The exception to this was for the outcome of complete healing for the comparison of foam

and hydrocolloid dressings, where the evidence was of moderate quality.

Conclusion: The authors stated that there is no evidence to suggest that foam dressings are better or worse than any other primary wound contact dressings for healing venous leg ulcers when applied beneath compression systems. Good-quality evidence from well-designed RCTs is needed before definitive conclusions about the efficacy of foam dressings (or other dressings included in the Cochrane review) for managing venous leg ulcers can be drawn, and recommendations about their use can be made.

Cochrane review: Topical agents or dressings for pain in venous leg ulcers

In this Cochrane review (<u>Briggs et al. 2012</u>) no trials were identified comparing different dressings for relieving pain in venous leg ulceration.

The Cochrane review found 2 RCTs (n=470) that evaluated ibuprofen slow-release foam dressings for persistent venous leg ulcer pain. In 1 RCT (n=348), compared with local best practice, statistically significantly more participants in the ibuprofen dressing group achieved more than a 50% reduction in pain between day 1 and day 5 (RR 1.63, 95% CI 1.24 to 2.15; number needed to treat 6, 95% CI 4 to 12). In the second RCT (n=122), compared with an identical non-ibuprofen foam dressing, there was no statistically significant difference in the proportion of participants experiencing slight to complete pain relief on the first evening of treatment. Limited data were available to assess healing rates or adverse events.

Conclusions: The authors concluded that there is some evidence that foam dressings containing ibuprofen provide pain relief for some people with painful venous leg ulcers. However, they state that variability in the pain assessment method and the reporting of pain outcomes across trials, coupled with the potential bias associated with unblinded outcome assessment, makes interpretation of the current evidence base for topical ibuprofen in the management of chronically painful leg ulcers difficult. Also, the release of ibuprofen into the wound bed depends on the presence of wound exudate and, therefore, these dressings are not suitable for people with venous leg ulcers that that have low levels of, or no, exudate.

Chronic venous ulcers: a comparative effectiveness review of treatment modalities

The Agency for Healthcare Research and Quality (AHRQ 2014) in the USA has

systematically reviewed the literature on the effectiveness and safety of advanced wound dressings, systemic antibiotics and surgical interventions in people with chronic venous leg ulcers. One of the key questions in the review considered the benefits and harms of dressings that regulate wound moisture with or without active chemical, enzymatic, biologic or antimicrobial components in conjunction with compression systems compared with compression systems alone.

In terms of the proportion of ulcers healed, no statistically significant difference was found between the groups for:

- film (1 non-randomised study, n=54), alginate (1 RCT, number of participants not reported) and antimicrobial dressings (2 RCTs, n=194) compared with compression alone
- hydrocolloid (4 RCTs, n=420), film (1 RCT, n=20) and alginate dressings (1 RCT, n=113) compared with other types of dressings
- head-to-head comparisons of different types of alginate (2 RCTs, n=101), foam (3 RCTs, n=296) and antimicrobial dressings (2 RCTs, n=342).

Definitive conclusions could not be drawn for these comparisons because of limitations in study quality, imprecise estimates and <u>heterogeneity</u> in study designs (insufficient strength of evidence).

Hydrocolloid dressings were not found to be statistically significantly more effective than compression alone in terms of the proportion of chronic venous ulcers healed. The results from the 3 RCTs (n=361) addressing this comparison were imprecise and subject to some bias (low strength of evidence).

Silver dressings did not statistically significantly improve wound healing compared with non-silver dressings (<u>VULCAN trial</u>, n=213; moderate strength of evidence). See below for more information on silver dressings.

Conclusions about the effects of advanced wound dressings on pain or quality of life could not be made due to inconsistent reporting of these outcomes. Also, conclusions about the effect of advanced wound dressings on the condition of the wound bed could not be made because of heterogeneity in study designs and inconsistency in evaluating and reporting on the condition of the wound bed.

Evidence was lacking on the effects of advanced wound dressings on maceration, contact dermatitis, venous or arterial impairment and cellulitis.

Conclusion: The AHRQ concluded that there was a general lack of well-designed, well-controlled studies, as well as a lack of a standard case definition, or approaches to managing confounders and interactions. For advanced wound dressings, there was no impact on wound healing when compared with compression therapy alone.

