Evidence-based Practice Center Systematic Review Protocol
Pressure Ulcer Treatment Strategies: A Comparative Effectiveness Review

I. Background and Objectives for the Systematic Review

Uninterrupted pressure exerted on the skin, soft tissue, muscle, and bone can lead to the development of localized ischemia, tissue inflammation, tissue anoxia, and necrosis. Pressure ulcers can result from these effects; about 3 million adults in the United States suffer from pressure ulcers. Estimates of the incidence of pressure ulcers vary according to the setting and range from 0.4 to 38.0 percent in acute-care hospitals, from 2.2 to 23.9 percent in long-term nursing facilities, and from 0 to 17 percent in the home-care setting.[1,2] Various systems have been used to assess the severity of pressure ulcers, but most use a four-stage categorization with higher numbers indicating higher severity.[3] Healing rates of pressure ulcers vary considerably and are dependent on comorbidities, clinical interventions, and severity of the ulcer. This variability can add to the length of hospitalization and impede the return of patients to full functioning.[2] Data on the costs of treatment for a pressure ulcer vary, but some estimates range between $37,800 and $70,000, with total annual costs in the United States as high as $11 billion.[1,4]

Interventions to treat pressure ulcers are numerous and diverse and include strategies such as reducing pressure with various support surfaces, wound debridement and cleansing, surgical repair, and the use of various wound dressings, various biologic agents, and nutritional supplementation.[1,4] In addition, various adjunctive therapies have been evaluated, including vacuum-assisted closure, ultrasound therapy, electrical stimulation, and hyperbaric oxygen therapy. The approach to treatment typically varies, depending on the stage of the wound and patient-related factors such as the existence of particular comorbidities.[5, 6,7]

This topic was selected for review based on two separate nominations. The Key Questions (KQs) were developed with input from Key Informants representing clinicians, wound care researchers, and patient advocates. The general categories of treatment to be reviewed include support surfaces, nutritional supplements, wound dressings, biologic agents, surgical procedures, and various adjunctive therapies. We will evaluate the evidence based on comparisons within the general categories (e.g., comparisons between two types of dressings). We also will evaluate direct evidence on comparisons across the general categories. Our review will include an assessment of adverse effects or harms associated with pressure ulcer treatment such as dermatologic complications, bleeding, pain, or infection. It will also assess future research needs on this important clinical topic.

II. The Key Questions

A preliminary set of KQs was posted on the Effective Health Care Program Web site of the Agency for Healthcare Research and Quality (AHRQ), and public comments were collected and evaluated.

A Summary of the Public Comments

Most of the public comments addressed specific patient or treatment characteristics and settings. Commenters suggested that the review should address combinations of treatments, comorbid conditions, and ulcer characteristics that require an individualized approach to treatment. These comments led us to expand the potential range of treatments evaluated in the review. Because treatment goals for patients in hospice care differ widely from patients with pressure ulcers in other settings (wound healing may not be a goal of hospice care), we excluded hospice from the list of care settings to be reviewed. The final set of KQs is as follows:

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Final Key Questions

Question 1

In adults with pressure ulcers, what is the comparative effectiveness of treatment strategies for improved health outcomes including but not limited to: complete wound healing, healing time, reduced wound surface area, pain, and prevention of serious complications of infection?

Question 1a

Does the comparative effectiveness of treatment strategies differ according to features of the pressure ulcers, such as anatomic site or severity at baseline?

Question 1b

Does the comparative effectiveness of treatment strategies differ according to patient characteristics, including but not limited to: age; race/ethnicity; body weight; specific medical comorbidities; and known risk factors for pressure ulcers, such as functional ability, nutritional status, or incontinence?

Question 1c

Does the comparative effectiveness of treatment strategies differ according to patient care settings such as home, nursing facility, or hospital, or according to features of patient care settings, including but not limited to nurse/patient staffing ratio, staff education and training in wound care, the use of wound care teams, and home caregiver support and training?

Question 2

What are the harms of treatments for pressure ulcers?

