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Pressure Ulcer Risk Assessment and Prevention: A Comparative Effectiveness Review

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Preface

The Agency for Healthcare Research and Quality (AHRQ) conducts the Effective Health Care Program as part of its mission to organize knowledge and make it available to inform decisions about health care. As part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress directed AHRQ to conduct and support research on the comparative outcomes, clinical effectiveness, and appropriateness of pharmaceuticals, devices, and health care services to meet the needs of Medicare, Medicaid, and the Children's Health Insurance Program (CHIP).

AHRQ has an established network of Evidence-based Practice Centers (EPCs) that produce Evidence Reports/Technology Assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care. The EPCs now lend their expertise to the Effective Health Care Program by conducting comparative effectiveness reviews (CERs) of medications, devices, and other relevant interventions, including strategies for how these items and services can best be organized, managed, and delivered.

Systematic reviews are the building blocks underlying evidence-based practice; they focus attention on the strength and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews are useful because they define the strengths and limits of the evidence, clarifying whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about systematic reviews, see http://www.effectivehealthcare.ahrq.gov/reference/purpose.cfm

AHRQ expects that CERs will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. In addition, AHRQ is committed to presenting information in different formats so that consumers who make decisions about their own and their family's health can benefit from the evidence.

Transparency and stakeholder input from are essential to the Effective Health Care Program. Please visit the Web site (http://www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an e-mail list to learn about new program products and opportunities for input. Comparative Effectiveness Reviews will be updated regularly.

We welcome comments on this CER. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by e-mail to epc@ahrq.hhs.gov.

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Pressure Ulcer Prevention and Risk Assessment

Structured Abstract

Objectives: While pressure ulcers commonly occur and are associated with significant health burdens, they are potentially preventable. This report systematically reviews the evidence on 1) risk assessment scales for identifying people at higher risk of pressure ulcers and 2) preventive interventions to decrease incidence or severity of pressure ulcers. The Agency for Healthcare Research and Quality also commissioned a separate report on effectiveness of interventions to treat pressure ulcers.

Data Sources: MEDLINE, the Cochrane Central Register of Controlled Trials, clinical trials registries, and reference lists.

Review Methods: We used predefined criteria to determine study eligibility. We selected randomized trials and cohort studies on effects of use of risk assessment tools and preventive interventions on clinical outcomes. We also selected prospective studies on the diagnostic accuracy of risk assessment tools for predicting incidence of pressure ulcers. The quality of included studies was assessed, data were extracted, and results were summarized.

Results: Of the 4,559 citations identified at the title and abstract level, we screened and reviewed 686 full-text articles. A total of 105 studies (in 107 publications) were included. One good and two poor-quality studies evaluated effects of using a risk assessment tool on clinical outcomes, with the good-quality randomized trial showing no difference between uses of the Waterlow scale or the Ramstadius tool compared with clinical judgment in subsequent risk of pressure ulcers. Studies of diagnostic accuracy found that commonly used risk assessment instruments (such as the Braden, Norton, and Waterlow scales) can identify patients at increased risk for ulcers, with no clear difference between instruments in diagnostic accuracy. In higher-risk populations, fair-quality randomized trials consistently found more advanced static support surfaces associated with lower risk of pressure ulcers versus standard mattresses in higher-risk patients (relative risk range 0.20 to 0.60), with no clear differences between different advanced static support surfaces. Evidence on the effectiveness and comparative effectiveness of other support surfaces, including more advanced dynamic support surfaces, was limited, with some trials showing no clear differences between dynamic and static support surfaces. One fair-quality trial found stepped care with dynamic support surfaces associated with substantially decreased risk of ulcers versus stepped care beginning with static support surfaces. In lower-risk populations of patients undergoing surgery, two trials found use of a foam overlay associated with an increased risk or trend towards increased risk of pressure ulcers versus a standard operating room mattress. Evidence on effectiveness of other preventive interventions (nutritional supplementation; repositioning; pads and dressings; lotions, creams, and cleansers; and intraoperative warming therapy for patients undergoing surgery) versus standard care was sparse and insufficient to reach reliable conclusions.

Conclusions: Although risk assessment instruments can identify patients at higher risk for pressure ulcers, more research is needed to understand how the use of risk assessment instruments impacts pressure ulcer incidence compared with clinical judgment. More advanced

static support surfaces are more effective than standard mattresses for preventing ulcers in higher-risk populations. More research is needed to understand the effectiveness of other preventive interventions over usual care, and the comparative effectiveness of preventive interventions.

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Pressure Ulcer Risk Assessment and Prevention

Executive Summary

The Effective Health Program was initiated in 2005 to provide valid evidence about the comparative effectiveness of different medical interventions. The object is to help consumers, health care providers, and others in making informed choices among treatment alternatives. Through its Comparative Effectiveness Reviews, the program supports systematic appraisals of existing scientific evidence regarding treatments for high-priority health conditions. It also promotes and generates new scientific evidence by identifying gaps in existing scientific evidence and supporting new research. The program puts special emphasis on translating findings into a variety of useful formats for different stakeholders including consumers.

The full report and this summary are available at www.effectivehealthcare.ahrq.gov. Ahrq.gov/reports/final.cfm

Background

Pressure ulcers are defined by the National Pressure Ulcer Advisory Panel (NPUAP) as "localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear and/or friction."[1] Pressure ulcers are a common condition, affecting an estimated 3 million adults in the United States.[2] In 2006, there were more than 500,000 hospital stays in which pressure ulcers were reported.[3] Estimates of pressure ulcers prevalence range from 0.4 to 38 percent in acute care hospitals, 2 to 24 percent in long-term nursing facilities, and 0 to 17 percent in home care settings.[4-6] The prevalence of facility-acquired pressure ulcers was 6 percent in 2008 and 5 percent in 2009.[6]

A number of risk factors are associated with increased risk of pressure ulcer development, including older age, black skin, higher body weight, physical or cognitive impairment, poor nutritional status, incontinence, and specific medical comorbidities that affect circulation such as diabetes or peripheral vascular disease. Pressure ulcers are often associated with pain and can contribute to decreased function or lead to complications such as infection.[2] In some cases, pressure ulcers may be difficult to treat despite surgical and other invasive treatments. In the inpatient setting, pressure ulcers are associated with increased length of hospitalization and delayed return to function.[3] In addition, the presence of pressure ulcers is associated with poorer general prognosis and may contribute to mortality risk.[3] Between 1990 and 2001, pressure ulcers were reported as a cause of death in nearly 115,000 people, and listed as the underlying cause in more than 21,000.[7] Estimates of the costs of treatment for pressure ulcers vary, but range between $37,800 and $70,000 per case, with total annual costs in the United States as high as $11 billion.[2, 8]

A number of instruments have been developed to assess for risk of pressure ulcers. The three most widely used instruments are the Braden Scale (6 items, total scores range from six to 23), the Norton Scale (5 items, total scores range from five to 20), and the Waterlow Scale (11 items, total scores range from one to 64).[2, 9-11] All three scales include items related to activity,

mobility, nutritional status, incontinence, and cognition, though they are weighted differently across studies.[10]

Recommended prevention strategies for pressure ulcers generally involve use of risk assessment tools to identify people at higher risk for developing ulcers in conjunction with interventions for preventing ulcers.[12-14] A variety of diverse interventions are available for the prevention of pressure ulcers. Categories of preventive interventions include support surfaces (including mattresses, integrated bed systems, overlays, and cushions), repositioning, skin care (including lotions, dressings, and management of incontinence), and nutritional support.[13, 14] Each of these broad categories encompasses a variety of interventions.

The purpose of this report is to review the comparative clinical utility and diagnostic accuracy of risk assessment instruments for evaluating risk of pressure ulcers, and to evaluate the benefits and harms of preventive interventions for pressure ulcers, in different settings and patient populations.

Objectives

This comparative effectiveness review (CER) topic was nominated by the American College of Physicians, which intends to develop a guideline on prevention and management of pressure ulcers (i.e., prevention of ulcers in people without ulcers at baseline). This report focuses on the comparative effectiveness of various pressure ulcer risk assessment and prevention approaches; the treatment of pressure ulcers is addressed in a separate review.[15]

The following key questions are the focus of this report:

Key Question 1. For adults in various settings[*], is the use of any risk assessment tool[†] effective in reducing the incidence or severity of pressure ulcers, compared with other risk assessment tools, clinical judgment alone, and/or usual care?

Key Question 1a. Does the effectiveness and comparative effectiveness of risk assessment tools differ according to setting[*]?

Key Question 1b. Does the effectiveness and comparative effectiveness of risk assessment tools differ according to patient characteristics[‡], and other known risk factors for pressure ulcers, such as nutritional status or incontinence?

Key Question 2. How do various risk assessment tools compare with one another in their ability to predict the incidence of pressure ulcers?

Key Question 2a. Does the predictive validity of various risk assessment tools differ according to setting[*]?

Key Question 2b. Does the predictive validity of various risk assessment tools differ according to patient characteristics[‡]?

Key Question 3. In patients at increased risk of developing pressure ulcers, what is the effectiveness and comparative effectiveness of preventive interventions in reducing the incidence or severity of pressure ulcers?

Key Question 3a. Does the effectiveness and comparative effectiveness of preventive interventions differ according to risk level as determined by different risk assessment methods and/or by particular risk factors?

Key Question 3b. Does the effectiveness and comparative effectiveness of preventive interventions differ according to setting[*]?

Key Question 3c. Does the effectiveness and comparative effectiveness of preventive interventions differ according to patient characteristics‡?

Key Question 4. What are the harms of interventions for the prevention of pressure ulcers?

Key Question 4a. Do the harms of preventive interventions differ according to the type of intervention?

Key Question 4b. Do the harms of preventive interventions differ according to setting*?

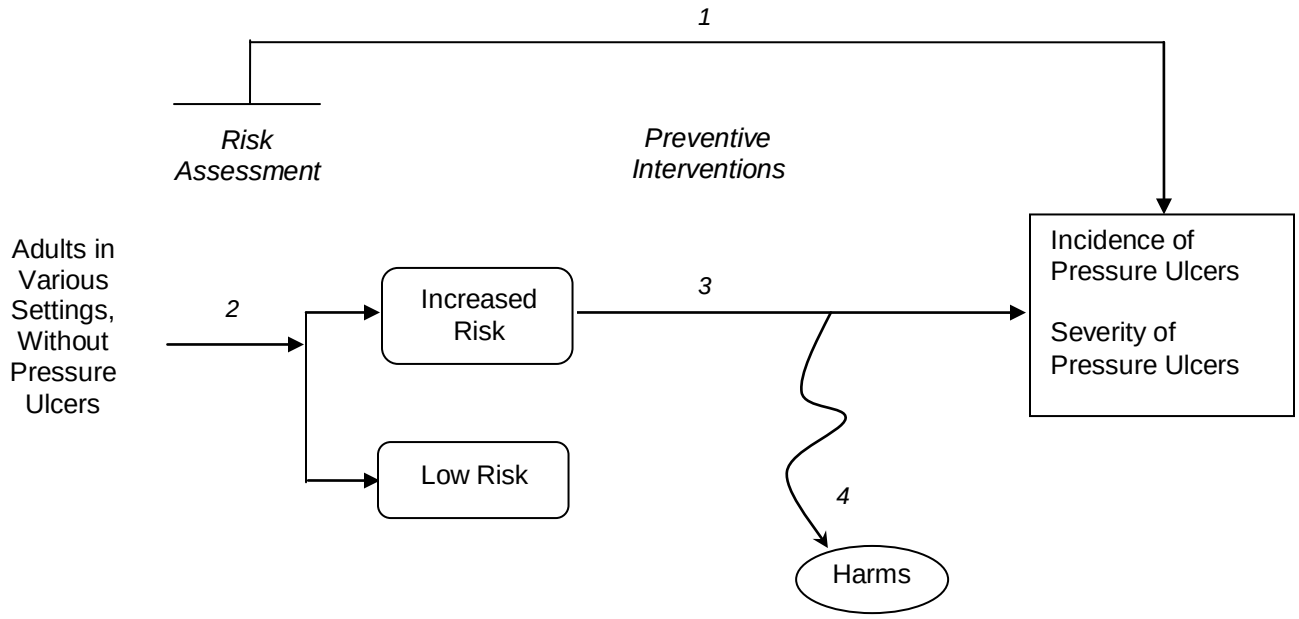
Key Question 4c. Do the harms of preventive interventions differ according to patient characteristics‡?

*Including acute care hospital, long-term care facility, rehabilitation facility, operating room, home care, and wheelchair users in the community.
†Such as the Braden Scale, the Norton Scale, the Waterlow Scale, or others.
‡Such as age, race or skin tone, physical impairment, body weight, or specific medical comorbidities (e.g., diabetes and peripheral vascular disease).

Analytic Framework

The analytic framework (Figure A) used to guide this report shows the target populations, preventive interventions, and health outcomes we examined.

Figure A. Analytic framework: Pressure ulcer risk assessment and prevention



Methods

Input from Stakeholders

The key questions for this CER were developed with input from key informants, representing clinicians, wound care researchers, and patient advocates, who helped refine key questions, identify important methodological and clinical issues, and define parameters for the review of

evidence. The revised key questions were then posted to the Agency for Healthcare Research and Quality (AHRQ) public Web site for a 4-week public comment period. The AHRQ and the Evidence-based Practice Center (EPC) agreed upon the final key questions after reviewing the public comments and receiving additional input from a Technical Expert Panel (TEP) convened for this report. The TEP consisted of people with expertise in pressure ulcer treatment and research, from disciplines including geriatrics, primary care, hospital medicine, and nursing. We then drafted a protocol for the CER, which was reviewed by the TEP. The final protocol developed prior to initiation of the review is available at http://effectivehealthcare.ahrq.gov/ehc/products/309/926/Pressure-Ulcer-Prevention_Protocol_20120110.pdf.

Search Strategy and Study Selection

A research librarian conducted searches on MEDLINE (Ovid®) from 1946 to October, 2011; CINAHL (EBSCOhost®) from 1988 through October, 2011; and the Cochrane Central Register of Controlled Trials and Cochrane Database of Systematic Reviews using EBM Reviews (Ovid®) through the 4th Quarter, 2011. The search strategies were peer reviewed by another information specialist and revised prior to finalizations. We also hand-searched the reference lists of relevant studies. In addition, scientific information packets (SIPs) were requested from identified drug and device manufacturers of pressure ulcer treatments, who had the opportunity to submit data using the portal for submitting SIPs on the Effective Health Care Program Web site. Searches will be updated prior to finalization of the report to identify any relevant new publications.

We developed criteria for inclusion and exclusion of studies based on the key questions and the populations, interventions, comparators, outcomes, timing, types of studies, and setting (PICOTS) approach. Papers were selected for review if they were about prevention of pressure ulcers, were relevant to a key question, and met the pre-defined inclusion criteria. We restricted inclusion to English language articles. Studies of non-human subjects and studies with no original data were excluded. Abstracts and full-text articles were dual-reviewed for inclusion. Full-text articles were obtained for all studies that either investigator identified as potentially meeting inclusion criteria. Two investigators independently reviewed all full-text articles for final inclusion or exclusion. Discrepancies were resolved through discussion and consensus, with a third investigator making the final decision if necessary.

As treatment of existing pressure ulcers is addressed in a separate report,[15] we excluded studies that enrolled >10 percent of the population with pressure ulcers at baseline. We included studies that did not report the proportion of patients with pressure ulcers at baseline only if they restricted inclusion to people with no or stage I ulcers (i.e., no skin breakdown) or were clearly prevention-focused, and reported incident pressure ulcers. We did not restrict inclusion to studies that only enrolled people at higher risk for ulcers, although most studies focused on higher risk people. We evaluated patient subgroups defined by age, race or skin tone, physical impairment, body weight, or specific medical comorbidities (e.g., urinary incontinence, diabetes and peripheral vascular disease). We did not exclude studies based on setting.

For Key Question 1, we included studies that compared effects of using a risk assessment instrument, such as the Braden, Norton, or Waterlow Scales, with clinical judgment or another risk assessment instrument. For Key Question 2, we included studies that reported the diagnostic accuracy of validated risk assessment instruments for predicting incident pressure ulcers. For Key Questions 3 and 4, we included studies that compared interventions to prevent pressure

ulcers with usual care, or no treatment, or that compared one preventive intervention with another.

For Key Questions 1, 3 and 4, we included controlled clinical trials and cohort studies. For Key Question 2 we included prospective studies that reported diagnostic accuracy of risk prediction instruments. We excluded systematic reviews, although we reviewed their reference lists for additional citations.

Data Extraction and Quality Assessment

We extracted the following information from included trials into evidence tables: study design, setting, inclusion and exclusion criteria, population characteristics (including sex, age, race, ethnicity, prevalent ulcers, risk for ulcers), sample size, duration of followup, attrition, intervention characteristics, method for assessing ulcers, and results. Data extraction for each study was performed by two investigators: the first investigator extracted the data, and the second investigator independently reviewed the extracted data for accuracy and completeness.

For studies of diagnostic accuracy, we attempted to create two-by-two tables from information provided (usually sample size, prevalence, sensitivity, and specificity) and compared calculated measures of diagnostic accuracy based on the two-by-two tables with reported results. We noted discrepancies between calculated and reported results when present. When reported, we also extracted relative measures of risk (relative risk [RR], odds ratio, hazards ratio) and the area under the receiver operating characteristic (AUROC) curve. The AUROC, which is based on sensitivities and specificities across a range of test results, is a measure of discrimination, or the ability of a test to distinguish people with a condition from people without the condition.[16, 17] An AUROC of 1.0 indicates perfect discrimination, and an AUROC of 0.5 indicates complete lack of discrimination. Interpretation of AUROC values between 0.5 and 1.0 is somewhat arbitrary, but a value of 0.90 to <1.0 has been classified as excellent, 0.80 to <0.90 good, 0.70 to <0.80 fair, and <0.70 poor.

We assessed the quality of each study based on predefined criteria. We adapted criteria from methods proposed by Downs and Black (observational studies),[18] the United States Preventive Services Task Force (USPSTF),[18] and the Quality Assessment of Diagnostic Accuracy Studes-2 Group.[18] The criteria used are consistent with the approach recommended by AHRQ in the Methods Guide for Comparative Effectiveness Reviews.[19] We used the term “quality” rather than the alternate term “risk of bias;” both refer to internal validity.

We rated the quality of each randomized trial based on the methods used for randomization, allocation concealment, and blinding; the similarity of compared groups at baseline; maintenance of comparable groups; adequate reporting of dropouts, attrition, crossover, adherence, and contamination; loss to followup; the use of intent-to-treat analysis; and ascertainment of outcomes.[20] For cluster randomized trials, we also evaluated whether the study evaluated cluster effects.[21]

We rated the quality of each cohort study based on whether it used nonbiased selection methods to create an inception cohort; whether it evaluated comparable groups; whether rates of loss to followup were reported and acceptable; whether it used accurate methods for ascertaining exposures, potential confounders, and outcomes; and whether it performed appropriate statistical analyses of potential confounders.[20] We rated the quality of each diagnostic accuracy study based on whether it evaluated a representative spectrum of patients, whether it enrolled a random or consecutive sample of patients meeting predefined criteria, whether it used a credible reference standard, whether the same reference standard was applied to all patients, whether the reference

standard was interpreted independently from the test under evaluation, and whether thresholds were predefined.[20, 22] In addition, unblinded use of a risk prediction instrument (as was typical in the studies) could result in differential use of preventive interventions based on assessed risk, and thereby alter the likelihood of the predicted outcome and compromise measures of diagnostic accuracy (e.g., if more intense and effective interventions are used in higher-risk patients). Therefore, we also assessed whether studies on diagnostic accuracy reported use of subsequent interventions, and whether risk estimates (when reported) were adjusted for potential confounders.

Following assessment of individual quality criteria, individual studies were rated as "good," "fair," or "poor" quality, as defined below.[23]

Good-quality studies are considered likely to be valid. Good-quality studies clearly describe the population, setting, interventions, and comparison groups; use a valid method for allocation of patients to interventions; clearly report dropouts and have low dropout rates; use appropriate methods for preventing bias; and appropriately measure outcomes and fully report results.

Fair-quality studies have some methodological deficiencies, but no flaw or combination of flaws judged likely to cause major bias. The study may be missing information, making it difficult to assess its methods or assess limitations and potential problems. The fair-quality category is broad, and studies with this rating vary in their strengths and weaknesses: the results of some fair-quality studies are likely to be valid, while others are only probably valid.

Poor-quality studies have significant flaws that may invalidate the results. They have a serious or "fatal" flaw in design, analysis, or reporting; large amounts of missing information; or discrepancies in reporting. The results of these studies are judged to be at least as likely to reflect flaws in the study design as true effects of the interventions under investigation. We did not exclude studies rated poor-quality *a priori*, but they were considered to be the least reliable studies when synthesizing the evidence, particularly when discrepancies between studies were present.

Data Synthesis and Rating the Strength of the Body of Evidence

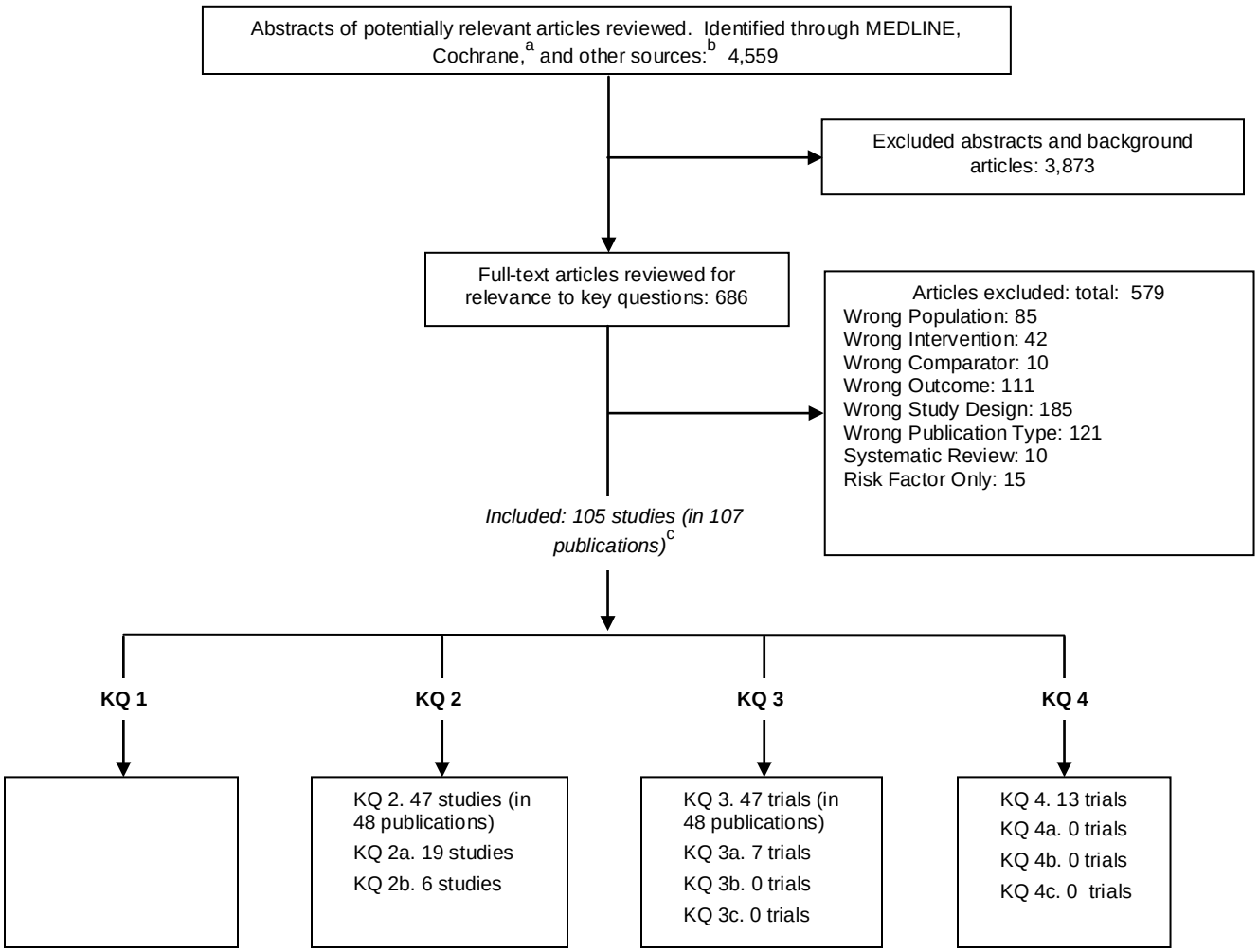
We did not attempt to pool studies on preventive interventions due to methodological limitations in the studies and substantial clinical diversity with respect to the populations, settings, comparisons, and outcomes evaluated (i.e., how pressure ulcers were assessed and graded). We also did not quantitatively pool results on diagnostic accuracy (such as creating summary receiver operating characteristic curves) due to differences across those studies in populations evaluated, differences in how pressure ulcers were assessed and graded, and methodological limitations in the studies. Instead, we created descriptive statistics with the median sensitivity and specificity at specific cutoffs and reported AUROCs, along with associated ranges. Although studies varied in what cutoffs were evaluated, and some evaluated a range of cutoffs without a pre-specified threshold, we focused on cutoffs for the most common risk instruments (Braden, Norton, and Waterlow) based on recommended thresholds, which may vary depending on the setting and timing of assessments: ≤15 to 18 for the Braden scale,[24-28] ≤12 to 16 for the Norton scale,[29-31] and ≥10 to 15 for the Waterlow scale.[30, 32] On the less commonly-used Cubbin and Jackson scale, a score of ≤29 has been used to identify people at increased risk.[33] The total range across studies for the various measures of diagnostic accuracy, rather than the interquartile range, was reported because the summary range highlighted the greater variability and uncertainty in the estimates.

We assessed the overall strength of evidence for each body of evidence in accordance with the AHRQ Methods Guide for Comparative Effectiveness Reviews.[34] We synthesized the quality of the studies; the consistency of results within and between study designs; the directness of the evidence linking the intervention and health outcomes; and the precision of the estimate of effect (based on the number and size of studies and confidence intervals for the estimates). We were not able to formally assess for publication bias in studies of interventions due to small number of studies, methodological shortcomings, or differences across studies in designs, measured outcomes, and other factors. We rated the strength of evidence for each key question using the four categories recommended in the AHRQ Methods Guide[34]: A "high" grade indicates high confidence that the evidence reflects the true effect and that further research is very unlikely to change our confidence in the estimate of effect. A "moderate" grade indicates moderate confidence that the evidence reflects the true effect and further research may change our confidence in the estimate of effect and may change the estimate. A "low" grade indicates low confidence that the evidence reflects the true effect and further research is likely to change the confidence in the estimate of effect and is likely to change the estimate. An "insufficient" grade indicates evidence either is unavailable or does not permit a conclusion.

Results

The search and selection of articles are summarized in the study flow diagram (Figure B):

Figure B. Literature flow diagram



[a] Cochrane databases include the Cochrane Central Register of Controlled Trials and the Cochrane Database of Systematic Reviews.
[b] Other sources include reference lists, suggested by peer reviewers, etc.
[c] Some articles are included for more than one key question.

Database searches resulted in 4,559 potentially relevant articles. After dual review of abstracts and titles, 686 articles were selected for full text review, and 105 studies (in 107 publications) were determined by dual review at the full-text level to meet inclusion criteria and were included in this review.

One good and two poor-quality studies evaluated effects of using a risk assessment instrument on clinical outcomes. The good-quality trial found no difference between use of the Waterlow scale, the Ramstadius tool, or clinical judgment and subsequent pressure ulcer development. One poor-quality, non-randomized study found use of the modified Norton scale (in conjunction with a standardized intervention protocol based on assessed risk) associated with lower risk of pressure ulcers compared with clinical judgment, and one poor-quality trial found no difference between use of the Braden scale compared with clinical judgment. There was no evidence on the effectiveness of risk assessment tools on clinical outcomes according to setting or patient characteristics.

Studies of diagnostic accuracy found that commonly used risk assessment instruments (such as the Braden, Norton, and Waterlow scales) can identify patients at increased risk for ulcers, with no clear difference between instruments in diagnostic accuracy. Few studies evaluated the same risk assessment instrument and stratified results according to setting or patient characteristics.

In higher-risk populations, fair-quality randomized trials consistently found more advanced static support surfaces associated with lower risk of pressure ulcers compared with standard mattresses in higher-risk patients (RR range 0.20 to 0.60), with no clear differences between different advanced static support surfaces. Evidence on the effectiveness and comparative effectiveness of other support surfaces, including more advanced dynamic support surfaces, was limited, with some trials showing no clear differences between dynamic and static support surfaces. One fair-quality trial found stepped care with dynamic support surfaces associated with substantially decreased risk of ulcers compared with stepped care beginning with static support surfaces. In lower-risk populations of patients undergoing surgery, two trials found use of a foam overlay associated with an increased risk or trend towards increased risk of pressure ulcers compared with a standard operating room mattress. Evidence on effectiveness of other preventive interventions (nutritional supplementation; repositioning; pads and dressings; lotions, creams, and cleansers; and intraoperative warming therapy for patients undergoing surgery) compared with standard care was sparse and insufficient to reach reliable conclusions.

Too few studies evaluated harms of preventive interventions to draw conclusions about their safety.

Table A (below) summarizes the findings of this review:

Table A. Summary of evidence

Key Question	Strength of Evidence	Conclusion
Key Question 1. For adults in various settings, is the use of any risk assessment tool effective in reducing the incidence or severity of pressure ulcers, compared with other risk assessment tools, clinical judgment alone, and/or usual care?		
Pressure ulcer incidence or severity: Waterlow scale vs. clinical judgment	Low	One good-quality, randomized trial (n=1231) found no difference in pressure ulcer incidence between patients assessed with either the Waterlow or Ramstadius scales compared with clinical judgment alone (RR 1.4, 95% CI 0.82 to 2.4 and RR 0.77, 95% CI 0.44 to 1.4, respectively).
Pressure ulcer incidence or severity: Norton scale vs. clinical judgment	Insufficient	One poor-quality, nonrandomized study (n=240) found use of a modified version of the Norton scale to guide use of preventive interventions associated with lower risk of pressure ulcers compared with nurses' clinical judgment alone (RR 0.11, 95% CI 0.03 to 0.46).
Pressure ulcer incidence or severity: Braden scale vs. clinical judgment	Insufficient	One poor-quality, cluster randomized trial (n=521) found no difference between training in and use of the Braden score vs. nurses' clinical judgment in risk of incident pressure ulcers, but included patients with prevalent ulcers.
Key Question 1a. Does the effectiveness and comparative effectiveness of risk assessment tools differ according to setting?	Insufficient	No study evaluated how effectiveness of risk assessment tools varies according to care setting.
Key Question 1b. Does the effectiveness and comparative effectiveness of risk assessment tools differ according to patient characteristics, and other known risk factors for pressure ulcers, such as nutritional status or incontinence?	Insufficient	No study evaluated how effectiveness of risk assessment tools varies in subgroups defined by patient characteristics
Key Question 2. How do various risk assessment tools compare with one another in their ability to predict the incidence of pressure ulcers?		
Diagnostic accuracy: Braden Scale	Moderate	In two good- and five fair-quality studies, the median AUROC for the Braden scale was 0.77 (range 0.55 to 0.88). In sixteen studies, based on a cutoff of ≤18, the median sensitivity was 0.74 (range 0.33 to 1.0) and median specificity 0.68 (range 0.34 to 0.86).
Diagnostic accuracy: Norton scale	Moderate	In three studies (one good- and two fair quality), the median AUROC for the Norton scale was 0.74 (range 0.56 to 0.75). In five studies, using a cutoff of ≤14, median sensitivity was 0.75 (range 0.0 to 0.89) and median specificity 0.68 (range 0.59 to 0.95).
Diagnostic accuracy: Waterlow scale	Moderate	In four studies (one good- and three-fair quality), the median AUROC for the Waterlow scale was 0.61 (range 0.54 to 0.66). In two studies, based on a cutoff of ≥10, sensitivities were 0.88 and 1.0 and specificities 0.13 and 0.29.

