

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Centre for Clinical Practice

Review consultation document

Review of Clinical Guideline (CG29) – Pressure ulcers: the management of pressure ulcers in primary and secondary care

1. Background information

Guideline issue date: 2005

3 year review: 2008

6 year review: 2011

National Collaborating Centre: National Clinical Guidelines Centre

2. Consideration of the evidence

Literature search

From initial intelligence gathering and a high-level randomised control trial (RCT) search clinical areas were identified to inform the development of clinical questions for focused searches. Through this stage of the process 34 studies were identified relevant to the guideline scope. The identified studies were related to the following clinical areas within the guideline:

- Dressings and topical agents for the treatment of pressure ulcers
- Adjunctive therapies for the treatment of pressure ulcers
- Support surfaces for the treatment of pressure ulcers
- Nutrition in the treatment of pressure ulcers

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18 April – 08 May 2011

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Four clinical questions were developed based on the clinical areas above, qualitative feedback from other NICE departments and the views expressed by the Guideline Development Group, for more focused literature searches. The results of the focused searches are summarised in the table below. All references identified through the initial intelligence gathering, high-level RCT search and the focused searches can be viewed in [Appendix 1](#).

Clinical area 1: Dressings and topical agents for the treatment of pressure ulcers		
Clinical question	Summary of evidence	Relevance to guideline recommendations
Q1: What are the clinical and cost effectiveness of modern dressings versus conventional dressings in the management of pressure ulcers?	Through the focused search 12 studies relevant to the clinical question were identified. <u>Hydrocolloids, hydrogels, foams, alginates (six studies)</u> One systematic review on the use of hydrocolloids in the treatment of pressure ulcers suggested that hydrocolloids were more effective than conventional gauze dressings for the reduction of the wound size, absorption capacity, the time needed for dressing changes, the pain during dressing changes and adverse effects. Also, based on available costing data, hydrocolloids were less expensive compared with collagen-, saline- and povidine-soaked gauze but more expensive compared to hydrogel, polyurethane foam and collagenase. Another meta-analysis also showed greater efficacy of hydrocolloid dressings compared with conventional ones in the treatment of pressure ulcers.	No new evidence was identified which would invalidate current guideline recommendations.

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	• A systematic review of modern wound dressings found that, among 54 RCTs evaluating absorbent wound dressings, one RCT found calcium alginate dressings improved healing compared with dextranomer paste. However, no other one dressing was superior to alternatives. • One RCT examined the antimicrobial-performance of an ionic silver alginate/carboxymethylcellulose (SACMC) dressing compared to a non-silver calcium alginate fibre (AF) dressing, on chronic venous leg and pressure ulcers. The SACMC group showed a statistically significant improvement to healing as indicated by a reduction in the surface area of the wound, over the 4-week study period, compared with AF controls. • One RCT also assessed the differences in treatment costs and cost-effectiveness between a modern foam dressing (self-adhesive polyurethane foam) and saline-soaked gauze in patients with a stage II pressure ulcer at five centres in the United States. The study showed that the foam dressing was a more cost-effective treatment than saline-soaked gauze for the treatment of stage II pressure ulcers.	
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	• One RCT found that patients treated by hydrogel dressing had higher wound healing rate compared to standard treatment of pressure ulcers (gauze with povidone-iodine). However, the effect was not statistically significant. Overall, new evidence identified supports current recommendations on the use of modern dressings (e.g. hydrocolloids, hydrogels, foams, alginates) in preference to basic conventional dressings (e.g. gauze, paraffin gauze and simple dressing pads). However, the evidence-base is still insufficient to guide decision making on which particular modern dressing is the most effective compared to other modern dressings. <u>Other modern dressings (currently not covered in the guideline) (six studies)</u> • One RCT suggested that Allevyn adhesive was significantly less likely to delaminate than Biatain adhesive in the treatment of pressure ulcers. However, no direct outcome on wound healing was reported. • One RCT compared an activated charcoal dressing (Actisorb) with a	
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	hydrocolloid dressing in its ability to reduce the wound area of pressure ulcers. There were differences in results at week 1 in favour of the activated charcoal dressing. However, the results between the two groups became comparable at week 4. • One RCT suggested that patients treated by resin salve of the Norway spruce (<i>Picea abies</i>) had higher complete wound healing rate in grade II-IV pressure ulcers, compared to sodium carboxymethylcellulose hydrocolloid polymer treatment. • Another RCT also suggested that patients treated by a bioactive dressing (containing hydrophilic mucopolysaccharide, chitosan) had higher wound healing rate and lower incidence of infection, compared to conservative treatment (gauze). • One RCT examined whether cicatrization on pressure ulcers presents more rapidly with local cleaning with soap, application of zinc oxide paste and clg-pvp compared with local cleaning with soap, application of zinc oxide paste and placebo (saline solution with polyvinylpyrrolidone). Despite the greater diameter reduction in the first group, the effect was not statistically significant due to short follow-up	
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	and small sample size. • Another RCT also compared the effectiveness of polyvinylidene (PVL) food wrap as a dressing material versus conventional ointments and gauze dressings for pressure ulcers in patients aged 60 years or over. The treatment group showed significant greater improvement in pressure ulcer scores than the control group at 12 weeks. Overall, there is insufficient evidence on the effectiveness of the above modern dressings as each was only supported by one RCT with small sample size (less than 100 patients).	
Clinical area 2: Adjunctive therapies for the treatment of pressure ulcers		
Clinical question	Summary of evidence	Relevance to guideline recommendations
Q1: What is the clinical effectiveness of adjunctive therapies (electrotherapy,	Through the focused search 11 studies relevant to the clinical question were identified. <u>Electrotherapy, electromagnetic therapy, ultrasound therapy (five studies)</u>	Potential new evidence that may invalidate current guideline recommendations.