Question 2a

Do the harms of treatment strategies differ according to features of the pressure ulcers, such as anatomic site or severity at baseline?

Question 2b

Do the harms of treatment strategies differ according to patient characteristics, including: age, race/ethnicity; body weight; specific medical comorbidities; and knows risk factors for pressure ulcers, such as functional ability, nutritional status, or incontinence?

Question 2c

Do the harms of treatment strategies differ according to patient care settings such as home, nursing facility, or hospital, or according to features of patient care settings, including but not limited to nurse/patient staffing ratio, staff education and training in wound care, the use of wound care teams, and home caregiver support and training?

The following PICOTS were identified for each KQ and include:

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Population

- Adults ages 18 and older with pressure ulcers.

Interventions

- Various treatment strategies for pressure ulcers including but not limited to therapies that address the underlying contributing factors (e.g., support surfaces and nutritional supplements); therapies that address local wound care (e.g., absorbent wound dressings and biological agents); surgical repair; and adjunctive therapies (e.g., physical therapy).

- Combined treatment modalities (cointerventions) will also be evaluated (such as comparing two treatments in combination with a single treatment).

Comparators

- Placebo or active control, usual care, or other interventions

Outcomes

- For effectiveness: complete wound healing, healing time, reduced wound surface area, pain, and prevention of serious complications of infection
- For harms of treatment: pain, dermatologic complications, bleeding, and infection

Timing

- Any duration of followup

Settings

- Patient care settings, such as home, nursing facility, or hospital

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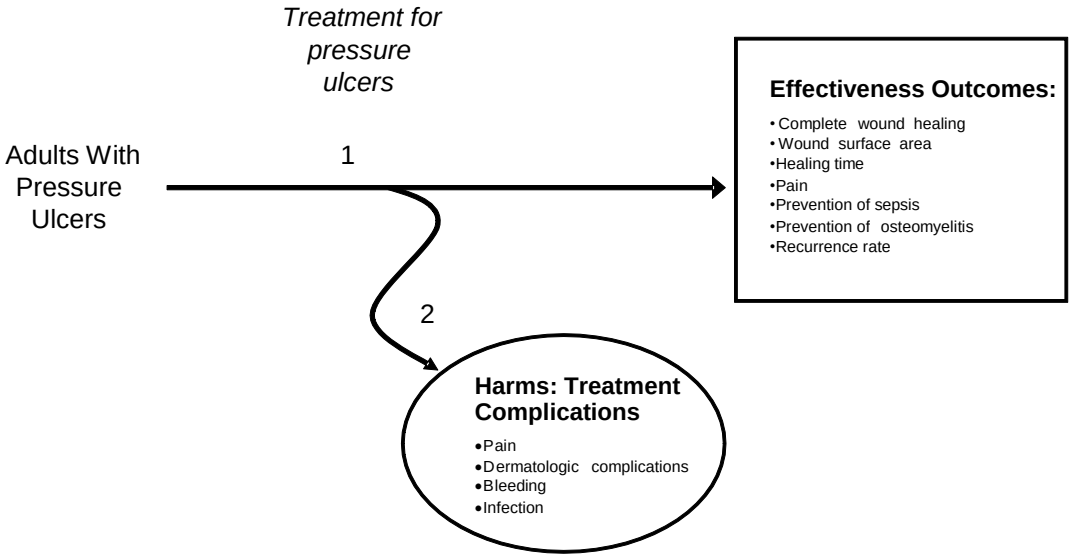
III. Analytic Framework

Figure 1. Analytic framework for the comparative effectiveness review of pressure ulcer treatment strategies



IV. Methods

A. Criteria for Inclusion/Exclusion of Studies in the Review

The criteria for inclusion and exclusion of studies will be based on the KQs and the populations, interventions, comparators, outcomes, timing, and setting (PICOTS) approach. To enhance consistency and reduce bias in our study selection process, each reviewer will initially evaluate the same set of 200 citations for inclusion, and kappa values will be calculated to estimate inter-reviewer reliability. After discussing and reconciling disagreements between reviewers, the same four team members will review an additional 100 citations. This process will continue until a kappa value of >0.50 for each pair of reviewers is reached. For the remaining references, each reviewer will review each title and abstract for inclusion and exclusion, using the pre-established inclusion/exclusion criteria to determine eligibility for inclusion in the evidence synthesis. To ensure accuracy, a secondary review of all excluded abstracts will be conducted by a senior investigator/clinician. All citations deemed appropriate for inclusion by one or both of the reviewers will be retrieved for review as full-text articles.

