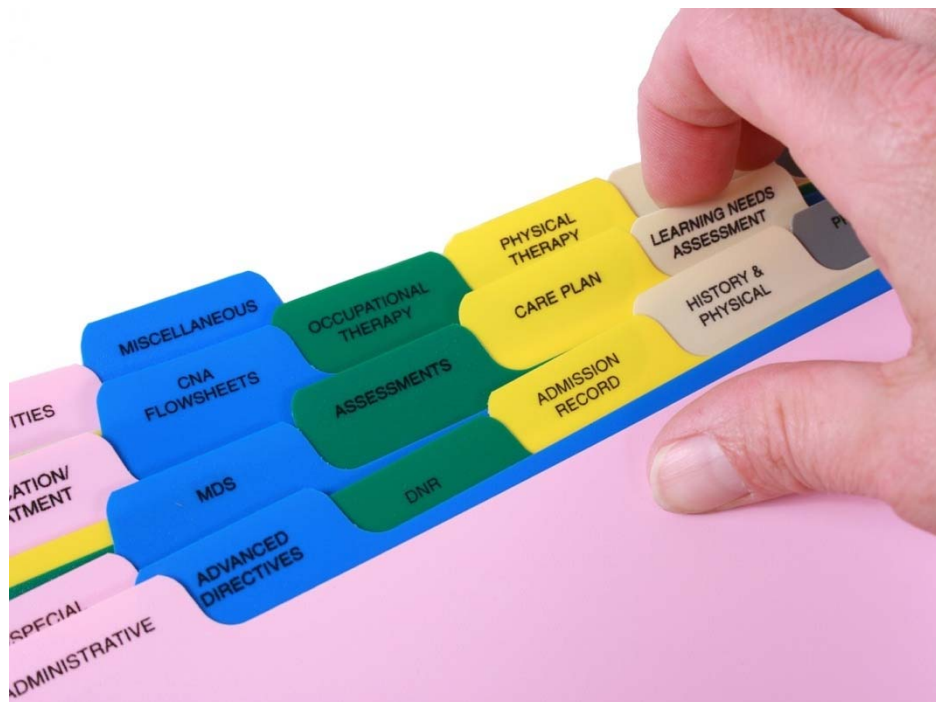


A NATIONAL GUIDELINE FOR THE TREATMENT OF PRESSURE ULCERS

SYNTHESIS





Belgian Health Care Knowledge Centre

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SYNTHESIS

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Disclaimer:	<p>The external experts were consulted about a (preliminary) version of the scientific report. Their comments were discussed during meetings. They did not co-author the scientific report and did not necessarily agree with its content.</p> <p>Subsequently, a (final) version was submitted to the validators. The validation of the report results from a consensus or a voting process between the validators. The validators did not co-author the scientific report and did not necessarily all three agree with its content.</p> <p>Finally, this report has been approved by common assent by the Executive Board.</p> <p>Only the KCE is responsible for errors or omissions that could persist. The policy recommendations are also under the full responsibility of the KCE.</p>
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■ FOREWORD

We present here the previously announced follow-up to the guideline for the prevention of pressure ulcers published in January of this year: a national guideline for the treatment of pressure ulcers. This new publication was again made possible thanks to the contribution of the expert teams at Ghent University (UGent) and Leuven Catholic University (KULeuven) and our British colleagues of the National Clinical Guideline Centre (NCGC, London) that produces guidelines on behalf of NICE (now renamed the National Institute for Health and Care Excellence).

This was no easy task. To the great frustration of the research team, there are very few or no good-quality studies for most of the aspects of care. Nevertheless, much time and effort was spent in systematically going through the scientific literature based on the highest international standards. This guideline at least taught us that there is virtually no convincing scientific evidence in support of many of the widely used and accepted treatment techniques. This meant that we were forced to rely on studies of lesser quality, with all the ensuing dangers of bias and wishful thinking, and on the consensus of experts in the field.

