National Clinical Guideline Centre

Appendix M

Pressure ulcer prevention and management

Research recommendations

Commissioned by the National Institute for Health and Care Excellence

Royal College of Physicians
The Royal College of Surgeons of England
RCGP Royal College of General Practitioners
Royal College of Nursing
NICE accredited
www.nice.org.uk/accreditation

Funding
National Institute for Health and Care Excellence 2014.

Contents

Appendix M: Research recommendations

M.1 Research question: What is the effect of enzymatic debridement of non-viable tissue compared with sharp debridement on the rate of healing of pressure ulcers in adults?

Why this is important:

The debridement of non-viable tissue within a pressure ulcer is thought to help healing occur as quickly as possible, as the presence of dead tissue can delay healing and encourage infection. Autolytic debridement via natural processes, often supported by the use of an appropriate dressing, provided for other purposes, is considered to be adequate for the majority of pressure ulcers and is current standard care. However, many other methods of debriding non-viable tissue are available, including mechanical, enzymatic, surgical and sharp debridement and larval therapy. A pressure ulcer with non-viable tissue may have levels of exudate and odour that are affecting quality of life, therefore it may be desirable to expedite the debridement process to improve this. Expert consensus suggests there may be an association between the presence of non-viable tissue and the probability of wound infection. Where the risk of infection is thought to be present the healthcare professional needs to identify the most appropriate method of debridement for the individual.

There is currently limited high quality evidence available to suggest whether the removal of non-viable tissue via sharp debridement (carried out at the bed side, by an appropriately qualified healthcare professional) or enzymatic debridement, produces the best outcomes and allows for quicker healing of the pressure ulcer. Currently within the UK, the use of enzymatic debridement is limited and the availability of these agents is variable however, it is frequently used in other countries. Additionally, there is some suggestion that the removal of non-viable tissue via enzymatic debridement may be slower than using sharp debridement and that it may result in the removal of otherwise viable tissue.

Identifying the best method of removing non-viable tissue may have significant benefits in terms of patient quality of life, for example, by reducing the length of stay for people in hospital or the about of time spent on bed rest.

Criteria for selecting high-priority research recommendations:

PICO question	Does enzymatic or sharp debridement of non-viable tissue improve healing of pressure ulcers in adults who have developed a pressure ulcer?
Importance to patients or the population	Identifying the best method of removing non-viable tissue as quickly and painlessly as possible may impact upon a person's quality of life both by reducing pain and discomfort associated with certain debridement methods, the results of debridement and reducing the time taken to heal a pressure ulcer.
Relevance to NICE guidance	Future updates of the guideline would be able to produce a stronger recommendation in this area, and potentially influence debridement methods used in other wounds (for example, venous leg ulcers).
Relevance to the NHS	There are economic implications to the NHS of using different methods of debridement, as different strategies require different upfront resources, and some are likely to promote healing better than others. It is therefore vital that the most effective method of debridement is identified, as this will help identify the most cost-effective strategy, and could lead to cost savings from a reducing time to healing (and the associated reductions in treatment costs) and reduced length of stay.

PICO question	Does enzymatic or sharp debridement of non-viable tissue improve healing of pressure ulcers in adults who have developed a pressure ulcer?
National priorities	None.
Current evidence base	A small number of low quality randomised controlled trials have suggested some clinical benefit, for complete healing, of collagenase (an enzymatic debridement agent) compared with autolytic debridement supported by the use of a hydrocolloid or hydrogel dressing. However, these studies have used small numbers of patients and some comparators were not representative of current clinical practice (for example, egg white). Further high quality research comparing enzymatic debridement to other relevant forms of debridement, such as sharp debridement is needed to identify which method of removing non-viable tissue is preferential.
Equality	No known equality issues.
Study design	Randomised controlled trial.
Feasibility	No known feasibility issues.
Other comments	None.
Importance	High: the research is essential to inform future updates of key recommendations in the guideline High:

M.2 Research question: Does negative pressure wound therapy (with appropriate dressing) improve the healing of pressure ulcers, compared to the use of dressing alone in adults with pressure ulcers?

Why this is important:

Negative pressure wound therapy (NPWT) is used for a variety of wounds, including pressure ulcers, with the intention of assisting healing, reducing the surface area of a wound and the removal of wound exudate. NPWT aims to create a suction force which enables the drainage of wounds and promote wound healing. Although there is evidence to suggest benefit in the use of NPWT in some other wound areas (for example, surgical wounds) there is limited evidence to support the use of NPWT in pressure ulcers.

Despite this, NPWT is used variably across the NHS and many trusts have purchased or hired NPWT pumps. Given this, it is likely that there would be benefits to both patients and the NHS in identifying whether the use of NPWT may be beneficial to improving the healing of pressure ulcers.