Key Question	Strength of Evidence	Conclusion
Diagnostic accuracy: Cubbin and Jackson scale	Moderate	In three studies (one good- and two fair-quality), the median AUROC for the Cubbin and Jackson scale was 0.83 (range 0.72 to 0.90). In three studies, based on a cutoff of ≤24 to 29, median sensitivity was 0.89 (range 0.83 to 0.95) and median specificity was 0.61 (0.42 to 0.82).
Diagnostic accuracy: Direct comparisons between risk assessment scales	Moderate	In two good- and four fair-quality studies that directly compared risk assessment tools, there were no clear differences between scales based on the AUROC.
Key Question 2a. Does the predictive validity of various risk assessment tools differ according to setting?		
Diagnostic accuracy: Braden scale, across settings	Low	One fair-quality study found a Braden scale score of ≤18 associated with similar sensitivities and specificities in acute care and skilled nursing settings. Twenty-eight studies (10 good-, 16 fair- and 2 poor-quality) that evaluated the Braden scale in different settings found no clear differences in the AUROC or in sensitivities and specificities at standard (≤15 to 18) cutoffs.
Diagnostic accuracy: Cubbin and Jackson, ICU setting	Low	Two studies (one good- and one fair-quality) found the Cubbin and Jackson scale associated with similar diagnostic accuracy compared with the Braden or Waterlow scales in intensive care patients.
Diagnostic accuracy: Braden scale, optimal cutoff in different settings	Low	One good-quality study reported a lower optimal cutoff on the Braden scale in an acute care setting (sensitivity 0.55 and specificity 0.94 at a cutoff of ≤15) than a long-term care setting (sensitivity 0.57 and specificity 0.61 at a cutoff of ≤18), but the statistical significance of differences in diagnostic accuracy was not reported. Two studies of surgical patients (one good- and one fair-quality) found lower optimal cutoff scores than observed in studies of patients in other settings.
Key Question 2b. Does the predictive validity of various risk assessment tools differ according to patient characteristics?		
Diagnostic accuracy: Braden scale, differences according to race	Low	One fair-quality study reported similar AUROCs for the Braden scale in black and white patients in acute care or skilled nursing settings.
Diagnostic accuracy: Braden scale, differences according to baseline pressure ulcer risk	Moderate	Three studies (one good- and two fair-quality) found no clear difference in AUROC estimates based on the presence of higher or lower mean baseline pressure ulcer risk scores.
Key Question 3. In patients at increased risk of developing pressure ulcers, what is the effectiveness and comparative effectiveness of preventive interventions in reducing the incidence or severity of pressure ulcers?		

Key Question	Strength of Evidence	Conclusion
Pressure ulcer incidence or severity: Static support surface vs. standard mattress	Moderate	Five fair-quality trials (n=83 to 543) found a more advanced static mattress or overlay associated with decreased risk of incident pressure ulcers (RR range 0.20 to 0.60) or a trend towards decreased risk (RR 0.28, 95% CI 0.06 to 1.3) compared with a standard mattress, and two of the trials found no difference in length of stay. Six poor-quality trials reported results that were generally consistent with these findings, though two trials found no benefit. The static support surfaces evaluated in the trials varied.
Pressure ulcer incidence or severity: Static support surface vs. static support surface	Moderate	Six trials (n=52 to 100, three trials fair-quality) found no differences between different advanced static support surfaces in risk of pressure ulcers. One fair-quality trial (n=40) of nursing home patients found a foam replaceable parts mattress associated with lower risk of ulcers compared with a 4 inch thick, dimpled foam overlay (25% vs. 60%, RR 0.42, 95% CI 0.18 to 0.96)
Pressure ulcer incidence or severity: More sophisticated wheelchair cushions vs. standard wheelchair cushions	Low	Four trials (n=32 to 248, three fair-quality and one poor-quality) found inconsistent evidence on effects of more sophisticated wheelchair cushions compared with standard wheelchair cushions on risk of pressure ulcers, with the largest trial finding no difference between a contoured, individually customized foam cushion compared with a slab cushion. Results are difficult to interpret because the trials evaluated different cushions.
Pressure ulcer incidence or severity: Heel ulcer prevention intervention vs. usual care	Low	One fair-quality trial (n=239) of fracture patients found the Heelift Suspension Boot associated with decreased risk of heel, foot, or ankle ulcers compared with usual care (7% vs. 26% for any ulcer, RR 0.26, 95% CI 0.12 to 0.53; 3.3% vs. 13.4% for grade II ulcers, RR 0.25, 95% CI 0.09 to 0.72), but one poor-quality trial (n=52) of hospitalized patients found no difference in risk of ulcers between a boot (Foot Waffle) and usual care (hospital pillow to prop up legs).
Pressure ulcer incidence or severity: Heel ulcer preventive intervention vs. heel ulcer preventive intervention	Insufficient	One poor-quality trial (n=240) of hospitalized patients found no differences between three different types of boots (Bunny Boot, egg-crate heel lift positioner, and Foot Waffle) in risk of ulcers, though the overall incidence of ulcers was low (5% over 3 years) and results could have been confounded by differential use of co-interventions.
Pressure ulcer incidence or severity: Dynamic vs. static support surfaces	Low	Six trials (n=32 to 487, two fair-quality and four poor-quality) that compared a dynamic alternating air pressure mattress or overlay compared with a static support surface reported somewhat inconsistent results, with one fair-quality trial showing no difference in risk of pressure ulcers and another fair-quality trial showing lower risk of pressure ulcers with initial use of dynamic support surfaces using a stepped care approach (4.3% vs. 55%, RR 0.08, 95% CI 0.01 to 0.56). One of the trials found no difference in length of stay.

Key Question	Strength of Evidence	Conclusion
Pressure ulcer incidence or severity: Dynamic vs. dynamic support surface	Low	Two fair-quality (n=44 and 62) trials of hospitalized patients found no differences in risk of pressure ulcers or length of stay between different dynamic support surfaces, though one poor-quality trial (n=108) found an alternating double-layer air cell layer associated with decreased risk of pressure ulcers compared with an alternating single-layer overlay.
Pressure ulcer incidence or severity: Nutritional supplementation vs. standard hospital diet	Low	Three poor-quality randomized trials (n=56 to 672) reported inconsistent results for effects of oral nutritional supplementation compared with standard hospital diet on incidence of pressure ulcer risk, with two randomized trials reporting no benefit.
Pressure ulcer incidence or severity: Repositioning intervention vs. usual care	Low	One fair-quality cluster randomized trial (n=213) found repositioning at a 30-degree tilt every 3 hours associated with lower risk of pressure ulcer compared with usual care (90-degree lateral repositioning every 6 hours during the night) after 28 days (3.0% vs. 11%, RR 0.27, 95% CI 0.08 to 0.93). Two other randomized trials (n=46 and 838) evaluated repositioning interventions but only followed patients for one night or are susceptible to confounding due to differential use of support surfaces.
Pressure ulcer incidence or severity: Changing incontinence pad three vs. two times daily	Low	One fair-quality cross-over trial (n=81) found no statistically significant difference in risk of pressure ulcers between changing incontinence pads three times vs. twice a night after 4 weeks.
Pressure ulcer incidence or severity: REMOIS pad vs. no pad	Insufficient	One poor-quality randomized trial (n=37) found use of the REMOIS Pad (consisting of a hydrocolloid skin adhesive layer, a support layer of urethane film, and an outer layer of multifilament nylon) on the greater trochanter associated with decreased risk of stage I ulcers compared to no pad on the contralateral trochanter after 4 weeks (5.4% vs. 30%, RR 0.18, 95% CI 0.05 to 0.73).
Pressure ulcer incidence or severity: Intraoperative warming vs. usual care	Low	One fair-quality randomized trial (n=324) of patients undergoing major surgery found no statistically significant difference in risk of pressure ulcers between patients who received an intraoperative warming intervention (forced-air warming and warming of all intravenous fluids) compared with usual care.
Pressure ulcer incidence or severity: Corticotropin vs. sham	Insufficient	One poor-quality randomized trial (n=85) of patients undergoing femur or hip surgery found no difference in risk of pressure ulcers between those who received 80 IU of corticotrophin intramuscularly compared with a sham injection.
Pressure ulcer incidence or severity: Cream or lotion vs. placebo	Insufficient	Evidence from four poor-quality trials was insufficient to determine effectiveness of different creams or lotions for preventing pressure ulcers.
Pressure ulcer incidence or severity: Skin cleanser vs. standard soap and water	Low	One fair-quality randomized trial (n=93) found use of Clinisan cleanser associated with lower risk of ulcer compared with standard soap and water in patients with incontinence at baseline (18% vs. 42%; RR 0.43, 95% CI 0.19 to 0.98).

Key Question	Strength of Evidence	Conclusion
Key Question 3a. Does the effectiveness and comparative effectiveness of preventive interventions differ according to *risk level* as determined by different risk assessment methods and/or by particular risk factors?		
Pressure ulcer incidence or severity: Static foam overlay vs. standard care, lower-risk surgical population	Moderate	Two trials (one good- and one fair-quality) found use of a foam overlay associated with increased risk or a trend towards increased risk of pressure ulcers compared with standard care in lower-risk surgical patients (OR 1.9, 95% CI 1.0 to 3.7 and RR 1.6, 95% CI 0.76 to 3.3).
Pressure ulcer incidence or severity: Static dry polymer overlay vs. standard care, lower-risk surgical population	Low	Two trials (one good- and one poor-quality) found a dry polymer overlay associated with decreased risk of pressure ulcers compared with standard care in lower-risk surgical patients.
Pressure ulcer incidence or severity: Static foam block mattress vs. standard care, lower-risk surgical population	Insufficient	One poor-quality trial found no significant difference between a static foam block mattress and a standard hospital mattress in pressure ulcer incidence.
Pressure ulcer incidence or severity: Dynamic vs. static support surfaces, lower-risk surgical population	Low	Two trials (one good- and one poor-quality) found no differences between dynamic vs. static support surfaces in risk of pressure ulcer incidence or severity.
Key Question 3b. Does the effectiveness and comparative effectiveness of preventive interventions differ according to *setting*?	Insufficient	No study evaluated how effectiveness of preventive interventions varies according to care setting.
Key Question 3c. Does the effectiveness and comparative effectiveness of preventive interventions differ according to *patient characteristics*?	Insufficient	No study evaluated how effectiveness of preventive interventions varies in subgroups defined by patient characteristics.

Key Question	Strength of Evidence	Conclusion
Key Question 4. What are the harms of interventions for the prevention of pressure ulcers?		
Harms: Support surfaces	Low	Seven of 39 trials of support surfaces reported harms. • Three trials (n=297 to 588) reported cases of heat-related discomfort with sheepskin overlays, with one trial reporting increased risk of withdrawal due to heat discomfort compared with a standard mattress (5% vs. 0%, RR 0.95, 95% CI 0.93 to 0.98). • One trial (n=39) that compared different dynamic mattresses reported some differences in pain and sleep disturbance. • One trial (n=198) reported no differences in risk of adverse events between a multi-cell, pulsating dynamic mattress compared with a static gel pad overlay. • One trial (n=239) of heel ulcer preventive interventions reported no difference in risk of adverse events between the Heelift Suspension Boot and standard care in hip fracture patients. • One trial (n=141) reported a urethane and gel wheelchair pad (Jay cushion) associated with increased risk of withdrawal due to discomfort compared to a standard foam wheelchair pad (8% vs. 1%, RR 0.94, 95% CI 0.88 to 1.0).
Harms: Repositioning	Low	Two (n=46 and 838) of three trials of repositioning interventions reported harms. Both trials reported more nonadherence due to intolerability of a 30 degree tilt position compared with standard positioning.
Harms: Lotions and creams	Low	Three (n=93 to 203) of five trials of lotions or creams reported harms. One trial found no differences in rash between different creams and two trials each reported one case of a wet sore or rash.
Harms: Dressings	Low	One (n=37) of two trials of dressings reported harms. It reported that application of the REMOIS pad resulted in pruritus in one patient.
Key Question 4a. Do the harms of preventive interventions differ according to the type of intervention?	Insufficient	No study evaluated how harms of preventive interventions vary according to the type of intervention.
Key Question 4b. Do the harms of preventive interventions differ according to setting?	Insufficient	No study evaluated how harms of preventive interventions vary according to care setting.
Key Question 4c. Do the harms of preventive interventions differ according to patient characteristics?	Insufficient	No study evaluated how harms of preventive interventions vary in subgroups defined by patient characteristics.

Abbreviations: AUROC, area under the receiver operator characteristic; CI, confidence interval; OR, odds ratio; RR, risk ratio.

Discussion

Key Findings and Strength of Evidence

Evidence on optimal methods to prevent pressure ulcers was extremely limited in a number of areas, including the effects of use of risk assessment instruments on the subsequent incidence of pressure ulcers and benefits of preventive interventions other than support surfaces. Evidence on harms of preventive interventions was extremely sparse, with most trials not reporting harms at all, and poor reporting of harms in those that did. Nonetheless, serious harms seem rare, consistent with what might be expected given the generally non-invasive nature of most of the preventive interventions evaluated (skin care, oral nutritional support, repositioning, and support surfaces). In addition, limited evidence was available to evaluate how the diagnostic accuracy of risk assessment instruments or benefits and harms of preventive interventions might vary depending on differences in setting, patient characteristics, or other factors.

Only one good-quality study and two poor-quality studies[35-37] attempted to evaluate the effects of standardized use of a risk assessment instrument on the incidence of pressure ulcers. The good-quality trial found no difference in incidence of pressure ulcer development in patients assessed with the Waterlow scale, the Ramstadius tool, or clinical judgment alone.[35] The two poor-quality studies evaluated the modified Norton scale[36] and the Braden scale,[37] with only a non-randomized study of the Norton scale[36] finding reduced risk of pressure ulcer compared with clinical judgment.[35, 36]

Studies of diagnostic accuracy found that commonly used risk assessment instruments can identify patients at increased risk for ulcers who might benefit from more intense or targeted interventions. No study that reported risk estimates attempted to control for potential confounding effects of differential use of interventions. There was no clear difference between commonly used risk assessment instruments in diagnostic accuracy, though direct comparisons were limited.[29, 33, 38-41]

About three-quarters of the trials of preventive interventions focused on evaluations of support surfaces. In higher-risk populations, fair-quality trials consistently found more advanced static support surfaces associated with lower risk of pressure ulcers compared with standard mattresses in higher-risk patients (RR range 0.20 to 0.60),[42-46] with no clear differences between different advanced static support surfaces.[47-53] Evidence on the effectiveness and comparative effectiveness of other support surfaces, including more advanced dynamic support surfaces, was limited, with some trials[54, 55] showing no clear differences between dynamic and static support surfaces. One fair-quality trial found stepped care with dynamic support surfaces associated with substantially decreased risk of ulcers compared with stepped care with static support surfaces,[56] suggesting that this might be both an effective as well as efficient approach, since care was initiated with the least expensive alternatives. In lower-risk populations of patients undergoing surgery, two trials found use of a foam overlay associated with an increased risk or trend towards increased risk of pressure ulcers compared with a standard operating room mattress.[57, 58] The few trials that evaluated length of stay found no differences between various support surfaces.[43, 44, 59-63]

Evidence on other preventive interventions (nutritional supplementation; repositioning; pads and dressings; lotions, creams, and cleansers; and intraoperative warming therapy for patients undergoing surgery) was very sparse and insufficient to reach reliable conclusions. An exception was repositioning, for which the trials were of somewhat higher quality, but limited to only three

trials, reporting somewhat inconsistent results.[64-66] One trial found a repositioning intervention was more effective than usual care in preventing pressure ulcers.[65]

Findings in Relationship to What is Already Known

Our findings of limited evidence on effects of risk assessment instruments in reducing the incidence or severity of pressure ulcers are consistent with other recent systematic reviews.[67, 68] One of these reviews also evaluated the diagnostic accuracy of risk assessment instruments.[68] It reported higher sensitivity and lower specificity for the Waterlow (0.82 and 0.27) compared with the Norton (0.47 and 0.62) and Braden (0.57 and 0.68) scales, but pooled data without regard for differences in cutoff scores and across study settings, and included four studies that we excluded due to retrospective design,[69] inadequate details to determine eligibility for inclusion,[70] availability only in Spanish,[71] or that we were unable to obtain.[72]

Our findings on effectiveness of preventive interventions are generally consistent with other systematic reviews that found some evidence that more advanced static support surfaces are associated with decreased risk of pressure ulcers compared with standard hospital mattresses,[8, 73] limited evidence on the effectiveness and comparative effectiveness of dynamic support surfaces,[8, 73] and limited evidence on other preventive interventions.[8, 74] All reviews noted methodological shortcomings in the trials and variability in interventions and comparisons across studies. These reviews differed from ours by including trials that enrolled patients with pre-existing ulcers and including trials published only as abstracts.

Applicability

The studies included in this review generally enrolled patients at higher risk for pressure ulcers, though eligibility criteria varied between studies. The studies are most applicable to acute care and long-term care settings, with few studies evaluating patients in community or home settings, including specific populations such as wheelchair bound people in the community. Some trials specifically evaluated lower risk patients undergoing surgery and were reviewed separately (see Key Question 3a). Although black and Hispanic patients represent the fastest growing populations of frail elderly in the United States, these populations were largely underrepresented in the studies.[75]

Another important issue in interpreting the applicability of this review is that patients in studies of diagnostic accuracy as well as in studies of interventions generally received standard of care treatments. For example, no study of diagnostic accuracy blinded caregivers to the results of risk assessment scores, which would be expected to lead to the use of more intensive preventive interventions and care in higher-risk people. If such interventions are truly effective, they would be expected to result in underestimates of pressure ulcers. For trials of preventive interventions, usual care includes repositioning every 2 to 4 hours, skin care, standard nutrition, and standard support surfaces. Therefore, most trials of preventive interventions represent comparisons of more intensive interventions plus multi-component standard care compared with standard care alone, rather than compared with no care. One factor that may affect applicability is that the more intensive preventive interventions evaluated in many of the studies included in this review may require additional training or resources.

Evidence to evaluate potential differences in comparative benefits or harms in patient subgroups based on baseline pressure ulcer risk, specific risk factors for ulcers, setting of care, and other factors was very limited, precluding any reliable conclusions.

Implications for Clinical and Policy Decisionmaking

Our review has potential implications for clinical and policy decisionmaking. Despite insufficient evidence to determine whether use of risk assessment instruments reduces risk of incident pressure ulcers, studies suggest that: a) commonly used instruments can predict which patients are more likely to develop an ulcer, and b) there are no clear differences in diagnostic accuracy. Decisions about whether to use risk assessment instruments and which risk assessment instrument to use may depend on considerations such as a desire to standardize and monitor practices within a clinical setting, ease of use, nursing or other caregiver preferences, and other factors.

Evidence suggests that more advanced static support surfaces are more effective than standard mattresses for reducing risk of pressure ulcers, though more evidence is needed to understand the effectiveness and comparative effectiveness of dynamic and other support surfaces. One trial found that a stepped care approach that utilized lower-cost dynamic support surfaces before switching to higher-cost interventions in patients with early ulcers could be effective as well as efficient; this finding warrants further study.[56] Although evidence is insufficient to guide recommendations on use of other preventive interventions, these findings are contingent on an understanding that usual care practices were the comparator treatment in most studies. Therefore, it would be inappropriate to conclude that standard repositioning, skin care, nutrition, and other practices should be abandoned, as these were the basis of usual care comparisons.

Although studies of preventive interventions primarily focused on effects on pressure ulcer incidence and severity, other factors such as effects on effects on resource utilization (including length of hospitalization and costs) and patient preferences may affect clinical decisions. However, cost and patient preferences were outside the scope of this report and data on resource utilization was limited to a few studies that found no effects of various support surfaces on length of stay.

Limitations of the Comparative Effectiveness Review Process

We excluded non-English language articles which could result in language bias, although a recent systematic review found little empirical evidence that exclusion of non-English language articles leads to biased estimates for non complementary or alternative medicine interventions.[76] In addition, we did not exclude poor-quality studies *a priori*. Rather, we described the limitations of the studies, emphasized higher-quality studies when synthesizing the evidence, and performed sensitivity analyses that excluded poor-quality studies.

We did not attempt to pool studies of diagnostic accuracy due to clinical heterogeneity across studies and methodological shortcomings. Rather, we synthesized results qualitatively, and described the range of results, in order to highlight the greater uncertainty in findings.

We did not formally assess for publication bias with funnel plots due to small numbers (<10) of studies for all comparisons and due to important clinical heterogeneity and methodological shortcomings in the available studies.

Limitations of the Evidence Base

We identified a number of limitations in the evidence base on preventive interventions. Most included studies had important methodological shortcomings, with 4 of 47 studies of diagnostic accuracy and 27 of 54 studies of preventive interventions rated poor-quality, and only 12 studies

of diagnostic accuracy and three studies of preventive interventions rated good-quality. Few studies of diagnostic accuracy reported measures of discrimination, such as the AUROC, many studies failed to pre-define cutoff thresholds, few studies reported differential use of interventions according to baseline risk score (which could affect estimates of diagnostic accuracy), and some studies evaluated modified or ad hoc versions of standard risk assessment instruments. An important limitation of the evidence on preventive interventions is that few trials compared the same intervention, and methods for assessing and reporting ulcers varied. There was almost no evidence to determine how diagnostic accuracy of risk assessment instruments or the effectiveness and comparative effectiveness of preventive interventions varies according to care setting, patient characteristics, or other factors. Harms were reported in only 13 of 54 trials of preventive interventions, and poorly reported when any data were provided. Only about half of the studies reported funding source. Among those that did report funding source, most were sponsored by institutions or governmental organizations.

Future Research

Future research is needed on the effectiveness of standardized use of risk assessment instruments compared with clinical judgment or non-standardized use in preventing pressure ulcers. Studies should evaluate validated risk assessment instruments and employ a clearly described protocol for use of preventive interventions based on the risk assessment score. In addition to comparing the risk and severity of ulcers across groups, studies should also report effects on use of preventive interventions as well as other important outcomes, such as length of hospital stay and measures of resource utilization.

Future research that simultaneously evaluates the diagnostic accuracy of different risk assessment instruments is needed to provide more direct evidence on how their performance compares with one another. Studies should at a minimum report how use of preventive interventions differed across intervention groups, and consider reporting adjusted risk estimates to account for such potential confounders. Studies of diagnostic accuracy should also use pre-defined, standardized cutoffs and routinely report measures of discrimination such as the AUROC.

More research is needed to understand the effectiveness of preventive interventions. It is critical that future studies of preventive interventions adhere to methodological standards including appropriate use of blinding (such as blinding of outcome assessors even when blinding of patients and caregivers is not feasible) and clearly describe usual care and other comparison treatments. Studies should routinely report baseline pressure ulcer risk in enrolled patients and consider predefined subgroup analyses to help better understand how preventive interventions might be optimally targeted. More studies are needed to better understand the comparative effectiveness of dynamic and reactive support surfaces compared with static support surfaces, as well as strategies such as stepped care approaches that might be more efficient than using costly interventions in all patients.

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Internet Citation

To be added.

Introduction

Background

Condition

Pressure ulcers are defined by the United States National Pressure Ulcer Advisory Panel (NPUAP) as "localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear and/or friction."[1] Pressure ulcers are a common condition, affecting an estimated 3 million adults in the United States.[2] In 2006, there were more than 500,000 hospital stays in which pressure ulcers were reported. Estimates of pressure ulcers prevalence range from 0.40 to 38 percent in acute care hospitals, 2 to 24 percent in long-term nursing facilities, and 0 to 17 percent in home care settings.[3-5] The prevalence of facility-acquired pressure ulcers was 6 percent in 2008 and 5 percent in 2009.[5]

Pressure ulcers are often associated with pain and can contribute to decreased function or lead to complications such as infection.[2] In some cases, pressure ulcers may be difficult to treat despite surgical and other invasive treatments. In the inpatient setting, pressure ulcers are associated with increased length of hospitalization and delayed return to function.[6] In addition, the presence of pressure ulcers is associated with poorer general prognosis and may contribute to mortality risk.[6] Between 1990 and 2001, pressure ulcers were reported as a cause of death in nearly 115,000 people, and listed as the underlying cause in more than 21,000.[7] Estimates of the costs of treatment for pressure ulcers vary, but range between $37,800 and $70,000 per case, with total annual costs in the United States as high as $11 billion.[2, 8]

Most current grading systems for pressure ulcers, including the commonly utilized NPUAP and the European Pressure Ulcer Advisory Panel (EPUAP) classification systems, assign one of four grades, based on the depth of the ulcer and tissue involvement, with higher grades indicating greater severity (Table 1).[9, 10] With either system, stage I is defined as superficial erythema without skin breakdown, stage II as partial thickness ulceration, stage III as full thickness ulceration, and stage IV as full thickness with involvement of muscle and bone. When an ulcer has overlying purulent material or eschar so that it is not possible to determine the depth or extent of tissue involvement, the ulcer is classified as unstageable, or stage X.

Risk factors for pressure ulcers include those physical and/or cognitive impairments, older age, and other comorbidities that affect soft tissue integrity and healing (such as urinary incontinence, edema, impaired microcirculation, hypoalbuminemia, and malnutrition).[2, 11] Given the negative impact and burdens associated with pressure ulcers, interventions that can prevent their occurrence or reduce their severity could have an important impact on quality of life and health status. Such an approach may also be more efficient than interventions for treating ulcers that have already developed. According to one estimate, treatment costs may be as much as 2.5 times the cost of prevention.[2] A number of diverse interventions are available as potential preventive interventions for pressure ulcers. Because patients vary in their propensity to develop pressure ulcers and the underlying reasons for being at increased risk, methods for accurately assessing risk could help more efficiently target the use or intensity of preventive interventions. A number of risk assessment instruments and preventive interventions are available.[12-14]

The purpose of this report is to review the comparative clinical utility and diagnostic accuracy of risk assessment instruments for evaluating risk of pressure ulcers, and to evaluate the

benefits and harms of preventive interventions for pressure ulcers, in different settings and patient populations. People at risk for pressure ulcers are cared for in diverse settings, including acute care hospitals, long-term care facilities, and the community at large. This report therefore also reviews how effectiveness varies in specific patient subgroups and in different settings.

Table 1. Pressure ulcer grading classification

Grade	Description
I	Intact skin with nonblanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area. Red area: Present longer that 30 minutes, but less than 24 hours Present longer than 24 hours
II	Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled blister. Epidermis and/or dermis ulcerated with no adipose tissue observed.
III	Full thickness tissue loss. Adipose tissue may be visible but bone, tendon or muscles are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling. Adipose tissue observed, no muscle observed.
IV/V	Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often include undermining and tunneling. Muscle/ fascia observed, but no bone observed Bone observed, but no involvement of joint space.
X	Given that it is based on depth and tissue involvement, when an ulcer has overlying purulent material or eschar prohibiting the ability to determine the depth or extent of tissue involvement, the ulcer is classified as unstageable, or stage X.

National Pressure Ulcer Advisory Panel (NPUAP) (2007). Support Surfaces Standards Initiative - Terms and Definitions Related to Support Surfaces. 10.

Prevention Strategies

Recommended prevention strategies for pressure ulcers generally involve the use of risk assessment tools to identify people at higher risk for developing ulcers in conjunction with interventions for preventing ulcers.[10, 15, 16] Use of preventive interventions is based in part on assessed risk, with higher-risk patients receiving more intensive interventions. Pressure ulcers are associated with a number of risk factors, including older age, black skin color, higher body weight, physical or cognitive impairment, poor nutritional status, incontinence, and specific medical comorbidities that affect circulation such as diabetes or peripheral vascular disease.

A number of instruments have been developed to assess for risk for pressure ulcers. The three most widely used instruments are the Braden Scale (six items, total scores range from 6 to 23), the Norton Scale (five items, total scores range from 5 to 20), and the Waterlow Scale (11 items, total scores range from 1 to 64) (Table 2).[2, 17-19] All three scales include items related to activity, mobility, nutritional status, incontinence, and cognition, though they are weighted differently across studies.[18]

Table 2. Commonly used scales for risk assessment of pressure ulcers[20-25]

Scale	Description	Population	Scoring
Braden	6 subscales: mobility, activity, sensory perception, skin moisture, nutrition state and friction/shear	General	6-23; lower scores indicate higher pressure ulcer risk
Cubbin and Jackson	15 subscales: age, weight, medical history, skin condition, mental state, mobility, nutrition, respiration, incontinence, hygiene, hemodynamic state, oxygen requirements; use of blood products, surgery within 24 hours, hypothermia	Intensive care unit	9-48; lower scores indicate higher pressure ulcer risk
Norton	5 subscales: physical condition, mental state, activity, mobility, incontinence	General	5-20; lower scores indicate higher pressure ulcer risk
Waterlow	11 subscales: build/weight for height, skin condition, sex and age, continence, mobility, appetite, medication, other risk factors (tissue malnutrition, neurological deficit, major surgery or trauma)	General	1-64; higher scores indicate higher pressure ulcer risk

A variety of diverse interventions are available for the prevention of pressure ulcers. Categories of preventive interventions include support surfaces (including mattresses, integrated bed systems, overlays, and cushions), repositioning, skin care (including lotions, dressings, and management of incontinence), and nutritional support.[15, 16] Each of these broad categories encompasses a variety of interventions. The term "support surfaces" refers to devices "for pressure redistribution designed for management of tissue loads, micro-climate, and/or other therapeutic functions."[26] Criteria for classifying support surfaces have historically included the material used (e.g., foam, air, gel, beads, water), whether the support surface is static or dynamic (e.g., an alternating-air pressure mattress), and whether the support surface requires power.[27] More recent proposals are to reclassify support surfaces as "reactive" (a powered or nonpowered support surface with the capacity to change its load distribution properties only in response to applied load) or "active" (a power supported surface that can alter when and where load is applied to a person who sits or lies upon it and does not require a high applied load to redistribute body weight).[26, 27] However, most published trials have used older methods for describing and classifying support surfaces. In this report, we classified support surfaces as static or dynamic, with additional subgrouping based on the material and type of support surface.