Meta-analyses: Silver dressings for venous leg ulcers (<u>Greer et al. 2013</u> and <u>Leaper et al. 2013</u>)

A study by <u>Greer et al. (2013)</u> evaluated the benefits and harms of advanced wound care therapies for non-healing diabetic, venous and arterial ulcers. Most of the comparisons have been covered by the systematic reviews outlined above but the paper includes a meta-analysis of 2 RCTs (including <u>VULCAN</u>; n=255) on silver dressings for venous leg ulcers. This found that there was no statistically significant difference between silver dressings and non-silver dressings. The RCTs were reported to be fair quality using a modification of the Cochrane approach to determining risk of bias and a scale of good, fair or poor.

A second, manufacturer-sponsored study by <u>Leaper et al. (2013)</u> evaluated the effects of a specific brand of silver dressing (Biatain Ag) on hard-to-heal venous leg ulcers (defined as clinical signs of infection [exudates, pain, discoloration and odour] and/or less than 20% ulcer size reduction over 4 weeks). The study included 4 RCTs (n=1,055), some of which included people with pressure ulcers, diabetic ulcers or arterial ulcers. <u>Leaper et al. (2013)</u> excluded people without venous or mixed aetiology leg ulcers and those who had been treated with an active comparator or gauze (n=370) from the meta-analyses.

<u>Leaper et al. (2013)</u> found that, in meta-analyses of data from the 4 RCTs (n=685) compared with control (foam or alginate dressings, or local best practice including passive and non-antimicrobial dressings), silver dressings statistically significantly:

- reduced ulcer area over 4 weeks (relative reduction 26.3% compared with 43.5% respectively, p<0.0001)
- increased the response rate (the proportion of people with a relative ulcer area reduction of 40% or more at 4 weeks; 37% compared with 52% respectively, p<0.001) and

complete healing at 4 weeks (6% compared with 12% respectively, p=0.002).

The meta-analysis has many limitations that affect its interpretation. For example, it did not report the quality of the evidence or assess the risk of bias, only 1 brand of silver dressings was assessed and, as well as sponsoring the study, the manufacturer of that brand of dressing was involved in authoring the paper. Also, complete data were not reported for all outcomes (for example, numbers of patients and 95% confidence intervals).

Conclusion: The authors noted that the included RCTs on silver dressings are heterogeneous with study designs and populations varying considerably (for example, age, ulcer size, type of ulcer and presence of infection). Also, the RCTs may have been too short to reliably assess complete healing, the outcome which is likely to be most relevant to patients. They concluded there is evidence that silver dressings can improve outcomes at 4 weeks when used for treating hard-to-heal venous leg ulcers.

More information on the evidence for silver dressings is available in the <u>infected wounds</u> <u>section</u> of this evidence summary.

Cost effectiveness of silver dressings for venous leg ulcers

Economic modelling of data from the <u>VULCAN trial</u> found that silver dressings were associated with an incremental cost of £97.85 compared with control dressings when used for treating venous leg ulcers. The additional cost of silver dressings was partly due to an increased cost of dressings, but also due to a greater number of dressing changes in the silver dressings group. Although experts involved in the production of this evidence summary advised that it reflected standard practice at the time it was undertaken, this study (and its cost-effectiveness analysis) has been criticised for its relevance and generalisation to everyday clinical care; for example, participants in the study did not necessarily have wounds that were infected or at high risk of becoming infected (<u>Gottrup and Apelqvist 2010</u>).

<u>Jemec et al. (2014)</u> used data from the meta-analysis by <u>Leaper et al. (2013)</u> to evaluate the cost effectiveness of a specific brand of silver dressings (Biatain Ag) compared with non-silver dressings for treating hard-to-heal venous leg ulcers in UK primary care for 4 weeks.

The study estimated that the initial 4 weeks of treatment in primary care was more expensive for the group treated with silver dressings (£623.52) compared with non-silver

dressings (£533.60). However, because of a shorter time to wound healing (13.8 weeks compared with 16.7 weeks) and less need for referral for specialist care, the average total treatment cost per person was lower for silver dressings (£1,326.57) compared with non-silver dressings (£1,468.14) with a cost saving of £141.57 (95% CI £7.24 to £275.97). It is unclear how the outcome time to wound healing was obtained from the outcomes presented by Leaper et al. (2013) (primarily reduced ulcer area).