Criteria for selecting high-priority research recommendations:

PICO question	Does negative pressure wound therapy (with appropriate dressing) improve the healing of pressure ulcers compared with the use of dressing alone in adults with pressure ulcers?
Importance to patients or the population	Anecdotal evidence has suggested that there are both benefits and harms to the patient in the use of NPWT. There is some suggestion, particularly in other chronic wounds, that the use of NPWT may increase the rate of healing, reduce the need for further treatment and reduce time in hospital and therefore have a positive impact upon a patient's quality of life., However, patients have reported tolerability issues relating to the use of NPWT, particularly with regards to noise levels and comfort and the impact upon mobility and any therapy provided. It is therefore important to ascertain whether there are any potential benefits

PICO question	Does negative pressure wound therapy (with appropriate dressing) improve the healing of pressure ulcers compared with the use of dressing alone in adults with pressure ulcers?
	and/or harms of using NPWT to improve healing of pressure ulcers.
Relevance to NICE guidance	Any evidence generated would be likely to strengthen any recommendations in future updates of the guideline. Any evidence may also help to inform related guidance that consider the use of NPWT for healing of wounds.
Relevance to the NHS	NPWT is currently used across the NHS to varying degrees and can be costly as there are costs associated with hiring or purchasing NPWT pumps. If there is no clinical benefit of this therapy in pressure ulcers, it is unlikely that NPWT is cost-effective and therefore efficiencies can be gained by reducing its use. However, if NPWT is found to promote healing, cost savings may even be realised, as shorter treatment times and reduced hospital stays may outweigh the upfront cost of the therapy. Evidence on clinical effectiveness it vital to identify cost impact.
National priorities	None.
Current evidence base	Only 3 low quality randomised controlled trials were identified on the use of negative pressure wound therapy, specifically focusing on pressure ulcers. No clinical benefit was found. Further high quality research is required to identify whether there are any potential benefits to the use of NPWT.
Equality	None known.
Study design	Randomised controlled trial.
Feasibility	There are no known feasibility issues.
Other comments	This research would benefit from being publically funded, rather than funded by industry.
Importance	High: the research is essential to inform future updates of key recommendations in the guideline

M.3 Research question: In adults who have adequate nutritional status and who have a pressure ulcer, does providing further nutritional supplementation improve healing of the pressure ulcer?

Why this is important:

Various nutrients have been associated with promoting pressure ulcer repair through their role in collagen formation and development of connective tissue. For example, nutrients such as protein, vitamin C, zinc have historically been considered important because of their role in protein synthesis and collagen formation. Other nutrients are posited as also improving pressure ulcer healing for example, arginine by, among other things, promoting protein synthesis, collagen formation and wound strength; or collagen protein hydolysate by providing increased protein content. There is currently weak, low quality evidence to support the use of nutritional supplements in people who have pressure ulcers, in studies with small sample sizes, lack of blinding and using mixed nutritional supplements. Further evidence would help to identify suitable composition of supplements, which could potentially provide benefit.

Criteria for selecting high-priority research recommendations:

PICO question	In adults who have adequate nutritional status and who have a pressure ulcer, does providing further nutritional supplementation improve healing of the pressure ulcer?
Importance to patients or the population	Should nutritional supplements improve pressure ulcer healing rates, it is likely that there would be an improvement in patient quality of life. It is possible that there would be side effects associated with the provision of some nutritional supplements such as taste issues although these are thought to be minimal.
Relevance to NICE guidance	Further evidence in this area would help to support updated recommendations in any future updates of this guideline and be beneficial to other guidelines focusing on healing of chronic wounds.
Relevance to the NHS	Provision of nutritional supplements to people who have pressure ulcers would potentially be cost saving to the NHS. By generating good quality evidence more confidence can be attributed to any cost incurred.
National priorities	None.
Current evidence base	Current evidence is of low quality and considered the use of nutritional supplementation in people who have a pressure ulcer and who did not have adequate nutritional status. The majority of studies identified did not consider overall calorie intake against individual requirements and were mainly carried out on those who were malnourished. Thus making it unclear if it was the correction of malnutrition which was causing any benefit. For some studies, there was a conflict when those in control groups also had supplements due to an insufficient dietary intake. Lack of blinding was also a frequent issue as was variation at baseline. Additionally, the evidence was difficult to interpret as the supplements used contained a variety of components, making it difficult to isolate which element provided any benefit. Finally, many nutritional supplements were used alongside other treatment interventions such as dressings, repositioning strategies and pressure redistributing devices. No randomised controlled trials or cohort studies were identified on the use of nutritional supplementation to aid the healing of pressure ulcers in neonates, infants, children and young people.
Equality	None.
Study design	Randomised controlled trial.
Feasibility	Achieving blinding in studies focusing on nutritional supplementation can be difficult.
Other comments	None.
Importance	Medium: the research is relevant to the recommendations in the guideline, but the research recommendations are not key to future updates

M.4 Research question: Do pressure redistributing devices reduce the development of pressure ulcers for those who are at risk of developing a pressure ulcer?