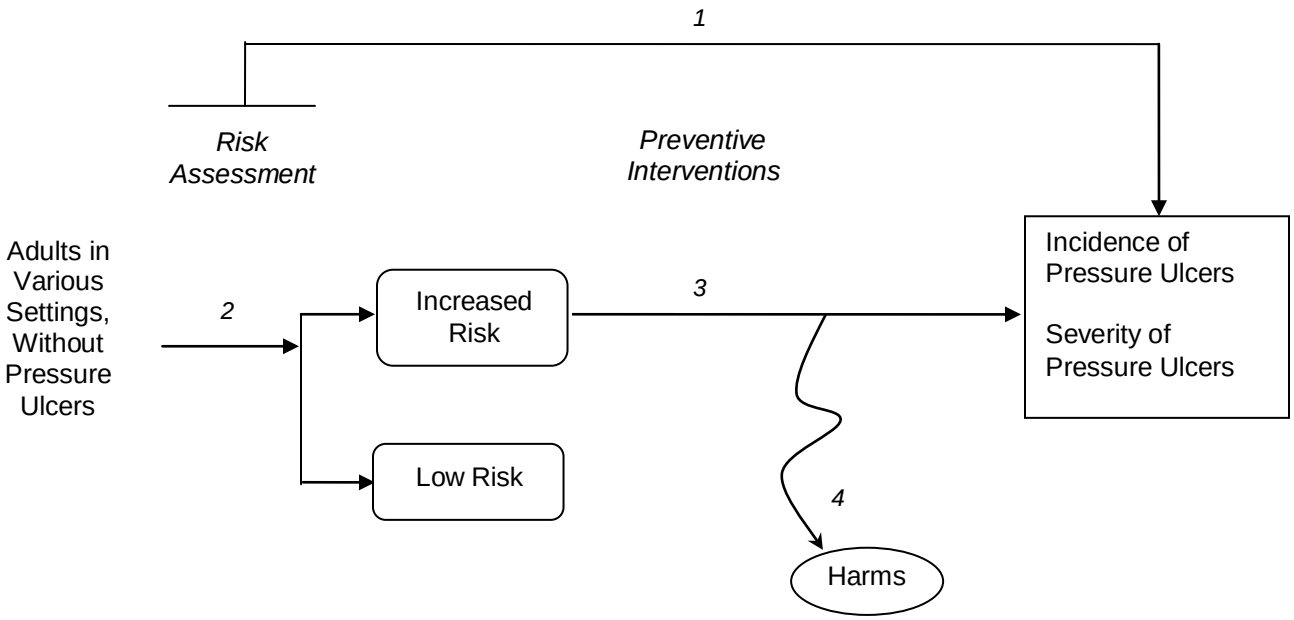
The use of preventive interventions vary according to the level of assessed risk, as well as according to specific patient characteristics or differences in settings. For example, a nutritional supplement may be of limited use in a patient who is not malnourished, and skin care needs may differ for people with incontinence compared to those without. Some interventions that require substantial nursing resources or specialized equipment may not be as feasible for community settings. Preventive interventions may also be used in combination or as part of complex multi-component interventions including repositioning, nutritional support, skin care, and support surfaces.

Scope of Review and Key Questions

This topic was nominated for review by the American College of Physicians, which intends to develop a guideline on prevention and management of pressure ulcers. This report focuses on pressure ulcer risk assessment and prevention approaches (i.e., prediction of and prevention of ulcers in people without ulcers at baseline). Treatment of pressure ulcers is addressed in a separate report.[28]

The analytic framework and key questions used to guide this report are shown below (Figure 1). The analytic framework shows the target populations, interventions, and health outcomes we examined.

Figure 1. Analytic framework



The following key questions are the focus of our report:

Key Question 1. For adults in various settings*, is the use of any risk assessment tool† effective in reducing the incidence or severity of pressure ulcers, compared with other risk assessment tools, clinical judgment alone, and/or usual care?

Key Question 1a. Does the effectiveness and comparative effectiveness of risk assessment tools differ according to setting*?

Key Question 1b. Does the effectiveness and comparative effectiveness of risk assessment tools differ according to patient characteristics‡, and other known risk factors for pressure ulcers, such as nutritional status or incontinence?

Key Question 2. How do various risk assessment tools compare with one another in their ability to predict the incidence of pressure ulcers?

Key Question 2a. Does the predictive validity of various risk assessment tools differ according to setting*?

Key Question 2b. Does the predictive validity of various risk assessment tools differ according to patient characteristics[‡]?

Key Question 3. In patients at increased risk of developing pressure ulcers, what is the effectiveness and comparative effectiveness of preventive interventions in reducing the incidence or severity of pressure ulcers?

Key Question 3a. Does the effectiveness and comparative effectiveness of preventive interventions differ according to risk level as determined by different risk assessment methods and/or by particular risk factors?

Key Question 3b. Does the effectiveness and comparative effectiveness of preventive interventions differ according to setting[*]?

Key Question 3c. Does the effectiveness and comparative effectiveness of preventive interventions differ according to patient characteristics[‡]?

Key Question 4. What are the harms of interventions for the prevention of pressure ulcers?

Key Question 4a. Do the harms of preventive interventions differ according to the type of intervention?

Key Question 4b. Do the harms of preventive interventions differ according to setting[*]?

Key Question 4c. Do the harms of preventive interventions differ according to patient characteristics[‡]?

*Including acute care hospital, long-term care facility, rehabilitation facility, operating room, home care, and wheelchair users in the community.
†Such as the Braden Scale, the Norton Scale, the Waterlow Scale, or others.
‡Such as age, race or skin tone, physical impairment, body weight, or specific medical comorbidities (e.g., diabetes and peripheral vascular disease).

Key Question 1 focuses on direct evidence showing that using a risk assessment tool is associated with reduced incidence or severity of pressure ulcer. An implicit assumption with this key question is that results of the risk assessment will inform the use of preventive interventions. Because direct evidence on the effects of risk assessment tools on clinical outcomes may be limited, the remainder of the key questions addresses the indirect chain of evidence necessary to assess strategies for prevention of pressure ulcers. Optimal prevention strategies require accurate identification of people at risk as well as effective interventions to reduce risk. Therefore, Key Question 2 addresses the diagnostic accuracy of risk assessment instruments, and Key Questions 3 and 4 evaluate the benefits and harms associated with various preventive interventions, compared with usual care or each other. Each key question also has sub-questions that address how estimates of diagnostic accuracy or clinical benefits vary in different patient groups defined by various risk factors, or in different care settings.

Methods

This comparative effectiveness review (CER) follows the methods suggested in the Agency for Healthcare Research and Quality (AHRQ) Methods Guide for Effectiveness and Comparative Effectiveness Reviews.[29] All methods were determined *a priori*.

Input from Stakeholders

The key questions for this CER were developed with input from key informants, representing clinicians, wound care researchers, and patient advocates who helped refine key questions, identify important methodological and clinical issues, and define parameters for the review of evidence. The revised key questions were then posted to the AHRQ public Web site for a 4-week public comment period. The AHRQ and our Evidence-based Practice Center (EPC) agreed upon the final key questions after reviewing the public comments, receiving additional input from a Technical Expert Panel (TEP) convened for this report, and revising the key questions. We then drafted a protocol for the CER, which was reviewed by the TEP. The TEP consisted of people with expertise in pressure ulcer treatment and research, from disciplines including geriatrics, primary care, hospital medicine, and nursing.

Prior to participation in this report, the TEP members disclosed all financial or other conflicts of interest. The AHRQ Task Order Officer and the authors reviewed the disclosures and determined the panel members had no conflicts of interest that precluded participation.

With input from the TEP, the final protocol was developed prior to initiation of the review, and is available at http://effectivehealthcare.ahrq.gov/ehc/products/309/926/Pressure-Ulcer-Prevention_Protocol_20120110.pdf.

Literature Search Strategy

A research librarian conducted searches on MEDLINE (Ovid) from 1946 to October, 2011; CINAHL (EBSCOhost) from 1988 through October, 2011; and the Cochrane Central Register of Controlled Trials and Cochrane Database of Systematic Reviews using EBM Reviews (Ovid) through the 4th Quarter, 2011 (see Appendix A for full search strategies). The search strategies were peer reviewed by another information specialist and revised prior to finalizations. We also hand-searched the reference lists of relevant studies. In addition, scientific information packets (SIPs) were requested from identified drug and device manufacturers of pressure ulcer treatments, who had the opportunity to submit data using the portal for submitting SIPs on the Effective Health Care Program Web site.

Searches will be updated prior to finalization of the report to identify any relevant new publications.

Study Selection

We developed criteria for inclusion and exclusion of studies based on the key questions and the populations, interventions, comparators, outcomes, timing, types of studies, and setting (PICOTS) approach. Inclusion and exclusion criteria, summarized below, are described in more detail by key question in Appendix B. Papers were selected for review if they were about prevention of pressure ulcers, were relevant to a key question, and met the predefined inclusion criteria. We excluded studies of non-human subjects and studies with no original data. Abstracts and full-text articles were reviewed by two investigators for inclusion for each key question.

Full-text articles were obtained for all studies that either investigator identified as potentially meeting inclusion criteria. Two investigators independently reviewed all full-text articles for final inclusion. A list of the included studies can be found in Appendix C, and the excluded studies can be found in Appendix D, with primary reasons for exclusion. We restricted inclusion to English language articles. Titles and abstracts of non-English language articles that may be relevant can be found in Appendix E. Discrepancies were resolved through discussion and consensus, with a third investigator making the final decision if necessary.

Population and Conditions of Interest

The target population was adult patients (>18 years of age) without pressure ulcers at baseline. We excluded studies that enrolled >10 percent of the population with pressure ulcers at baseline. We included studies that did not report the proportion of patients with pressure ulcers at baseline only if they reported incidence pressure ulcers and either restricted inclusion to people with no or only stage I ulcers (i.e., no skin breakdown) or were clearly prevention-focused. We did not restrict inclusion to studies that only enrolled people at higher risk for ulcers, though most studies focused on higher risk people. We evaluated patient subgroups defined by age, race or skin tone, physical impairment, body weight, or specific medical comorbidities (e.g., urinary incontinence, diabetes and peripheral vascular disease). We excluded studies of children and adolescents.

Interventions and Comparisons

For Key Question 1, we included studies that compared effects of using a risk assessment instrument, primarily the Braden Scale, Norton Scale, or Waterlow Scale, with clinical judgment or another risk assessment instrument. We excluded studies that evaluated individual risk factors outside of a risk assessment instrument. For Key Question 2, we included studies that reported the diagnostic accuracy of validated risk assessment tools for predicting incident pressure ulcers. For Key Questions 3 and 4, we included studies that compared interventions to prevent pressure ulcers with usual care, or no treatment, or that compared one preventive intervention with another.

Outcomes

For Key Questions 1 and 3, included outcomes were pressure ulcer incidence and severity, as well as resource utilization (such as duration of hospital stay or cost). For Key Question 2, we included outcomes related to the predictive validity of the risk assessment tools, including diagnostic accuracy (sensitivity, specificity, positive predictive value, negative predictive value, positive likelihood ratio, negative likelihood ratio), measures of risk (hazard ratios, odds ratios, and relative risks), and discrimination (area under the receiver operating characteristic [AUROC] curve). For Key Question 4, we included harms (such as dermatologic reactions, discomfort, and infection).

Timing

We did not restrict inclusion of studies based on duration of followup.

Types of Studies

For Key Questions 1, 3 and 4, we included controlled clinical trials and cohort studies. For Key Question 2 we included prospective studies that reported diagnostic accuracy of risk prediction instruments. We excluded systematic reviews, though we reviewed their reference lists for additional citations. We also excluded studies published only as conference abstracts.

Setting

We did not exclude studies based on setting. Settings of interest included acute care hospitals, long-term care facilities, rehabilitation facilities, operative and postoperative settings, and non-healthcare settings (e.g., home care and wheelchair users in the community).

Data Extraction

We extracted the following information from included trials into evidence tables: study design, setting, inclusion and exclusion criteria, population characteristics (including sex, age, ethnicity, prevalent ulcers, risk for ulcers), sample size, duration of followup, attrition, intervention characteristics, method for assessing ulcers, and results. Data extraction for each study was performed by two investigators: the first investigator extracted the data, and the second investigator independently reviewed the extracted data for accuracy and completeness.

For studies of diagnostic accuracy, we attempted to create two-by-two tables from information provided (sample size, prevalence, sensitivity, and specificity) and compared calculated measures of diagnostic accuracy based on the two-by-two tables with reported results. We noted discrepancies between calculated and reported results when present. When reported, we also extracted relative measures of risk (relative risk [RR], odds ratio, hazards ratio) and the AUROC. The AUROC, which is based on sensitivities and specificities across a range of test results, is a measure of discrimination, or the ability of a test to distinguish people with a condition from people without.[30, 31] An AUROC of 1.0 indicates perfect discrimination, and an AUROC of 0.5 indicates complete lack of discrimination. Interpretation of AUROC values between 0.5 and 1.0 is somewhat arbitrary, but a value of 0.90 to <1.0 has been classified as excellent, 0.80 to <0.90 good, 0.70 to <0.80 fair, and <0.70 poor.

Assessing Quality

We assessed the quality of each study based on predefined criteria. We adapted criteria from methods proposed by Downs and Black (observational studies),[32] the United States Preventive Services Task Force (USPSTF),[33] and the Quality Assessment of Diagnostic Accuracy Studies-2 Group.[34] The criteria used are consistent with the approach recommended by AHRQ in the Methods Guide for Comparative Effectiveness Reviews.[29] We used the term “quality” rather than the alternate term “risk of bias;” both refer to internal validity.

We rated the quality of each randomized trial based on the methods used for randomization, allocation concealment, and blinding; the similarity of compared groups at baseline; maintenance of comparable groups; adequate reporting of dropouts, attrition, crossover, adherence, and contamination; loss to followup; the use of intent-to-treat analysis; and ascertainment of outcomes.[33] For cluster randomized trials, we also evaluated whether the study evaluated cluster effects.[35]

We rated the quality of each cohort study based on whether it used nonbiased selection methods to create an inception cohort; whether it evaluated comparable groups; whether rates of

loss to followup were reported and acceptable; whether it used accurate methods for ascertaining exposures, potential confounders, and outcomes; and whether it performed appropriate statistical analyses of potential confounders.[33]

We rated the quality of each diagnostic accuracy study based on whether it evaluated a representative spectrum of patients, whether it enrolled a random or consecutive sample of patients meeting predefined criteria, whether it used a credible reference standard, whether the same reference standard was applied to all patients, whether the reference standard was interpreted independently from the test under evaluation, and whether thresholds were predefined.[33, 34] In addition, unblinded use of a risk prediction instrument (as was typical in the studies) could result in differential use of preventive interventions depending on assessed risk, alter the likelihood of the predicted outcome, and compromise measures of diagnostic accuracy (e.g., if more intense and effective interventions are used in higher-risk patients). Therefore, we also assessed whether studies on diagnostic accuracy reported use of subsequent interventions, and whether risk estimates (when reported) were adjusted for potential confounders.

Following assessment of individual quality criteria, individual studies were rated as "good," "fair," or "poor" quality, as defined below.[29]

Good-quality studies are considered likely to be valid. Good-quality studies clearly describe the population, setting, interventions, and comparison groups; use a valid method for allocation of patients to interventions; clearly report dropouts and have low dropout rates; use appropriate methods for preventing bias; and appropriately measure outcomes and fully report results.

Fair-quality studies have some methodological deficiencies, but no flaw or combination of flaws judged likely to cause major bias. The study may be missing information, making it difficult to assess its methods or assess limitations and potential problems. The fair-quality category is broad, and studies with this rating vary in their strengths and weaknesses: the results of some fair-quality studies are likely to be valid, while others are only probably valid.

Poor-quality studies have significant flaws that may invalidate the results. They have a serious or "fatal" flaw in design, analysis, or reporting; large amounts of missing information; or discrepancies in reporting. The results of these studies are judged to be at least as likely to reflect flaws in the study design as true effects of the interventions under investigation. We did not exclude studies rated poor-quality *a priori*, but they were considered to be the least reliable studies when synthesizing the evidence, particularly when discrepancies between studies were present. For detailed quality assessment methods see Appendix F.

Assessing Research Applicability

Applicability is defined as the extent to which the effects observed in published studies are likely to reflect the expected results when a specific intervention is applied to the population of interest under "real-world" conditions.[36] It is an indicator of the extent to which research included in a review might be useful for informing clinical and/or policy decisions in specific situations. Applicability depends on the particular question and the needs of the user of the review. There is no generally accepted universal rating system for applicability. In addition, applicability depends in part on context. Therefore, we did not assign a rating of applicability (such as "high" or "low") because applicability may differ based on the user of this report. Rather, we recorded factors important for understanding the applicability of studies, such as whether the publication adequately described the study population, how similar patients were to populations likely to be targeted by screening, whether differences in outcomes were clinically (as well as statistically) significant, and whether the interventions and tests evaluated were

reasonably representative of standard practice.[37] We also recorded the funding source and role of the sponsor.

We specifically assessed applicability as related to subpopulations directly addressed by the key questions.

Evidence Synthesis and Rating the Body of Evidence

We did not attempt to pool studies on preventive interventions due to methodological limitations in the studies and substantial clinical diversity with respect to the populations, settings, comparisons, and outcomes evaluated (i.e., how pressure ulcers were assessed and graded). We also did not quantitatively pool results on diagnostic accuracy (such as creating summary receiver operating characteristic curves) due to differences across those studies in populations evaluated, differences in how pressure ulcers were assessed and graded, and methodological limitations in the studies. Instead, we created descriptive statistics with the median sensitivity and specificity at specific cutoffs and reported AUROCs, along with associated ranges. Although studies varied in what cutoffs were evaluated, and some evaluated a range of cutoffs without a pre-specified threshold, we focused on cutoffs for the most common risk instruments (Braden, Norton, and Waterlow) based on recommended thresholds, which may vary depending on the setting and timing of assessments: ≤15 to 18 for the Braden scale,[14, 22, 38-40] ≤12 to 16 for the Norton scale,[23, 41, 42] and ≥10 to 15 for the Waterlow scale.[23, 43] On the less commonly used Cubbin and Jackson scale, a score of ≤29 has been used to identify people at increased risk.[25] The total range across studies for the various measures of diagnostic accuracy, rather than the interquartile range, was reported because the summary range highlighted the greater variability and uncertainty in the estimates.

We assessed the overall strength of evidence for each body of evidence in accordance with the AHRQ Methods Guide for Comparative Effectiveness Reviews.[44] We synthesized the quality of the studies; the consistency of results within and between study designs; the directness of the evidence linking the intervention and health outcomes; and the precision of the estimate of effect (based on the number and size of studies and confidence intervals for the estimates). We were not able to formally assess for publication bias in studies of interventions due to small number of studies, methodological shortcomings, or differences across studies in designs, measured outcomes, and other factors. We rated the strength of evidence for each key question using the four categories recommended in the AHRQ Methods Guide:[44] A “high” grade indicates high confidence that the evidence reflects the true effect and that further research is very unlikely to change our confidence in the estimate of effect. A “moderate” grade indicates moderate confidence that the evidence reflects the true effect and further research may change our confidence in the estimate of effect and may change the estimate. A “low” grade indicates low confidence that the evidence reflects the true effect and further research is likely to change the confidence in the estimate of effect and is likely to change the estimate. An “insufficient” grade indicates evidence either is unavailable or does not permit a conclusion. See Appendix G for the strength of evidence table.

Peer Review and Public Commentary

Experts in prevention and management of pressure ulcers, geriatric medicine, wound care research, and epidemiology, as well as individuals representing important stakeholder groups, were invited to provide external peer review of this CER. The AHRQ Task Order Officer and a designated EPC Associate Editor will also provide comments and editorial review. To obtain

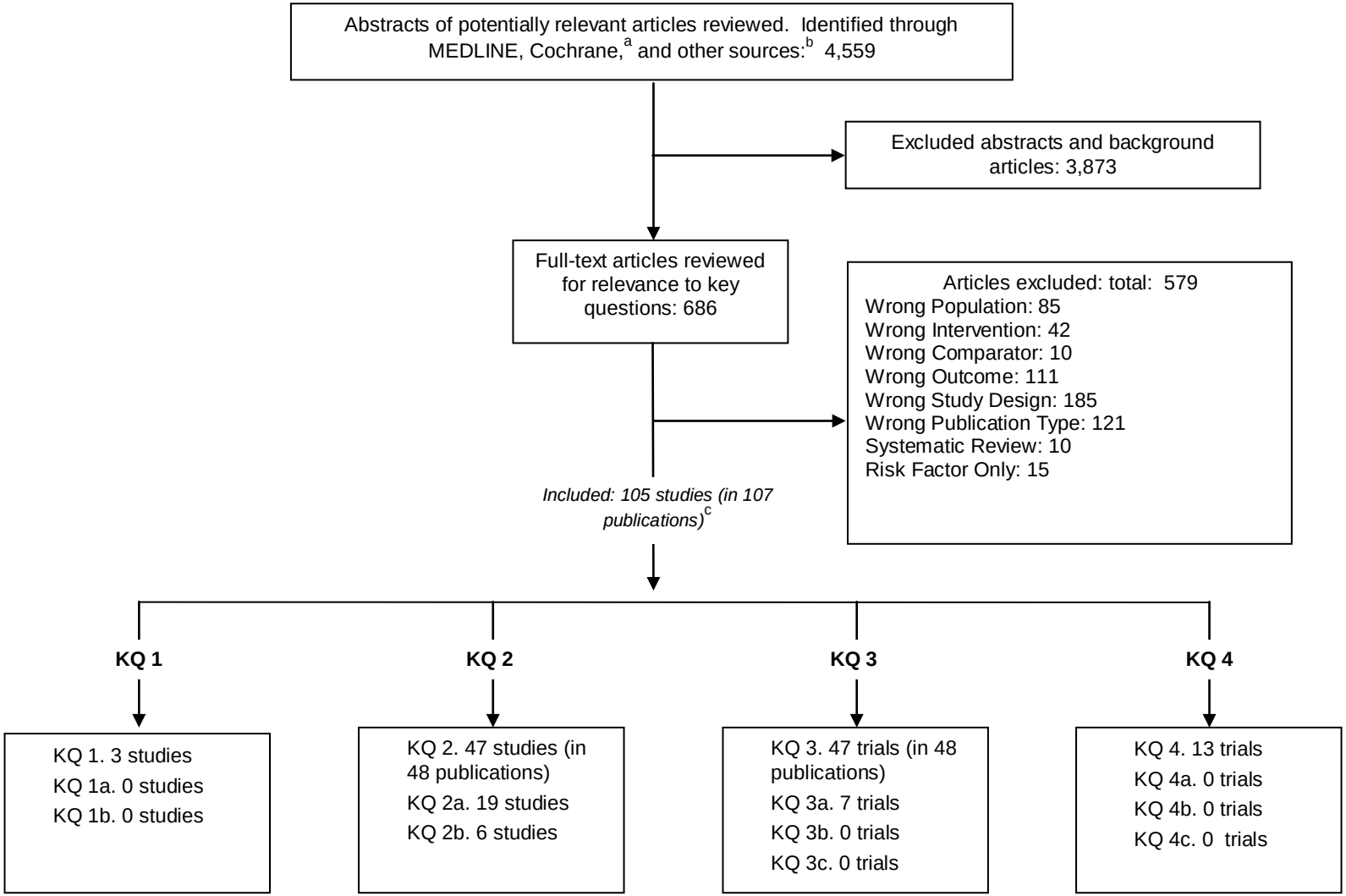
public comment, the draft report will be posted on the AHRQ Web site for 4 weeks. After addressing the public and peer review comments, a disposition of comments report detailing the authors' responses will be made available 3 months after the AHRQ posts the final CER on the public Web site.

Results

Overview

The search and selection of articles are summarized in the study flow diagram (Figure 2). Database searches resulted in 4,559 potentially relevant articles. After dual review of abstracts and titles, 686 articles were selected for full-text review, and 105 studies (in 107 publications) were determined by dual review at the full-text level to meet inclusion criteria and were included in this review. Data extraction and quality assessment details for all included studies per key question are available in Appendix H.

Figure 2. Literature flow diagram



[a] Cochrane databases include the Cochrane Central Register of Controlled Trials and the Cochrane Database of Systematic Reviews.
[b] Other sources include reference lists, suggested by peer reviewers, etc.
[c] Some articles are included for more than one key question.

Key Question 1. For adults in various settings, is the use of any risk assessment tool effective in reducing the incidence or severity of pressure ulcers, compared with other risk assessment tools, clinical judgment alone, and/or usual care?

Key Points

- One good-quality, randomized trial (n=1231) found no difference in pressure ulcer incidence between patients assessed with either the Waterlow or Ramstadius scales compared with clinical judgment alone (relative risk [RR] 1.4, 95% CI 0.82 to 2.4 and RR 0.77, 95% confidence interval [CI] 0.44 to 1.4, respectively) (strength of evidence: insufficient).
- One poor-quality, nonrandomized study (n=240) found use of a modified version of the Norton scale in conjunction with standardized use of preventive interventions based on risk score associated with lower risk of pressure ulcers compared with nurses' clinical judgment alone (RR 0.11, 95% CI 0.03 to 0.46) (strength of evidence: insufficient).
- One poor-quality, cluster randomized trial (n=521) found no difference between training in and use of the Braden score compared with nurses' clinical judgment in risk of incident pressure ulcers, but included patients with prevalent ulcers (strength of evidence: insufficient).

Detailed Synthesis

One good-quality study and two poor-quality studies evaluated effects of using a formal risk assessment instrument compared with nurses' judgment alone on subsequent risk of pressure ulcers (Appendix H1, H2, and H3).[13, 45, 46] The good-quality study was a randomized, controlled trial comparing the Waterlow and Ramstadius scales to clinical judgment.[13] Of the two poor-quality studies, one was a non-randomized study[45] that evaluated a modified version of the Norton scale, and the other was a cluster randomized trial[46] that evaluated the Braden scale.

The good-quality randomized trial (n=1,231) randomized newly admitted internal medicine or oncology patients to either the Waterlow scale, Ramstadius tool (an unvalidated risk assessment and intervention protocol) or nurses' judgment.[13] Baseline risk scores were not reported, though 6 percent of patients had a pressure ulcer at baseline (primarily stage I or II). There was no difference between interventions in risk of pressure ulcers after a mean of nine days (8 vs. 5 vs. 7 percent for Waterlow vs. Ramstadius vs. clinical judgment; RR 1.4, 95% CI 0.82 to 2.4 for Waterlow vs. clinical judgment and RR 0.77, 95% CI 0.44 to 1.4 for Ramstadius vs. clinical judgment), or in length of stay (8.8 vs. 9.4 vs. 8.5 days, respectively). The proportion of patients that received more intensive preventive interventions (more advanced support surfaces, documented pressure ulcer care plan, skin integrity referral, or dietician referral) was similar between groups.

The nonrandomized study (n=240) evaluated hospice patients during an intervention period in which a modified Norton scale was applied and used to inform pressure ulcer prevention interventions (based on a standardized protocol), compared with a non-concurrent control period in which the modified Norton scale was applied but not used to inform interventions.[45] The

modified Norton scale replaced the items “activity” and “mental conditions” with “nutritional status” and “pain,” and included additional items (diabetes, vascular disease, intravenous infusions or epidurals, altered mental status, lymphedema or ascites, fungating wound, and paraplegia), resulting in a possible range of scores of 5 to 39 (higher score indicating greater risk), compared with 5 to 20 on the original Norton scale. In the intervention period, patients with a score ≤10 received a hollow core fiber overlay; with a score between 11 and 15, a basic alternating air mattress overlay; and with a score ≥16, a more sophisticated alternating pressure mattress replacement. Patients in the comparison group received a hollow core fiber overlay unless they requested a special overlay or mattress used prior to admission. In addition, patients at high risk based on nurses’ judgment received the same alternating pressure mattress replacement as the highest risk patients (score ≥ 16) in the intervention group. The intervention was associated with a lower risk of incident pressure ulcers (2.5 vs. 22 percent, RR 0.11; 95% CI, 0.03 to 0.46), with more patients in the intervention compared with the comparison group receiving the sophisticated alternating pressure mattress (29 vs. 7.5 percent). Two-thirds of the ulcers were grade I and about one-third were grade II. Methodological shortcomings included use of a nonrandomized design and an unvalidated modification of the Norton scale, higher baseline pressure ulcer risk scores in the intervention group (29 vs. 20 percent had scores ≥16), no statistical adjustment for confounders, and unclear blinding of nurses to modified Norton scores during the comparison period.

A cluster randomized trial (n=521) of patients with a Braden score ≤18 evaluated three interventions: a) pressure ulcer prevention training of nurses with education in use of the Braden scale, and mandatory use of the Braden scale; b) pressure ulcer prevention training of nurses with education in use of the Braden scale, but no mandatory use; and c) no additional pressure ulcer prevention training or training in use of the Braden scale, although pressure ulcer risk was assessed using an ad hoc five-level scale.[46] Ward nurses in all three groups also participated in a one-day wound care management training. There was no difference in risk of incident pressure ulcers (22 vs. 22 vs. 15 percent, respectively, p=0.38). Differences between groups in use of preventive interventions were not reported. Methodological shortcomings in this study included unclear methods of randomization and allocation concealment, baseline differences in Braden scores, failure to evaluate cluster effects, and failure to blind outcome assessors to risk assessment scores. In addition, although incident pressure ulcers were reported, patients with pressure ulcers at baseline were included. Both the proportion of patients with ulcers at baseline and the proportion of incident ulcers that occurred in patients with ulcers at baseline were unclear.

A third, nonrandomized study compared use of the Norton Scale with nurses’ clinical judgment in reducing pressure ulcers, but was excluded because it included patients with prevalent pressure ulcers at baseline and did not report incident pressure ulcers.[47]

Key Question 1a. Does the effectiveness and comparative effectiveness of risk assessment tools differ according to setting?

- No study evaluated how effectiveness of risk assessment tools varies according to care setting (strength of evidence: insufficient).

Three trials on the effects of the use of a formal risk assessment instrument compared with nurses' judgment on risk of pressure ulcers were conducted in different settings (acute care hospital vs. hospice care) but evaluated different risk assessment instruments and preventive interventions, and two of the studies had important methodological shortcomings, precluding judgments about whether effectiveness varied according to setting.[13, 45, 46]

Key Question 1b. Does the effectiveness and comparative effectiveness of risk assessment tools differ according to patient characteristics, and other known risk factors for pressure ulcers, such as nutritional status or incontinence?

- No study evaluated how effectiveness of risk assessment tools varies in subgroups defined by patient characteristics (strength of evidence: insufficient).

Three trials on the effects of the use of a formal risk assessment instrument compared with nurses' judgment on risk of pressure ulcers did not evaluate effectiveness in subgroups defined by patient characteristics.[13, 45, 46]

Key Question 2. How do various risk assessment tools compare with one another in their ability to predict the incidence of pressure ulcers?