Such information is not without value - pressure ulcers are indeed effectively treated -, but hard proof in the field would of course be much appreciated. This would be beneficial for example when making the choice whether or not to invest in costly dressings or equipment. At any rate, attentive, individually-adapted care provided by professional caregivers (nurses, doctors, dieticians ...) remains the foundation for success. During periods of budgetary restrictions, some may be tempted to make cuts in these areas and replace some with machines... the efficacy of which has not been proven. One of the fundamental messages of this guideline is that high-quality, multidisciplinary care that gives priority to the patient's needs is and remains priceless.

Christian LÉONARD
Deputy general director

Raf MERTENS
General director



■ SYNTHESIS

1. OBJECTIVES AND SCOPE OF THIS GUIDELINE

The aim of the current clinical practice guideline (CPG) is to offer an overview of the current evidence on treatment of patients with pressure ulcers and to formulate recommendations to health care providers in hospitals, long-term care facilities (including nursing homes, rehabilitation facilities and long-term chronic care hospitals) and home care.

This guideline on treatment follows the publication of a national CPG on the prevention of pressure ulcers (see KCE-report 193^a).

This guideline focuses on the following topics:

- Nutritional support;
- Pressure-redistributing devices (mattresses, overlays, beds, cushions);
- Debridement;
- Topical agents;
- Dressings;
- Indications for surgery;
- Systemic antimicrobials;
- Electrotherapy;
- Light therapy;
- Hyperbaric oxygen therapy;
- Negative pressure wound therapy;
- Heel ulcers.

^a Beeckman D, Mathei C, Van Lancker A, Van Houdt S, Vanwalleghem G, Gryson L, et al. A national guideline for the prevention of pressure ulcers. Brussels: Belgian Healthcare Knowledge Centre (KCE); 2013. KCE reports 193C D/2013/10.273/97



Incontinence-associated dermatitis (IAD) is often misclassified as a pressure ulcer in clinical practice. However, this CPG will not cover the management of incontinence-associated dermatitis because of the unique nature and the specific aetiology of this skin disorder.

2. DEFINITION AND EPIDEMIOLOGY

The European Pressure Ulcer Advisory Panel (EPUAP) defines a pressure ulcer as a localized injury of the skin and/or underlying tissue resulting from an internal response to an external mechanical load, applied to soft biological tissues, generally over a bony prominence. This external mechanical load can be a force perpendicular to the skin surface (pressure), a force parallel to the skin surface (shear), or a combination of pressure and shear.

The severity of a pressure ulcer varies from non-blanchable erythema of the intact skin to tissue destruction involving skin, subcutaneous fat, muscle and bone. In its classification system, EPUAP defined a pressure ulcer Category I as non-blanchable erythema of the intact skin, a pressure ulcer Category II as an abrasion or a blister, a pressure ulcer Category III as a superficial ulcer, and a pressure ulcer Category IV as a deep ulcer.

Reported pressure ulcer prevalence rates in European countries remain high: from 8.9% to 18.1% in hospitals and from 6.4% to 31.4% in nursing homes. In Belgium, the prevalence of pressure ulcers on a national level has only been studied within the hospital setting, with a reported prevalence of 12.1% (Category I-IV). Pressure ulcers are associated with considerable discomfort, comorbidity and costs.



3. METHODS

3.1. Systematic review of the literature

This guideline was developed in collaboration with The National Clinical Guideline Centre (NCGC, UK) and the elaboration of the topics has been divided between both organisations (KCE and NCGC).

The search in OVID Medline, EMBASE, CINAHL and the Cochrane Library (conducted between September 2012 and April 2013) systematic reviews and randomized controlled trials (RCTs). If no RCTs were found for the topics studied, cohort studies with control group were also included.

3.2. Elaboration of the recommendations

On the basis of the evidence collected, the research team elaborated a first draft of recommendations.