Conclusion: The limitations of the study by <u>Leaper et al. (2013)</u> subsequently limit the quality of the cost-effectiveness analysis and affect its application to practice. Also, <u>Jemec et al. (2014)</u> only assessed use of silver dressings for 4 weeks and cost effectiveness of use for shorter and longer periods is not known. The study by <u>Leaper et al. (2013)</u> used Biatain Ag dressings and costs may differ for other silver dressings. <u>Jemec et al. (2014)</u> also assumed that all ulcers would heal, whereas in practice some ulcers may become re-infected or worsen, and other complications may occur.

Arterial leg ulcers

Although most leg ulcers are due to venous disease, a significant number (around 22%) of people have arterial insufficiency. Arterial leg ulcers are due to inadequate blood supply to the skin, which may be caused by atherosclerosis. The most common accompanying complaint is pain and intermittent claudication, although people with neuropathy may not experience this pain (Forster and Pagnamenta 2015).

Unlike venous leg ulcers, compression therapy is generally not used for arterial leg ulcers because it can cause necrosis or even lead to amputation. The aim of treatment of arterial insufficiency is to improve the blood supply; surgery is often needed to bypass or clear blockages. Non-surgical options include good wound care, exercise to increase blood supply to the leg, pharmaceutical interventions or physical therapies, such as hyperbaric oxygen (Forster and Pagnamenta 2015).

Cochrane review: Dressings and topical agents for arterial leg ulcers

This Cochrane review (<u>Forster and Pagnamenta 2015</u>) found no studies on wound dressings that met the inclusion criteria.

Conclusion: There is insufficient evidence to determine whether the choice of dressing (or topical agent) affects the healing of arterial leg ulcers.

Infected wounds

For local wound infections, the <u>antimicrobial dressings</u> section of the BNF advises that a topical antimicrobial dressing can be used to reduce the level of bacteria at the wound surface but that it will not eliminate a spreading infection. The amount of exudate present and the level of infection should be taken into account when selecting an antimicrobial dressing. Medical grade honey has antimicrobial and anti-inflammatory properties. Dressings impregnated with iodine can be used to treat clinically infected wounds. Dressings containing silver should be used only when clinical signs or symptoms of infection are present.

Public Health England has issued guidance for primary care on <u>diagnosing and investigating venous leg ulcers</u>. This advises that all venous leg ulcers contain bacteria; however, some are just colonisers and not all bacteria cause clinical infection. Microbiological investigations should only be undertaken when there are clinical signs of infection (increased pain, enlarging ulcer, cellulitis and pyrexia). Empirical treatment with flucloxacillin (or erythromycin if the person is hypersensitive to penicillin) should be started after the ulcer has been swabbed and be reviewed after 3 days when the microbiology results are available.

The BNF section on <u>skin infections</u> advises that topical antibacterials should generally be avoided on leg ulcers, and that treatment of bacterial colonisation is generally inappropriate. To minimise the development of resistant organisms it is advisable to limit the choice of antibacterials applied topically to those antibacterials that are not used systemically.

Cochrane review: Topical silver for treating infected wounds

This Cochrane review (<u>Vermeulen et al. 2007</u>), which has already been considered in the <u>venous leg ulcers section</u> of this evidence summary, identified only 3 RCTs (n=847) with a short follow-up of 4 weeks. Silver-containing foam and alginate dressings did not statistically significantly increase complete ulcer healing compared with standard foam dressings or best local practice after up to 4 weeks of follow-up, although a greater reduction in ulcer size was observed with the silver-containing foam.

Conclusion: The authors of the Cochrane review noted that the 3 RCTs were small and of low power, and did not use measures of wound infection as outcomes. Therefore, they concluded that, although the methodology of the included RCTs was acceptable, there

was insufficient evidence to recommend the use of silver dressings in the treatment of infected or contaminated wounds.

Meta-analysis: Silver treatments and dressings for leg wounds and ulcers

This meta-analysis (<u>Carter et al. 2010</u>) included 10 RCTs (n=1,356) that assessed silver treatments and silver dressings for healing leg wounds and ulcers. Meta-analyses found no statistically significant difference between silver dressings and control dressings in complete wound healing (7 RCTs, n=1,118), although reduction in wound size was greater with silver dressings (5 RCTs, n=1,000; mean difference 10.29%, 95% CI 3.86% to 16.71%).