Key Points

- In two good- and five fair-quality studies (n=92 to 1,772), the median AUROC for the Braden scale was 0.77 (range 0.55 to 0.88). In 16 studies, based on a cutoff of ≤18, the median sensitivity was 0.74 (range 0.33 to 1.0) and median specificity 0.68 (range 0.34 to 0.86) (strength of evidence: moderate).
- In three studies (one good- and two fair-quality; n=1,190 to 1,772), the median AUROC for the Norton scale was 0.74 (range 0.56 to 0.75). In five studies, using a cutoff of ≤14, median sensitivity was 0.75 (range 0.0 to 0.89) and median specificity 0.68 (range 0.59 to 0.95) (strength of evidence: moderate).
- In four studies (one good- and three-fair quality; n=98 to 1,229), the median AUROC for the Waterlow scale was 0.61 (range 0.54 to 0.66). In two studies, based on a cutoff of ≥10, sensitivities were 0.88 and 1.0 and specificities 0.13 and 0.29 (strength of evidence: moderate).
- In three studies (one good- and two fair-quality; n=112 to 534), the median AUROC for the Cubbin and Jackson scale was 0.83 (range 0.72 to 0.90). In three studies, based on a cutoff of ≤24 to 29, median sensitivity was 0.89 (range 0.83 to 0.95) and median specificity was 0.61 (0.42 to 0.82) (strength of evidence: moderate).
- In six studies (two good- and four fair-quality) that directly compared risk assessment tools (n=112 to 1,772), there were no clear differences between scales based on the AUROC (strength of evidence: moderate).

Detailed Synthesis

Forty-seven prospective cohort studies (assessing 53 separate populations in 48 publications) evaluated the diagnostic accuracy of pressure ulcer risk assessment tools (Appendix H4).[17, 18, 20-25, 39-43, 45, 48-81] Sample sizes ranged from 31 to over 3,000 patients; the mean age for participants in most studies was between 55 and 65 years. Seven studies assessed patients in community-based care facilities[41, 45, 51, 57, 71, 78, 80] and four studies included populations from mixed settings;[22, 40, 52, 63] the remainder evaluated hospitalized patients. Twelve studies were rated good-quality,[17, 18, 21, 39, 42, 51, 53, 63, 64, 66, 67, 73, 79] four studies poor-quality[24, 48, 71, 77] and the remainder fair-quality (Appendix H5). Common methodological shortcomings in the fair- or poor-quality studies included unclear methods of patient selection, failure to predefine cutoff scores, poorly described reference standards, and failure to blind outcomes assessment to risk assessment scores. Seventeen studies reported how use of interventions differed according to baseline risk score, but none adjusted for such differences in analyses.[18, 21, 25, 39, 41-43, 45, 49, 51, 57, 59-61, 64, 68, 70] Duration of followup following risk assessment was generally not reported.

Braden Scale

The Braden scale was evaluated in 32 studies (in 33 publications) (Appendix H4 and H5). [17, 18, 20-23, 39-42, 49-55, 58-61, 63, 64, 66-68, 70-73, 75, 77, 79] Two studies evaluated modified versions of the Braden in addition to the standard Braden: one added a blood circulation subscale,[61] while the other added subscales for skin tone and body type.[42]

In seven studies of the standard Braden, the median AUROC was 0.77 (range 0.55 to 0.88) (Table 3).[20, 21, 41, 55, 70, 73, 75] The other studies did not report the AUROC. Estimates for sensitivity and specificity varied depending on the cutoff (Appendix H6). At a cutoff of ≤15 on the standard Braden, median sensitivity was 0.33 (range 0.09 to 0.82) and median specificity was 0.91 (range 0.67 to 0.95) in 12 studies (Table 4).[17, 22, 39, 40, 49, 59, 61, 63, 64, 68, 71, 72] At a cutoff of ≤16, median sensitivity was 0.77 (range 0.35 to 1.0) and median specificity was 0.64 (range 0.14 to 1.0) in eight studies.[17, 21, 50, 54, 58, 60, 66, 67, 77] At a cutoff ≤18, median sensitivity was 0.74 (range 0.33 to 1.0) and median specificity was 0.68 (range 0.34 to 0.86) in 16 studies.[17, 18, 22, 39-41, 53, 59, 61, 63, 64, 67, 68, 71-73] Excluding two poor-quality studies[71, 77] or including two studies that evaluated modified versions of the Braden[42, 61] resulted in similar estimates.

Four fair-quality studies reported odds ratios for subsequent pressure ulcers based on Braden scale scores at baseline,[41, 52, 54, 61] but none adjusted for potential confounders. In addition, cutoffs varied between studies and studies that used the same cutoff reported inconsistent estimates (Appendix H4). For example, one study of 1,772 long-term care patients reported an odds ratio of 6.9 (CI not reported) at a Braden cutoff of ≤18,[41] but a study of 813 hospitalized inpatients reported an odds ratio of 2.1 (p=0.03, CI not reported) at the same cutoff.[52]

Table 3. Key Question 2: Pressure ulcer risk assessment scales AUROC

Study	Setting	AUROC	Quality Rating	Comments
Braden				
Chan et al, 2009[55]	Hospital inpatient n=197	0.68	Fair	
Perneger et al, 2002[70]	Hospital inpatient n=1,190	0.74	Fair	
Schoonhoven et al, 2002[73]	Hospital inpatient n=1,229	0.55	Good	
Kim et al, 2009[20]	Hospital inpatient; ICU n=219	0.88	Fair	
Seongsook et al, 2004[21]	Hospital inpatient; ICU n=112	0.71	Good	
Serpa et al, 2011[75]	Hospital inpatient; ICU n=92	0.79	Fair	1st assessment
	Hospital inpatient; ICU n=92	0.79	Fair	2nd assessment
	Hospital inpatient; ICU n=92	0.8	Fair	3rd assessment
DeFloor et al, 2005[41]	Long-term care facilities n=1,772	0.77	Fair	
	Median (range):	**0.77 (0.55 to 0.88)**		
Norton				
Perneger et al, 2002[70]	Hospital inpatient n=1,190	0.74	Fair	
Schoonhoven et al,[73]	Hospital inpatient n=1,229	0.56	Good	
DeFloor et al, 2005[41]	Long-term care facilities n=1,772	0.75	Fair	
	Median (range):	**0.74 (0.56 to 0.75)**		
Waterlow				
Schoonhoven et al, 2002[73]	Hospital inpatient n=1,229	0.61	Good	
Boyle et al, 2001[25]	Hospital inpatient; ICU n=534	0.66	Fair	
Compton et al, 2008[56]	Hospital inpatient; ICU n=698	0.58	Fair	
Serpa et al, 2009[74]	Hospital inpatient n=98	0.64	Fair	1st assessment
	Hospital inpatient n=98	0.54	Fair	2nd assessment
	Median (range):	**0.61 (0.54 to 0.66)**		
Cubbin and Jackson				
Boyle et al, 2001[25]	Hospital inpatient; ICU n=534	0.72	Fair	
Kim et al, 2009[20]	Hospital inpatient; surgical ICUn=219	0.9	Fair	
Seongsook et al, 2004[21]	Hospital inpatient; surgical, internal or neurological ICU n=112	0.83	Good	
	Median (range):	**0.83 (0.72 to 0.9)**		

Abbreviations: AUROC, area under the receiver operator characteristic curve; ICU, intensive care unit.

Table 4. Key Question 2: Sensitivity and specificity of pressure ulcer risk assessment scales

Cut-off	Number of Studies	Sensitivity	Specificity
Braden			
≤10	1 study[49]	0.91	0.96
≤12	2 studies[75, 77]	0.86, 0.14	0.65, 0.94
≤13	1 study[75]	0.71	0.82
≤14	2 studies[20, 42]	0.93, 0.89	0.70, 0.72
≤15	12 studies[17, 22, 39, 40, 49, 59, 61, 63, 64, 68, 71, 72]	Median 0.33 (range 0.09 to 0.82)	Median 0.91 (range 0.67 to 0.95)
≤16	9 studies [17, 21, 50, 54, 58, 60, 66, 67, 77]	Median 0.77 (range 0.35 to 1)	Median 0.64 (range 0.14 to 1)
<17	2 studies[41, 82]	0.80, 0.59	0.65, 0.41
≤18	16 studies[17, 18, 22, 39-41, 53, 59, 61, 63, 64, 67, 68, 71-73]	Median 0.74 (range 0.33 to 1)	Median 0.68 (range 0.34 to 0.86)
≤20	1 study[58]	0.97	0.05
Norton			
≤10	1 study[45]	1.00	0.31
<12	1 study[41]	0.62	0.72
≤14	5 studies[a] [41, 42, 65, 80, 83]	Median 0.75 (range 0 to 0.89)	Median 0.68 (range 0.59 to 0.95)
≤16	3 studies[18, 73, 84]	Median 0.75 (range 0.46 to 0.81)	Median 0.59 (range 0.55 to 0.6)
Modified Norton			
≤21	1 study[58]	0.33	0.94
≤23	1 study[58]	0.41	0.88
≤25	1 study[58]	0.58	0.47
Waterlow			
>9	1 study[73]	0.46	0.60
≥10	2 studies[25, 80]	1.00, 0.88	0.13, 0.29
≥15	2 studies[43, 81]	0.67, 0.81	0.79, 0.29
≥16	1 study[18]	0.95	0.44
≥17	1 study[74]	0.71	0.67
≥20	1 study[74]	0.86	0.33
Cubbin and Jackson			
≤24	1 study[21]	0.89	0.61
≤28	1 study[20]	0.95	0.82
≤29	1 study[25]	0.83	0.42

[a] Included one study that used a slightly modified version of the Norton scale; sensitivity analysis excluding that study had similar results.

Norton Scale

The Norton scale was evaluated in 12 studies (Appendix H4 and H5).[18, 23, 41, 42, 45, 58, 65, 70, 73, 76, 80, 84] Three studies evaluated a modified Norton scale. In one of these studies, small clarifications were incorporated within existing items,[76] one added skin condition, motivation and age to the five existing items,[58] and the third added additional items (e.g. presence of diabetes) and reversed the scoring method, so that higher scores were associated with higher pressure ulcer risk.[45] In three studies of the standard Norton, the median AUROC was 0.74

(range 0.56 to 0.75) (Table 3).[41, 70, 73] At a cutoff of ≤14, median sensitivity was 0.75 (range 0.0 to 0.89) and median specificity was 0.68 (range 0.59 to 0.95) in five studies (Table 4).[41, 42, 65, 76, 80] Two studies[65, 76] reported very low sensitivities (0.0 and 0.16) compared with the other three studies (range 0.75 to 0.89). One of these studies (sensitivity 0.16) evaluated a slightly modified version of the Norton scale in patients undergoing elective cardiovascular surgery or neurosurgery.[76] The other study (sensitivity 0.0), which used the standard Norton scale, only reported five incident ulcers in 36 older patients in an acute care setting. Excluding these studies had little effect on median sensitivity or specificity (Appendix H6). At a cutoff of ≤16, median sensitivity and specificity was 0.75 (range 0.46 to 0.81) and 0.59 (range 0.55 to 0.60), respectively, in three studies.[18, 73, 84] None of the studies were rated poor-quality. One study reported an unadjusted odds ratios for incidence pressure ulcers of 4.2 for a cutoff of 12 and 6.6 for a cutoff of 14 (CIs not reported).[41]

Waterlow Scale

The Waterlow scale was evaluated in ten studies (Appendix H4 and H5).[18, 23, 25, 43, 56, 57, 73, 74, 80, 81] In four studies, the median AUROC was 0.61 (range 0.54 to 0.66) (Table 3).[25, 56, 73, 74] At a cutoff of ≥10, sensitivities were 0.88 and 1.0 and specificities were 0.13 and 0.29 in two studies.[25, 80] Sensitivity (0.81) and specificity (0.29) were similar in one study that evaluated a cutoff ≥15.[43] However, another study that evaluated the same cutoff (≥15) reported a lower sensitivity (0.67) but higher specificity (0.79).[81] In this study, 5 percent (15/274) of patients had pressure ulcers at baseline and 27 percent (74/274) of enrolled patients did not have a baseline Waterlow score; both factors may have affected these results. In another study, a cutoff score of ≥9 was associated with a sensitivity of 0.46 and a specificity of 0.60 (Table 4).[73]

Other Scales

Few other risk assessment scales were assessed in more than one study. The Cubbin and Jackson scale, consisting of 10 items with total scores ranging from 10 to 40, was associated with a median AUROC of 0.83 (range 0.72 to 0.9) in three studies (Table 3).[20, 21, 25] Based on cutoffs of ≤24 to 29, median sensitivity was 0.89 (range 0.83 to 0.95) and specificity was 0.61 (0.42 to 0.82) in three studies (Table 4).[20, 21, 25] Two of the studies were rated fair-quality and the other good-quality; the good-quality study reported a sensitivity of 0.89 and specificity of 0.61.[21] Other risk assessment tools were evaluated in one study each, including the Gosnell,[23] Song and Choi,[20] Fragmment,[70] Douglas,[21] Knoll,[78] Risk Assessment Pressure Score Scale (RAPS),[24] Northern Hospital Pressure Ulcer Prevention Plan (TNH-PUPP),[69] the Dutch CBO Score, [84] and others,[48, 62] precluding reliable conclusions regarding diagnostic accuracy (Appendix H4).

Direct Comparisons

Five good-quality[18, 21, 42, 73, 79] and nine fair-quality[20, 23, 25, 41, 58, 70, 72, 80, 84] studies directly compared one pressure ulcer risk assessment scale to another (Appendix H4 and H5).

Six studies directly compared the AUROC for two or more risk assessment scales (Table 5).[20, 21, 25, 41, 70, 73] In three studies, the AUROC was very similar for the Braden and Norton scales.[41, 70, 73] Two studies that compared the Braden and the Cubbin and Jackson scales also reported similar AUROCs.[20, 21] One study reported similar AUROCs for the Waterlow compared with the Braden or Norton scales (range 0.55 to 0.61).[73]

Eight studies directly compared sensitivity and specificity for different risk assessment scales based on the standard cutoffs discussed above (Braden ≤16 to 18, Norton ≤12 to 16, Waterlow

≥10 to 15 and/or Cubbin and Jackson ≤24 to 29) (Table 5).[18, 21, 25, 41, 42, 73, 80, 84] They reported comparable sensitivities and specificities for different risk assessment instruments,[18, 42, 73, 84] or the expected tradeoff of higher sensitivity for one scale compared with another, but lower specificity.[21, 25, 41, 80]

Table 5. Key Question 2: Direct comparisons of pressure ulcer risk assessment scales

Author, Year	Setting	Braden	Norton	Waterlow	Cubbin and Jackson	Other	Quality Rating
Area Under the ROC Curve							
Boyle et al, 2001[25]	Hospital inpatient; ICU n=534	Not examined	Not examined	0.66	0.72	Not examined	Fair
Kim et al, 2009[20]	Hospital inpatient; surgical ICU n=219	0.88	Not examined	Not examined	0.9	Song/Choi 0.89	Fair
Perneger et al, 2002[70]	Hospital inpatient n=1,190	0.74 (95% CI 0.70 to 0.78)	0.74 (95% CI 0.70 to 0.78)	Not examined	Not examined	Fragmment 0.79 (95% CI 0.75 to 0.82)	Fair
Schoonhoven et al, 2002[73]	Hospital inpatient n=1,229	0.55 (95% CI 0.49 to 0.6)	0.56 (95% CI 0.51 to 0.61)	0.61 (95% CI 0.56 to 0.66)	Not examined	Not examined	Good
Seongsook et al, 2004[21]	Hospital inpatient; surgical, internal or neurological ICU n=112	0.71	Not examined	Not examined	0.83	Douglas 0.79	Good
DeFloor et al, 2005[41]	Long-term care facilities n=1,772	0.77	0.75	Not examined	Not examined	Not examined	Fair
Sensitivity and specificity[a]							
Kwong et al, 2005[42]	Hospital inpatient n=429	Sensitivity: 0.89 Specificity: 0.75	Sensitivity: 0.89 Specificity: 0.61	Not examined	Not examined	Not examined	Good
Pang et al, 1998[18]	Hospital inpatient n=106	Sensitivity: 0.91 Specificity: 0.62	Sensitivity: 0.81 Specificity: 0.59	Not examined	Not examined	Not examined	Good
Schoonhoven et al, 2002[73]	Hospital inpatient n=1,229	Sensitivity: 0.44 Specificity: 0.68	Sensitivity: 0.46 Specificity: 0.6	Not examined	Not examined	Not examined	Good
Boyle et al, 2001[25]	Hospital inpatient; ICU n=534	Not examined	Not examined	Sensitivity: 1 Specificity: 0.13	Sensitivity: 0.83 Specificity: 0.42	Not examined	Fair

Author, Year	Setting	Braden	Norton	Waterlow	Cubbin and Jackson	Other	Quality Rating
Seongsook et al, 2004[21]	Hospital inpatient; surgical, internal or neurological ICU n=112	Sensitivity: 0.97 Specificity: 0.26	Not examined	Not examined	Sensitivity: 0.89 Specificity: 0.61	Not examined	Good
Wai-Han et al, 1997[80]	Geriatric care facility n=185	Not examined	Sensitivity: 0.75 Specificity: 0.68	Sensitivity: 0.88 Specificity: 0.29	Not examined	Not examined	Fair
DeFloor et al, 2005[41]	Long-term care facilities n=1,772	Sensitivity: 0.8, 0.83 Specificity: 0.65, 0.58	Sensitivity: 0.62, 0.82 Specificity: 0.72, 0.59	Not examined	Not examined	Clinical judgment Sensitivity: 0.74 Specificity: 0.5	Fair
van Marum et al, 2000[84]	Long-term care facility n=267	Not examined	Sensitivity: 0.75 Specificity 0.55	Not examined	Not examined	Dutch CBO Sensitivity: 0.58 Specificity: 0.57	Fair

Abbreviations: CI, confidence interval; ICU, intensive care unit.
[a] Braden cutoffs 16-18; Norton 12 to 16; Waterlow 10 to 15; Cubbin and Jackson 24 to 29.

Key Question 2a. Does the predictive validity of various risk assessment tools differ according to setting?

Key Points

- One fair-quality study (n=843) found a Braden scale score of ≤18 associated with similar sensitivities and specificities in acute care and skilled nursing settings. Twenty-eight studies (10 good-, 16 fair- and two poor-quality) that evaluated the Braden scale in different settings found no clear differences in the AUROC or in sensitivities and specificities at standard (≤15 to 18) cutoffs (strength of evidence: low).
- Two studies (one good- and one fair-quality) found the Cubbin and Jackson scale associated with similar diagnostic accuracy compared with the Braden or Waterlow scales in intensive care patients (strength of evidence: low).
- One good-quality study reported a lower optimal cutoff on the Braden scale in an acute care setting (sensitivity 0.55 and specificity 0.94 at a cutoff of ≤15) compared with a long-term care setting (sensitivity 0.57 and specificity 0.61 at a cutoff of ≤18), but the statistical significance of differences in diagnostic accuracy was not reported. Two studies (one good- and one fair-quality) found that optimal cutoff scores on the Braden scale were lower in surgical patients compared to optimal cutoff scores observed from other studies of patients in different settings, but no study directly compared optimal cutoffs in surgical compared with other care settings (strength of evidence: low).

Detailed Synthesis

Pressure ulcer risk assessment tools have been evaluated in various care settings, including five studies of non-surgical intensive care patients,[21, 25, 39, 56, 75] five studies of post-surgery patients,[20, 43, 58, 64, 76] six studies of long-term care settings (including nursing homes and skilled care),[22, 40, 41, 51, 63, 84] two studies of home care settings,[57, 71] and one study of hospice patients (Appendix H4).[45]

Only one study evaluated the same risk assessment tool in patient subgroups defined by care setting in which the tool was applied. It found a Braden scale score of ≤18 associated with similar sensitivities and specificities in two acute care (sensitivities 0.88 and 0.60; specificities 0.68 and 0.81) and one skilled nursing setting (sensitivity 0.72; specificity 0.68) (Appendix H7).[40]

The usefulness of indirect comparisons across studies to assess how diagnostic accuracy might differ according to care setting was very limited. The AUROC was infrequently reported, differences in estimates across studies performed in different settings were small, and confidence intervals were not reported by most studies, making it difficult to determine the significance of any differences. For example, for the Braden scale, which was evaluated in the most studies, the AUROC was 0.71 and 0.80 in two studies of intensive care unit patients,[21, 75] 0.88 in one study of surgical patients,[20] and 0.77 in one study of long-term care patients[41] (Appendix H8). Based on a cutoff of ≤15 on the Braden Scale, one study performed in an intensive care unit[39] reported a higher sensitivity (0.75) and similar specificity (0.67) compared to studies in surgical (one study),[64] long-term care (two studies),[22, 40] or home care (one study)[71] settings, where sensitivities ranged from 0.14 to 0.33, and specificity from 0.83 to 0.95 (Appendix H7). Based on a cutoff of ≤18 on the Braden scale, the median sensitivity was 0.72 and median specificity 0.70 in acute care settings (eight studies[18, 39, 40, 53, 59, 61, 68, 72]), compared with 0.76 and 0.65, respectively, in long-term care settings (four studies[22, 40, 41, 63]). Other cutoffs and risk assessment instruments were evaluated in too few studies to assess differences in diagnostic accuracy across studies.

Although the Cubbin and Jackson scale was specifically designed for use in intensive care patients, two studies reported a similar AUROC compared with the Braden or Waterlow scales.[21, 25]

Some studies attempted to determine optimal cutoff scores for the Braden scale in specific settings, based on the best combination of sensitivity and specificity (Appendix H9). One study reported a lower optimal cutoff on the Braden scale in an acute care setting (sensitivity 0.55 and specitivity 0.94 at a cutoff of ≤15) compared with a long-term care setting (sensitivity 0.57 and specificity 0.61 at a cutoff of ≤18), but the statistical significance of differences in diagnostic accuracy was not reported, and estimates were not reported at the same cutoff across settings.[63] Two studies of surgical patients found that optimal Braden cutoff scores were lower (≤13 or 14)[20, 64] than the optimal cutoffs (≤15 to 18) observed in other studies of acute and long-term care settings.[22, 41, 53, 55, 63, 68] However, no study directly compared optimal Braden scale cutoffs in surgical compared with other care settings. Estimates of the optimal cutoff for the Norton, Waterlow and Cubbin and Jackson scales were not frequently reported.

Key Question 2b. Does the predictive validity of various risk assessment tools differ according to patient characteristics?

Key Points

- One fair-quality study (n=834) reported similar AUROCs for the Braden scale in black and white patients in acute care or skilled nursing settings (strength of evidence: low).

Three studies (one good- and two fair-quality; n=534 to 1,772) found no clear difference in AUROC estimates based on the presence of higher or lower mean baseline pressure ulcer risk scores (strength of evidence: moderate).

Detailed Synthesis

Few studies assessed the predictive validity of pressure ulcer risk assessment instruments in different patient subgroups defined by patient demographics or clinical characteristics. (Appendix H4). Two studies evaluated the predictive validity of a pressure ulcer risk assessment tool in subgroups defined by patient demographics or clinical characteristics.[52, 67] One study (n=834) reported similar AUROCs for the Braden scale in black (0.82) compared with white (0.75) patients in acute care or skilled nursing settings, as well as similar sensitivity and specificity using a cutoff of ≤18.[52] The second study (n=74) found that in an acute care hospital setting, a Braden scale cutoff of ≤16 resulted in sensitivities of 0.77 and 0.9 in older (age 60-74) blacks and Hispanics, with low specificities (0.5 and 0.14).[66]

Although patient characteristics varied across studies of diagnostic accuracy, such differences are often associated with differences in care setting. In addition, few studies reported the AUROC, and studies applied different thresholds when estimating sensitivity and specificity. In three studies that reported the AUROC and mean baseline pressure ulcer risk scores, there was no clear difference in estimates based on the presence of higher or lower baseline pressure ulcer risk scores (Appendix H10).[21, 25, 41, 73] One small (n=36) study of younger trauma patients (mean age 32 years) found a Braden cutoff of ≤10 (lower than the usual cutoff range of 15-18) associated with high sensitivity (0.91) and specificity (0.96).[49] No other studies exist in this specific population.

Key Question 3. In patients at increased risk of developing pressure ulcers, what is the effectiveness and comparative effectiveness of preventive interventions in reducing the incidence or severity of pressure ulcers?

Key Points

Support Surfaces

Static Support Surfaces

- Five fair-quality trials (n=83 to 543) found a more advanced static mattress or overlay associated with decreased risk of incident pressure ulcers (RR range 0.20 to 0.60) or a trend towards decreased risk (RR 0.28, 95% CI 0.06 to 1.3) compared with a standard mattress, and two of the trials found no difference in length of stay. Six poor-quality trials

reported results that were generally consistent with these findings, though two trials found no benefit. The static support surfaces evaluated in the trials varied (strength of evidence: moderate).

- Six trials (n=52 to 100, three trials fair-quality) found no differences between different advanced static support surfaces in risk of pressure ulcers. One fair-quality trial (n=40) of nursing home patients found a foam replaceable parts mattress associated with lower risk of ulcers compared with a 4 inch thick, dimpled foam overlay (25 vs. 60 percent, RR 0.42, 95% CI 0.18 to 0.96) (strength of evidence: moderate).
- Four trials (n=32 to 248, three fair-quality and one poor-quality) found inconsistent evidence on effects of more sophisticated wheelchair cushions compared with standard wheelchair cushions on risk of pressure ulcers, with the largest trial finding no difference between a contoured, individually customized foam cushion compared with a slab cushion. Results are difficult to interpret because the trials evaluated different cushions (strength of evidence: low).
- One fair-quality trial (n=239) of fracture patients found the Heelift Suspension Boot associated with decreased risk of heel, foot, or ankle ulcers compared with usual care (7 vs. 26 percent for any ulcer, RR 0.26, 95% CI 0.12 to 0.53; 3.3 vs. 13.4 percent for grade II ulcers, RR 0.25, 95% CI 0.09 to 0.72), but one poor-quality trial (n=52) of hospitalized patients found no difference in risk of ulcers between a boot (Foot Waffle) and usual care (hospital pillow to prop up legs) (strength of evidence: low).
- One poor-quality trial (n=240) of hospitalized patients found no differences between three different types of boots (Bunny Boot, egg-crate heel lift positioner, and Foot Waffle) in risk of ulcers, though the overall incidence of ulcers was low (5 percent over 3 years) and results could have been confounded by differential use of co-interventions (strength of evidence: insufficient).

Dynamic Support Surfaces

- Six trials (n=32 to 487, two fair-quality and four poor-quality) that compared a dynamic alternating air pressure mattress or overlay compared with a static support surface reported somewhat inconsistent results, with one fair-quality trial showing no difference in risk of pressure ulcers and another fair-quality trial showing lower risk of pressure ulcers with initial dynamic support surfaces using a stepped care approach (4.3 vs. 55 percent, RR 0.08, 95% CI 0.01 to 0.56). One of the trials found no difference in length of stay (strength of evidence: low).
- Two fair-quality (n=44 and 62) trials of hospitalized patients found no differences in risk of pressure ulcers or length of stay between different dynamic support surfaces; one poor-quality trial (n=108) found an alternating double-layer air cell layer associated with decreased risk of pressure ulcers compared with an alternating single-layer overlay (3.4 vs. 19 percent, RR 0.22, 95% CI 0.03 to 1.8) (strength of evidence: low).

Nutritional Supplementation

- Three poor-quality trials (n=56 to 672) reported inconsistent results for effects of oral nutritional supplementation compared with standard hospital diet on incidence of pressure ulcer risk, with two trials reporting no benefit (strength of evidence: low).

Repositioning

- One good-quality cluster trial (n=213) found repositioning at a 30-degree tilt every 3 hours associated with lower risk of pressure ulcer compared with usual care (90-degree lateral repositioning every 6 hours during the night) after 28 days (3.0 vs. 11 percent, RR 0.27, 95% CI 0.08 to 0.93). Two other trials (n=46 and 838) evaluated repositioning interventions but only followed patients for one night or were susceptible to confounding due to differential use of support surfaces (strength of evidence: low).

Dressings

- One fair-quality cross-over trial (n=81) found no statistically significant difference in risk of pressure ulcers between changing incontinence pads three times compared with twice a night after 4 weeks (strength of evidence: low).
- One poor-quality trial (n=37) found use of the REMOIS Pad (consisting of a hydrocolloid skin adhesive layer, a support layer of urethane film, and an outer layer of multifilament nylon) on the greater trochanter associated with decreased risk of stage I ulcers compared to no pad on the contralateral trochanter after 4 weeks (5.4 vs. 30 percent, RR 0.18, 95% CI 0.05 to 0.73) (strength of evidence: insufficient).

Intraoperative Warming

- One fair-quality trial (n=324) of patients undergoing major surgery found no statistically significant difference in risk of pressure ulcers between patients who received an intraoperative warming intervention (forced-air warming and warming of all intravenous fluids) compared with usual care (strength of evidence: low).

Drugs

- One poor-quality trial (n=85) of patients undergoing femur or hip surgery found no difference in risk of pressure ulcers between those who received 80 IU of corticotrophin intramuscularly compared with a sham injection (strength of evidence: insufficient).

Creams, Lotions and Cleansers

- Evidence from four poor-quality trials (n=79 to 258) was insufficient to determine effectiveness of different creams or lotions for preventing pressure ulcers (strength of evidence: insufficient).
- One fair-quality trial (n=93) found use of Clinisan cleanser associated with lower risk of ulcer compared with standard soap and water in patients with incontinence at baseline (18 vs. 42 percent; RR 0.43, 95% CI 0.19 to 0.98) (strength of evidence: low).

Detailed Synthesis

Support Surfaces

Thirty-three randomized trials evaluated support surfaces for prevention of pressure ulcers in patients at increased risk[85-117] (Appendix H11). Criteria for classifying support surfaces have historically included the material used (e.g., foam, air, gel, beads, water), whether the support surface is static or dynamic (e.g., an alternating-air pressure mattress), and whether the support surface requires power.[27] In this report, we classified support surfaces as static or dynamic, with

additional subgrouping based on the material and type of support surface. Sample sizes ranged from 32 to 523 subjects, and followup ranged from 7 days to 6 months or until time to pressure ulcer development, hospital discharge, or death. Increased risk was based on risk assessment scale scores at baseline, including Braden ≤15-18, Norton ≤12-16, Waterlow ≥10-15, Cubbin and Jackson score ≤29, and others. When reported, mean Braden scores ranged from 9.4 to 16[85, 90, 94, 95, 101, 103, 111-113, 117] Norton scores from 12 to 13,[86-88, 96, 106, 108, 115] and Waterlow scores from 13 to 19.[91, 92, 98, 105] Trials of patients at lower baseline risk were typically conducted in surgical settings and are discussed below (see Key Question 3a).[118-123]

Seventeen trials were rated fair-quality[85-101] and 16 poor-quality;[102-117] no trial was rated good-quality (Appendix H12). Many of the poor-quality trials were older and methods were inadequately reported, including unclear methods of randomization and allocation concealment and failure to report blinding of outcomes assessors. A challenge in interpreting the trials is that in some studies, patients who developed pressure ulcers received additional interventions to preventing further skin damage. Studies varied in how they accounted for these differences in treatments, but none reported adjusted risk estimates.