Why this is important:

Pressure relieving and redistributing devices are widely accepted methods preventing the development of pressure ulcers for patients assessed as being at risk of developing pressure ulcers. These devices include different types of mattresses, overlays, cushions and seating and work by either reducing pressure, friction or shearing forces. There is currently limited evidence (most of

which is funded by industry) to identify whether certain features of these devices are beneficial. Furthermore, these devices can vary significantly in cost and it is currently unclear whether the provision of more advance devices, for example, alternating pressure devices, provide any additional benefit compared to static low tech devices such as high specification foam mattresses.

There is also limited evidence to identify whether different at risk sites benefit from different pressure redistributing devices. For example, it has been suggested that some pressure redistributing devices used for pressure relief of other sites can cause further pressure to be inflicted upon the heel and therefore result in an increase in the incidence of pressure ulcer development. Further research is needed to identify what devices are beneficial for specific at-risk sites, including the heel.

Criteria for selecting high-priority research recommendations:

PICO question	Do pressure redistributing devices reduce the development of pressure ulcers for adults who are at risk of developing a pressure ulcer?
Importance to patients or the population	The provision of pressure redistributing devices to all individuals who are at risk of developing a pressure ulcer, both in primary care, community and secondary care settings could reduce the incidence of pressure ulcers. in turn this would lead to an improvement in quality of life and reduced treatment time. Patients also often find the air mattress to be noisy and these can restrict therapy.
Relevance to NICE guidance	Further evidence in this area would help to inform recommendations in future updates of the guideline.
Relevance to the NHS	Preventing pressure ulcers in all people at risk of developing a pressure ulcer would have a substantial impact upon resources required, for example a reduction in healthcare professional time. Identifying the most effective pressure redistributing device may have both clinical and economic benefits through a reduced incidence of pressure ulcers and therefore associated treatment costs, or from a reduction in resources used to reposition patients. Redistributing devices can be costly to purchase, therefore it is important that the most effective devices are identified so that resources can be allocated appropriately, and cost-effective strategies implemented.
National priorities	The NHS Safety Thermometer gathers data on the incidence of pressure ulcers, the data from which is used as part of the Commissioning for Quality and Innovation (CQUIN) payment programme.
Current evidence base	High quality research is limited and is often biased by the use of other preventative strategies, alongside varying frequencies and positions of repositioning. In addition, much of the current evidence has been funded by industry and could be subject to bias. No studies in neonates, infants, children or young people were identified.
Equality	No known equality issues.
Study design	Randomised controlled trial.
Feasibility	No known feasibility issues.
Other comments	The research would benefit by being publically funded, rather than by industry.
Importance	High: the research is essential to inform future updates of key recommendations in the guideline

M.5 Research question: When repositioning a person who is at risk of developing a pressure ulcer, what is the most effective position –

and optimum frequency of repositioning – to prevent a pressure ulcer developing?

Why this is important:

It is generally accepted that repositioning individuals, both neonates, infants, children, young people and adults who are at risk of developing a pressure ulcer can prevent the development of a pressure ulcer by redistributing pressure at the at risk site.[1] However, encouraging people who are at risk of developing a pressure ulcer or providing them with help with frequent repositioning can impact substantially upon a patient's comfort, particularly when this is done at night or when repositioning is painful. In addition, this can have substantial cost implications, particularly in terms of staff time. It is therefore important to identify the most efficient position and frequency of repositioning, to minimise discomfort to the patient, ensure that benefits in terms of pressure ulcer prevention are maximised and resources are used efficiently.

There is limited RCT evidence available to suggest the most efficient position and frequency of repositioning in populations of all ages. Of the evidence that is available, many studies include patients who are on pressure redistributing surfaces, meaning that it is unclear whether any benefit in pressure ulcer prevention is provided by the support surface or repositioning intervention. Therefore there is a need for a study to randomise patients to different frequencies and positions of repositioning, whilst receiving a standard support surface for example, a high specification foam mattress.