Although they noted that all of the RCTs on silver dressings had quality or bias issues, none were considered by the authors to be poor quality. However, this study assessed the quality of the evidence using an atypical approach that included reporting quality, external validity, bias, confounding and power, using differing methodologies. This means the quality of the meta-analysis is questionable.

Conclusion: The authors concluded that the results provide some evidence that silver dressings improve wound healing, in terms of reduction in wound size, in the short term. However, there was no evidence that silver dressings are effective for complete wound healing and measures of infection were not assessed. Also, the included RCTs had limitations, including lack of blinding or allocation concealment, use of inappropriate analyses, incomplete reporting, lack of generalisability to real world populations, differences in baseline characteristics and loss of patients to follow-up.

Cochrane review: Topical silver for preventing wound infection

This Cochrane review (<u>Storm-Versloot et al. 2010</u>) on topical silver products (dressings or creams) for preventing wound infection identified 26 RCTs (n=2,066), 20 of which considered burns. Six RCTs compared sulfadiazine cream with silver dressings, 2 in partial thickness burns (n=132) and 4 in full-thickness or severe burns (n=267). One RCT (n=27) showed statistically significantly fewer infections with silver dressings compared with silver sulfadiazine, the remaining 5 found no evidence of a difference.

Six RCTs compared silver sulfadiazine or silver dressings with non-silver dressings for acute, chronic or mixed wounds. Most comparisons found no statistically significant differences in infection rates, although 1 RCT (n=292) in a variety of wounds found statistically significantly fewer infections with silver sulfadiazine plus hydrocolloid

dressings compared with paraffin-impregnated gauze dressings. An RCT in acute wounds (n=209) found significantly more infections with silver sulfadiazine compared with neomycin sulphate. One RCT (n=434), which compared silver-containing hydrofibre dressings with calcium alginate dressings in people with diabetic foot ulcers, found a statistically significant reduction in healing time with silver dressings.

Most of the trials were small and of poor quality, with many demonstrating a high or uncertain risk of bias.

Conclusion: Overall, the authors of the Cochrane review considered that there was insufficient evidence to support the use of silver-containing dressings or creams because, generally, they did not promote wound healing or prevent wound infections.

Cochrane review: Honey as a topical treatment for wounds

This Cochrane review (<u>Jull et al. 2015</u>) compared honey applied topically by any means, alone or in combination with other dressings or components, compared with dressings or other topic agents. A diverse range of acute and chronic wounds was considered.

This Cochrane review found there is high-quality evidence (2 RCTs, n=992) that honey dressings heal partial thickness burns more quickly than conventional dressings (polyurethane film dressings, paraffin gauze, sterile linen, framycetin-impregnated tulle or left exposed). However, it is unclear if there is a difference in rates of adverse events (very low-quality evidence) or infection (low-quality evidence).

There is very low-quality evidence (4 RCTs, n=332) that burns treated with honey heal more quickly than those treated with silver sulfadiazine. High-quality evidence from 6 RCTs (n=462) found that there is no difference between these treatments in the overall risk of healing within 6 weeks, but an increased risk of adverse events with silver sulfadiazine.

There is low-quality evidence (2 RCTs, different comparators, n=140) that honey heals a mixed population of acute and chronic wounds more quickly than silver sulfadiazine or sugar dressings. Honey healed infected post-operative wounds more quickly than antiseptic washes followed by gauze and was associated with fewer adverse events (1 RCT, n=50: moderate-quality evidence).

Very low-quality evidence from another small RCT (n=40) suggests that honey may heal

pressure ulcers more quickly than saline soaks. The effect of honey relative to comparators is unclear for venous leg ulcers (2 RCTs, n=476; low-quality evidence), diabetic foot ulcers (2 RCTs, n=93; low-quality evidence) and mixed chronic wounds (2 RCTs, n=150; low-quality evidence).

The patient populations and comparators studied were heterogeneous and the evidence was affected by bias and imprecision, and was generally low quality.

Conclusion: The authors of the Cochrane review concluded that honey appeared to heal partial thickness burns and infected post-operative wounds more quickly than comparators. However, the comparators used may not be relevant to current practice, reducing the relevance and generalisability of the results. Evidence for differences in the effects of honey and comparators when used for other wounds is of low or very low quality and does not form a robust basis for decision-making.