The support surfaces evaluated in the trials varied (Table 6). They included static support surfaces such as mattresses or overlays filled with air, foam, gels, beads, silicone, or water; medical sheepskin overlays; and various static heel supports, boots, or wheelchair cushions. Trials also evaluated dynamic support surfaces such as air-alternating mattresses/bed systems and some constant-low-pressure mattresses/bed systems (e.g., air-fluidized support surfaces, which circulate warm air through siliconized beads to simulate effects of floating).

Table 6. Types of support surfaces[a]

Study	Type (e.g. mattress, integrated bed system, mattress replacement, overlay, seat cushion etc).	Material (foam, air, gel, water, beads, etc.)	Active/Dynamic (only alternating-air pressure) vs. Reactive/Static (everything else)	Powered or Nonpowered
Andersen et al, 1982[102]	Alternating-air pressure mattress	Air	Dynamic	Powered
	Water mattress	Water	Static	Nonpowered
	Standard hospital mattress	Unclear	Static	Nonpowered
Aronovitch et al, 1999[118]	Alternating-air pressure mattress (Micropulse)	Air	Dynamic	Powered
	Gel pad (Action Pad) on operating room table, then replacement hospital mattress (Pressure Guard II)	Gel/Unclear	Static	Nonpowered
Berthe et al,[124]	Kliniplot mattress system, segmented foam blocks	Foam	Static	Nonpowered
	Standard hospital mattress	Unclear	Static	Nonpowered
Brienza et al, 2010[103]	Solid foam seat cushion	Foam	Static	Nonpowered
	Segmented air seat cushion (Quadtro)	Air	Static	Nonpowered
	Separate fluid and urethane foam bladders on foam base seat cushion (J2 Deep Contour)	Foam, Fluid	Static	Nonpowered
	Viscoelastic foam with urethane foam and optional solid gel insert seat cushion (Infinity MC)	Foam, Gel	Static	Nonpowered

Study	Type (e.g. mattress, integrated bed system, mattress replacement, overlay, seat cushion etc).	Material (foam, air, gel, water, beads, etc.)	Active/Dynamic (only alternating-air pressure) vs. Reactive/Static (everything else)	Powered or Nonpowered
Collier et al, 1996[104]	Standard King's Fund mattress, 130mm	Foam	Static	Nonpowered
	Clinifloat	Foam	Static	Nonpowered
	Cyclone	Foam	Static	Nonpowered
	Omnifoam	Foam	Static	Nonpowered
	Softform	Foam	Static	Nonpowered
	STM5	Foam	Static	Nonpowered
	Therarest	Foam	Static	Nonpowered
	Transfoam	Foam	Static	Nonpowered
	Vapourlux	Unclear	Unclear	Unclear
Conine et al, 1993[87]	Slab seat cushion	Foam	Static	Nonpowered
	Contoured seat cushion	Foam	Static	Nonpowered
Conine et al, 1994[88]	Polyurethane foam cushion	Foam	Static	Nonpowered
	Combination foam and gel cushion (Jay Cushion)	Foam, Gel	Static	Nonpowered
Conine et al, 1990[86]	Alternating pressure overlay	Air	Dynamic	Powered
	Siliconized hollow fiber overlay	Fiber	Static	Nonpowered
Cooper et al, 1998[105]	Segmented air cell mattress (Sofflex)	Air	Static	Nonpowered
	Segmented air cell mattress (Roho)	Air	Static	Nonpowered
Daechsel & Conine,1985[106]	Alternating pressure overlay	Air	Dynamic	Powered
	Siliconized hollow fiber overlay	Fiber	Static	Nonpowered
Donnelly et al, 2011[85]	Heelift Suspension Boot	Foam	Static	Nonpowered
	Pentaflex mattress	Foam	Static	Nonpowered
	AlphaXcell mattress overlay	Air	Dynamic	Powered
	Alternating pressure mattress (Nimbus III)	Air	Dynamic	Powered
Feuchtinger et al, 2006[119]	Water-filled warming mattress	Water	Static	Powered
	Viscoelastic foam overlay	Foam	Static	Nonpowered
Gebhardt et al, 1996[89]	Grant Dynacare overlay	Air	Dynamic	Powered
	AlphaXcell mattress overlay	Air	Dynamic	Powered
	APM 15 overlay	Air	Dynamic	Powered
	Double Bubble Air Flotation overlay	Air	Dynamic	Powered
	Large Cell Ripplebed overlay	Air	Dynamic	Powered
	Ultimat Antidecubitus Mattress overlay	Fiber	Static	Nonpowered
	Slumberland Gold overlay	Fiber	Static	Nonpowered
	Surgigoods Hollowcore Pad overlay	Fiber	Static	Nonpowered
	Tendercare Full Bed Pad overlay	Fiber	Static	Nonpowered
	Clinifloat mattress	Foam	Static	Nonpowered
	Omnifoam mattress	Foam	Static	Nonpowered
	Stoke Mandeville No 4 Mattress	Foam	Static	Nonpowered
	Bodigard Clinical Flotation overlay	Foam	Static	Nonpowered
	Contoured Propad	Foam	Static	Nonpowered
	Lyopad Mattress	Foam	Static	Nonpowered

Study	Type (e.g. mattress, integrated bed system, mattress replacement, overlay, seat cushion etc).	Material (foam, air, gel, water, beads, etc.)	Active/Dynamic (only alternating-air pressure) vs. Reactive/Static (everything else)	Powered or Nonpowered
	Carelite Inflatable Mattress overlay	Air	Static	Nonpowered
	Sofcare Bed Cushion overlay	Air	Static	Nonpowered
	Waffle Mattress overlay	Air	Static	Nonpowered
	Action Bed Pad overlay	Gel	Static	Nonpowered
	Elwa Water Mattress overlay	Water	Static	Nonpowered
	Bay Jacobson Mattress overlay	Bead	Static	Nonpowered
	Pegasus Airwave System alternating pressure mattress	Air	Dynamic	Powered
	Nimbus Dynamic Flotation System alternating pressure mattress	Air	Dynamic	Powered
	Paragon Convertible low-air-loss mattress	Air	Static	Powered
	Roho Mattress overlay	Air	Static	Nonpowered
Geyer et al, 2001[90]	Convoluted Foam Cushion (Sunrise Medical)	Foam	Static	Nonpowered
	Pressure Reducing Cushion	Varies	Varies	Varies
Gilcreast et al, 2005[107]	High Cushion Kodel heel protector (bunny boot)	Fiber	Static	Nonpowered
	Egg Crate heel lift positioner (Sunshine Medical)	Foam	Static	Nonpowered
	EHOB Foot Waffle Air Cushion	Air	Static	Nonpowered
Goldstone et al, 1982[108]	Beaufort Bead Bed system (aka Neumark-Macclesfield Support System)	Bead	Static	Nonpowered
	Standard hospital surfaces	Unclear	Static	Nonpowered
Gray & Campbell, 1994[91]	Softform mattress (Medical Support Systems Ltd, now Invacare)	Foam	Static	Nonpowered
	standard NHS foam mattresses (Recticel Ltd)	Foam	Static	Nonpowered
Gray & Smith, 2000[92]	Transfoam mattress (Karomed)	Foam	Static	Nonpowered
	Transfoamwave mattress (Karomen)	Foam	Static	Nonpowered
Gunningberg et al, 2000[109]	Visco elastic foam mattress (Tempur-Pedic)	Foam	Static	Nonpowered
	Standard hospital mattress	Foam	Static	Nonpowered
Hofman et al, 1994[110]	DeCube Cubed foam mattress (Comfortex)	Foam	Static	Nonpowered
	Standard polypropylene SG40 hospital foam mattress (Vredestein)	Foam	Static	Nonpowered
Hoshowsky et al, 1994[120]	Standard foam operating room table mattress	Foam	Static	Nonpowered
	Akros foam and gel operating room table mattress	Foam/Gel	Static	Nonpowered
	Viscoelastic dry polymer mattress overlay (Action Products Inc)	Rubber	Static	Nonpowered

Study	Type (e.g. mattress, integrated bed system, mattress replacement, overlay, seat cushion etc).	Material (foam, air, gel, water, beads, etc.)	Active/Dynamic (only alternating-air pressure) vs. Reactive/Static (everything else)	Powered or Nonpowered
Inman et al, 1993[93]	Standard ICU mattress (Gaymar)	Unclear	Unclear	Unclear
	Standard ICU mattress (Kinetic Concepts, Inc.)	Foam	Static	Nonpowered
	Sof-Care overlay (Gaymar)	Air	Static	Nonpowered
	Therarest mattress replacement (Kinetic Concepts, Inc.)	Foam	Static	Nonpowered
	ASM replacement mattress (Gaymar)	Air/Foam	Dynamic	Powered
	First Step Select mattress replacement system (Kinetic Concepts, Inc.)	Air	Dynamic	Powered
	SPR Plus low air loss overlay (Gaymar)	Air	Dynamic	Powered
	Kin Air III low-air-loss bed (Kinetic Concepts, Inc.)	Air	Dynamic	Powered
	SPR Plus low air loss overlay (Gaymar)	Air	Dynamic	Powered
	Therapulse low-air-loss bed (Kinetic Concepts, Inc.)	Air	Dynamic	Powered
Jesurum et al, 1996[111]	Standard bed with pressure reducing mattress replacement	Foam	Static	Nonpowered
	Low-air-loss bed	Air	Dynamic	Powered
Jolley et al, 2004[94]	Australian medical sheepskin overlay	Fiber	Static	Nonpowered
	Standard hospital mattress and other pressure relieving devices as needed	Varies	Varies	Varies
Kemp et al, 1993[95]	Convoluted foam overlay	Foam	Static	Nonpowered
	Solid foam overlay	Foam	Static	Nonpowered
Lim et al, 1988[96]	Foam slab cushion	Foam	Static	Nonpowered
	Foam contoured cushion	Foam	Static	Nonpowered
McGowan et al, 2000[112]	Australian medical sheepskin overlay	Fiber	Static	Nonpowered
	Standard hospital mattress and other pressure relieving devices as needed	Varies	Varies	Varies
Mistiaen et al, 2010[97]	Australian medical sheepskin overlay (Yellow Earth)	Fiber	Static	Nonpowered
	Standard hospital mattress	Varies	Varies	Varies
Nixon et al, 1998[121]	Visco-elastic polymer pad	Dry polymer	Static	Nonpowered
	Standard operating table mattress	Unclear	Unclear	Unclear
	Gamgee pad heel support	Fiber	Static	Nonpowered
Russell et al, 2000[122]	Multi-cell pulsating dynamic mattress system (MicroPulse, Inc)	Air	Dynamic	Powered
	Gel pad (Action Pad) on operating room table, then standard hospital mattress (HillRom)	Gel/Unclear	Static	Nonpowered
Sanada et al,	Double-layer air cell overlay (Tricell)	Air	Dynamic	Powered

Study	Type (e.g. mattress, integrated bed system, mattress replacement, overlay, seat cushion etc).	Material (foam, air, gel, water, beads, etc.)	Active/Dynamic (only alternating-air pressure) vs. Reactive/Static (everything else)	Powered or Nonpowered
2003[113]	Single-layer air cell overlay (Air Doctor)	Air	Dynamic	Powered
	Standard hospital mattress (Paracare)	Foam	Static	Nonpowered
Schultz et al, 1999[123]	Mattress overlay	Foam	Static	Nonpowered
	Standard care (including gel pads, foam mattresses, ring cushions [donuts] etc)	Varies	Varies	Varies
Sideranko et al, 1992[114]	Lapidus Airfloat System alternating-air pressure mattress	Air	Dynamic	Powered
	Sofcare Bed Cushion overlay (Gaymar)	Air	Static	Nonpowered
	Lotus water mattress (Connecticut Artcraft Co.)	Water	Static	Nonpowered
Stapleton et al, 1986[115]	Large Cell Ripplebed overlay	Air	Dynamic	Powered
	Polyether foam pad	Foam	Static	Nonpowered
	Spenco bed pad	Fiber	Static	Nonpowered
Takala et al, 1996[116]	Carital Optima alternating pressure mattress	Air	Dynamic	Powered
	Standard hospital mattress (Espe Inc.)	Foam	Static	Nonpowered
Taylor et al, 1999[98]	Alternating-air pressure mattress (Pegasus Trinova)	Air	Dynamic	Powered
	Alternating-air pressure mattress (unnamed)	Air	Dynamic	Powered
Theaker et al, 2005[99]	Therapulse pulsating air suspension mattress (Kinetic Concepts, Inc.)	Air	Dynamic	Powered
	Duo constant low pressure mattress	Air	Static	Powered
Tymec et al, 1997[117]	Foot waffle (EHOB)	Air	Static	Nonpowered
	Hospital pillow	Fabric	Static	Nonpowered
van Leen et al., 2011[100]	Silhouette Cold foam mattress (Comfortex) with static air overlay	Foam/Air	Static	Nonpowered
	Silhouette Cold foam mattress (Comfortex)	Foam	Static	Nonpowered
Vyhlidal et al, 1997[101]	Iris 3000 foam overlay (Bio Clinic of Sunrise Medical Co.)	Foam	Static	Nonpowered
	Maxifloat foam mattress replacement (BG Industries)	Foam	Static	Nonpowered

Abbreviations: ICU, intensive care unit.
[a] Table includes all studies for Key Questions 3 and 3a.

Static Support Surfaces

Mattresses and Overlays

Eighteen trials[91-97, 100, 101, 104, 105, 108-112, 115, 116] (sample sizes 36 to 543) evaluated static mattresses and/or mattress overlays to prevent pressure ulcers. Nine were rated fair-quality[91-97, 100, 101] and nine poor-quality.[104, 105, 108-112, 115, 116] Duration of followup ranged from 7 days to 6 months. Trial settings included acute care hospitals (including the intensive care unit and post-

operative settings)[85, 89, 91-95, 98, 99, 102, 104, 105, 107-117, 122] and long-term care nursing facilities.[86, 95, 97, 100, 101, 106]

Eleven trials compared a more advanced static support surface to a standard mattress control.[91, 93, 94, 97, 100, 108-112, 116] All five fair-quality trials (n=83 to 543) found the more advanced static mattress or overlay associated with decreased risk of any (primarily grade I) incident pressure ulcers (RR range 0.20 to 0.60)[91, 93, 94, 97] or a trend towards decreased risk (RR 0.28, 95% CI 0.06 to 1.3) (Table 7).[100] Duration of followup ranged from 7 days to 6 months. The static support surfaces evaluated in the trials were the Softform mattress,[91] a sheepskin overlay,[94, 97] an air suspension bed,[93] and an air overlay.[100] One trial also found a more advanced static support surface (an air suspension bed) associated with decreased risk of grade II or higher pressure ulcers compared with a standard intensive care unit bed (4.1 vs. 29 percent, RR 0.21, 95% CI 0.11 to 0.39),[93] but there were too few events in these trials to reliably evaluated effects on risk of more severe (grade II or higher) incident pressure ulcers.

Four poor-quality trials also found a more advanced static support surface (bead overlay, cubed foam mattress, medical sheepskin, or low air pressure mattress) associated with decreased incidence of pressure ulcers compared with a standard mattress.[108, 110, 112, 116] Two other poor-quality trials evaluating a visco-elastic foam mattress[109] or a low-air-loss mattress[111] found no benefit compared with a standard mattress.

Four trials (two fair-quality and two poor-quality) found no difference between a more advanced static support and a standard mattress in length of stay.[92,93,109,110]

Seven trials compared different advanced support surfaces.[92, 95, 96, 101, 104, 105, 115] Three fair-quality trials (samples sizes 52 to 100) found no difference in pressure ulcer incidence between the Transfoamwave and Transfoam mattresses,[92] a convoluted compared with solid foam overlay,[95] or a contoured compared with slab foam cushion[96] in risk of pressure ulcers. One other fair-quality trial of newly admitted nursing home residents (n=40) found a foam replaceable parts mattress (Maxifloat; BG Industries, Northridge, CA) associated with lower risk of ulcers (all ulcers stage I or II) compared with a 4-inch-thick, dimpled foam overlay (Iris 3999; Bio Clinic of Sunrise Medical Group, Ontario, CA) after 10 to 21 days (25 vs. 60 percent, RR 0.42, 95% CI 0.18 to 0.96).[101] (Table 7). Three poor-quality trials (n=90 to 100) found no differences between different various static support surfaces.[104, 105, 115] However, in a subgroup analysis of patients $\geq$80 years of age, one of these trials found a polyether foam pad associated with greater risk of ulcers compared with the Spenco pad (63 vs. 32 percent; RR 1.99, 95% CI 0.98 to 4.00; p=0.055).[115]

One other trial of patients in a critical care unit (n=123) that did not meet inclusion criteria because it was published only as an abstract also found no difference between the KinAir low air-loss specialty bed and the EHOB Waffle air mattress overlay in risk of pressure ulcers.[125]

Table 7. Key Question 3: Effectiveness of pressure ulcer prevention support surfaces in at-risk patients—static compared with static mattresses and overlays

Author, year Quality rating	Setting Country Followup	Intervention (N)	Baseline demographics A vs. B	Baseline ulcer risk score A vs. B	Results – Incidence A vs. B	Results – Severity A vs. B	Results – Length of Stay A vs. B
Fair-quality Efficacy Trials							
Gray & Campbell, 1994[91] Fair	Hospital United Kingdom 10 days	A. Softform mattress (n=90) B. Standard 130 mm NHS foam mattress (n=80)	Mean age: 76 vs. 74 years Percent female: 63.3% vs. 58.8%	Waterlow score: 18.03 vs. 16.01	Grade II or greater ulcer incidence (number ulcers): 7% vs. 34%, p<0.001	NR	NR
Inman et al, 1993[93] Fair	Intensive care Canada 18.8 days vs. 15.4 days	A. Air suspension bed with separate air-controlled settings for each section (n=49) B. Standard ICU bed (undefined), plus repositioning every 2 hours (n=49)	Mean age: 63.4 vs. 65.4 years Percent female: 40.8% vs. 55.1%	Unclear	Incidence Overall: 16.3% (8/49) vs. 79.6% (39/49); RR 0.21, 95% CI 0.11 to 0.39 Effect of air suspension bed on presence of pressure ulcers: OR 0.18 (0.08-0.41), p=0.0001 Single pressure ulcers: 12% (6/49) vs. 51% (25/49) Multiple pressure ulcers: 2% (1/49) vs. 24% (12/49) Effect of air suspension bed on presence of pressure ulcers: OR 0.11 (0.02-0.54), p=0.007	Severe (>1 on Shea grading assessment) pressure ulcers: 4.1%% (2/49) vs. 28.6% (14/49) Effect of air suspension bed on presence of pressure ulcers: OR 0.16 (0.06-0.44), p=0.0005	Length of stay: 19 vs. 15.4 days; p=NS
Jolley et al, 2004[94] Open label randomized trial Fair	Hospital Australia 7-7.9 days	A. Sheepskin mattress overlay (n=218) B. Usual care as determined by ward staff. (n=223) Both groups received usual care	Mean age: 63.2 vs. 61.1 years Percent female: 49% vs. 52%	Mean Braden score: 15.7 vs. 15.9	Incidence of pressure ulcers (number patients): 9.6% (21/218) of patients developed 27 ulcers vs. 16.6% (37/223) patients developed 58 ulcers Rate ratio 0.42, 95% CI, 0.26 to 0.67)	Incidence of pressure ulcers: All ulcers (grade I and II; no grade III or IV recorded) Number of incident grade II ulcers (% of all ulcers): 12 (44%) vs. 20 (34%)	Mean bed days: 7.9 vs. 7.0; p=NS

Author, year Quality rating	Setting Country Followup	Intervention (N)	Baseline demographics A vs. B	Baseline ulcer risk score A vs. B	Results – Incidence A vs. B	Results – Severity A vs. B	Results – Length of Stay A vs. B
Mistiaen et al, 2010[97] Fair	Long-term care facilityNetherlands30 days	A. Australian Medical Sheepskin overlay (buttocks area) (n=271)B. Control (n=272)Both groups received usual care	Mean age: 78 vs. 78 years% Percent female: 71% vs. 67%	Braden score ≤20: 70% vs. 71%Braden score ≤18: 47% vs. 47%	Incidence (number sacral pressure ulcers):8.9% (24/271) vs. 14.7% (40/272), p=0.035 After adjustment for baseline patient characteristics, differences between groups shows protective effect of sheepskin: OR 0.53 (95% CI, 0.29 to 0.95) Incidence (number ulcers elsewhere than sacral area; intervention only covers sacral area):16.4% vs. 15.1%, p=0.69	Severity, number sacral pressure ulcers (EPUAP grades):Grade I = 50 Grade II = 12 Grade III = 2 p=NS between groups	NR
van Leen et al, 2011[100] Fair	Long-term care nursing facility Netherlands 6 months	A. Static air overlay on top of cold foam mattress (n=41) B. Standard cold foam mattress - control (n=42) Repositioning begun when signs of developing a pressure ulcer of >grade II occurred	Mean age: 81.1 vs. 83.1 years Percent female: 78.6% vs. 82.9%	Norton score between 5 to 8: 61.9% vs. 53.7% Norton score between 9 to 12: 38.1% vs. 46.3%	Incidence (number patients with ulcers): 4.8% (2/42) vs. 17.1% (7/41); RR 0.28, 95% CI 0.06 to 1.3	Severity (number patients with ulcers): Grade II: 1 vs. 2 Grade III: 1 vs. 5	NR

Author, year Quality rating	Setting Country Followup	Intervention (N)	Baseline demographics A vs. B	Baseline ulcer risk score A vs. B	Results – Incidence A vs. B	Results – Severity A vs. B	Results – Length of Stay A vs. B
Poor-quality Efficacy Trials							
Goldstone et al, 1982[108] Poor	Hospital United Kingdom Unclear	A. Beaufort bead bed system overlay, renamed as "Neumark-Macclesfield Support System" (n=32) B. Standard supports (n=43)	Age: >60 years Percent female: 90.6% and 83.7% Fracture patients	Mean Norton score: 13	Incidence (overall pressure ulcers): 15.6% (5 lesions in 5 patients) vs. 48.8% (35 lesions in 21 patients), p<0.005 Heel pressure ulcers: 0% vs. 32.6%	Severity Overall maximum width of broken skin (mean): 6.4 mm vs. 29.5 mm, p=0.03 Buttocks maximum width (mean): 5.7 mm vs. 23.9 mm, p=0.018 Sacrum, maximum width (mean): 7.5 mm vs. 56.0 mm, p=NR	NR
Gunningberg et al, 2000[109] Poor	Hospital, surgery Sweden14 days post-op	A: Visco-elastic foam mattress (n=48)B: Standard mattress (n=53) Both groups received usual care	Mean age: 84 vs. 85 years Percent female: 79% vs. 81%Fracture patients	Mean Modified Norton Scale: 19 vs. 19 (score of <21 considered at risk)	Incidence (patients):25% (12/48) vs. 32% (17/53), p=NS	Severity: Grade I: 17% (8/48) vs. 17% (9/53), p=NS Grade II: 8% (4/48) vs. 14%, (7/53), p=NS Grade III: 0% (0/48) vs. 0% (0/53), p=NS Grade IV: 0% (0/48) vs. 2% (1/53), p=NS Grade II-IV: 8% (4/48) vs. 15% (8/53), p=NS	NR
Hofman et al, 1994[110] RCT, stopped early due to efficacy Poor	Surgery Netherlands 14 days post-op	A. Cubed foam mattress (n=21) B. Standard hospital mattress (n=23) Both groups received usual care	Age: 85 vs. 83.9 years Percent female: 76.2% vs. 95.7% Fracture patients	Mean 1985 Dutch consensus meeting score: 21 vs. 23 (high risk)	Incidence of at least grade II ulcers (number patients): 24% (4/17) vs. 68% (13/19), p=0.008% (Includes withdrawals)	Grade 0: 11 vs. 5 Grade 1: 2 vs. 1 Grade 2: 1 vs. 5 Grade 3: 3 vs. 5 Grade 4: 0 vs. 3 p=0.0067 (1985 Dutch consensus meeting grading scale, 0-4)	Length of stay: 21 vs. 23 days; p=NS

Author, year Quality rating	Setting Country Followup	Intervention (N)	Baseline demographics A vs. B	Baseline ulcer risk score A vs. B	Results – Incidence A vs. B	Results – Severity A vs. B	Results – Length of Stay A vs. B
Jesurum et al, 1996[111] Quasi-experimental pilot study Poor	Hospital United States Post-op	A. Low-air-loss mattress (n=16) B. Standard foam mattress (n=20)	Mean age: 67 vs. 69 years Percent female: 44% vs. 15% Race: 81% vs. 80% White; 13% vs. 15% Hispanic; 6% vs. 0 Black; 0 vs. 5% East Indian Cardiovascular surgical patients	Mean Braden score: 9.68 vs. 9.45	Incidence (number patients), early post-op: 19% (3/16) patients developed 7 ulcers vs.15% (3/20) patients developed 5 ulcers, p=NS Incidence (number patients), later post-op: 31% (5/16) patients vs. 20% (4/20 patients, p=0.46	Severity (early post-op only): Stage I or II: 3 vs. 1 Stage III or IV: 0 vs. 2	Length of stay: 17 vs. 21 days; p=NS
McGowan et al, 2000[112] Poor	Hospital AustraliaPost-op	A. Australian Medical Sheepskin overlay (n=155)B. Standard hospital mattress with usual care, as needed (n=142)	Mean age: 73.6 vs. 74 years Percent female: 54% vs. 61% Orthopedic patients	Mean Braden score: 13.9 vs. 14.01	Incidence: 9% (14/155) patients developed 21 ulcers vs. 30.3% (43[a]/142) patients developed 67 ulcers, p<0.0001 Rate Ratio 0.28 (95% CI, 0.16 to 0.46)[a] 40 with valid data	Severity Grade I: All others Grade II: 4 Grade IV: 2 (both in same patient)	NR
Takala et al, 1996[116] Poor	Hospital Intensive care unit Finland 14 days	A. Constant, static low pressure mattress (n=21) B. Standard hospital foam mattress (n=19)	Mean age: 60 vs. 63 years Percent female: 43% vs. 32% Acute respiratory organ failure patients	All patients <8 on Norton Scale	Incidence: 0 vs. 37% (7/19 patients) developed 13 ulcers, p<0.005	Grade IA: 9 Grade IB: 4 (all in control group)	NR
Fair-quality Comparative Effectiveness Trials							
Gray & Smith, 2000[92] Fair	Surgical, orthopedic, and medical wards United Kingdom 10 days	A. Transfoamwave pressure reducing mattress (n=50) B. Transfoam pressure reducing mattress (n=50)	Mean age: 69 vs. 61 years Percent female: 40% vs. 38%	Mean Waterlow score: 13 vs. 14	Incidence of pressure ulcers: 4% (2/50) vs. 4% (2/50), p=NS	Grade I: 1 vs. 1 Grade II: 1 vs. 0 Grade IV: 0 vs. 1	NR

Author, year Quality rating	Setting Country Followup	Intervention (N)	Baseline demographics A vs. B	Baseline ulcer risk score A vs. B	Results – Incidence A vs. B	Results – Severity A vs. B	Results – Length of Stay A vs. B
Kemp et al, 1993[95] Fair	Hospital and long-term care United States 1 month	A. Convoluted foam overlay (n=45) B. Solid foam overlay (n=39) Both groups received usual care	Mean age: 79.31 vs. 82.64 years Percent female: 68.8% vs. 93.1% Race: 51% vs. 56% Black; 47% vs. 44% White; 2% vs. 0% Hispanic	Mean Braden score: 14.00 vs. 13.85	Incidence (number of patients): 46.7% (21/45) vs. 30.8% (12/39), p=0.18	Severity: Grade I: 10 Grade II: 47	NR
Lim et al, 1988[96] Fair	Extended care facility Canada 5 months	A. Contoured foam cushion (n=26) B. Foam slab cushion (n=26) Both groups received usual care	Mean age: 83 vs. 84.6 years Percent female: 76.9% vs. 69.2%	All patients ≤14 on Norton scale	Incidence of ulcers:By ulcer: 35 vs. 37, p>0.05By patient: 69% (18/26) vs. 73% (19/26), p>0.05	Severity Overall: 60% (44/72) of ulcers were grade 1; none progressed past grade 3 (Exton-Smith scale) number ulcers per group: 35 vs. 37, p>0.05	NR
Vyhlidal et al, 1997[101] Fair	Skilled nursing facility United States 10-21 days	A. Foam replaceable parts mattress (n=20) B. Foam overlay with a dimpled surface (n=20) Both groups received usual care	Mean age: 74.3 vs. 80.2 years Percent female: 55% vs. 55%	Mean Braden scale: 14.7 vs. 14.5	Incidence (number patients with ulcers): 25% (5/20) vs. 60% (12/20); RR 0.42, 95% CI 0.18 to 0.96 Incidence (number ulcers): 5 vs. 16	Severity (number patients): Stage 1: 2 vs. 4 Stage 2: 3 vs. 8	NR

Author, year Quality rating	Setting Country Followup	Intervention (N)	Baseline demographics A vs. B	Baseline ulcer risk score A vs. B	Results – Incidence A vs. B	Results – Severity A vs. B	Results – Length of Stay A vs. B
Poor-quality Comparative Effectiveness Trials							
Collier et al,1996[104] Poor	Hospital United Kingdom Hospital stay	Comparison of 8 foam mattresses: A. New standard hospital mattress (n=9) B. Clinifloat (n=11) C. Omnifoam (n=11) D. Softform (n=12) E. STM5 (n=10) F. Therarest (n=13) G. Transfoam (n=10) H. Vapourlux (n=14)	Percent female: 60%	Waterlow score range: 3 to 25	Incidence: No patients developed a pressure ulcer of any grade during the study	NR	NR
Cooper et al, 1998[105] Poor	Acute care United Kingdom 7 days	A. Sofflex immersion air mattress (n=51) B. Roho immersion air mattress (n=49)	Mean age: 83 vs. 83 years Percent female: 86% vs. 82% Orthopedic patients	Mean Waterlow score: 17 vs. 16	Incidence: 7% of patients (3/51) developed an ulcer vs. 12% (5/49) of patients developed an ulcer; p=NR	Severity: Only 1 pressure ulcer involved a break in the skin (Stirling grade 2.4, Group A Sofflex group)	NR
Stapleton et al, 1986[115] Poor	Hospital United Kingdom unclear	A. Large cell ripple pads (n=32) B. Polyether foam pad (n=34) C. Spenco pad (n=34)	Mean age: 81 years Percent female: 100%	Mean Norton score: 12 vs. 12.8 vs. 12.9	Incidence (number patients that developed ulcers): 34% (11/32) vs. 41% (14/34) vs. 35% (12/34); RR 1.99, 95% CI 0.98-4.00; p=0.055 Patients >80 years incidence (number patients that developed ulcers):45% vs. 63%[a] vs. 32%, p=significant, but NR	Severity (Border grading scale): Grade A: 2 vs. 1 vs. 2 Grade B: 9 vs. 5 vs. 8 Grade C: 0 vs. 3 vs. 2 Grade D: 0 vs. 5 vs. 0	NR

Abbreviations: CI, confidence interval; NR, not reported; RR, relative risk.
[a] Pressure Ulcer Risk Assessment general cutoffs for at risk:
Braden scores <15-18. Lower scores indicate higher pressure ulcer risk.
Cubbin and Jackson nscore <29. Lower scores indicate higher pressure ulcer risk.
Norton scores <12-16. Lower scores indicate higher pressure ulcer risk.
Waterlow scores >10-15. Higher scores indicate higher pressure ulcer risk.