To determine the level of evidence and strength of recommendation, the GRADE methodology was followed (Tables 1 & 2).

Recommendations based on expert consensus were labeled as “best practices”. Two existing guidelines (i.e. EPUAP/NPUAP 2009 & NICE 2005) were used as a basis to formulate best practices. These guidelines were selected on the basis of a systematic search and quality evaluation (using AGREE II) carried out by three independent reviewers.

Recommendations and best practices were then submitted to a panel of clinical experts (see colophon), who rated them with a score ranging from 1 (‘completely disagree’) to 5 (‘completely agree’) and discussed them during a face to face meeting.

Finally, three external validators assessed and validated this guideline by using the AGREE II checklist. The validation process was chaired by CEBAM (Belgian Centre for Evidence-Based Medicine).

Declarations of interest were requested from all experts involved.

Table 1 – Levels of evidence according to GRADE^b

Quality level	Definition	Methodological Quality of Supporting Evidence
High	We are very confident that the true effect lies close to that of the estimate of the effect	RCTs without important limitations or overwhelming evidence from observational studies
Moderate	We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different	RCTs with important limitations (inconsistent results, methodological flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies
Low	Our confidence in the effect estimated is limited: the true effect may be substantially different from the estimate of the effect	RCTs with important limitations or observational studies or case series
Very low	We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of the effect	

^b Balshem H, Helfand M, Schunemann HJ, Oxman AD, Kunz R, Brozek J, et al. GRADE guidelines: 3. Rating the quality of evidence. J Clin Epidemiol. 2011;64(4):401-6.

**Table 2 – Strength of recommendations according to GRADE^c**

Grade	Definition
Strong	The desirable effects of an intervention clearly outweigh the undesirable effects (<i>the intervention is to be put into practice</i>), or the undesirable effects of an intervention clearly outweigh the desirable effects (<i>the intervention is not to be put into practice</i>).
Weak	The desirable effects of an intervention probably outweigh the undesirable effects (<i>the intervention probably is to be put into practice</i>), or the undesirable effects of an intervention probably outweigh the desirable effects (<i>the intervention probably is not to be put into practice</i>).

^c Guyatt GH, Oxman AD, Kunz R, Falck-Ytter Y, Vist GE, Liberati A, et al. Going from evidence to recommendations.[Erratum appears in BMJ. 2008 Jun 21;336(7658): doi:10.1136/bmj.a402]. BMJ. 2008;336(7652):1049-51.



4. CLINICAL RECOMMENDATIONS

First general considerations are formulated based on two existing guidelines (i.e. EPUAP/NPUAP 2009 & NICE 2005) and expert consensus. The details of the evidence underpinning the recommendations and best practices below are in the scientific report and its supplements.

4.1. General considerations

4.1.1. *Tailoring pressure ulcer treatment to each patient*

Best Practices

Pressure ulcer treatment should be a combined approach, tailored to individual patient needs and situations and should be based on the principles of shared decision making:

- **Treatment should take into account several factors such as the individual's medical condition, the overall plan of care and the individual's preferences. The needs of the individual and the context should be re-assessed regularly;**
- **An individual plan of care should be elaborated based on assessment data, identified risk factors and individual goals and preferences. The plan is elaborated in collaboration with the patient, informal caregivers and the healthcare professionals. The planned and agreed/refused actions are documented in the patient record and communicated to all relevant caregivers (also in case transition between care settings takes place).**

4.1.2. *Holistic assessment and individual plan of care*

Best Practices

Patients with pressure ulcers should receive an holistic initial assessment including:

- **The individual's medical condition;**
- **The individual's preferences;**
- **Risk factors for development and deterioration of pressure ulcers (see prevention guideline^d);**
- **A focused physical examination that includes:**
 - **Factors that may affect healing (e.g., impaired perfusion, impaired sensation, systemic infection);**
 - **Vascular assessment in the case of extremity ulcers (e.g., physical examination, history of claudication, ankle-brachial index,...);**
 - **Pain assessment (see below);**

^d Beeckman D, Mathei C, Van Lancker A, Van Houdt S, Vanwalleghem G, Gryson L, et al. A national guideline for the prevention of pressure ulcers. Brussels: Belgian Healthcare Knowledge Centre (KCE); 2013. KCE reports 193C D/2013/10.273/97



Best Practices

- Nutritional assessment (see below);
- Ulcer assessment (see below).