The studies meeting the inclusion/exclusion criteria will consist of randomized and nonrandomized trials, observational studies, and case series. Systematic reviews will be used as primary sources of evidence if they are considered to be of good quality; if there is no additional evidence or if the additional evidence does not substantially change the results, the systematic

reviews will be used for background information or to ensure completeness of the literature search. The target population is adult patients with pressure ulcers; studies in pediatric populations, in hospice and palliative care settings, and with nonhuman subject studies will not be included in this review. Sample size restrictions will not be set a priori, and case series may be used; however, case studies with only one patient will not be included. The publication date range will include all citations currently available in the electronic databases at the time of the initial search in June 2011, with a time frame of January 1985 to the present, and citations obtained when an updated search is conducted after peer review of the draft report. According to current guidance from the U.S. Preventive Services Task Force (USPSTF), ARHQ, the European Pressure Ulcer Advisory Panel and recommendations from our Technical Expert Panel (TEP), nearly all of the treatment modalities and procedures for treating and healing pressure ulcers used in clinical practice today were either manufactured or developed within the past 30 years. We feel confident that current literature (1985–present) not only captures historically significant treatments and evidence but also provides the most current information and treatments used in clinical practice today. Non–English-language studies will be included in the abstract triage and translated for full-text review as feasible. If a sufficient body of English-language evidence is available, non–English-language studies may not be translated or used. Grey literature—including unpublished data, abstracts, dissertations, and individual product packets from manufacturers—will be solicited and included if they add meaningful data or other information beyond what is found in the published literature. To obtain additional data for evidence tables or quality ratings, study authors may be contacted for those data or for unpublished protocols.

Based on input from our TEP, we will exclude single-site studies (typically small series) reporting the results of specific surgical techniques for pressure ulcer management. Because surgical outcomes are heavily influenced by individual surgeons, local practice patterns, and other contextual factors, we felt that data from single-site studies would have limited generalizability and would not provide a sound basis for making indirect comparisons across studies. However, we will include multicenter studies in which large series of patients underwent surgery for pressure ulcer, because we feel that the results of these studies have greater generalizability. We will also include studies that provide direct, head-to-head comparisons of different surgical techniques.

Each full-text article will be independently reviewed by two team members. If a consensus is reached between the two, then the article will be either included or excluded accordingly. In cases of disagreement, a senior investigator will review the article and adjudicate the decision to include or exclude it. A record of excluded studies with reasons for exclusion will be maintained. Data from included studies will be extracted into evidence tables and entered into an electronic database.

Library searches will be updated while the draft report is posted for public comment and peer review to capture any new publications. Literature identified during the updated search will be assessed by using the same process of dual review as all other studies considered for inclusion in our report. If we identify any pertinent new literature for inclusion in the report, it will be incorporated before the final submission of the report.

B. Searching for the Evidence: Literature Search Strategies for Identification of Relevant Studies To Answer the Key Questions

To identify primary literature, we will search the following databases: MEDLINE® (Ovid), EMBASE® (Elsevier), CINAHL® (EBSCOhost), Evidence-Based Medicine Reviews (Ovid), the Cochrane Central Register of Controlled Trials, the Cochrane Database of Systematic Reviews (CDSR), the Database of Abstracts of Reviews of Effects (DARE), and the Health Technology Assessment (HTA) Database. We will search broadly for pressure ulcer treatments with a date limit of 1985 to the present (i.e., 2011); Table 1 shows a sample of the search strategy we will

use. Grey literature will be identified by soliciting stakeholders, seeking recommendations from the TEP, and searching relevant Web sites including: clinical trial registries (ClinicalTrials.gov, Current Controlled Trials, ClinicalStudyResults.org, and the World Health Organization International Clinical Trials Registry Platform); regulatory documents (Drugs@FDA and Devices@FDA); conference proceedings and dissertations (Conference Papers Index [ProQuest® CSA], Scopus® (Elsevier), and Dissertations & Theses Database (ProQuest® UMI)), and individual product Web sites. Additional studies will be identified by reviewing the reference lists of published clinical trials and review articles.