Heel Supports/Boots

Three trials (n=52 to 240) evaluated static heel supports in hospital settings (Table 8).[85, 107, 117] One fair-quality trial (n=239) of fracture patients found the Heelift Suspension Boot associated with decreased risk of heel, foot, or ankle ulcers compared with usual care (7 vs. 26 percent for any ulcer; RR 0.26, 95% CI 0.12 to 0.53; 3.3 vs. 13 percent for grade II ulcers, RR 0.25, 95% CI 0.09 to 0.72).[85] One poor-quality trial (n=52) of hospitalized patients found no difference in risk of ulcers between a boot (Foot Waffle) and usual care (hospital pillow to prop up legs) in risk of incident ulcers (6 vs. 2 events, group sizes not reported).[117] One other poor-quality (n=240) trial of hospitalized patients found no differences between three different types of boots (Bunny Boot, egg-crate heel lift positioner, and Foot Waffle) in risk of ulcers, though the overall incidence of ulcers was low (5 percent over 3 years) and nurses added pillows to the Bunny Boot, which could have confounded results.[107] None of the trials evaluated length of stay or measures of resource utilization. Shortcomings in the poor-quality trials included unclear allocation concealment,[117] significant differences between groups at baseline,[107] failure to report attrition,[107, 117] lack of blinding of outcome assessors,[107, 117] and failure to perform intention-to-treat analysis.[107, 117]

Table 8. Key Question 3: Effectiveness of pressure ulcer prevention support surfaces in at-risk patients—static heel supports

Author, year Quality rating	Setting Country Followup	Intervention (N)	Baseline Demographics (age, percent women, race, as reported) A vs. B	Baseline Ulcer Risk Score A vs. B	Results – Incidence A vs. B	Results – Severity A vs. B	Results – Length of Stay A vs. B
Donnelly et al, 2011[85] Fair	Hospital United Kingdom 10.8 to 12.2 days	A. Heelift Suspension Boot (n=120) B. Usual care (n=119)	Mean age: 80.9 vs. 80.8 years Percent female: 79.2% vs. 74.8% Fracture patients	Mean Braden score: 14.8 vs. 15	Incidence (number patients): 7% (8/120) of patients vs. 26% (31/119) of patents; RR 0.26, 95% CI 0.12 to 0.53 Incidence (number heel, foot, or ankle pressure ulcers): 0% (0/120) vs. 24.4% (29/119); RR 0.25, 95% CI 0.09 to 0.72	Severity (number pressure ulcers): Grade I: 0 vs. 18 Grade II: 4 vs. 16 Ungraded: 5 vs. 5 Note: Excluding Grade I ulcers did not change results	NR
Gilcreast et al, 2005[107] Poor	Military tertiary-care academic medical centers United States 7.5 days	A. Bunny Boot (n=77) B. Egg crate heel lift positioner (n=87) C. Foot waffle air cushion (n=76) Nurses added pillows to the bunny boot group	Mean age: 63.9 years Percent female: 42% Race: 68% White, 15.4% Black, 16.3% Hispanic, 1% Asian	Braden score ≤14	Incidence (heel pressure ulcers; unclear whether the unit was number of ulcers or number of patients): Total 5% (12/240) incidence in both groups over 3 years; 1.68% per year 4% (3/77) vs. 5% (4/87) vs. 7% (5/76), p=0.416	NR	NR
Tymec et al, 1997[117] Poor	Hospital United States Unclear	A. Foot Waffle B. Hospital pillow under both legs from below knee to the Achilles tendon (n=52 total)	Mean age: 66.6 years Percent women: 44% Race: 61% Black, 37% White, 2% Asian	Mean Braden score: 11.8	Incidence (ulcers): 6 vs. 2, p=NS	NR	NR

Abbreviations: CI, confidence interval; NR, not reported; NS, not significant; RR, relative risk.
Note: Pressure Ulcer Risk Assessment general cutoffs for at risk:
Braden scores <15-18. Lower scores indicate higher pressure ulcer risk.
Cubbin and Jackson nscore <29. Lower scores indicate higher pressure ulcer risk.
Norton scores <12-16. Lower scores indicate higher pressure ulcer risk.
Waterlow scores >10-15. Higher scores indicate higher pressure ulcer risk.

Wheelchair Cushions

Four trials evaluated static wheelchair cushions with more sophisticated cuts, materials, or shapes compared with standard wheelchair cushions (Table 9).[87, 88, 90, 103] Three were rated fair-quality[87, 88, 90] and one poor-quality.[103] All of the trials were conducted in extended care facilities or nursing homes and followed patients for three to six months. Results of the fair-quality trials were somewhat inconsistent and difficult to interpret because the trials evaluated different cushions. The largest (n=248) fair-quality trial found no difference between a contoured, individually customized foam cushion compared with a slab cushion in risk of ulcers (68 vs. 68 percent; RR 1.0, 95% CI 0.84 to 1.2).[87] A small (n=32) pilot trial also found no difference between a pressure-reducing wheelchair cushion with incontinence cover compared with a generic foam cushion in risk of ulcers (40 vs. 59 percent; RR 0.68, 95% CI 0.33 to 1.4).[90] However, the third fair-quality trial (n=141) found the Jay cushion (contoured urethane foam with a gel pad topper) associated with decreased risk of ulcers compared with a standard foam cushion (25 vs. 41 percent, RR 0.61, 95% CI 0.37 to 1.0).[88] The Jay cushion was also associated with decreased risk when the analysis was restricted to grade II or 3 ulcers (8.8 vs. 26 percent, RR 0.36, 95% CI 0.15 to 0.85). A poor-quality (due to unclear allocation concealment, unclear blinding of outcome assessors, and high loss to followup) trial (n=232) found various skin protection wheelchair cushions associated with lower risk of ischial tuberosity ulcers (primarily stage II) compared with a standard segmented foam cushion (9.9 vs. 6.7 percent, RR 0.13, 95% CI 0.02 to 1.0), but the results were just above the standard threshold for statistical significance (p=0.054).[103] None of the trials evaluated length of stay or measures of resource utilization.

Table 9. Key Question 3: Effectiveness of pressure ulcer prevention support surfaces in at-risk patients—static wheelchair cushions

Author, year Quality rating	Setting Country Followup	Intervention (N)	Baseline Demographics A vs. B	Baseline Ulcer Risk Score A vs. B	Results – Incidence A vs. B	Results – Severity A vs. B	Results – Length of Stay A vs. B
Conine et al, 1993[87] Fair	Extended care facility, wheelchair cushions Canada 3 months	A. Contoured foam cushion (n=123) B. Slab cushion (n=125)	Mean age: 84 vs. 83.5 years Percent female: 79.6 vs. 77.6%	Mean Norton score at baseline: 11.5 vs. 12.1	Incidence: 175 sores in 84/123 patients vs. 184 sores in 85/125 patients; RR 1.0, 95% CI 0.84 to 1.2	Severity: Grade I: 57% (105/184) vs. 56% (98/175) Grade II: 24% (45/184) vs. 27% (48/175) Grade III: 17% (32/184) vs. 15% (27/175) Grade IV: 1% (2/184) vs. 1% (2/175) p=NS	NR
Conine et al, 1994[88] Modified sequential randomized trial Fair	Extended care facility, wheelchair cushions Canada 3 months	A. Jay cushion (n=68) B. Foam cushion (n=73)	Mean age 82 years Percent female: 85%	Mean Norton score of patients at baseline: 12	Incidence: 26/68 lesions in 17 patients (25%) vs. 42/68 lesions in 30 patients (41%); RR 0.61, 95% CI 0.37 to 1.0	Severity: Grade I: 77% (20/26) vs. 57% (24/42) Grade II: 11.5% (3/26) vs. 29% (12/42) Grade III: 11.5% (3/26) vs. 14% (6/42) p=NS Grade II or 3: 8.8% (6/73) vs. 26% (18/68); RR 0.36, 95% CI 0.15 to 0.85	NR
Geyer et al, 2001[90] Pilot Fair	Nursing homes United States 76 to 100 days	A. Pressure reducing wheelchair cushion (n=15) B. Generic convoluted foam cushion (n=17)	Mean age: 85.2 vs. 84.1 years Percent female: 93.3% vs. 94%	Initial Braden score, mean: 12.5 vs. 13.4	Incidence (number ulcers): 40% (6/15) vs. 59% (10/17); RR 0.68, 95% CI 0.33 to 1.4	NR	NR

Author, year Quality rating	Setting Country Followup	Intervention (N)	Baseline Demographics A vs. B	Baseline Ulcer Risk Score A vs. B	Results – Incidence A vs. B	Results – Severity A vs. B	Results – Length of Stay A vs. B
Brienza et al, 2010[103] Poor	Nursing homes United States 6 months	A: Skin protection cushions (n=113) B: Segmented foam cushion (SFC) (n=119)	Mean age: 86.8 vs. 86.6 years Percent female: 80.5% vs. 89.1% % Nonwhite: 8.8% vs. 6.7%	Mean Braden score: 15.4 (SD ± 1.4) vs. 15.5 (SD ± 1.5)	Incidence (number ischial tuberosity pressure ulcers): 0.9% (1/113) vs. 6.7% (8/119); RR 0.13, 95% CI 0.02-1.04 p=0.054 Incidence (number combined ischial tuberosity and sacral pressure ulcers): 10.6% (12/113) vs. 17.6% (21/119), p=0.14	Severity: Stage 1: 1 Stage 2: 7 Ungradable: 1	NR

Abbreviations: CI, confidence interval; NR, not reported; NS, not significant; RR, relative risk.
Note: Pressure Ulcer Risk Assessment general cutoffs for at risk:
Braden scores <15-18. Lower scores indicate higher pressure ulcer risk.
Cubbin and Jackson nscore <29. Lower scores indicate higher pressure ulcer risk.
Norton scores <12-16. Lower scores indicate higher pressure ulcer risk.
Waterlow scores >10-15. Higher scores indicate higher pressure ulcer risk.

Dynamic Support Surfaces

Dynamic compared with Static Support Surfaces

Six trials (n=32 to 487, two fair-quality[86, 89] and four poor-quality[102, 106, 113]) compared a dynamic alternating-air pressure mattress or overlay with static support surfaces (Table 10). Methodological shortcomings in the poor-quality trials included unclear methods of randomization and allocation concealment, failure to blind outcome assessors, high loss to followup, and failure to perform intention-to-treat analysis.

One fair-quality[86] and one poor-quality[106] trial conducted in long-term care settings found no differences between an alternating air pressure overlay compared with a silicone/cotton overlay in incidence or severity of pressure ulcers (54 vs. 59 percent, RR 0.91, 95% CI 0.69 to 1.2[86] and 25 vs. 25 percent, RR 1.0, 95% CI 0.30 to 3.3).[106] One other poor-quality study (n=57) conducted in an intensive-care setting also found no differences between an alternating-pressure mattress and two types of static mattress in pressure ulcer incidence or severity (25 vs. 5 vs. 12 percent; p=NS), or in length of stay (10 vs. 9.4 vs. 8.9 days, p>0.05).[123] However, another fair-quality trial (n=43) of intensive care unit patients found stepped care initially with alternating air pressure mattresses associated with decreased risk of pressure ulcers after 11 to 12 days compared with stepped care initially with static support surfaces (4.3 vs. 55 percent for any ulcer; RR 0.08, 95% CI 0.01 to 0.56; 0 vs. 35 percent excluding grade I ulcers, RR 0.06, 95% CI 0.00 to 0.96).[89] An earlier abstract for the same study that reported results for a larger sample that included intensive care unit and non-intensive care unit patients (n=230) also found the alternating pressure air mattress intervention associated with decreased risk of pressure ulcers (13 vs. 34 percent, RR 0.38, 95% CI 0.22 to 0.66).[126]

Two poor-quality trials also found dynamic support surfaces associated with lower risk of pressure ulcers compared with static support surfaces.[102, 113] One trial (n=108) of stroke, post-operative, or terminally ill patients found an alternating double-layer air cell overlay associated with decreased risk of pressure ulcers compared with an alternating single-layer air cell overlay or a standard hospital mattress (3.4 vs. 37 percent for any ulcer, RR 0.10, 95% CI 0.01 to 0.76; 3.4 vs. 22 percent for stage II ulcers, RR 0.17, 95% CI 0.02 to 1.3).[113] The other trial (n=487) found an alternating air-pressure mattress associated with decreased risk of ulcers compared with a standard hospital mattress in risk of pressure ulcers after 10 days (4.2 vs. 13 percent; RR 0.32, 95% CI 0.14 to 0.74), though there was no difference in risk of ulcers compared with a water mattress (4.2 vs. 4.5 percent).[102] Pressure ulcer severity was not reported in this trial.

Table 10. Key Question 3: Effectiveness of pressure ulcer prevention support surfaces in at-risk patients—dynamic compared with static mattresses and overlays

Author, year Quality rating	Setting Country Followup	Intervention (N)	Baseline Demographics A vs. B	Baseline Ulcer Risk Score A vs. B	Results – Incidence A vs. B	Results – Severity A vs. B	Results – Length of Stay A vs. B
Conine et al, 1990[86] Fair	Extended care facility Canada 3 months	A. Alternating air pressure overlay (n=72) B. Spenco silicone overlay (n=76) Both groups received usual care	Mean age: 38.8 vs. 35.6 years Percent female: 56.9% vs. 61.8%	Mean Norton score: 12.9 vs. 12.4	Incidence: 133 ulcers in 54% (39/72) patients in group A vs. 148 ulcers in 59% (45/76) patients in group B; RR 0.91, 95% CI 0.69 to 1.2	Severity: Grade I: 64% (95/133) vs. 41% (91/148) Grade II: 12% (15/133) vs. 13% (19/148) Grade III: 24% (33/133) vs. 14% (36/148) Grade IV: 0 vs. 1% (2/148) (p=NS for all)	NR
Gebhardt et al, 1996[89] Cluster trial Fair	Intensive care unit United Kingdom Mean 11-12 days	A. Alternating air pressure mattress (n=23) B. Various support surfaces (mostly static) (n=20)	Mean age: 55 vs. 60 Percent female: 47.8% vs. 35%	Norton score >8: n=5 vs. n=1 Norton score ≤8: n=18 vs. n=19	Incidence (number pressure ulcers): Grade I: 1 vs. 3 Grade II: 0 vs. 4 Grade III: 0 vs. 3 p-value NR; RR 0.08, 95% CI 0.01 to 0.56 Excluding Grade I ulcers: RR 0.06, 95% CI 0.00-0.96	NR	NR
Andersen et al, 1982[102] Poor	Acute care Denmark 10 days	A. Alternating air pressure mattress (n=166) B. Water mattress (n=155) C. Standard hospital mattress (n=166)	Age: Majority >60 years Percent female: 56% vs. 52.9% vs. 62.7%	Scores ranged from 2 to 7 (total scale range 0-11), p=NS Study's own risk assessment tool, score of >2 indicates at risk	Incidence (number pressure ulcers): 4.2% (7/166) vs. 4.5% (7/155) vs. 13.0% (21/161) A vs. C: RR 0.32, 95% CI 0.14-0.74 B vs. C: RR 0.35, 95% CI 0.15-0.79	NR	NR

Author, year Quality rating	Setting Country Followup	Intervention (N)	Baseline Demographics A vs. B	Baseline Ulcer Risk Score A vs. B	Results – Incidence A vs. B	Results – Severity A vs. B	Results – Length of Stay A vs. B
Daechsel & Conine, 1985[106] Poor	Long-term care Canada 3 months	A. Alternating pressure mattress (n=16) B. Silicone-filled mattress (n=16)	Mean age: 42.6 vs. 38.5 years Percent female: 37.5% vs. 62.5% All chronic neurologic patients	Mean Norton score: 13.4 vs. 13.0	Incidence: 25% (4/16) of patients developed 5 ulcers vs. 25% (4/16) of patients developed 5 ulcers; RR 1.0, 95% CI 0.30 to 3.3	Severity: Mean Exton-Smith scores: 2.25 (0.82 SD) vs. 2.75 (0.74 SD), p=0.39	NR
Sanada et al, 2003[113] Poor	Hospital JapanUnclear	A. Double-layer air cell overlay (n=37) B. Single-layer air cell overlay (n=36) C. Standard hospital mattress (n=35) Both groups received usual care	Mean age: 69.5 vs. 73.9 vs. 70.6 years Percent female: 51.7 vs. 42.3 vs. 51.9 All patients required head elevation, including stroke patients, recovering from surgery, and terminally ill	Mean Braden scale: 12.5 vs. 12.1 vs. 12.7	Incidence (number patients that developed pressure ulcers): 3.4% (1/26) vs. 19.2% (5/29) vs. 37.0% (10/27), p<0.01 A vs. B: RR 0.22, 95% CI 0.03 to1.79 A vs. C: RR 0.10, 95% CI 0.01 to 0.76	Grade I (number ulcers): 0% (0/26) vs. 3% (1/29) vs. 15% (4/27), p=NR Grade II (number ulcers): 4% (1/26) vs. 14% (4/29) vs. 22% (6/27), p=NR	NR
Sideranko et al, 1992[114] Poor	Surgical intensive care unit United States	A. Alternating air mattress: 1.5-inch thick Lapidus Airfloat System (n=20) B. Static air mattress: 4-inch thick Gay Mar Sof Care (n=20) C. Water mattress: 4-inch thick Lotus PXM 3666 (n=17)	Mean age: 67.9 (11.1 SD) vs. 63.6 (16.6 SD) vs. 66.1 (15.6 SD) Mean days of surgical ICS stay: 10.0 (10.9 SD) vs. 9.4 (8.8 SD) vs. 8.9 (7.1 SD) Mean days on mattress: 20.3 (21.4 SD) vs. 19.8 (14.7 SD) vs. 20.5 (17.5 SD) % women (reported for whole group): 42.1% (24/57) (p=NS for all)	Unclear	Incidence (number of patients that developed ulcers): 25% (5/20) vs. 5% (1/20) vs. 12% (2/17), p=NS	NR	Length of stay: 10 vs. 9.4 vs. 8.9 days; p=NS

Abbreviations: CI, confidence interval; NR, not reported; NS, not significant; RR, relative risk.
Note: Pressure Ulcer Risk Assessment general cutoffs for at risk:
Braden scores <15-18. Lower scores indicate higher pressure ulcer risk.
Cubbin and Jackson nscore <29. Lower scores indicate higher pressure ulcer risk.
Norton scores <12-16. Lower scores indicate higher pressure ulcer risk.
Waterlow scores >10-15. Higher scores indicate higher pressure ulcer risk.

Dynamic compared with Dynamic Support Surfaces

Three trials compared different dynamic support surfaces.[98, 99, 113] Two fair-quality (n=44 and 62) trials of hospitalized patients found no differences in risk of pressure ulcers after 2 weeks between different (7.5 vs. 10 minute cycles) alternating air pressure mattresses (0 vs. 9 percent, RR 0.20, 95% CI 0.01 to 3.9) or between the KCI TheraPulse pulsating air suspension mattress compared with the Hill-Rom Duo (options for either alternating air pressure or constant low pressure) mattress (10 vs. 19 percent, RR 0.53, 95% CI 0.15 to 1.9) after 2 weeks (Table 11).[98, 99] In both trials combined, only one ulcer was more severe than grade II. Neither of the trials found any differences in length of stay. A poor-quality trial (n=108) found an alternating double-layer air cell overlay associated with decreased risk of pressure ulcers compared with an alternating single-layer air cell overlay (3.4 vs. 19 percent for any ulcer; RR 0.22, 95% CI 0.03 to 1.8; 3.4 vs. 14 percent for stage II ulcers; RR 0.28, 95% CI 0.03 to 2.3).[113]

Table 11. Key Question 3: Effectiveness of pressure ulcer prevention support surfaces in at-risk patients—dynamic compared with dynamic mattresses and overlays

Author, year Quality rating	Setting Country Followup	Intervention (N)	Baseline Demographics A vs. B	Baseline Ulcer Risk Score A vs. B	Results - Incidence A vs. B	Results - Severity A vs. B	Results – Length of Stay A vs. B
Gebhardt et al, 1996[89] Cluster trial Fair	Intensive care unit United Kingdom 11 to 12 days (mean)	A. Alternating-pressure air mattress (n=23) B. Various support surfaces including static support surfaces (n=20)	Mean age: 55 vs. 60 years Percent female: 47.8% vs. 35%	Norton score >8: n=5 vs. n=1 Norton score ≤8: n=18 vs. n=19	Incidence (number pressure ulcers): Grade I: 1 vs. 3 Grade II: 0 vs. 4 Grade III: 0 vs. 3 p value NR	NR	NR
Taylor et al, 1999[98] Fair	Hospital United Kingdom 10.5 to 11.6 days (mean)	A. Alternating air pressure mattress (Pegasus Trinova) (n=22) B. Alternating air pressure system (unnamed) (n=22)	Mean age: 66.50 vs. 70.27 years Percent female: 45.5% vs. 40.9%	Waterlow score: 19 vs. 17	Incidence (number of patients that developed ulcers): 0% (0/22) vs. 9% (2/22); RR 0.20, 95% CI 0.01 to 3.9	Both "superficial"	Length of stay: 10.5 vs. 11.6 days; p=NS
Theaker et al, 2005[99] Fair	Hospital, Intensive care United Kingdom 14 days	A. KCI TheraPulse pulsating air suspension mattress (n=30) B. Hill-Rom Duo, constant low pressure or alternating-air options (n=32)	Mean age: 65 years Percent female: 37% (23/62)	High risk, details NR	Incidence (number of patients that developed ulcers): 10% (3/30) vs. 19% (6/32); RR 0.53, 95% CI 0.15 to 1.9	Grade II: 8 Grade III: 1	Length of stay: no differences between groups in duration spent on mattresses
Sanada et al, 2003[113] Poor	Hospital Japan Unclear	A. Double-layer alternating air pressure overlay (n=37) B. Single-layer alternating air pressure overlay (n=36) C. Standard hospital mattress (n=35) All groups received usual care	Mean age: 69.5 vs. 73.9 vs. 70.6 years Percent female: 51.7% vs. 42.3 %vs. 51.9% All patients required head elevation, including stroke patients, recovering from surgery, and terminally ill	Mean Braden scale: 12.5 vs. 12.1 vs. 12.7	Incidence (number patients that developed pressure ulcers): 3.4% (1/26) vs. 19.2% (5/29) vs. 37.0% (10/27), p<0.01 A vs. B: RR 0.22, 95% CI 0.03-1.79 A vs. C: RR 0.10, 95% CI 0.01-0.76	Grade I (number ulcers): 0% (0/26) vs. 3% (1/29) vs. 15% (4/27), p=NR Grade II (number ulcers): 4% (1/26) vs. 14% (4/29) vs. 22% (6/27), p=NR	NR

Abbreviations: CI, confidence interval; NR, not reported; RR, relative risk.
Note: Pressure Ulcer Risk Assessment general cutoffs for at risk:
Braden scores <15-18. Lower scores indicate higher pressure ulcer risk.
Cubbin and Jackson nscore <29. Lower scores indicate higher pressure ulcer risk.
Norton scores <12-16. Lower scores indicate higher pressure ulcer risk.
Waterlow scores >10-15. Higher scores indicate higher pressure ulcer risk.

Nutritional Supplementation

Three poor-quality randomized trials (n=56 to 672) examined nutritional interventions for preventing pressure ulcers (Table 12, Appendix H13).[127-129] All of the trials compared liquid nutritional supplements plus standard hospital diet compared with the standard hospital diet alone. Methodological limitations in the trials included inadequate description of randomization and allocation concealment (Appendix H14). One trial also reported baseline differences between intervention groups in risk factors for pressure ulcers,[127] and one had high attrition.[128] Only one trial described measures to blind patients and caregivers to the nutritional intervention;[129] no trial described blinding of outcomes assessors.

The largest trial (n=672) found high-calorie oral liquid nutritional supplements plus standard hospital diet associated with slightly lower risk of pressure ulcers (AHCPR grading system) at 15 days compared with standard hospital diet alone in elderly patients (32 percent with Norton score of ≤10 at baseline) in the acute phase of a critical illness (40 vs. 48 percent, RR 0.83, 95% CI 0.7 to 0.99).[127] Although there were differences across intervention groups in markers of pressure ulcer risk, the nutritional intervention remained associated with lower risk after adjustment for these risk factors (RR 0.64, 95% CI 0.42 to 0.97). However, two smaller trials found no effects of a nutritional intervention on risk of pressures ulcers following hip fractures. One trial (n=103, mean CBO score 11 on a 0 to 39 scale) found no difference in risk of EPUAP grade I or II pressure ulcers (there were no grade III or IV ulcers) between a standard hospital diet plus one daily oral liquid nutritional supplement (with protein, arginine, zinc, and antioxidants) compared with a standard hospital diet plus identical-appearing non-caloric water based placebo after 2 weeks (35 vs. 58 percent, RR 0.92, 95% CI 0.65 to 1.3).[129] There was also no difference in risk of grade II ulcers when they were evaluated separately (18 vs. 27 percent, RR 0.66, 95% CI 0.31 to 1.4). One other trial (n=59, baseline pressure ulcer risk not assessed) found no statistically significant difference between a high-calorie oral nutritional supplement (mean 32 days of supplementation) plus hospital diet compared with hospital diet alone in risk of pressure ulcers at discharge (0 vs. 20 percent, RR 0.79, 95% CI 0.14 to 4.4) or at 6 month followup (0 vs. 7 percent, RR 0.23, 95% CI 0.01 to 4.3), although estimates were very imprecise due to small numbers of ulcers.[128] None of the trials reported length of stay or measures of resource utilization.

Table 12. Key Question 3: Effectiveness of nutritional supplementation for pressure ulcer prevention

Author, year Duration Quality rating	Setting	Patient Characteristics	Interventions	Ulcer Risk	Results
Bourdel-Marchasson et al, 2000[127] 15 days or until death or discharge Poor	Hospital wards and geriatric inpatient units France	N=672 A vs. B Mean age:83.6 vs. 83 Percent female: 67.5% vs. 63.1% Percent white: NR Nutritional intervention group had significantly lower Norton and Kuntzman scores, at baseline	A: Nutritional intervention group (n=295): standard diet (1.8 kcal/d) and 2 oral supplements per day (with 200 mL; 200 kcal, 30% protein; 20% fat; 50% carbohydrate; minerals and vitamins such as 1.8 mg zinc and 15 mg vitamin C) B: Control group (n=377): standard diet (1.8 kcal daily).	A vs. B: Norton Score 5-10: 28.5% vs. 35.5% 11-14: 40.3% vs. 46.9% >14: 31.2% vs. 18.6%	A vs. B Cumulative 15-day incidence: 40% vs. 48%; RR 0.83 (95% CI 0.7-0.99); adjusted RR[a]
Houwing et al, 2003[129] 28 days or until discharge Poor	3 centers The Netherlands	N=103 A vs. B: Mean age: 81.5 +/- 0.9 vs. 80.5 +/- 1.3 Percent female: 78% vs. 84% Percent white: NR	A: Nutritional supplement (400 mL; 500 kcal; 40 g protein; 6 g L-arginine; 20 mg zinc; 500 mg vitamin C; 200 mg vitamin E; 4 mg carotenoids) (n=51) B: Non-caloric, water-based placebo (n=52)	A vs. B: Dutch Consensus Meeting scoring system (CBO-risk assessment tool): 11.1 +/- 0.3 vs. 11.2 +/- 0.2 (p=0.629)	A vs. B Incident ulcers: 55.1% vs. 58.8%; RR 0.92, 95% CI 0.65 to 1.3 PU incidence according to severity: Grade I: 36.7% vs. 31.4%; p=0.674 Grade II: 18.4% vs. 27.5%; p=0.345
Delmi et al, 1990[128] Mean duration of supplement 32 days; measurement at admission, day 14, 21, 28, discharge from hospital, and 6 months Poor	Orthopaedic unit of the University hospital of Geneva and "second (recovery)" hospital Switzerland	N=59 A vs. B: Mean age: 80.4 +/- 8.5 vs. 82.9 (+/- 7.9) Percent female: 88.9% vs. 90.6%	A: Standard hospital diet with daily oral nutrition supplement (250 mL; 254 kcal; 20.4 g protein; 29.5 g carbohydrate; 5.8 g lipid; 525 mg calcium; 750 IU vitamin A; 25 IU vitamin D3, vitamins E, B1, B2, B6, B12, C, nicotinamide, folate, calcium pantothenate, biotin, minerals), started on admission, continued throughout second hospital (mean period 32 days); given at 8 PM daily (n=27) B: Standard hospital diet (n=32)	NR	A vs. B Incident ulcers at discharge: 0/9 vs. 3/15; RR 0.79, 95% CI 0.14 to 4.4 Incident ulcers at 6 months: 0/25 vs. 2/27; RR 0.23, 95% CI 0.01 to 4.3

Abbreviations: CI, confidence interval; NR, not reported; PU, pressure ulcer; RR, relative risk.
[a] Adjusted for intervention group, serum albumin, Kuntzman score, Norton score, and diagnosis.
Note: Pressure Ulcer Risk Assessment general cutoffs for at risk:
Braden scores <15-18. Lower scores indicate higher pressure ulcer risk.
Cubbin and Jackson nscore <29. Lower scores indicate higher pressure ulcer risk.
Norton scores <12-16. Lower scores indicate higher pressure ulcer risk.
Waterlow scores >10-15. Higher scores indicate higher pressure ulcer risk.

Repositioning

Three randomized trials (n=46 to 838) examined the effectiveness of repositioning for prevention of pressure ulcers (Appendix H15 and H16).[130-132] All trials classified patients as higher-risk for ulcers based on the Braden or Waterlow scales. One good-quality trial[130] and one fair-quality trial[131] were conducted in long-term-care facilities of patients in their 80s. One fair-quality trial (attrition 15 percent and adherence 57 percent) was conducted in an acute care ward in a somewhat younger (mean age 70 years) population.[132] The repositioning interventions and standard care comparators varied between trials (Appendix H15). Standard care included less structured or frequent repositioning, instead of no repositioning.

