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Number 87

Pressure Ulcer Risk Assessment and Prevention: Comparative Effectiveness



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Pressure Ulcer Risk Assessment and Prevention: Comparative Effectiveness

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Prepared by:

Oregon Evidence-based Practice Center
Oregon Health and Science University
Portland, OR

Investigators:

Roger Chou, M.D.
Tracy Dana, M.L.S.
Christina Bougatsos, M.P.H.
Ian Blazina, M.P.H.
Amy Starmer, M.D., M.P.H.
Katie Reitel, M.S.W., M.P.H.
David Buckley, M.D., M.P.H.

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This report is based on research conducted by the Oregon Evidence-based Practice Center (EPC) under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. 290-2007-10057-I). The findings and conclusions in this document are those of the authors, who are responsible for its contents; the findings and conclusions do not necessarily represent the views of AHRQ. Therefore, no statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

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None of the investigators has any affiliations or financial involvement that conflicts with the material presented in this report.
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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of systematic reviews to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. These reviews provide comprehensive, science-based information on common, costly medical conditions, and new health care technologies and strategies.

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 can help clarify whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about AHRQ EPC systematic reviews, see www.effectivehealthcare.ahrq.gov/reference/purpose.cfm.

AHRQ expects that these systematic reviews will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the Web site (www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an email list to learn about new program products and opportunities for input.

We welcome comments on this systematic review. 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 email to epc@ahrq.hhs.gov.

Carolyn M. Clancy, M.D.
Director
Agency for Healthcare Research and Quality

Jean Slutsky, P.A., M.S.P.H.
Director, Center for Outcomes and Evidence
Agency for Healthcare Research and Quality

Stephanie Chang, M.D., M.P.H.
Director
Evidence-based Practice Program
Center for Outcomes and Evidence
Agency for Healthcare Research and Quality

Christine Chang, M.D., M.P.H.
Task Order Officer
Center for Outcomes and Evidence
Agency for Healthcare Research and Quality

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Key Informants

In designing the study questions, the EPC consulted several Key Informants who represent the end-users of research. The EPC sought the Key Informant input on the priority areas for research and synthesis. Key Informants are not involved in the analysis of the evidence or the writing of the report. Therefore, in the end, study questions, design, methodological approaches, and/or conclusions do not necessarily represent the views of individual Key Informants.

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

The list of Key Informants who participated in developing this report follows:

Mona Baumgarten, Ph.D., M.Sc.
Associate Professor, Department of Epidemiology and Preventive Medicine
University of Maryland School of Medicine
Baltimore, MD

Barbara Braden, Ph.D., R.N.
Creighton University, University College Deans Office
Omaha, NE

Tom Denberg, M.D., Ph.D.
American College of Physicians
Vice President, Quality and Patient Safety
Atrius Health and Harvard Vanguard Medical Associates
Cambridge, MA

Mary Forceia, M.D., M.P.H.
Clinical Associate Professor of Medicine
University of Pennsylvania
Philadelphia, PA

Bonnie Hilburn
Senior National Service Officer
Paralyzed Veterans of America
Kansas City, MO

Courtney H. Lyder, N.D., G.N.P., FAAN
Professor, Internal Medicine and Geriatrics
Dean and Professor, School of Nursing
University of California–Los Angeles
Los Angeles, CA

Lana McKenzie
Associate Executive Director of Medical Services and Health Policy
Paralyzed Veterans of America
Washington, DC

Susan Miller
Centers for Medicare & Medicaid Services
Timonium, MD

Zena Moore, Ph.D., M.Sc., P.G. Dip., FFMRCISI
Faculty of Nursing and Midwifery, Royal College of Surgeons in Ireland
Dublin, Ireland

Jennifer Murphy, M.D.
Assistant Professor in the Department of Surgery
Oregon Health & Science University
Portland, OR

Jyme Schafer, M.D., M.P.H.
Centers for Medicare & Medicaid Services
Timonium, MD

JoAnne D. Whitney, R.N., Ph.D.
Professor and Associate Dean for Research, University of Washington School of Nursing
University of Washington
Seattle, WA

Technical Expert Panel

The EPC also consulted several technical and content experts regarding the study questions and methodology during the early stages of the report. Broad expertise and perspectives were sought. Divergent and conflicted opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design, methodologic approaches, and/or conclusions do not necessarily represent the views of individual technical and content experts.