Table 1. Sample search strategy

1	Pressure Ulcer/dh, dt, nu, rt, rh, su, th, ae, co, in, mo, po, to
2	pressure ulcer/ and (treatment or healing or management or therapy).hw.
3	((pressure ulcer$ or pressure sore$ or bed sore$ or bedsore$ or decubitus ulcer$) adj5 (treat$ or heal$ or manag$ or therap$)).ti,ab.
4	1 or 2 or 3
5	limit 4 to yr="1985 -Current"
6	remove duplicates from 5

Scientific information packets (SIPs) will be requested from identified manufacturers. Other drug or device manufacturers not identified in the SIP requisition process will have the opportunity to submit data for this review by using the online SIP portal (http://effectivehealthcare.ahrq.gov/index.cfm/submit-scientific-information-packets/) on the AHRQ Effective Health Care Program Web site. Reviewers will evaluate the SIPs we receive for data relevant to our review.

Additional studies will be identified by reviewing the reference lists of published clinical trials and review articles.

The literature searches will be updated during the peer review process, at which time additional studies will be evaluated and synthesized for the review.

C. Data Abstraction and Data Management

After studies are selected for inclusion, data will be abstracted and used to assess the applicability and quality of the study, including but not limited to: study design; year; inclusion and exclusion criteria; population and clinical characteristics (including sex, age, body mass index, ethnicity, primary disease, comorbidities, functional ability, ulcer stage); intervention characteristics; results for each outcome of interest (effectiveness: resolution of ulcer; healing time; wound surface area, pain, and prevention of serious complications of infection such as sepsis or osteomyelitis; harms: pain, dermatologic reaction, bleeding, and complications including but not limited to infection and need for surgical intervention); setting (patient-care settings, such as home, nursing facility, and hospital); and, if available, the number of patients randomized relative to the number of patients enrolled, how similar those patients are to the target population, and the funding source. We will record intention-to-treat results when available. All study data will be verified for accuracy and completeness by a second team member.[8]

D. Assessment of Methodological Quality of Individual Studies

Predefined criteria will be used to assess the quality of individual controlled trials, systematic reviews, and observational studies. Each study evaluated will be reviewed dually by 2 individuals, a principal investigator and a research staff member, who will use a clearly defined template and criterion to assess methodological quality. Randomized trials and cohort studies will be evaluated by using appropriate criteria and methods developed by the USPSTF.[9]These will be used in conjunction with the approach recommended in the chapter "Assessing the Risk of Bias of Individual Studies When Comparing Medical Interventions" in the AHRQ *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*.[8]

Individual studies will be rated as "good," "fair," or "poor." Studies rated "good" will be considered to have the least risk of bias, and their results will be considered valid. Good-quality studies include clear descriptions of the population, setting, interventions, and comparison groups; a valid method for allocating patients to treatment; low dropout rates and clear reporting of dropouts; appropriate means for preventing bias; and appropriate measurement of outcomes.

Studies rated "fair" will be susceptible to some bias, though not enough to invalidate the results. These studies may not meet all the criteria for a rating of good quality, but no flaw is likely to cause major bias. The study may be missing information, making it difficult to assess limitations and potential problems. The "fair" quality category is broad, and studies with this rating will vary in their strengths and weaknesses; the results of some fair-quality studies are likely to be valid, while others may be only possibly valid.