Reassess on regular basis and document the findings.

Patients with pressure ulcers should receive an initial and ongoing ulcer assessment. The aim of ulcer assessment is to establish the severity of the ulcer, to develop a treatment plan, to evaluate treatment interventions, to assess for complications and to communicate information about the pressure ulcer to the relevant members of the multidisciplinary team.

- The ulcer assessment should include:
 - Cause of the ulcer (e.g. pressure ulcer due to nasogastric tube, oxygen mask, pressure on bony prominences);
 - Site/location;
 - Time since pressure ulcer occurrence;
 - Stage or category;
 - Dimensions of ulcer and type of tissue;
 - Exudate amount and type;
 - Local signs of infection;
 - Pain;
 - Wound appearance (e.g. wound edges, undermining/tracking (sinus or fistula), necrotic tissue, presence/absence of granulation tissue, and epithelialisation);
 - Surrounding skin;
 - Odour;
 - Dressing appearance (exudate saturation, color, adhesion, ...).
- A structured approach for ulcer assessment and monitoring should be used. This structured approach could include:
 - The consistent use of uniform measurement methods of the dimensions of the pressure ulcer (i.e. wound length and width, depth, tunneling and undermining) to facilitate consistent follow-up over time. The deepest part of the wound should be measured using a sterile probe and care should be taken to avoid causing injury;
 - The assessment of healing signs such as decreasing amount of exudate, decreasing wound size and improvement in wound bed tissue;
 - The use of photographs to monitor pressure ulcer healing over time;
 - The use of a standardized classification system for the initial assessment of the pressure ulcer category (e.g. NPUAP/EPUAP Classification System);

**Best Practices**

- The regular assessment and monitoring (e.g. PUSH-tool; PSST; Sessing scale^e), with the frequency depending on the condition of the wound and the result of the holistic assessment of the patient. With each dressing change, the pressure ulcer should be observed for developments that may indicate the need for a change in treatment (e.g., wound improvement, wound deterioration, more or less exudate, signs of infection or other complications);
- All assessments and actions should be documented and time stamped.

Any relevant change in the wound characteristics should be documented, and the information should be made accessible and communicated to the members of the multidisciplinary team.

*4.1.3. Primary and secondary prevention***Best Practices**

Patients with a pressure ulcer should be considered at risk of developing additional pressure ulcers. Therefore the general principles of pressure ulcer prevention (see prevention guideline^f: risk and skin assessment; repositioning) should be applied to:

- Prevent the development of new pressure ulcers;
- Prevent the pressure ulcers to get worse;
- Support the healing process.

With regard to nutrition and re-distributing devices, specific recommendations for the treatment of pressure ulcers are formulated (see below).

*4.1.4. Pain assessment and management***Best Practices**

Pain assessment and management are of utmost importance and have to be integrated in the general plan of care. The evidence about treatment of pain related to pressure ulcers has not been studied specifically for the purpose of this guideline. Therefore we refer to generally accepted pain assessment and treatment procedures.