Systematic review: lodine in wound care

This systematic review (<u>Vermeulen et al. 2010</u>) included 27 RCTs (number of participants not reported) that reported on chronic and acute wounds, burn wounds, pressure sores and skin grafts. No meta-analyses could be performed because of heterogeneity in wound care products, wound types and outcomes.

Most RCTs reportedly showed no substantial differences in beneficial or adverse effects between iodine (mainly povidone or cadexomer iodine) and comparators. Results did not differ between different types of wounds.

In RCTs that found a statistically significant difference, iodine was found to be superior to non-antiseptic dressings (paraffin dressings, dextranomer and zinc paste) and other antiseptic agents (such as silver sulfadiazine or chlorhexidine dressings), but inferior to a local antibiotic (rifamycin) in reducing bacterial count and/or wound size. The number of RCTs and participants for comparisons are not clearly reported in the paper.

In 3 RCTs, no effect of iodine on thyroid function was seen. However, the authors noted that the design of the RCTs included in the systematic review may not have been appropriate to assess adverse events.

Trial quality was assessed using a Cochrane Collaboration checklist and additional criteria and, overall, was found to be limited. Many of the RCTs were over 10 years old at the time

of the systematic review (2010) and not performed to present-day standards. Comparators used may not reflect current practice.

Conclusion: The authors concluded that iodine does not appear to be inferior to other antiseptic agents and does not impair wound healing. However, there is a need for high-quality RCTs addressing the effectiveness and safety of iodine to treat or prevent wound infection, in order to clearly determine its place in present-day wound care.

Evidence strengths and limitations

In their Cochrane review, <u>Forster and Pagnamenta (2015)</u> note that there are many issues that make it difficult to design and perform RCTs on wound care. Participants vary in a large number of respects, for example comorbidities, size and duration of wounds, and concurrent treatments (such as wound cleansing, exercise, nutrition and other self-care activities). Other challenges in designing a double-blind RCT on dressing efficacy include recruiting enough participants and validating outcomes (for example, infection, inflammation and wound sizes, and subjective assessments such as comfort and user friendliness).

Dressings are generally classified as medical devices. This is the case even for antimicrobial dressings, provided the antimicrobial agent is considered to provide an ancillary action on the wound (Centre for Evidence-based Purchasing Buyer's guide: advanced wound dressings). In accordance with the Medical Devices Directive (93/42/EEC), dressings must meet the applicable 'essential requirements' on safety and performance. Clinical data are usually necessary to demonstrate satisfactory performance of a medical device and establish any adverse effects. However, unlike medicines, for which data from RCTs are generally required, for devices this can take the form of a review of the relevant scientific literature; clinical trial data are not always required. Standard laboratory performance tests are required that measure the physical properties of dressings (for example, absorbency, moisture vapour transmission, waterproofness and conformability). However, these cannot predict reliably how dressings will perform in the clinical situation (Centre for Evidence-based Purchasing Buyer's guide: advanced wound dressings).

The lack of requirement for good-quality evidence for approval of medical devices is reflected in the poor quality of many of the RCTs in this area. Many RCTs used sample sizes too low to reliably detect differences between treatments. Other limitations in study methodology include, for example, poor reporting of assessor <u>blinding</u>, randomisation

methods, <u>allocation concealment</u> and baseline characteristics. Important patient-oriented outcomes such as pain, number of dressing changes, patient satisfaction, withdrawals and adverse events were often not reported, and outcome assessments were often subjective and not blinded. Follow-up was sometimes too short to assess complete wound healing. Use of inappropriate comparators in some RCTs means their results are not generalisable to a real-world population. Appropriate analyses (for example, <u>intention-to-treat</u>) were not always performed, and many of the RCTs were subject to bias. Industry sponsorship was common.

The limitations of the RCTs, and subsequently the systematic reviews and meta-analyses based on those RCTs, mean that good-quality evidence is available for few analyses of advanced wound dressings for managing chronic wounds. Overall, the clinical evidence is generally uncertain and not optimal in terms of informing clinical practice. Studies are also lacking on the cost effectiveness of advanced dressings for managing chronic wounds.

Context

Costs of wound dressings

Although representing only 1 route by which dressings are procured within the NHS, the prescription costs of advanced wound dressings and antimicrobial dressings in primary care in England were over £110 million in the year to August 2015 (based on BNF 69 sections at presentation level; personal communication: NHS Business Services Authority [BSA] 2015). A breakdown of the volumes prescribed and their associated costs according to the BNF category of dressing is shown in figures 1 and 2 (figures created using data provided by the NHSBSA). There is considerable variation in the cost of dressings both between categories and within each category. For example, silver dressings accounted for about 9% of items supplied on prescription, but in view of their relatively high cost were associated with over 18% (£20.5 million) of the total cost of advanced wound dressings.