Studies rated "poor" will have significant flaws that imply biases of various types that may invalidate the results. They will have a serious or "fatal" flaw in design, analysis, or reporting; large amounts of missing information; discrepancies in reporting; or serious problems in the delivery of the intervention. The results of these studies will be at least as likely to reflect flaws in the study design as the true difference between the compared therapies. We will not exclude studies rated poor in quality a priori, but poor-quality studies will be considered to be less reliable than studies of higher quality when synthesizing the evidence, particularly if discrepancies between studies are present.

E. Data Synthesis

We will construct evidence tables identifying the study characteristics, quality ratings, and results for all included studies. We will review studies by using a hierarchy of evidence approach, where the best evidence is the focus of our synthesis for each KQ, population, intervention, outcome, and setting. Studies that evaluate one intervention for treating a pressure ulcer against another provide direct evidence of comparative effectiveness and adverse event rates. Where possible, these data will be the primary focus. When direct evidence is not available, trials that compare one intervention to placebo, or observational studies including case series without a comparative arm, will be used for indirect comparisons. Results from noncomparative studies can be difficult to interpret primarily because of the heterogeneity of trial populations, interventions, and outcomes assessment. Data from indirect comparisons will be used to support direct comparisons when they exist and will be used as the primary comparison when there are no direct comparisons exist but should always be interpreted with caution.

Meta-analyses will be conducted to summarize data and obtain more precise estimates on outcomes for which studies are homogeneous enough to provide a meaningful combined estimate. The feasibility of a quantitative synthesis will depend on the number and completeness of reported outcomes and a lack of heterogeneity among the reported results. To determine whether meta-analysis can be meaningfully performed, we will consider the quality of the studies and the heterogeneity among studies in design, patient population, interventions, and outcomes. When meta-analysis cannot be performed, the data will be summarized qualitatively. For continuous outcomes, we will use the mean difference between treatment groups as the effect

measure, estimated based on mean change scores and standard errors from baseline to followup for each group from each study. For dichotomous outcomes, the relative risk or odds ratio will be used as the effect measure. The Q statistic and/or the I^2 statistic (the proportion of variation in study estimates due to heterogeneity) will be calculated as possible to assess heterogeneity in effects between studies.

As outlined in the subsets of each KQ, subgroups will be explored to explain potential heterogeneity in effects. Included in these subgroups are anatomic site or ulcer severity at baseline; patient characteristics including but not limited to age, race/ethnicity, body weight, medical comorbidities, functional ability, nutritional status, and incontinence; patient care settings including home, nursing facility, and hospital; and features of the patient care setting including nurse/patient staffing ratio, staff education and training in wound care, the use of wound care teams, and home caregiver support and training.

The results will be presented in tables to outline the key outcomes including complete wound healing, healing time, wound surface area, pain, and prevention of infection for effectiveness, and pain, dermatologic reaction, bleeding, and complications including but not limited to infection and the need for surgical intervention for harm. Our Key Informants directed the choice of included outcomes, and our TEP will assist us if necessary in prioritizing data as they become available.

F. Grading the Evidence for Each Key Question

The strength of evidence for each KQ will be assessed by one researcher for each applicable outcome by using the approach described by Owens et al.[10] To ensure consistency and validity of the evaluation, the grades of each reviewer will be reviewed by the entire team of investigators to evaluate:

- Risk of bias (low, medium, or high)
- Consistency (consistent, inconsistent, or unknown/not applicable)
- Directness (direct or indirect)
- Precision (precise or imprecise)

We will also estimate publication bias by examining whether studies with smaller sample sizes tended to have positive or negative assessments of pressure ulcer treatment.

The strength of evidence will be assigned an overall grade of high, moderate, low, or insufficient according to a four-level scale:

- High—High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect.
- Moderate—Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.
- Low—Low confidence that the evidence reflects the true effect. Further research is likely to change the confidence in the estimate of effect and is likely to change the estimate.
- Insufficient—Evidence either is unavailable or does not permit estimation of an effect.