^e See for examples at the website of the Belgian Ministry of Public Health (FOD/SPF): http://www.health.belgium.be/eportal/Healthcare/healthcareprofessions/Nursingpractitioners/EvidenceBasedNursing/physiologicaldomain/integrityoftissues/cwcare-pressureulcers/19074612_NL

^f Beeckman D, Mathei C, Van Lancker A, Van Houdt S, Vanwalleghem G, Gryson L, et al. A national guideline for the prevention of pressure ulcers. Brussels: Belgian Healthcare Knowledge Centre (KCE); 2013. KCE reports 193C D/2013/10.273/97



4.1.5. *Educating and training of professional caregivers in pressure ulcer treatment*

Best Practices

Training and education should be tailored both to the needs of individual caregivers and to the responsibilities of each specific group of professionals.

Consider following educational/training programme components :

- Holistic assessment and individual patient planning;
- Ulcer assessment;
- Normal healing process;
- Pain assessment;
- Nutritional support;
- Recognising inflammation and infection signs;
- Exudates management;
- Local treatment options, methods for debridement and/or protection of tissue;
- Skin protection;
- Properties and effectiveness of different types of dressing;
- Positioning/repositioning;
- Properties and effectiveness of different types of support surfaces (e.g. mattresses, devices for heel elevation, seat cushions).

4.2. Nutritional support

Best Practices

Monitoring of the nutritional status of patients with pressure ulcers should be part of a general assessment procedure and an ongoing process throughout an individual's episode of care. The initial assessment should include documentation of the following factors:

- Current weight and height;
- Recent weight loss;
- Usual eating habits;
- (Recent changes in) eating habits and intake;
- The adequacy of total nutrient intake (food, fluid, oral supplements, enteral/parenteral feedings).

**Best Practices**

The nutritional support for the treatment of patients with pressure ulcers should be based on:

- A formal nutritional assessment, (e.g. Mini-Nutritional Assessment);
- General medical condition;
- Patient preferences;
- Advice from a professional with specific competencies in nutritional care in order to provide sufficient calories, protein, fluid, micronutrients, particularly when dietary intake is poor or deficiencies are confirmed or suspected.

Recommendation	Strength of Recommendation	Level of Evidence
<p>A care professional with specific competencies in nutritional care may recommend nutritional interventions (e.g. nutritional supplements) for patients with pressure ulcers.</p> <p>As clinical studies did not demonstrate the superiority of one nutritional intervention over another, we cannot recommend a specific complementary diet (type and quantity) with nutritional supplements.</p>	Weak	Very Low

4.3. Pressure redistributing devices

Recommendations	Strength of Recommendation	Level of Evidence
<p>The use of pressure-redistributing devices (low-tech constant low pressure surfaces or high-tech support surfaces) is recommended for patients who have a pressure ulcer. Redistributing devices should be used in combination with regular repositioning.</p>	Strong	Very low
<p>As clinical studies did not demonstrate the superiority of one pressure redistributing device over another (e.g. air-fluidised therapy, alternating-pressure mattress), decisions about which pressure redistributing device to use should be based on an overall assessment of the patient, including wound evolution and offloading possibilities, level of risk, comfort and general health state.</p>	Weak	Very low



Best practices

When pressure ulcers deteriorate or fail to heal, or when there is an increase in risk status:

- The professional caregiver should consider changing the existing redistributing device with one that will reduce time of applied pressure and/or improve pressure redistribution and reduce shearing forces;
- Preventive interventions and local wound care should also be intensified;
- Before replacing the existing mattress, evaluate the effectiveness of previous and current prevention and treatment plans.

4.4. Debridement

Best practices

Debride devitalized tissue within the wound bed or edge of pressure ulcers.

If debridement is considered, the choice of the method(s) (chemical, bioactive, surgical, autolytic, enzymatic, mechanical debridement) will be based on: the patient's condition; goals of care; ulcer/periulcer status; type, quantity, and location of necrotic tissue; care setting; availability of products for debridement and the available professional skills.