One fair-quality cluster randomized trial (n=213) of higher-risk patients (baseline risk determined by the activity and mobility components of the Braden scale) in long-term-care facilities found repositioning at a 30-degree tilt every 3 hours associated with lower risk of pressure ulcer compared with usual care (90-degree lateral repositioning every 6 hours during the night) after 28 days (3.0 vs. 11 percent, RR 0.27, 95% CI 0.08 to 0.93).[131] Clustering effects were negligible. All of the ulcers were graded as stage 1 or 2 (EPUAP). A fair-quality randomized trial (n=46) of higher-risk (Waterlow score >10) patients in an acute-care ward found 30-degree tilt repositioning associated with no statistically significant difference in incidence of stage 1 ulcers (13 vs. 8.7 percent, RR 1.5, 95% CI 0.28 to 8.2), but only followed patients for one night.[132]

A third, good-quality trial compared repositioning interventions that alternated the semi-Fowler position (30-degree elevation of the head and feet) and a lateral position (patient turned 30 degrees and supported by a pillow between the shoulders and pelvis) at four different intervals (2, 3, 4, or 6 hours) compared with usual preventive care (repositioning method not specified, based on nurse clinical judgment) in 838 at-risk (Braden score <17) patients in nursing homes.[130] It found no difference between groups in risk of grade I ulcers (AHCPR) after 4 weeks, which ranged in incidence from 44 to 48 percent across groups. The 4 hour repositioning intervention was associated with the lowest risk of grade II or higher ulcers compared with the other interventions (3.0 percent vs. 14 to 24 percent; OR 0.12, 95% CI 0.03 to 0.48). However, whether the difference was due to the repositioning interval is difficult to determine because the 4 and 6 hour repositioning interventions also included use of a pressure-reducing foam mattress (standard institutional mattresses were used in the other arms).

None of the trials reported length of stay or measures of resource utilization.

Dressings and Pads

Two randomized trials addressed the effectiveness of dressings or pads for prevention of pressure ulcers (Appendix H17 and H18).[133, 134] One trial compared more with less frequent incontinence pad changes,[133] and the other compared use of a dressing compared with no dressing.[134]

A fair-quality cross-over trial of female nursing home patients (n=81, mean Braden 13 at baseline) found no statistically significant difference in risk of grade II pressure ulcers (method used to classify pressure ulcers not reported) after 4 weeks between changing incontinence pads three times compared with twice a night, though no ulcers occurred in patients during the more frequent change period compared with five during the less frequent change period (odds ratio not reported, 95% CI 0 to 1.1; p=0.1).[133] Methodological shortcomings included inadequate allocation concealment and failure to blind care providers and patients.

A poor-quality trial of 37 patients (mean Braden 10 at baseline) in a long-term care facility found use of the REMOIS Pad (consisting of a hydrocolloid skin adhesive layer, a support layer of urethane film, and an outer layer of multifilament nylon) on the greater trochanter associated with decreased risk of persistent erythema (stage 1 ulcer) compared to use of no pad on the contralateral trochanter after 4 weeks (5.4 vs. 30 percent, RR 0.18, 95% CI 0.05 to 0.73).[134] Important methodological shortcomings included inadequate randomization and allocation concealment, and a lack of blinding. Neither trial reported length of stay or measures of resource utilization.

Intraoperative Warming

One fair-quality (unclear randomization method) randomized trial (n=324) of patients undergoing major surgery found no statistically significant difference in risk of pressure ulcers (method for grading ulcers not specified and duration of postoperative followup not reported) between patients who received intraoperative warming (forced-air warming and warming of all intravenous fluids) compared with usual care, although results favored the warming intervention (5.6 vs. 10 percent, RR 0.54, 95% CI 0.25 to 1.2) (Appendix H19 and H20).[135] Length of stay and measures of resource utilization were not reported.

Drugs

One poor-quality randomized trial (n=85) of patients undergoing femur or hip surgery found no difference in risk of pressure ulcers between those who received 80 IU of corticotrophin intramuscularly compared with a sham injection (12 vs. 28 percent, RR 0.43, 95% CI 0.16 to 1.1) (Appendix H19 and H20).[136] Length of stay and measures of resource utilization were not reported. Methodological shortcomings included unclear randomization technique, inadequate allocation concealment, unclear blinding methods, lack of intention-to-treat analysis, and failure to report demographic characteristics, ulcer risk, eligibility criteria, and attrition.

Creams, Lotions, and Cleansers

Four poor-quality randomized trials (reported in five publications) evaluated lotions, creams, or cleansers[137-141] and one fair-quality trial evaluated a skin cleanser[142] in various settings, including nursing homes, long-term care facilities, and acute care hospitals (Table 13; Appendix H21 and H22). None of the poor-quality trials[137-141] reported adequate methods for randomization and/or allocation concealment, only two trials reported blinding of care providers or patients,[137, 139] and only one trial reported low loss to followup.[137] In addition, one cluster randomized trial[140, 141] failed to assess cluster effects. Four trials evaluated older (mean age ≥80 years), predominantly female (range 67 to 81 percent) patients in long-term care settings or a geriatric care unit.[137, 138, 140-142] The fifth trial evaluated younger (mean age 60 years) patients (proportion female not reported) in an intensive care unit.[139] Three trials compared a lotion or cream with placebo[137, 139-141] and the fourth[138] compared two lotions. The fifth trial compared a foam cleanser (Clinisan) to standard hospital soap.[142]

One poor-quality trial (n=258) of patients in long-term care facilities found Conotrane cream (benzalkonium chloride [an antiseptic] plus dimeticone [a silicone fluid which is water repellant]) associated with a trend towards lower risk of any pressure ulcer (Barbarel score) after 24 weeks compared with placebo cream, though the results were not statistically significant (27 vs. 36 percent, RR 0.74, 95% CI 0.52 to 1.07).[137]

A poor-quality crossover trial (n=79) of nursing home patients at higher risk for ulcers (Braden score at baseline ≤20) found no differences between 5 percent dimethyl sulfoxide cream (DMSO, a commercial solvent with various purported medicinal properties), a placebo cream (Vaseline-cetomacrogol) or position changes without any cream in severity or incidence of pressure ulcers (any location) after 8 weeks (incidence 37 vs. 40 vs. 23 percent, respectively, during initial intervention and 34, 33, and 27 percent following crossover).[140] Patients allocated to either cream also received a 2 to 3 minute massage during application of the cream, and all groups underwent 30° repositioning every 6 hours. A subsequent analysis found the DMSO cream associated with increased risk of heel or ankle ulcers compared with the other treatments (55 vs. 16 percent, odds ratio 8.8, 95% CI 2.6 to 30).[141]

A poor-quality trial (n= 104) of higher-risk patients (mean Norton score 11 at baseline) in a hospital geriatric unit found no differences between the Prevasore (hexyl nicotinate, zinc stearate, isopropyl myristate, Dimethicone 350, cetrimide, and glycerol) compared with the Dermalex (hexachlorophene, squalene, and allantoin) creams in risk of skin deterioration after 3 weeks (13 vs. 22 percent, RR 0.59, 95% CI 0.25 to 1.4).[138]

A poor-quality trial (n= 86) of patients in an intensive care unit (mean Norton score 9) found a lotion consisting of 1.6 grams of essential fatty acids associated with decreased risk of pressure ulcers after 3 weeks compared with a mineral oil placebo lotion (stage I or stage II, 4.6 vs. 27 percent, RR 0.17, 95% CI 0.04 to 0.70; stage II only 0 vs. 27 percent, RR 0.04, 95% CI 0.00 to 0.66).[139]

One fair-quality trial (n=93) found use of Clinisan cleanser associated with lower risk of ulcer compared with standard soap and water in patients with incontinence at baseline (18 vs. 42 percent; RR 0.43, 95% CI 0.19 to 0.98).[142]

None of the trials reported length of stay or measures of resource utilization.

Table 13. Key Question 3: Effectiveness of lotions and cleansers for pressure ulcer prevention

Author, year Duration Quality rating	Setting	Patient Characteristics	Interventions	Ulcer Risk	Results
Cooper et al, 2001[142] Fair	5 long-term care facilities	n=93 (66 with intact skin at baseline) A vs. B Mean age 85 vs. 79 years 80% vs. 55% female	A. Clinisan cleanser (includes silicone, triclosan, benzylicum and emollients) B. Standard hospital soap	Not reported	A vs. B Incidence (among 66 patients with intact skin at baseline): 18% (6/33) vs. 42% (14/33); RR 0.43 (95% CI 0.19 to 0.98)
Declair et al, 1997[139] Mean 21 days Poor	Intensive care unit Brazil?	n = 86 A vs. B: NR Mean age: 60 years (range 26-78) Gender, race not reported	A: 1.6g EFA with linoleic acid extracted from sunflower oil, 112 IU B: 1.6 g mineral oil, 112 IU Vitamin A, 5 IU Vitamin E	A vs. B: NR Norton score: 9 (all pts.)	A vs. B Incident ulcers: 4.6% vs. 27%; p=NR PU incidence according to severity: Grade I: 4.6% vs. 0%; p=NR Grade II: 0% vs. 27%; p=NR
Duimel- Peeters et al, 2007[140] Two 4-week periods, with 2-week washout (Same study population as Houwing et al, 2008[141]) Poor	8 nursing homes Holland	n = 79 Mean age: 81.3 years 70% female Race not reported	A: 2-3 minute massage with a 5% DMSO cream, and repositioning every 6 hours B: 2-3 minute massage with an indifferent cream (cremor vaselini cetomacrogolis FNA), and repositioning every 6 hours C: Repositioning every 6 hours	A vs. B vs. C: NR Braden score, all ≤ 20 Mean BMI: 21.7	A vs. B vs. C <u>Treatment period 1</u> Incident ulcers: 62.1% vs. 41.9% vs. 38.9%; p=0.189 AOR: 2.57 (p=0.126) vs. 1.14 (p=0.834) vs. 0.64 (p=0.35) <u>Treatment period 2</u> Incident ulcers: 12.0% vs. 13.6% vs. 5.9%; p=0.726 AOR: 2.18 (p=0.516) vs. 2.53 (p=0.441) vs. 0.06 (p=0.007)
Houwing et al, 2008[141] 4 weeks (Same study population as Duimel-Peeters et al, 2007[140]) Poor	8 nursing homes Holland	n = 79 A vs. B vs. C Median age 81 vs. 85 vs. 82 years 62% vs. 75% vs. 72% female Race not reported	A: 30° tilt repositioning with massage using 5% DMSO cream B: 30° tilt repositioning every 6 hours, plus 3-minute massage of the buttock, heel, and ankle with an indifferent cream (Vaseline-cetomacrogol) every 6 hours C: 30° tilt repositioning every 6 hours	A vs. B vs. C Incontinence (sometimes/ always): 100% vs. 93.8% vs. 83.3%	A vs. B vs. C Incident ulcers, all locations: 62.1% (18/29) vs. 31.3% (10/32) vs. 38.9% (7/18); OR 3.89 (95% CI 1.41-10.7) Incident ulcers, buttocks: 37.9% (11/29) vs. 21.9% (7/32) vs. 33.3% (6/18); OR 1.87 (95% CI 0.66-5.30) Incident ulcers, heel/ankle: 55.1% (16/29) vs. 15.6% (5/32) vs. 16.6% (3/18); OR 8.80 (95% CI 2.61-29.6)

Author, year Duration Quality rating	Setting	Patient Characteristics	Interventions	Ulcer Risk	Results
Smith et al, 1986[137] 24 weeks Poor	6 Long-term care facilities United Kingdom	n = 258 A vs. B Mean age: 82 vs. 83 years 81% vs. 82% female Race not reported	A: Conotrane (20% dimethicone 350 and .05% hydrargaphen) B: Unguentum (description NR)	NR	A vs. B Incident ulcers by pt.: 27.1% vs. 36.4%; p<0.05 Total incidence of PU: 84 vs. 109, p<0.05 By severity score (Barbarel et al): Grade I: 5.4% vs. 8.5%; p=NR Grade II: 17.8% vs. 24.0%; p=NR Grade III: 3.9% vs. 3.1%; p=NR Grade IV: 0% vs. .8%; p=NR
van der Cammen et al, 1987[138] 3 weeks Poor	Hospital (geriatric wards) United Kingdom	n = 104 A vs. B Mean age: 82 vs. 83 years 74% female in both groups Race not reported	A: Prevasore cream B: Dermalex cream	A vs. B Mean Norton score at entry: 11.4 vs. 11.5 Mean Norton score at 3 weeks: 13.4 vs. 13.9	A vs. B Direct comparisons between treatment groups was not significant (data not shown) By the end of week 3, 87% of Prevasore patients and 78% of Dermalex patients showed no deterioration or improvement (p=NS)

Abbreviations: CI, confidence interval; DMSO, dimethyl sulfoxide; NR, not reported; NS, not significant; OR, odds ratio; PU, pressure ulcer; RR, relative risk..
Note: Pressure Ulcer Risk Assessment general cutoffs for at risk:
Braden scores <15-18. Lower scores indicate higher pressure ulcer risk.
Cubbin and Jackson score <29. Lower scores indicate higher pressure ulcer risk.
Norton scores <12-16. Lower scores indicate higher pressure ulcer risk.
Waterlow scores >10-15. Higher scores indicate higher pressure ulcer risk.

Key Question 3a. Does the effectiveness and comparative effectiveness of preventive interventions differ according to risk level as determined by different risk assessment methods and/or by particular risk factors?

Key Points

Lower Risk Populations

Static Support Surfaces

- Two trials (one good- and one fair-quality; n=175 and 413) found use of a static foam overlay associated with increased risk or a trend towards increased risk of pressure ulcers compared with standard care in lower-risk surgical patients (OR 1.9, 95% CI 1.0 to 3.7 and RR 1.6, 95% CI 0.76 to 3.3) (strength of evidence: moderate).
- Two trials (one good- and one poor-quality; n=416 and 505) found a static dry polymer overlay associated with decreased risk of pressure ulcers compared with standard care in lower-risk surgical patients (strength of evidence: low).
- One poor-quality trial (n=1,729) found no significant difference between a static foam block mattress and standard hospital mattress support surfaces in pressure ulcer incidence (strength of evidence: insufficient).

Dynamic Support Surfaces

- Two trials (one good- and one poor-quality; n=198 and 217) found no differences between dynamic compared with static support surfaces in risk of pressure ulcer incidence or severity (strength of evidence: low).

Detailed Synthesis

No studies directly evaluated the effectiveness or comparative effectiveness of prevention interventions in patients stratified by risk level. Most trials evaluated higher-risk patients and are summarized above (see Key Question 3).

Seven trials (n=175 to 505) evaluated pressure ulcer preventive interventions in lower-risk patients undergoing surgery (Table 14; Appendix H11 and H12).[118-124] Patients were lower-risk based on pressure ulcer risk assessment scores, using the Braden (score ≥20),[121, 123] Norton (score ≥20),[119] modified Knoll (score≤4)[118, 122] or modified Ek (score 3-4) scales.[124] In all but one study, interventions were given in the operating room and three studies[118, 122] continued interventions into the post-operative period. In the other study, it is unclear if interventions were given in the operating room and post-operatively, or just post-operatively.[124] Post-operative followup ranged from 5 to 8 days, apart from one study that only evaluated patients in the immediate post-operative period[120] and one study that did not report mean study duration.[124] Four trials[119-121, 123] compared various static mattresses or overlays compared with standard operating room care and two compared a dynamic mattress to a static mattress.[118, 122] Two trials were rated good-quality,[122, 123] two fair-quality,[119, 121] and three poor-quality.[118, 120, 124] Methodological shortcomings in the poor-quality trials included inadequate randomization,

unclear methods of allocation concealment, and failure to blind outcome assessors. No trials reported length of stay or other resource utilization outcomes by treatment group.

Table 14. Key Question 3a: Effectiveness of pressure ulcer prevention support surfaces in low-risk patients

Author, year Quality rating	Setting Followup	Intervention	Baseline Demographics	Method of Risk Assessment Baseline Score	Results – Incidence and Severity
Static vs. Static					
Schultz et al, 1999[123] Good	Operating room 6 days post-op	A. Static: Foam overlay + heel and elbow protectors (n=206)B. Static: Standard perioperative care (n=207)	n=413A vs. B: Mean age: 66 vs. 66 years 35% vs. 36% women Mean BMI 27.06 vs. 27.03 Smoking status -Never 26% vs. 25% Past 50% vs. 52% Current 23% vs. 22% Diabetes: 22% vs. 24%	Braden Mean 22 for both groups	Incidence, A vs. B 27% (55/206) vs. 16% (34/207), p=0.02 OR 1.93 (95% CI 1.02 to 3.68) Severity, A vs. B ≥Grade II: 3% (6/206) vs. 1% (3/207), p=0.5 RR 2.01 (CI 0.51 to 7.93)
Feuchtinger et al, 2006[119] Fair	Operating room 5 days post-op	A. Static: Water-filled warming mattress + 4-cm thermoactive viscoelastic foam overlay (n=85) B. Static: Water-filled warming mattress alone (n=90)	n=175 A vs. B: Mean age 68 vs. 68 years 32% vs. 26% female Mean BMI 27.2 vs. 26.2 Mean time on OR table 5.8 hours vs. 5.6 hours	Norton Mean 22 for both groups	Incidence, A vs. B 18% (15/85) vs. 11% (10/90); p=0.22 RR 1.59 (CI 0.76 to 3.34) Severity, A vs. B Grade I ulcers: 15% (13/85) vs. 10% (9/90); p=0.4 RR 1.53 (CI 0.69 to 3.39) Grade II ulcers: 2% (2/85) vs. 1% (1/90); p=0.97 RR 2.12 (CI 0.2 to 22.93)
Nixon et al, 1998[121] Fair	Operating room 8 days post-op	A. Static: Dry visco-elastic polymer pad + standard operating table mattress (n=222) B. Static: Standard operating table mattress+ heel support (n=224)	n=416 A vs. B: 56% vs. 57% age 55-69 years 44% vs. 43% age ≥70 years 45% vs. 48% female Operating time - 23% vs. 18% <90 minute 49% vs. 49% 90-179 minutes 28% vs. 33% >180 minutes	Braden, Mean ≥20, A vs. B: 91% (202/222) vs. B 89% (200/224)	Incidence, A vs. B: 11% (22/205) vs. 20% (43/211) OR 0.46 (95% CI 0.26 to 0.82); p=0.01

Author, year Quality rating	Setting Followup	Intervention	Baseline Demographics	Method of Risk Assessment Baseline Score	Results – Incidence and Severity
Berthe et al, 2007[124] Poor	Hospital Unclear followup	A: Kliniplot foam block mattress (n=657) B: Standard hospital mattress (n=1072)	NR	Modified Ek Score (1-4) 87% low risk, no significant difference between groups	Incidence of pressure ulcers, A vs. B 3.2% (21/657) vs. 1.9% (21/1072); RR 1.63, 95% CI 0.90 to 2.96)
Hoshowsky et al, 1994[120] Poor	Operating room Immediate post-op period	A. Static: Viscoelastic dry polymer mattress overlay (n=unclear) B. Static: Nylon fabric covered 2-inch thick foam and gel OR table mattress (n=unclear) C. Static: Standard vinyl covered 2-inch thick foam or table mattress (n=unclear)	n=505 Mean age: 47 years 64% female 6% vascular disease 20% hypertension 8% diabetes mellitus 24% current smokers 2% past smokers (*Demographic data not stratified by intervention group)*	Hemphill's Guidelines for Assessment of Pressure Sore Potential (score 0-12= low risk) Mean not reported	Incidence A vs. B and C: OR 0.40 (CI 0.21 to 0.77; p<0.006)
Dynamic vs. Static					
Russell et al, 2000[122] Good	Operating room 7 days post-op	A. Dynamic: MicroPulse system in the OR and postoperatively (n=98) B. Static: Conventional care (n=100)	n=198 A vs. B: Mean age 65 vs. 65 years 23.5% vs. 25% female Race - 94.9% vs. 87.0% white 0 vs. 1.0% black 2.0% vs. 2.0% Asian 0 vs. 3.0% Hispanic 3.1% vs. 7.0% other Mean hours in surgery: 4.1 vs. 4.2	Modified Knoll Mean 4 in both groups	Incidence, A vs. B 2% (2/98) vs. 7% (7/100); p=0.18 RR 0.29 (CI 0.06 to 1.37) Severity, A vs. B Grade I: 0% (0/98) vs. 2% (2/100); p=0.57 RR 0.21 (CI 0.01 to 4.28) Grade II: 2% (2/98) vs. 5% (5/100); p=0.49 RR 0.41 (CI 0.08 to 2.05) Grade III: 0% (0/98) vs. 3% (3/100); p=0.32 RR 0.15 (CI 0.008 to 2.9)

Author, year Quality rating	Setting Followup	Intervention	Baseline Demographics	Method of Risk Assessment Baseline Score	Results – Incidence and Severity
Aronovitch et al, 1999[118] Poor	Operating room 7 days post-op	A. Dynamic: Alternating pressure system (n=105) B. Static: Conventional management (n=112)	n=217 A vs. B: Mean age 64 vs. 65 years 28% vs. 26% female Race- 96% vs. 92% white 4% vs. 7% black 0 vs. 1% Hispanic <1% vs. 0 other Duration of surgery 5 vs. 5 hours	Modified Knoll Risk Mean <4 for both groups	Incidence, A vs. B 1% (1/112) vs. 7% (7/105); p=0.07 RR 0.14 (CI 0.02 to 1.14)

Abbreviations: CI, confidence interval; NR, not reported; RR, relative risk.

Static compared with Static Support Surfaces

Static mattresses or overlays were compared with standard operating room mattresses in one good-quality, [123] two fair-quality[119, 121] and two poor-quality trials (Table 14).[120, 124] Two trials (n=175 and 413) found addition of a foam overlay to a standard operating mattress associated with increased risk of pressure ulcers (27 vs. 16 percent, OR 1.9, 95% CI 1.0 to 3.7)[123] or trend towards increased risk (18 vs. 11 percent, RR 1.6, 95% CI 0.76 to 3.3)[119] after five to six days, compared with a standard operating mattress alone. In both trials, about 90 percent of the ulcers were stage I and the remainder stage II, based on the AHCPR or EPUAP grading systems.

One fair-quality trial (n=416) found addition of a dry polymer overlay to a standard operating room mattress associated with decreased risk of incident pressure ulcers compared with standard care (11 vs. 20 percent, OR 0.46; 95% CI 0.26 to 0.82), based on assessments one day after surgery.[121] Most (86 percent) of ulcers were blanching erythema, with no cases of frank ulceration. A poor-quality trial also found a dry polymer overlay in the operating room associated with decreased risk of subsequent ulcers.[120]

A poor-quality trial found no difference in development of post-operative pressure ulcers in groups receiving a foam block mattress or a standard hospital mattress (3.2 vs. 1.9 percent; RR 1.6; 95% CI 0.90 to 3.0).[124]

Dynamic compared with Static Support Surfaces

One good-quality trial[122] and one poor-quality trial[118] compared dynamic support surfaces in the operating room compared with static, usual care surfaces and followed patients for 7 days post-operatively (Table 14). The good-quality trial found no statistically significant difference in pressure ulcer incidence or severity between the MicroPulse mattress system (in the operating room and continued post-operatively) compared with standard care, though there was a trend towards decreased risk with the dynamic system (2 vs. 7 percent for any ulcer, RR 0.29, 95% CI 0.06 to 1.4; 2 vs. 5 percent for stage II ulcer, RR 0.41, 95% CI 0.08 to 2.0).[122] A poor-quality trial reported a similar trend towards decreased risk of pressure ulcers with an alternating pressure system compared with standard operating room care (1 vs. 7 percent, RR 0.14, 95% CI 0.02 to 1.1).[118]

Key Question 3b. Does the effectiveness and comparative effectiveness of preventive interventions differ according to setting?

- No study evaluated how effectiveness of preventive interventions varies according to care setting (strength of evidence: insufficient).

No study directly evaluated how effectiveness of preventive interventions varies according to care setting. Due to small numbers of studies, differences in interventions and comparisons, and methodological limitations in the studies, it was not possible to assess how effectiveness or comparative effectiveness of preventive interventions varies according to care setting based on indirect comparisons across studies. Studies of low-risk surgical patients are reviewed elsewhere

(see Key Question 3a). Intraoperative warming therapy was also specifically evaluated in surgical patients.[135]

Key Question 3c. Does the effectiveness and comparative effectiveness of preventive interventions differ according to patient characteristics?

- No study evaluated how effectiveness of preventive interventions varies in subgroups defined by patient characteristics (strength of evidence: insufficient).

No study directly evaluated how effectiveness of preventive interventions varies in subgroups defined by patient characteristics. Due to small numbers of studies, differences in interventions and comparisons, and methodological limitations in the studies, it was not possible to assess how effectiveness or comparative effectiveness of preventive interventions varies according to patient characteristics based on indirect comparisons across studies.

Key Question 4. What are the harms of interventions for the prevention of pressure ulcers?

Key Points

- Seven of 39 trials of support surfaces reported harms (strength of evidence: low).
  - Three trials (n=297 to 588) reported cases of heat-related discomfort with sheepskin overlays, with one trial reporting increased risk of withdrawal due to heat discomfort compared with a standard mattress (5 vs. 0 percent, RR 0.95, 95% CI 0.93 to 0.98).
  - One trial (n=39) that compared different dynamic mattresses reported some differences in pain and sleep disturbance.
  - One trial (n=198) reported no differences in risk of adverse events between a multi-cell pulsating dynamic mattress compared with a static gel pad overlay.
  - One trial (n=239) of heel ulcer preventive interventions reported no difference in risk of adverse events between the Heelift Suspension Boot and standard care in hip fracture patients.
  - One trial (n=141) reported found a urethane and gel wheelchair pad (Jay cushion) associated with increased risk of withdrawal due to discomfort due to a standard foam wheelchair pad (8 vs. 1 percent, RR 0.94, 95% CI 0.88 to 1.0).
- Two (n=46 and 838) of three trials of repositioning interventions reported harms. Both trials reported more nonadherence due to intolerability of a 30 degree tilt position compared with standard positioning (strength of evidence: low).
- Three (n=93 to 203) of five trials of lotions or creams reported harms. One trial found no differences in rash between different creams and two trials each reported one case of a wet sore or rash (strength of evidence: low).
- One (n=37) of two trials of dressings reported harms. One trial reported that application of the REMOIS pad resulted in pruritus in one patient (strength of evidence: low).

Harms were reported in only 13[85, 88, 94, 97, 112, 122, 130, 132, 134, 137, 138, 142, 143] of 54 trials of preventive interventions. Of the trials reporting harms, few provided detailed information on specific harms, several only described single cases of harms, and none reported serious treatment-related harms.

Detailed Synthesis

Support Surfaces

Seven[85, 88, 94, 97, 112, 122, 143] of 39 trials of support surfaces reported harms (Table 15; Appendix H11 and H12). Three trials reported cases of heat-related discomfort with a sheepskin overlay, leading to some withdrawals in two trials.[94, 97, 112] The only trial to report quantitative data found the sheepskin overlay associated with increased risk of withdrawal due to discomfort compared to a standard mattress (5 vs. 0 percent; RR 0.95, 95% CI 0.93 to 0.98).[94]

One trial that compared dynamic mattresses reported less pain on the Nimbus II ($p<0.05$) and Quattro DC2000 ($p<0.01$) mattresses compared with the Pegasus Airwave Mattress.[143] The same trial reported less sleep disturbance with the Quattro DC2000 compared with the Nimbus II ($p<0.05$) and Pegasus Airwave ($p<0.01$). Another trial reported no differences in risk of adverse events between a multi-cell, pulsating dynamic mattress compared with a static gel pad overlay, but data were not reported.[122]

One trial of heel ulcer preventive interventions reported no difference in risk of adverse events between the Heelift Suspension Boot and standard care in hip fracture patients (20 vs. 23 adverse events, $p=0.69$; proportion of patients with adverse events not reported).[85]

One trial reported found a urethane and gel wheelchair pad (Jay cushion) associated with increased risk of withdrawal due to discomfort compared to a standard foam wheelchair pad (8 vs. 1 percent, RR 0.94, 95% CI 0.88 to 1.00).[88]

Table 15. Key Question 4: Harms of interventions for the prevention of pressure ulcers

Author, year Quality rating	Population	Intervention	Harms
Support surfaces			
Donnelly et al, 2011[85] Good	n=239 Hospital acute care patients	A: Heelift Suspension Boot B: Usual care	A vs. B Total adverse events: 20[a] vs. 23[a]; p=0.69
Russell et al, 2000[122] Good	n=198 Hospital acute surgical care	A. MicroPulse system in the OR and postoperatively B. Conventional care (gel pad in OR, standard mattress postoperatively)	A vs. B Adverse events: no difference between groups; no adverse events were treatment-related (no data reported)
Conine et al, 1994[88] Fair	n=141 Wheelchair users	A. Jay cushion: the Jay cushion is a contoured urethane foam base with gel pad over top B. Foam cushion: 32 kg/m3 density foam bevelled at the bottom to prevent sling effect	A vs. B Withdrawals due to discomfort: 8% (6/80) vs. 1% (1/83); RR 0.94 (95% CI 0.88 to 1.00)
Jolley et al, 2004[94] Fair	n=441 Hospital acute care patients	A. Sheepskin mattress overlay: leather-backed with a dense, uniform 25 mm wool pile B. Usual care	A vs. B Withdrawals due to heat-related discomfort: 5% (10/218) vs. 0% (0/223; RR 0.95, 95% CI 0.93 to 0.98)
Mistiaen et al, 2010[97] Fair	n=588 Nursing home patients	A. Australian Medical Sheepskin overlay B. Standard mattress	One-third of group A patients complained of heat-related discomfort, leading to withdrawal for 2/3 of these patients; no incidence in group B (no data reported)
Pring et al, 1998[143] Fair	n=39 Long-term care patients	A: Nimbus II mattress B: Pegasus Airwave mattress C: Quattro DC2000 mattress	A vs. B vs. C Pain: A ($p<0.05$) and C ($p<0.01$) < B Sleep disturbance: C < A ($p<0.05$) and B ($p<0.01$)
McGowan et al, 2000[112] Poor	n=297 Hospital acute care patients	A. Australian Medical Sheepskin overlay; sheepskin heel and elbow protectors as required. B. Standard hospital mattress	Heat-related discomfort reported in unspecified number of group A patients; no incidence in group B (no data reported)
Repositioning			
Defloor et al, 2005[130] Good	n=838 Nursing home patients	A: 2-hour turning B: 3-hour turning C: 4-hour turning D: 6-hour turning E. Usual care	Noted that not all patients in a 30 degree tilt position remained as such for the required amount of time per positioning schedule, but no details are provided about the reasons for the protocol violations
Young et al, 2004[132] Fair	n=46 Hospital acute care patients	A: 30 degree tilt repositioning B: Standard repositioning	A vs. B Difficulty tolerating positioning: 87% (20/23) vs. 24% (5/21); RR 0.17, 95% CI 0.06 to 0.51

Author, year Quality rating	Population	Intervention	Harms
Lotions, creams and cleansers			
Cooper et al, 2001[142] Fair	n=93 Long-term care patients	A. Clinisan cleanser (includes silicone, triclosan, benzylicum and emollients) B. Standard hospital soap	A vs. B Withdrawals: 7% (3/44) vs. 6% (3/49) Withdrawals due to adverse events: 2% (1/44) vs. 0% (0/49)
Smith et al, 1986[137] Poor	n=203 Long-term care patients	A: 20% dimethicone 350 and 0.05% hydrargaphen (Conotrane) B: placebo (Unguentum)	A vs. B Skin redness: 4% (4/104) vs. 6% (6/99); RR 1.02, 95% CI 0.96 to 1.09 Rash: 0% vs. 1% (1/99); RR 1.01, 95% CI 0.98 to 1.04 Withdrawals: 4% (4/104) and 5% (5/99); RR 0.99, 95% CI 0.95 to 1.04
van der Cammen et al, 1987[138] Poor	n=128 Wheelchair users	A: Prevasore cream B: Dermalex cream	A vs. B Development of wet sore: 2% (1/60) vs. 0% (0/60)
Dressings			
Nakagami et al, 2007[134] Poor	n=37 Long-term care patients	A: REMOIS dressing: a skin adhesive layer (hydrocolloid), a support layer (urethane film), outer layer of multifilament nylon fibers (intervention side) B: No dressing (control side)	A vs. B Pruritus: 3% (1/37) vs. (0/37)

Abbreviations: CI, confidence interval; RR, relative risk

[a] Denominator unclear; text reported 45 adverse events but only accounted for 43.