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electromagnetic therapy, ultrasound, negative wound pressure therapy and hyperbaric oxygen therapy) in the management of pressure ulcers?	• One RCT found that, patients treated with the decubitus direct current electro-stimulation had no significant different rates of complete closure of ulcers and the mean time needed to achieve complete wound closure compared to control group. • One RCT found that electric stimulation therapy (EST) administered as part of a community-based interdisciplinary wound care program (SWC) accelerated healing rate of pressure ulcers significantly in patients with spinal cord injury, compared to patients treated with SWC only. • One Cochrane systematic review found that there was no statistically significant difference between the healing rates of grade II and III pressure ulcers in people treated with electromagnetic therapy compared with those treated with sham electromagnetic therapy, or other (standard) treatment. • Another RCT examined the effectiveness of pulsed electromagnetic field therapy (PEMF) found that there was no significant difference in pressure ulcers healing rates between patients treated by PEMF and	
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	those who received sham treatment. • Another Cochrane systematic review also found that there was no evidence of benefit associated with the use of ultrasound in the treatment of pressure ulcers, compared with sham ultrasound or other standard treatment. Overall, new evidence identified on electrotherapy, electromagnetic therapy and ultrasound therapy potentially contradict current GDG consensus recommendation on the use of electro-therapy technologies based on individual patient's level of risk from holistic assessment/general skin assessment, general health status, previous experience and practitioner's competence. <u>Negative pressure wound therapy (NPWT) (four studies)</u> • A systematic review on the effectiveness and safety of NPWT had identified 14 RCTs in patients with pressure wounds, post-traumatic wounds, diabetic foot ulcers and miscellaneous chronic ulcers. Most evidence only supported the effectiveness of NPWT on chronic leg	
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	ulcers and post-traumatic ulcers. Only two trials were classified as high quality studies, whereas the remaining were classified as having poor internal validity. • Another systematic review also showed that, for diabetic foot ulcers (seven RCTs), there was evidence of the benefit of NPWT compared with control treatments. However, there were conflicting results for pressure ulcers (three RCTs) regarding the benefit of NPWT compared with control treatments. • Another systematic review on the clinical effectiveness and safety of NPWT in comparison to conventional wound therapy showed that significant differences in favor of NPWT for time to wound closure or incidence of wound closure were only indicated in two of five RCTs, and that the overall methodological quality of the trials was poor. The body of evidence available is insufficient to clearly prove an additional clinical benefit of NPWT. • One systematic review on the clinical effectiveness of NPWT in patients with chronic wound had identified seven RCTs that compared NPWT with five different active comparator treatments (i.e. gauze soaked in	
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	saline or Ringer's solution, hydrocolloid gel plus gauze, papain-urea topical treatment, cadexomer iodine or hydrocolloid, hydrogels, alginate and foam). None of the RCTs showed that NPWT significantly increased the healing rate of chronic wounds compared to other active comparators. Overall, new evidence identified on NPWT may potentially contradict current GDG consensus recommendation on the use of NPWT based on individual patient's level of risk from holistic assessment/general skin assessment, general health status, previous experience and practitioner's competence. <u>Hyperbaric oxygen therapy (HBOT) (one study)</u> One Cochrane systematic review on the benefits and harms of adjunctive HBOT for treating chronic ulcers of the lower limb (diabetic foot ulcers, venous and arterial ulcers and pressure ulcers) reported that no trials identified on pressure ulcers were included as the trials did not satisfy the inclusion criteria. Hence the review found no	
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	evidence to confirm or refute any effect of HBOT on pressure ulcers. <u>Other adjunctive therapy (one study)</u> One small RCT (N = 18) found that patients who were treated by intravenous Semelil (ANGIPARS [trademark]), a new herbal extract, together with conventional therapy had significant higher average reduction in pressure ulcer area compared to patients who were treated by conventional therapy alone. However, more large trials were needed to further establish its efficacy.	
Clinical area 3: Support surfaces for the treatment of pressure ulcers		
Clinical question	Summary of evidence	Relevance to guideline recommendations
Q1: What is the clinical effectiveness of alternating pressure mattresses in the treatment of pressure	Through the focused search only one study relevant to the clinical question were identified. One RCT examined the effectiveness of active alternating pressure mattresses showed significant decreases in pressure ulcer surface area	No new evidence was identified which would invalidate current guideline recommendations.