Figure 1 Annual prescribing volumes of advanced wound dressings in primary care in England (September 2014 to August 2015)

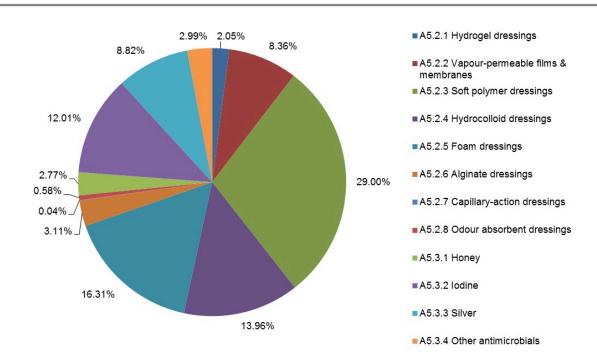
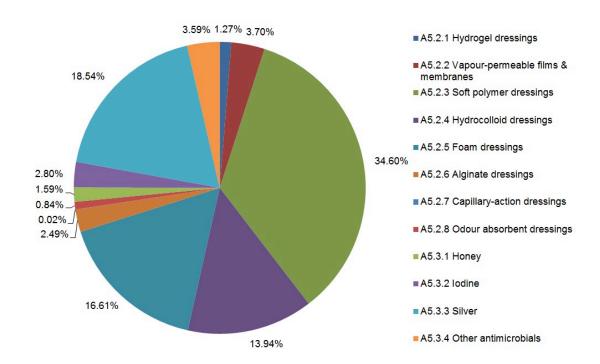


Figure 2 Annual prescribing costs of advanced wound dressings in primary care in England (September 2014 to August 2015)



Estimated impact for the NHS

Likely place in therapy

Safety, efficacy and cost effectiveness are important factors to consider when choosing dressings. However, a decision on which dressing is most appropriate for a specific chronic wound also requires careful clinical assessment of the person's wound, their clinical condition, any comorbidities and their personal circumstances and preferences.

There is little high-quality evidence from RCTs, or systematic reviews of controlled clinical trials on which to base dressing selection. From the studies included in this evidence summary, there is some limited evidence that some advanced dressings are more clinically effective than simple conventional dressings for treating some wounds. For example, systematic reviews and meta-analyses found:

- hydrogel dressings were more effective than basic wound contact dressings for complete healing of diabetic foot ulcers (low-quality evidence), as were foam dressings (very low-quality evidence)
- hydrocolloid and polyurethane film dressings were more effective than gauze dressings in terms of the proportion of pressure ulcers completely healed (low-quality evidence).

However, many of the conventional dressings used as comparators are no longer routinely recommended for chronic wounds (for example, gauze dressings) and there is generally insufficient evidence to distinguish between different types of advanced dressings.

The <u>silver dressings section</u> of the BNF states that antimicrobial dressings containing silvershould be used only when clinical signs or symptoms of infection are present. Silver ions exert an antimicrobial effect in the presence of wound exudate; therefore, the volume of wound exudate as well as the presence of infection should be considered when selecting a silver-containing dressing. Silver dressings should not be used routinely for managing uncomplicated ulcers, and the BNF recommends that these dressings should not be used on acute wounds because there is some evidence to suggest they delay wound healing. However, specialists involved in the production of this evidence summary advised that this evidence may relate to silver sulfadiazine only. Dressings impregnated with silver sulfadiazine have broad antimicrobial activity but, if silver sulfadiazine is applied to large areas or used for prolonged periods, there is a risk of blood disorders and skin

discoloration (see <u>silver sulfadiazine</u> in the BNF). Local protocols may be useful to help clinicians decide when silver dressings should be used.

When a specific dressing cannot be adequately justified on clinical grounds, it would seem appropriate for NHS healthcare professionals to routinely choose the least costly dressing of the type that meets the required characteristics appropriate for the type of wound and its stage of healing (for example, size, adhesion, conformability and fluid handling properties). The frequency of dressing change needs to be carefully considered and should be appropriate for the wound and dressing type. Patients should be assessed regularly. Prescribing the minimum quantity of dressings necessary to meet a person's needs can avoid wastage and stockpiling.