Repositioning

Two[130, 132] of three trials of repositioning reported harms (Table 15; Appendix H15 and H16). One trial found a 30 degree tilt repositioning position more difficult to tolerate than a standard 90 degree position (87 vs. 24 percent; RR 0.17, 95% CI 0.06 to 0.51).[132] One other trial noted that not all patients could tolerate a 30 degree tilt position for the intended amount of time, but details regarding protocol violations were not reported.[130]

Creams, Lotions, and Cleansers

Three[137, 138, 142] of five trials of lotions reported harms (Table 15; Appendix H21 and H22). One trial found no differences between a silicone and antiseptic cream (Conotrane) and a placebo cream (Unguentine) in risk of redness (4 vs. 6 percent; RR 1.02, 95% CI 0.96 to 1.09), rash (0 vs. 1 percent; RR 1.01, 95% CI 0.98 to 1.04), or withdrawals due to redness or rash (3 vs. 2 percent; RR 0.99, 95% CI 0.95 to 1.04).[137] Two other trials of lotions or creams reported blisters or a wet sore in one patient each.[138, 142]

Dressings

One of two trials of dressings reported harms. It reported pruritus in one patient following application of the REMOIS pad (Table 15; Appendix H19 and H20).[134]

Key Question 4a. Do the harms of preventive interventions differ according to the type of intervention?

- No study evaluated how harms of preventive interventions vary according to the type of intervention (strength of evidence: insufficient).

No study directly compared harms in different categories of interventions (e.g., dressings vs. repositioning or support surfaces vs. lotions) or presumed mechanism of action (e.g., nutritional support vs. relief of pressure vs. skin protection). Across studies, reporting of harms was too limited (see Key Question 4) to draw conclusions about how harms may differ according to the type of intervention.

Key Question 4b. Do the harms of preventive interventions differ according to setting?

- No study evaluated how harms of preventive interventions vary according to care setting (strength of evidence: insufficient).

No study directly evaluated how estimates of harms varied according to care setting. Across studies, reporting of harms was too limited (see Key Question 4) to draw conclusions about how harms may differ according to care setting.

Key Question 4c. Do the harms of preventive interventions differ according to patient characteristics?

- No study evaluated how harms of preventive interventions vary in subgroups defined by patient characteristics (no evidence).

No study directly evaluated harms of preventive interventions in subgroups defined by specific patient characteristics such as underlying risk level, specific risk factors, or other factors. Across studies, reporting of harms was too limited (see Key Question 4a) to draw conclusions about how harms may differ according to care setting.

Discussion

Summary

Table 16 summarizes the findings of this review. Details about the factors used to determine the overall strength of evidence for each key question are shown in Appendix F.

Evidence on optimal methods to prevent pressure ulcers was extremely limited in a number of areas, including the effects of use of risk assessment instruments on the subsequent incidence of pressure ulcers and benefits of preventive interventions other than support surfaces. Evidence on harms of preventive interventions was extremely sparse, with most trials not reporting harms at all, and poor reporting of harms in those that did. Nonetheless, serious harms seem rare, consistent with what might be expected given the generally non-invasive nature of most of the preventive interventions evaluated (skin care, oral nutritional support, repositioning, and support surfaces). In addition, limited evidence was available to evaluate how the diagnostic accuracy of risk assessment instruments or benefits and harms of preventive interventions might vary depending on differences in setting, patient characteristics, or other factors. Very few studies directly assessed how estimates varied according to these factors, and indirect comparisons across trials were not possible due to small numbers of studies, differences in interventions and comparisons, and methodological shortcomings.

Only one good- and two poor-quality studies[13, 45, 46] attempted to evaluate the effects of standardized use of a risk assessment instrument on the incidence of pressure ulcers. The good-quality trial found no difference in risk of pressure ulcers or length of stay in patients assessed with the Waterlow scale, the Ramstadius tool, or clinical judgment alone.[13] The two poor-quality studies evaluated the modified Norton scale[45] and the Braden scale,[46] with only a non-randomized study of the Norton scale[45] finding reduced risk of pressure ulcer compared with clinical judgment.[13, 45, 46]

Studies of diagnostic accuracy found that commonly used risk assessment instruments (such as the Braden, Norton, and Waterlow scales) can identify patients at increased risk for ulcers who might benefit from more intense or targeted interventions. Furthermore, diagnostic accuracy may have been underestimated in these studies if patients at higher risk were more likely to receive effective interventions to prevent ulcers. No study that reported risk estimates attempted to control for potential confounding effects of differential use of interventions. There was no clear difference between commonly used risk assessment instruments in diagnostic accuracy, though direct comparisons were limited.[20, 21, 25, 41, 70, 73]

About three-quarters of the trials of preventive interventions focused on evaluations of support surfaces. In higher-risk populations, fair-quality randomized trials consistently found more advanced static support surfaces associated with lower risk of pressure ulcers compared with standard mattresses in higher-risk patients (relative risk [RR] range 0.20 to 0.60),[91, 93, 94, 97, 100] with no clear differences between different advanced static support surfaces.[92, 95, 96, 101, 104, 105, 115] Evidence on the effectiveness and comparative effectiveness of other support surfaces, including more advanced dynamic support surfaces, was limited, with some trials[86, 106] showing no clear differences between dynamic and static support surfaces. One fair-quality trial found stepped care with dynamic support surfaces associated with substantially decreased risk of ulcers compared with stepped care with static support surfaces,[89] suggesting that this might be both an effective as well as efficient approach, since care was initiated with the least expensive alternatives. In lower-risk populations of patients undergoing surgery, two trials found use of a foam overlay associated with an increased risk or trend towards increased risk of pressure ulcers

compared with a standard operating room mattress.[119, 123] The few trials that evaluated length of stay found no differences between various support surfaces.[93, 94, 98, 99, 110, 111, 114]

Evidence on other preventive interventions (nutritional supplementation; repositioning; pads and dressings; lotions, creams, and cleansers; and intraoperative warming therapy for patients undergoing surgery) was very sparse and insufficient to reach reliable conclusions. In addition, most trials had important methodological shortcomings. An exception was repositioning, for which the trials were of somewhat higher quality, but limited to only three trials reporting somewhat inconsistent results.[130-132] One trial found a repositioning intervention was more effective than usual care in preventing pressure ulcers.[131] Although other trials of repositioning did not clearly find decreased risk of pressure ulcers compared with usual care, the usual care control group incorporated standard repositioning practices (i.e., the trials compared more intense repositioning with usual repositioning, not vs. no repositioning). A recently completed trial of repositioning, consisting of high-risk and moderate-risk arms that are randomized to repositioning at 2-, 3-, or 4-hour intervals, should provide more rigorous evidence on the effectiveness of repositioning.[144]

Table 16. Summary of evidence

Key Question	Strength of Evidence	Conclusion
Key Question 1. For adults in various settings, is the use of any risk assessment tool effective in reducing the incidence or severity of pressure ulcers, compared with other risk assessment tools, clinical judgment alone, and/or usual care?		
Pressure ulcer incidence or severity: Waterlow scale vs. clinical judgment	Low	One good-quality, randomized trial (n=1231) found no difference in pressure ulcer incidence between patients assessed with either the Waterlow or Ramstadius scales compared with clinical judgment alone (RR 1.4, 95% CI 0.82 to 2.4 and RR 0.77, 95% CI 0.44 to 1.4, respectively).
Pressure ulcer incidence or severity: Norton scale vs. clinical judgment	Insufficient	One poor-quality, nonrandomized study (n=240) found use of a modified version of the Norton scale to guide use of preventive interventions associated with lower risk of pressure ulcers compared with nurses' clinical judgment alone (RR 0.11, 95% CI 0.03 to 0.46).
Pressure ulcer incidence or severity: Braden scale vs. clinical judgment	Insufficient	One poor-quality, cluster randomized trial (n=521) found no difference between training in and use of the Braden score vs. nurses' clinical judgment in risk of incident pressure ulcers, but included patients with prevalent ulcers.
Key Question 1a. Does the effectiveness and comparative effectiveness of risk assessment tools differ according to setting?	Insufficient	No study evaluated how effectiveness of risk assessment tools varies according to care setting.
Key Question 1b. Does the effectiveness and comparative effectiveness of risk assessment tools differ according to patient characteristics, and other known risk factors for pressure ulcers, such as nutritional status or incontinence?	Insufficient	No study evaluated how effectiveness of risk assessment tools varies in subgroups defined by patient characteristics.
Key Question 2. How do various risk assessment tools compare with one another in their ability to predict the incidence of pressure ulcers?		
Diagnostic accuracy: Braden Scale	Moderate	In two good- and five fair-quality studies, the median AUROC for the Braden scale was 0.77 (range 0.55 to 0.88). In sixteen studies, based on a cutoff of ≤18, the median sensitivity was 0.74 (range 0.33 to 1.0) and median specificity 0.68 (range 0.34 to 0.86).
Diagnostic accuracy: Norton scale	Moderate	In three studies (one good- and two fair quality), the median AUROC for the Norton scale was 0.74 (range 0.56 to 0.75). In five studies, using a cutoff of ≤14, median sensitivity was 0.75 (range 0.0 to 0.89) and median specificity 0.68 (range 0.59 to 0.95).

Key Question	Strength of Evidence	Conclusion
Diagnostic accuracy: Waterlow scale	Moderate	In four studies (one good- and three-fair quality), the median AUROC for the Waterlow scale was 0.61 (range 0.54 to 0.66). In two studies, based on a cutoff of ≥10, sensitivities were 0.88 and 1.0 and specificities 0.13 and 0.29.
Diagnostic accuracy: Cubbin and Jackson scale	Moderate	In three studies (one good- and two fair-quality), the median AUROC for the Cubbin and Jackson scale was 0.83 (range 0.72 to 0.90). In three studies, based on a cutoff of ≤24 to 29, median sensitivity was 0.89 (range 0.83 to 0.95) and median specificity was 0.61 (0.42 to 0.82).
Diagnostic accuracy: Direct comparisons between risk assessment scales	Moderate	In two good- and four fair-quality studies that directly compared risk assessment tools, there were no clear differences between scales based on the AUROC.
Key Question 2a. Does the predictive validity of various risk assessment tools differ according to setting?		
Diagnostic accuracy: Braden scale, across settings	Low	One fair-quality study found a Braden scale score of ≤18 associated with similar sensitivities and specificities in acute care and skilled nursing settings. Twenty-eight studies (10 good-, 16 fair- and 2 poor-quality) that evaluated the Braden scale in different settings found no clear differences in the AUROC or in sensitivities and specificities at standard (≤15 to 18) cutoffs.
Diagnostic accuracy: Cubbin and Jackson, ICU setting	Low	Two studies (one good- and one fair-quality) found the Cubbin and Jackson scale associated with similar diagnostic accuracy compared with the Braden or Waterlow scales in intensive care patients.
Diagnostic accuracy: Braden scale, optimal cutoff in different settings	Low	One good-quality study reported a lower optimal cutoff on the Braden scale in an acute care setting (sensitivity 0.55 and specificity 0.94 at a cutoff of ≤15) than a long-term care setting (sensitivity 0.57 and specificity 0.61 at a cutoff of ≤18), but the statistical significance of differences in diagnostic accuracy was not reported. Two studies of surgical patients (one good- and one fair-quality) found lower optimal cutoff scores than observed in studies of patients in other settings.
Key Question 2b. Does the predictive validity of various risk assessment tools differ according to patient characteristics?		
Diagnostic accuracy: Braden scale, differences according to race	Low	One fair-quality study reported similar AUROCs for the Braden scale in black and white patients in acute care or skilled nursing settings.
Diagnostic accuracy: Braden scale, differences according to baseline pressure ulcer risk	Moderate	Three studies (one good- and two fair-quality) found no clear difference in AUROC estimates based on the presence of higher or lower mean baseline pressure ulcer risk scores.

Key Question	Strength of Evidence	Conclusion
Key Question 3. In patients at increased risk of developing pressure ulcers, what is the effectiveness and comparative effectiveness of preventive interventions in reducing the incidence or severity of pressure ulcers?		
Pressure ulcer incidence or severity: Static support surface vs. standard mattress	Moderate	Five fair-quality trials (n=83 to 543) found a more advanced static mattress or overlay associated with decreased risk of incident pressure ulcers (RR range 0.20 to 0.60) or a trend towards decreased risk (RR 0.28, 95% CI 0.06 to 1.3) compared with a standard mattress, and two of the trials found no difference in length of stay. Six poor-quality trials reported results that were generally consistent with these findings, though two trials found no benefit. The static support surfaces evaluated in the trials varied.
Pressure ulcer incidence or severity: Static support surface vs. static support surface	Moderate	Six trials (n=52 to 100, three trials fair-quality) found no differences between different advanced static support surfaces in risk of pressure ulcers. One fair-quality trial (n=40) of nursing home patients found a foam replaceable parts mattress associated with lower risk of ulcers compared with a 4 inch thick, dimpled foam overlay (25% vs. 60%, RR 0.42, 95% CI 0.18 to 0.96).
Pressure ulcer incidence or severity: More sophisticated wheelchair cushions vs. standard wheelchair cushions	Low	Four trials (n=32 to 248, three fair-quality and one poor-quality) found inconsistent evidence on effects of more sophisticated wheelchair cushions compared with standard wheelchair cushions on risk of pressure ulcers, with the largest trial finding no difference between a contoured, individually customized foam cushion compared with a slab cushion. Results are difficult to interpret because the trials evaluated different cushions.
Pressure ulcer incidence or severity: Heel ulcer prevention intervention vs. usual care	Low	One fair-quality trial (n=239) of fracture patients found the Heelift Suspension Boot associated with decreased risk of heel, foot, or ankle ulcers compared with usual care (7% vs. 26% for any ulcer, RR 0.26, 95% CI 0.12 to 0.53; 3.3% vs. 13.4% for grade II ulcers, RR 0.25, 95% CI 0.09 to 0.72), but one poor-quality trial (n=52) of hospitalized patients found no difference in risk of ulcers between a boot (Foot Waffle) and usual care (hospital pillow to prop up legs).
Pressure ulcer incidence or severity: Heel ulcer preventive intervention vs. heel ulcer preventive intervention	Insufficient	One poor-quality trial (n=240) of hospitalized patients found no differences between three different types of boots (Bunny Boot, egg-crate heel lift positioner, and Foot Waffle) in risk of ulcers, though the overall incidence of ulcers was low (5% over 3 years) and results could have been confounded by differential use of co-interventions.

Key Question	Strength of Evidence	Conclusion
Pressure ulcer incidence or severity: Dynamic vs. static support surfaces	Low	Six trials (n=32 to 487, two fair-quality and four poor-quality) that compared a dynamic alternating air pressure mattress or overlay compared with a static support surface reported somewhat inconsistent results, with one fair-quality trial showing no difference in risk of pressure ulcers and another fair-quality trial showing lower risk of pressure ulcers with initial use of dynamic support surfaces using a stepped care approach (4.3% vs. 55%, RR 0.08, 95% CI 0.01 to 0.56). One of the trials founds no difference in length of stay.
Pressure ulcer incidence or severity: Dynamic vs. dynamic support surface	Low	Two fair-quality (n=44 and 62) trials of hospitalized patients found no differences in risk of pressure ulcers or length of stay between different dynamic support surfaces, though one poor-quality trial (n=108) found an alternating double-layer air cell layer associated with decreased risk of pressure ulcers compared with an alternating single-layer overlay.
Pressure ulcer incidence or severity: Nutritional supplementation vs. standard hospital diet	Low	Three poor-quality randomized trials (n=56 to 672) reported inconsistent results for effects of oral nutritional supplementation compared with standard hospital diet on incidence of pressure ulcer risk, with two randomized trials reporting no benefit.
Pressure ulcer incidence or severity: Repositioning intervention vs. usual care	Low	One fair-quality cluster randomized trial (n=213) found repositioning at a 30-degree tilt every 3 hours associated with lower risk of pressure ulcer compared with usual care (90-degree lateral repositioning every 6 hours during the night) after 28 days (3.0% vs. 11%, RR 0.27, 95% CI 0.08 to 0.93). Two other randomized trials (n=46 and 838) evaluated repositioning interventions but only followed patients for one night or are susceptible to confounding due to differential use of support surfaces.
Pressure ulcer incidence or severity: Changing incontinence pad three vs. two times daily	Low	One fair-quality cross-over trial (n=81) found no statistically significant difference in risk of pressure ulcers between changing incontinence pads three times vs. twice a night after 4 weeks.
Pressure ulcer incidence or severity: REMOIS pad vs. no pad	Insufficient	One poor-quality randomized trial (n=37) found use of the REMOIS Pad (consisting of a hydrocolloid skin adhesive layer, a support layer of urethane film, and an outer layer of multifilament nylon) on the greater trochanter associated with decreased risk of stage I ulcers compared to no pad on the contralateral trochanter after 4 weeks (5.4% vs. 30%, RR 0.18, 95% CI 0.05 to 0.73.
Pressure ulcer incidence or severity: Intraoperative warming vs. usual care	Low	One fair-quality randomized trial (n=324) of patients undergoing major surgery found no statistically significant difference in risk of pressure ulcers between patients who received an intraoperative warming intervention (forced-air warming and warming of all intravenous fluids) compared with usual care.
Pressure ulcer incidence or severity: Corticotropin vs. sham	Insufficient	One poor-quality randomized trial (n=85) of patients undergoing femur or hip surgery found no difference in risk of pressure ulcers between those who received 80 IU of corticotrophin intramuscularly compared with a sham injection.

Key Question	Strength of Evidence	Conclusion
Pressure ulcer incidence or severity: Cream or lotion vs. placebo	Insufficient	Evidence from four poor-quality trials was insufficient to determine effectiveness of different creams or lotions for preventing pressure ulcers.
Pressure ulcer incidence or severity: Skin cleanser vs. standard soap and water	Low	One fair-quality randomized trial (n=93) found use of Clinisan cleanser associated with lower risk of ulcer compared with standard soap and water in patients with incontinence at baseline (18% vs. 42%; RR 0.43, 95% CI 0.19 to 0.98).
Key Question 3a. Does the effectiveness and comparative effectiveness of preventive interventions differ according to *risk level* as determined by different risk assessment methods and/or by particular risk factors?		
Pressure ulcer incidence or severity: Static foam overlay vs. standard care, lower-risk surgical population	Moderate	Two trials (one good- and one fair-quality) found use of a foam overlay associated with increased risk or a trend towards increased risk of pressure ulcers compared with standard care in lower-risk surgical patients (OR 1.9, 95% CI 1.0 to 3.7 and RR 1.6, 95% CI 0.76 to 3.3).
Pressure ulcer incidence or severity: Static dry polymer overlay vs. standard care, lower-risk surgical population	Low	Two trials (one good- and one poor-quality) found a dry polymer overlay associated with decreased risk of pressure ulcers compared with standard care in lower-risk surgical patients.
Pressure ulcer incidence or severity: Static foam block mattress vs. standard care, lower-risk surgical population	Insufficient	One poor-quality trial found no significant difference between a static foam block mattress and a standard hospital mattress in pressure ulcer incidence.
Pressure ulcer incidence or severity: Dynamic vs. static support surfaces, lower-risk surgical population	Low	Two trials (one good- and one poor-quality) found no differences between dynamic vs. static support surfaces in risk of pressure ulcer incidence or severity
Key Question 3b. Does the effectiveness and comparative effectiveness of preventive interventions differ according to *setting*?	Insufficient	No study evaluated how effectiveness of preventive interventions varies according to care setting
Key Question 3c. Does the effectiveness and comparative effectiveness of preventive interventions differ according to *patient characteristics*?	Insufficient	No study evaluated how effectiveness of preventive interventions varies in subgroups defined by patient characteristics.

Key Question	Strength of Evidence	Conclusion
Key Question 4. What are the harms of interventions for the prevention of pressure ulcers?		
Harms: Support surfaces	Low	Seven of 39 trials of support surfaces reported harms. • Three trials (n=297 to 588) reported cases of heat-related discomfort with sheepskin overlays, with one trial reporting increased risk of withdrawal due to heat discomfort compared with a standard mattress (5% vs. 0%, RR 0.95, 95% CI 0.93 to 0.98). • One trial (n=39) that compared different dynamic mattresses reported some differences in pain and sleep disturbance. • One trial (n=198) reported no differences in risk of adverse events between a multi-cell, pulsating dynamic mattress compared with a static gel pad overlay. • One trial (n=239) of heel ulcer preventive interventions reported no difference in risk of adverse events between the Heelift Suspension Boot and standard care in hip fracture patients. • One trial (n=141) reported a urethane and gel wheelchair pad (Jay cushion) associated with increased risk of withdrawal due to discomfort compared to a standard foam wheelchair pad (8% vs. 1%, RR 0.94, 95% CI 0.88 to 1.0).
Harms: Repositioning	Low	Two (n=46 and 838) of three trials of repositioning interventions reported harms. Both trials reported more nonadherence due to intolerability of a 30 degree tilt position compared with standard positioning.
Harms: Lotions and creams	Low	Three (n=93 to 203) of five trials of lotions or creams reported harms. One trial found no differences in rash between different creams and two trials each reported one case of a wet sore or rash.
Harms: Dressings	Low	One (n=37) of two trials of dressings reported harms. It reported that application of the REMOIS pad resulted in pruritus in one patient.
Key Question 4a. Do the harms of preventive interventions differ according to the type of intervention?	Insufficient	No study evaluated how harms of preventive interventions vary according to the type of intervention.
Key Question 4b. Do the harms of preventive interventions differ according to setting?	Insufficient	No study evaluated how harms of preventive interventions vary according to care setting.
Key Question 4c. Do the harms of preventive interventions differ according to patient characteristics?	Insufficient	No study evaluated how harms of preventive interventions vary in subgroups defined by patient characteristics

Abbreviations: AUROC, area under the receiver operator characteristic; CI, confidence interval; OR, odds ratio; RR, risk ratio.

Findings in Relationship to What Is Already Known

Our findings of limited evidence on effects of risk assessment tools in reducing the incidence or severity of pressure ulcers are consistent with other recent systematic reviews.[145, 146] One of these reviews also evaluated the diagnostic accuracy of risk assessment tools.[146] It reported higher sensitivity and lower specificity for the Waterlow (0.82 and 0.27) compared with the Norton (0.47 and 0.62) and Braden (0.57 and 0.68) scales, but pooled data without regard for differences in cutoff scores and across study settings, and included four studies that we excluded due to retrospective design,[147] inadequate details to determine eligibility for inclusion,[148] availability only in Spanish,[149] or that we were unable to obtain.[150]

Our findings on effectiveness of preventive interventions are generally consistent with other systematic reviews that found some evidence that more advanced static support surfaces are associated with decreased risk of pressure ulcers compared with standard hospital mattresses,[8, 151] limited evidence on the effectiveness and comparative effectiveness of dynamic support surfaces,[8, 151] and limited evidence on other preventive interventions.[8, 152] All reviews noted methodological shortcomings in the trials and variability in interventions and comparisons across studies. These reviews differed from ours by including trials that enrolled patients with pre-existing ulcers and including trials published only as abstracts.

Applicability

The studies included in this review generally enrolled patients at higher risk for pressure ulcers, though eligibility criteria varied between studies. The studies are most applicable to acute care and long-term care settings, with few studies evaluating patients in community or home settings, including specific populations such as wheelchair bound people in the community. Some trials specifically evaluated lower risk patients undergoing surgery and were reviewed separately (see Key Question 3a). Although black patients and Hispanics represent the fastest growing populations of frail elderly in the United States, these populations were severely underrepresented in the studies.[153]

Another important issue in interpreting the applicability of this review is that patients in studies of diagnostic accuracy as well as in studies of interventions generally received standard of care treatments. For example, no study of diagnostic accuracy blinded caregivers to the results of risk assessment scores, which would be expected to lead to the use of more intensive preventive interventions and care in higher-risk people. If such interventions are truly effective, they would be expected to result in underestimates of pressure ulcers. For trials of preventive interventions, usual care includes repositioning every 2 to 4 hours, skin care, standard nutrition, and standard support surfaces. Therefore, most trials of preventive interventions represent comparisons of more intensive interventions plus multi-component standard care compared with standard care alone, rather than compared with no care. One factor that may affect applicability is that the more intensive preventive interventions evaluated in many of the studies included in this review may require additional training or resources.

Evidence to evaluate potential differences in comparative benefits or harms in patient subgroups based on baseline pressure ulcer risk, specific risk factors for ulcers, setting of care, and other factors was very limited, which precluded any reliable conclusions.

The results of this CER are not applicable to populations excluded from the review, including patients with pressure ulcers at baseline, in which the risk of incident ulcers was not reported. A separate CER focuses on treatment of patients with pressure ulcers at baseline.[28]

Implications for Clinical and Policy Decisionmaking

Our review has potential implications for clinical and policy decisionmaking. Despite insufficient evidence to determine whether use of risk assessment instruments reduces risk of incident pressure ulcers, studies suggest that: a) commonly used instruments can predict which patients are more likely to develop an ulcer, and b) there are no clear differences in diagnostic accuracy. Decisions about whether to use risk assessment instruments and which risk assessment instrument to use may depend on considerations such as a desire to standardize and monitor practices within a clinical setting, ease of use, nursing preferences, and other factors.

Evidence suggests that more advanced static support surfaces are more effective than standard mattresses for reducing risk of pressure ulcers, though more evidence is needed to understand the effectiveness and comparative effectiveness of dynamic and other support surfaces. One trial found that a stepped care approach that utilized lower-cost dynamic support surfaces before switching to higher-cost interventions in patients with early ulcers could be effective as well as efficient; this finding warrants further study.[89] Although evidence is insufficient to guide recommendations on use of other preventive interventions, these findings are contingent on an understanding that usual care practices were the comparator treatment in most studies. Therefore, it would be inappropriate to conclude that standard repositioning, skin care, nutrition, and other practices should be abandoned, as these were the basis of usual care comparisons.

Although studies of preventive interventions primarily focused on effects on pressure ulcer incidence and severity, other factors such as effects on effects on resource utilization (including length of hospitalization and costs) and patient preferences may affect clinical decisions. However, cost and patient preferences were outside the scope of this report and data on resource utilization was limited to a small numbers of studies that found no effects of various support surfaces on length of stay.

Limitations of the Comparative Effectiveness Review Process

Our review had some potential limitations. We excluded non-English language articles which could result in language bias (Appendix E), though a recent systematic review found little empirical evidence that exclusion of non-English language articles leads to biased estimates for non-complementary or alternative medicine interventions.[154] In addition, we did not exclude poor-quality studies *a priori*. Rather, we described the limitations of the studies, emphasized higher-quality studies when synthesizing the evidence, and performed sensitivity analyses that excluded poor-quality studies.

We did not attempt to pool studies of diagnostic accuracy due to clinical heterogeneity across studies and methodological shortcomings. Rather, we synthesized results qualitatively, and described the range of results, in order to highlight the greater uncertainty in findings.

We did not formally assess for publication bias with funnel plots due to small numbers (<10) of studies for all comparisons and due to important clinical heterogeneity and methodological shortcomings in the available studies. Small numbers of studies can make interpretation of funnel plots unreliable, and experts suggest 10 studies as the minimum number of studies to perform funnel plots.[155] Inclusion of two studies of preventive interventions published only as conference abstracts would not have changed our results.[125, 126]

Limitations of the Evidence Base

We identified a number of limitations in the evidence base on preventive interventions. Most included studies had important methodological shortcomings, with 4 of 47 studies of diagnostic accuracy and 27 of 54 studies of preventive interventions rated poor-quality, and only 12 studies of diagnostic accuracy and three studies of preventive interventions rated good-quality. Few studies of diagnostic accuracy reported measures of discrimination such as the AUROC, many studies failed to pre-define cutoff thresholds, few studies reported differential use of interventions according to baseline risk score (which could affect estimates of diagnostic accuracy), and some studies evaluated modified or ad hoc versions of standard risk assessment instruments. An important limitation of the evidence on preventive interventions is that few trials compared the same intervention, and methods for assessing and reporting ulcers varied. There was almost no evidence to determine how diagnostic accuracy of risk assessment instruments or the effectiveness and comparative effectiveness of preventive interventions varies according to care setting, patient characteristics, or other factors. Harms were reported in only 13 of 54 trials of preventive interventions, and harms were poorly reported even when some data were provided. Only about half of the studies reported funding source. Among those that did report funding source, most were sponsored by institutions or governmental organizations.

Future Research

Future research is needed on the effectiveness of standardized use of risk assessment tools compared with clinical judgment or non-standardized use in preventing pressure ulcers. Studies should evaluate validated risk assessment instruments and employ a clearly described protocol for use of preventive interventions based on the risk assessment score. In addition to comparing the risk and severity of ulcers across groups, studies should also report effects on use of preventive interventions as well as other important outcomes, such as length of hospital stay and measures of resource utilization.

Future research that simultaneously evaluates the diagnostic accuracy of different risk assessment instruments is needed to provide more direct evidence on how their performance compares with one another. Studies should at a minimum report how use of preventive interventions differed across intervention groups, and consider reporting adjusted risk estimates to account for such potential confounders. Studies of diagnostic accuracy should also use pre-defined, standardized cutoffs and routinely report measures of discrimination such as the AUROC.

More research is needed to understand the effectiveness of preventive interventions. It is critical that future studies of preventive interventions adhere to methodological standards including appropriate use of blinding (such as blinding of outcome assessors even when blinding of patients and caregivers is not feasible) and clearly describe usual care and other comparison treatments. Studies should routinely report baseline pressure ulcer risk in enrolled patients and consider pre-defined subgroup analyses to help better understand how preventive interventions might be optimally targeted. More studies are needed to better understand the comparative effectiveness of dynamic and reactive support surfaces compared with static support surfaces, as well as strategies such as stepped care that might be more efficient than using costly interventions in all patients.

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Abbreviations

Abbreviation	Definition
AHRQ	Agency for Healthcare Research and Quality
AUROC	Area under the receiver operator characteristic
CER	Comparative effectiveness review
CI	Confidence interval
EPC	Evidence-based Practice Center
NPUAP	National Pressure Ulcer Advisory Panel
OR	Odds ratio
PICOTS	Populations, Interventions, Comparators, Outcomes, Timing and Setting
RR	Risk ratio
SIP	Scientific information packet
TEP	Technical Expert Panel
USPSTF	United States Preventive Services Task Force