G. Assessing Applicability

Applicability will be estimated by examining the characteristics of the patient populations and clinical settings in which the studies were performed. Variability in the specific features of each exists that may limit our ability to generalize the results to other populations and settings. Academic settings with experienced researchers often will have a more focused intervention

strategy and selective population that may not reflect the variability seen in a long-term care facility or a general clinical practice. In addition, pressure ulcer treatment typically involves multiple treatment modalities at once (e.g., support surface plus dressings plus nutritional supplementation), and often different treatments are applied at different stages of treatment. We will evaluate the comparative effectiveness of multimodal treatment approaches to the extent that they have been comparatively evaluated. If direct evidence is not found, we will also review comparisons between two treatment approaches within intervention categories. We will also pay attention, when it is explicitly reported, to staged application of different therapeutic modalities. Again, however, it may be difficult to discern the comparative effectiveness of different stepwise approaches to pressure ulcer treatment. Application of sequential approaches may be informed by the contexts (e.g., ulcer stage, prior treatments) in which different treatments appear to be effective, and we will report such contextual information when reported.

V. References

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VI. Definition of Terms

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Treatment strategies: Treatment strategies may fall into various categories according to the nature and target of the therapeutic intervention. These general categories are: therapies that address underlying contributing factors (e.g., support surfaces and nutritional supplements); therapies that address local wound care (e.g., absorbent wound dressings, and biological agents); surgical repair; and adjunctive therapies.

Treatment strategies to be compared within the general categories: For example, support surfaces would be compared with one another, and wound dressings would be compared with one another.

VII. Summary of Protocol Amendments

In the event of protocol amendments, the date of each amendment will be accompanied by a description of the change and the rationale.

VIII. Review of Key Questions

For all EPC reviews, key questions were reviewed and refined as needed by the EPC with input from Key Informants and the Technical Expert Panel (TEP) to assure that the questions are specific and explicit about what information is being reviewed. In addition, for Comparative Effectiveness reviews, the key questions were posted for public comment and finalized by the EPC after review of the comments.

IX. Key Informants

Key Informants are the end users of research, including patients and caregivers, practicing clinicians, relevant professional and consumer organizations, purchasers of health care, and others with experience in making health care decisions. Within the EPC program, the Key Informant role is to provide input into identifying the Key Questions for research that will inform health care decisions. The EPC solicits input from Key Informants when developing questions for systematic review or when identifying high-priority research gaps and needed new research. Key Informants are not involved in analyzing the evidence or writing the report and have not reviewed the report, except as given the opportunity to do so through the peer or public review mechanism.

Key Informants must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their role as end-users, individuals are invited to serve as Key Informants and those who present with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

X. Technical Experts

Technical Experts comprise a multidisciplinary group of clinical, content, and methodological experts who provide input in defining populations, interventions, comparisons, or outcomes as well as identifying particular studies or databases to search. They are selected to provide broad expertise and perspectives specific to the topic under development. Divergent and conflicted opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore study questions, design, and/or methodological approaches do not necessarily represent the views of individual technical and content experts. Technical Experts provide information to the EPC to identify literature search strategies and recommend approaches to specific issues as requested by the EPC. Technical Experts do not do

analysis of any kind nor contribute to the writing of the report and have not reviewed the report, except as given the opportunity to do so through the public review mechanism.

Technical Experts must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals are invited to serve as Technical Experts and those who present with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

XI. Peer Reviewers

Peer reviewers are invited to provide written comments on the draft report based on their clinical, content, or methodological expertise. Peer review comments on the preliminary draft of the report are considered by the EPC in preparation of the final draft of the report. Peer reviewers do not participate in writing or editing of the final report or other products. The synthesis of the scientific literature presented in the final report does not necessarily represent the views of individual reviewers. The dispositions of the peer review comments are documented and will, for CERs and Technical briefs, be published three months after the publication of the Evidence report.

Potential Reviewers must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Invited Peer Reviewers may not have any financial conflict of interest greater than $10,000. Peer reviewers who disclose potential business or professional conflicts of interest may submit comments on draft reports through the public comment mechanism.

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