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ulcers? (NICE research recommendation)	and pressure ulcer scores among medical ICU patients compared to reactive air mattresses.	
Clinical area 4: Nutrition in the treatment of pressure ulcers		
Clinical question	Summary of evidence	Relevance to guideline recommendations
Q1: What is the clinical effectiveness of nutritional supplements versus standard care for the treatment of pressure ulcers in non-malnourished patients? (NICE research recommendation)	Through the focused search 4 studies relevant to the clinical question were identified. <u>Protein, arginine, zinc, and vitamin C</u> - One RCT examined the effectiveness of supplementary arginine, vitamin C and zinc (together with standard hospital diet) in patients with stage 2, 3 or 4 pressure ulcers found that the treatment group had clinically significant improvement in pressure ulcer healing compared with those only received daily standard hospital diet. - Another RCT investigated the effectiveness of a high-protein, arginine- and micronutrient-enriched oral nutritional supplement (ONS) (together	Potential new evidence that may invalidate current guideline recommendations.

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	with regular diet and standard wound care) in non-malnourished patients with stage III or IV pressure ulcers found that, pressure ulcer healing rate, pressure ulcer severity scores and dressing requirement were significantly better in the ONS group compared to patients on regular diet and standard wound care only. • Another RCT also found that disease-specific nutritional approach (consisting of standard diet plus oral supplement or specific enteral formula enriched with protein, arginine, zinc, and vitamin C) was significantly more beneficial than a standard dietary approach in pressure ulcer healing rate, reduction in ulcer surface area and pressure ulcer scores in institutionalized elderly patients. • Finally, one RCT examined the effectiveness of a concentrated, fortified, collagen protein hydrolysate supplement (plus standard care) found that the pressure ulcer scores of long-term-care residents with stage II, III, or IV pressure ulcers were significantly lower at eight-week in the treatment group compared to the control group (placebo plus standard care).	
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Guideline Development Group and National Collaborating Centre perspective

A questionnaire was distributed to GDG members and the National Collaborating Centre (NCC) to consult them on the need for an update of the guideline. Only two responses were received with respondents highlighting that since publication of the guideline, there is variation in practice mainly due to the latest publication of the pressure treatment guideline from the European and US National Pressure Ulcer Advisory panel (EPUAP and NPUAP, 2010). One respondent also highlighted patient experience in terms of inappropriate pressure ulcer care reported in the 'Independent inquiry into Mid-Staffordshire NHS Foundation Trust (2010)'. The need to amalgamate existing guideline with 'CG7: The use of pressure-relieving devices for the prevention of pressure ulcers in primary and secondary care' was also emphasized.

No anecdotal efficacy or safety concerns were highlighted or any relevant ongoing research.

Both respondents felt that there is sufficient variation in current practice supported by adequate evidence at this time to warrant an update of the current guideline.

Implementation and post publication feedback

In total 69 enquiries were received from post-publication feedback, most of which were routine.

The NICE implementation programme has not looked at any routinely collected data in order to determine the uptake of this particular clinical guideline.

Several issues were highlighted through qualitative input from the field team. In particular, an audit which showed variation in existing practice, and concerns were expressed regarding consistency in the approach to pressure

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ulcer management. In addition, the inclusion of pressure ulcers in Quality Standards was highlighted as a significant local issue due to the potential impact upon increased length of hospital stay and delayed discharge.

Relationship to other NICE guidance

The following NICE guidance is related to CG29:

Guidance	Review date
CG7: The use of pressure-relieving devices for the prevention of pressure ulcers in primary and secondary care, 2003.	May 2011
CG74: Surgical site infection: prevention and treatment of surgical site infection, 2008.	July 2011
CG32: Nutrition support in adults: oral nutrition support, enteral tube feeding and parenteral nutrition, 2006.	July 2011
CG10: Type 2 diabetes: prevention and management of foot problems, 2004	July 2011
CG119: Diabetic foot: inpatient management of people with diabetic foot ulcers and infection, 2011 (Recommendation regarding support surfaces for patients with diabetic foot ulcer is cross-referred to CG29)	March 2014

Anti-discrimination and equalities considerations

No evidence was identified to indicate that the guideline scope does not comply with anti-discrimination and equalities legislation. The original scope contains recommendations on the management of people (adults, infants, children and young people) who have pressure ulcers, including secondary infection of the ulcer in primary and secondary care.

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Conclusion

From the evidence and intelligence identified through the process, it suggests that some areas of the guideline may need updating at this stage, particularly in relation to:

- Adjunctive therapies for the treatment of pressure ulcers (electrotherapy, electromagnetic therapy, ultrasound therapy and NPWT)
- Nutrition in the treatment of pressure ulcers
- Amalgamation of existing guideline with 'CG7: The use of pressure-relieving devices for the prevention of pressure ulcers in primary and secondary care'

3. Review recommendation

The guideline should be considered for an update at this time.

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Appendix 1

Adunsky, A., A. Ohry, and G. Ddct, Decubitus direct current treatment (DDCT) of pressure ulcers: results of a randomized double-blinded placebo controlled study. Archives of gerontology and geriatrics, 2005. 41(3): p. 261-269.

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