4.5. Dressings and Topical agents

Recommendation	Strength of Recommendation	Level of Evidence
<p>Consider improving wound healing environment by using modern dressings (see table 13) and topical agents (e.g. hydrocolloids, hydrogels, hydrofibres, foams, alginates, silver dressings) instead of basic dressing types (e.g. gauze, paraffin gauze and simple dressing pads).</p> <p>As clinical studies did not demonstrate the superiority of one type of modern dressing and topical agent over another, decisions about which type of modern dressing/topical agent to use should be based on:</p> <ul style="list-style-type: none">○ Ulcer assessment (condition of wound: tissue, exudate, depth, degree of infection, odor, pain, wound edges and wound environment);○ General skin assessment;○ Treatment objective;	Weak	Very low



Recommendation	Strength of Recommendation	Level of Evidence
<ul style="list-style-type: none">○ Dressing characteristics;○ Previous positive effect of particular dressing/topical agent;○ Manufacturer's indications for use and contraindications;○ Risk of adverse events;○ Patient preferences (lifestyle, abilities and comfort).		

4.6. Indications for surgery

An evaluation of the clinical effectiveness of the different surgical techniques used in the treatment of pressure ulcers was beyond the scope of this guideline; only the indications for surgery have been studied.

Best Practices

Referral for the surgical treatment of pressure ulcers should be based on:

- Level of risk (anaesthesia and surgical intervention);
- Recurrence;
- Patient preferences (lifestyle, abilities and comfort);
- Ulcer assessment (e.g. anatomical site, staging);
- General skin assessment;
- General health status;
- Competing care needs;
- Assessment of psychosocial risk factors of recurrence;
- Previous success of surgical techniques;
- Failure of previous conservative management interventions.



4.7. Systemic antimicrobials

Best practice

In the presence of systemic and/or local clinical signs of infection in the patient with a pressure ulcer, systemic anti-microbial therapy will be considered by the treating physician.

4.8. Adjuvant therapies

For this recommendation, we looked into the evidence on electrotherapy, hyperbaric oxygen therapy, light therapy and negative pressure wound therapy.

Recommendation	Strength of Recommendation	Level of Evidence
As clinical studies failed to demonstrate the clinical effectiveness of negative pressure wound therapy, electrotherapy, light therapy, hyperbaric oxygen therapy, we cannot recommend any of these technologies as routine treatments for pressure ulcers.	Weak	Low to Very Low

4.9. Treatment of heel ulcers

Best Practices

Heels with pressure ulcers should be offloaded maximally. The choice of devices to offload the heel could be informed by factors such as cost, ease of use, patient comfort, patient preferences, anatomical position of the ulcer site.

For bedridden patients or patients sitting in a chair in backward position with the feet up, heel-protection devices should offload the heel completely. This can be done by distributing the weight of the leg along the calf without putting pressure on the Achilles tendon. The knee should be in slight flexion and supported.



5. DISCUSSION

Despite current advances in medicine and nursing care, pressure ulcers remain a major cause of morbidity and mortality. Depending on the setting **clinicians have a plethora of options at their disposal to treat pressure ulcers**. Pressure ulcer management is highly demanding in terms of resources and product costs. The development of a clinical practice guideline is crucial to support clinicians in their decision making based on the best available evidence.

A large discrepancy exists between the high relevance of the topic and the **poor availability of methodologically sound clinical studies with a focus on pressure ulcer treatment**. In general, the available studies for each of the guideline topics are largely under-powered and suffer from methodological flaws such as: lack of allocation concealment; lack of baseline comparability; lack of blind – or independently verified – outcome assessment; poor description of standard care and co-interventions.

5.1. Best available evidence

It should be noted that for many of the frequently used treatment options, little (or no) evidence exists, or the available evidence has important methodological shortcomings. However, absence of evidence does not imply evidence of absence of effect. While awaiting more studies of high methodological quality in this domain, many, if not most of the options presented rely on international consensus, further confirmed by the Belgian experts consulted during this project.