In view of the many dressings available, the absence of good-quality evidence for national guidelines to base specific recommendations on, and recognising financial constraints, local formularies provide a means of rationalising the choice of dressings. The NICE guideline on <u>developing and updating local formularies</u> provides good practice recommendations for the systems and processes needed to ensure NHS organisations develop and update local formularies effectively and in accordance with statutory requirements. It supports the development of local formularies that reflect local needs, reduce variation in prescribing and allow rapid uptake of innovative treatments.

In line with these good practice recommendations, a 2008 Wounds UK best practice statement (Development of a formulary) advises that wound dressings formularies should be developed by multidisciplinary teams using a fair and impartial process. They should include a range of clinically and cost effective products to serve the range of wound types and stages of healing. A dressings formulary needs to be regularly updated and reviewed to ensure it meets the needs of patients and their wounds. Regular audit is needed to monitor which dressings are being used, in what quantities and whether their use is appropriate. According to the Wounds UK best practice statement, it is necessary to have an ongoing educational programme alongside the dressings formulary to ensure that all included wound dressings and their application, removal and appropriate use are optimised to the benefit of both patients and healthcare professionals.

Estimated usage

See the <u>costs of wound dressings section</u> of this evidence summary for information on the prescribing costs of advanced wound dressings in primary care in England. It is not possible to provide estimated usage in the NHS for dressings provided by other routes or

in secondary care based on the available data.

Relevance to NICE guidance programmes

NICE has issued guidance on <u>pressure ulcers</u>: <u>prevention and management</u> (NICE guideline CG179) and <u>diabetic foot problems</u>: <u>prevention and management</u> (NICE guideline NG19). A quality standard on pressure ulcers has also been published (NICE quality standard 89).

The following NICE guidance related to wound management is also available:

- The MIST Therapy system for the promotion of wound healing (NICE medical technology guidance 5)
- The Debrisoft monofilament debridement pad for use in acute or chronic wounds (NICE medical technology guidance 17)
- Parafricta Bootees and Undergarments to reduce skin breakdown in people with or at risk of pressure ulcers (NICE medical technology guidance 20)
- The ReCell Spray-On Skin system for treating skin loss, scarring and depigmentation after burn injury (NICE medical technology guidance 21)
- <u>Negative pressure wound therapy for the open abdomen</u> (NICE interventional procedure guidance 467)

The following Medtech innovation briefings are produced by NICE but are not formal NICE guidance. They differ in format, contain no judgement on the value of the technology and do not constitute a guidance recommendation:

- The Versajet II hydrosurgery system for surgical debridement of acute and chronic wounds and burns (NICE advice MIB1)
- Oxyzyme and lodozyme 2-layer hydrogel wound dressings with iodine for treating chronic wounds (NICE advice MIB11)
- The Juxta CURES adjustable compression system for treating venous leg ulcers (NICE advice MIB25)

The NICE key therapeutic topic on <u>wound care products</u> (NICE advice KTT14) supports medicines optimisation in this area but is also not NICE guidance.

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Development of this evidence summary: medicines

and prescribing briefing

This evidence summary: medicines and prescribing briefing has been developed using the processes described in the <u>integrated process statement for evidence summaries: new medicines</u>. This statement sets out the process NICE uses to select topics for the evidence summaries, and explains how they are developed, quality assured and approved for publication.

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Declarations of interest

Lizette Howers has accepted hospitality (refreshments) when speaking at local events and travel, accommodation, hospitality and refreshments for an overnight visit to the Convatec Manufacturing site. She regularly meets with pharmaceutical and appliance companies as part of her work.

Nicky Cullum, Mair Davies, Mary Harrison, Sue Murphy and Bethanie Walters declared no relevant interests.

About this evidence summary: medicines and prescribing briefing

'Evidence summary: medicines and prescribing briefings' aim to review the evidence for the clinical effectiveness of medicines within a therapeutic class or indication to provide advice on the relative position of each medicine as a therapeutic option. This will assist localities in their planning on medicines optimisation priorities as well as providing individual prescribers with information to help informed decision making. The strengths and weaknesses of the relevant evidence are critically reviewed to provide useful information, but this evidence summary: medicines and prescribing briefing is not NICE guidance.

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