Criteria for selecting high-priority research recommendations:

PICO question	What is the most effective position and frequency at which individuals at risk of developing a pressure ulcer should be repositioned to prevent the development of a pressure ulcer?
Importance to patients or the population	If the optimum frequency of repositioning was identified, patient comfort and pain may be reduced, particularly if the rate of repositioning was reduced during the night. Reduction in the number of pressure ulcers developed would have a significant positive impact upon a patient's quality of life. This benefit would be likely to affect a large proportion of the population, given that most adults admitted to secondary care settings are considered at risk of developing a pressure ulcer at some time during their hospital stay.
Relevance to NICE guidance	Identifying the most effective frequency and position of repositioning people at risk of developing a pressure ulcer would impact upon any future updates of this guideline, in terms of recommendations relating to repositioning and the use of other preventative interventions.
Relevance to the NHS	Repositioning all people at risk of developing a pressure ulcer can have a substantial impact upon resources required, particularly healthcare professional time, therefore it is important to establish whether repositioning represents a cost-effective use of resources. Repositioning is likely to improve quality of life, and lead to downstream cost savings through a reduced incidence of pressure ulcers leading to a reduction in treatment costs.
National priorities	The NHS Safety Thermometer gathers data on the prevalence of pressure ulcers, the data from which is used as part of the Commissioning for Quality and Innovation (CQUIN) payment programme.
Current evidence base	High quality research is limited and is often biased by the use of other preventative strategies for example, pressure redistributing surfaces alongside varying frequencies and positions of repositioning. There is one RCT of low quality which looks at the repositioning of children with acute lung injury. Further high quality research is needed in these specific

PICO question	What is the most effective position and frequency at which individuals at risk of developing a pressure ulcer should be repositioned to prevent the development of a pressure ulcer?
	populations to identify the most effective frequency and position for these age groups.
Equality	Any research should focus on people who are able to reposition themselves as well as those who are unable to reposition themselves (for example, people with significant mobility issues).
Study design	Randomised controlled trial.
Feasibility	No known feasibility issues.
Other comments	None.
Importance	High: the research is essential to inform future updates of key recommendations in the guideline

M.6 Research question: Which pressure ulcer risk assessment tools are most effective for predicting pressure ulcer risk in children?

Why this is important:

There are a few published pressure ulcer risk assessment tools for children, but most of these have no evidence of validity, and over half have been developed from adult pressure ulcer risk assessment tools. Of the tools which have validation data, the evidence is mainly poor quality.

When healthcare professionals are choosing a risk assessment tool to use in clinical practice, they should be looking for a tool that has evidence to demonstrate that it is good at predicting risk in the population of interest.

Criteria for selecting high-priority research recommendations:

PICO question	Are any paediatric pressure ulcer risk assessment tools superior to other tools for predicting pressure ulcers incidence in paediatric patient groups (e.g. paediatric patients in critical care, general paediatric wards or community).
Importance to patients or the population	Using the most effective pressure ulcer risk assessment tool for paediatric populations will more accurately alert carers to risk and institute preventative interventions. This should prevent more pressure ulcers in paediatric patients.
Relevance to NICE guidance	Future NICE guidance will have high quality studies comparing the effectiveness of different paediatric pressure ulcer risk assessment tools, so that recommendations can be made about which tool to use for certain paediatric patient populations.
Relevance to the NHS	Carers and clinical staff will be able to choose the most effective pressure ulcer risk assessment tool for paediatric patient populations, and be able to predict which patients are most at risk of pressure ulcers. This will enable them to use resources to prevent pressure ulcers more efficiently.
National priorities	There is a National initiative for no avoidable pressure ulcers in NHS provided care
Current evidence base	There are no published paediatric pressure ulcer incidence studies comparing the effectiveness of paediatric pressure ulcer risk assessment tools
Equality	The research question has no particular equality issues.
Study design	A paediatric pressure ulcer incidence study collecting patient data for two or more pressure ulcer risk assessment tools. The data should be used to calculate the sensitivity, specificity and predictive validity (area under the receiver operating characteristics curve) for each pressure ulcer risk assessment tool, then the validity of the tools can be compared.

PICO question	Are any paediatric pressure ulcer risk assessment tools superior to other tools for predicting pressure ulcers incidence in paediatric patient groups (e.g. paediatric patients in critical care, general paediatric wards or community).
Feasibility	Data should be collected at multiple paediatric inpatient units and combined, as the incidence of pressure ulcers in children may be too small for a single site study.
Other comments	None
Importance	Preventing pressure ulcers is a National priority. There is little evidence for paediatric patients in this area. High: the research is essential to inform future updates of key recommendations in the guideline

References

1 Defloor T, De BD, Grypdonck MH. The effect of various combinations of turning and pressure reducing devices on the incidence of pressure ulcers. International Journal of Nursing Studies. 2005; 42(1):37-46