5.2. How to use this guideline

Pressure ulcer treatment requires a patient-tailored multi-factorial approach including a holistic assessment, a structured approach to ulcer assessment and follow-up (e.g. photographs and ulcer assessment tools), and an individual plan of care that is agreed upon within the multidisciplinary team. This individualized care plan includes aspects of wound care (e.g. debridement, dressings, surgical wound closure), symptom management (e.g. pain management), primary and secondary prevention interventions (e.g. redistributing devices and repositioning) as well as systemic interventions to promote wound healing (e.g. nutritional support).

Similar to the national CPG on the prevention of pressure ulcers (see KCE-report 193)⁹ it is important to tailor the use of this guideline to the specific needs of the organisation or setting. In addition, given the low level of evidence it is important to include other considerations in decision making.

This guideline should be considered as one of the building blocks for organizations when developing their own comprehensive policy targeting each of the caregivers involved. This includes the development of organization specific protocols and procedures that take into account local circumstances. Clinicians and healthcare organisations should be informed about the limited evidence base of most treatment options.

The wound care associations (e.g. CNC, WCS, AFISCeP) and organisations of healthcare professions can support the implementation of this guideline in daily practice by making it available through their websites and in their educational activities. Healthcare organizations could also invest in multidisciplinary wound care teams that are responsible for supporting clinicians and organizations in making practice-informed choices, and that could engage in such activities as: the development of a wound care module in the (electronic) patient record, the organization of multidisciplinary continuous education, clinical bedside or remote wound care consultation (e.g. with photographs), follow-up of investment on patient outcomes.

5.3. Need for further research

Further research is needed, given the large discrepancy between the importance of this topic and paucity of methodologically sound clinical studies. As such, there is an urgent need for well designed, sufficiently powered, multi-centred, randomized, controlled trials to compare the clinical effectiveness of different types of treatment options. Priority should be given to studies about:

- The clinical effectiveness of 'High tech' pressure redistributing devices compared with 'lower-tech' alternatives (such as different types of foam mattresses).

⁹ Beeckman D, Mathei C, Van Lancker A, Van Houdt S, Vanwalleghem G, Gryson L, et al. A national guideline for the prevention of pressure ulcers. Brussels: Belgian Healthcare Knowledge Centre (KCE); 2013. KCE reports 193C D/2013/10.273/97



- The clinical effectiveness of different nutritional interventions (type and content) on the healing of pressure ulcers.
- The clinical effectiveness of modern dressing and topical agent types compared with each other. The modern dressing/topical agent type that is subject of the study should be compared with a clinically relevant comparator (e.g. alternative topical agent or dressing used for same indications).
- The clinical effectiveness of negative pressure wound therapy compared with dressings commonly used as alternatives to negative pressure wound therapy and for which there is good evidence of effect available.



■ RECOMMENDATIONS^h

To partners of the Health Research System:

- Support to develop research programs on the effectiveness of different treatment options (e.g. dressing types, Negative Pressure wound therapies) currently used to treat pressure ulcers in daily practice.

To the attention of the Federal Council on the quality of the Nursing activities and in consultation with the National Council of Quality Promotion:

- To develop and implement process and outcome indicators based on the content of this guideline. These should be aligned with existing pressure ulcer indicator initiatives.

To the attention of the FPS Public Health, Food Chain Safety and Environment:

- To transform and disseminate this guideline in procedures, protocols, educational programs, etc. that are in a user-friendly format for daily use. This should be done in close collaboration with professional organisations.

To the attention of the professionals leading and facilitating practice changes in home nursing as well as in hospitals and other institutional settings:

- To develop comprehensive programs for pressure ulcer treatment (e.g. monitoring and feedback, wound care resource nurses, multidisciplinary wound care committees) integrated in the global wound care policy. Next to nurses, this multidisciplinary approach should also involve geriatricians, plastic surgeons and dermatologists in hospitals, the coordinating physician in nursing homes and the general practitioner for patients receiving care in the home environment.

^h The KCE has sole responsibility for the recommendations.