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

The list of Technical Experts who participated in developing this report follows:

Dan Berlowitz, M.D., M.P.H.
Professor of Health Policy and Management
Boston University
Director of the Center for Health Quality, Outcomes and Economic Research
Bedford VA Medical Center
Bedford, MA

Joyce Black, R.N., Ph.D.
Associate Professor, College of Nursing
University of Nebraska Medical Center
Omaha, NE

Tom Denberg, M.D., Ph.D.
American College of Physicians
Vice President, Quality and Patient Safety
Atrius Health and Harvard Vanguard Medical Associates
Cambridge, MA

Courtney H. Lyder, N.D., G.N.P., FAAN
Professor, Internal Medicine and Geriatrics
Dean, School of Nursing
University of California – Los Angeles
Los Angeles, CA

Tanveer Mir, M.D., M.A.C.P.
American College of Physicians
Associate Chief, Geriatric and Palliative Medicine
Long Island Jewish Medical Center
Hyde Park, NY

Peer Reviewers

Prior to publication of the final evidence report, EPCs sought input from independent Peer Reviewers without financial conflicts of interest. However, the conclusions and synthesis of the scientific literature presented in this report do not necessarily represent the views of individual reviewers.

Peer Reviewers must disclose any financial conflicts of interest greater than \$10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential nonfinancial conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential nonfinancial conflicts of interest identified.

The list of Peer Reviewers follows:

Elizabeth Ayello, Ph.D., R.N., A.C.N.S.-B.C., C.W.O.N., E.T.N., M.A.P.W.C.A., FAAN
Professor, Geriatric Advisor, John A. Hartford Institute for Geriatric Nursing; School of Nursing
Excelsior College
Albany, NY

Mona Baumgarten, Ph.D., M.Sc.
Associate Professor, Department of Epidemiology and Preventive Medicine
University of Maryland School of Medicine
Baltimore, MD

Dan Berlowitz, M.D., M.P.H.
Professor of Health Policy and Management
Boston University
Director of the Center for Health Quality, Outcomes and Economic Research
Bedford VA Medical Center
Bedford, MA

Joyce Black, R.N., Ph.D.
Associate Professor, College of Nursing
University of Nebraska Medical Center
Omaha, NE

Nicky Cullum, Ph.D., R.G.N.
Professor of Nursing
University of Manchester
Manchester, England

Ruud J.G. Halfens, Ph.D.
Professor, CAPHRI School of Public Health and Primary Care, Department of Health Care and
Nursing Science, Faculty of Health, Medicine and Life Sciences
Maastricht University
Maastricht, The Netherlands

Elizabeth McInnes, R.N., Ph.D.
Associate Professor and Deputy Director, Nursing Research Institute
Australian Catholic University
Sydney, Australia

Tanveer Mir, M.D., M.A.C.P.
American College of Physicians
Associate Chief, Geriatric and Palliative Medicine
Long Island Jewish Medical Center
Hyde Park, NY

Zena Moore, Ph.D., M.Sc., P.G. Dip., FFNMRC SI
Faculty of Nursing and Midwifery, Royal College of Surgeons in Ireland
Dublin, Ireland

JoAnne D. Whitney, R.N., Ph.D.
Professor and Associate Dean for Research, University of Washington School of Nursing
University of Washington
Seattle, WA

Pressure Ulcer Prevention and Risk Assessment: Comparative Effectiveness

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. Articles were identified from searches of MEDLINE® (1946 to July 2012), CINAHL (1988 to July 2012), the Cochrane Central Register of Controlled Trials and Database of Systematic Reviews (through July 2012), clinical trials registries, and reference lists.

Review methods. We used predefined criteria to determine study eligibility. We selected randomized trials and cohort studies on the 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 4,733 citations identified at the title and abstract level, we screened and reviewed 747 full-text articles. A total of 120 studies (in 122 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 use 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 help identify patients at increased risk for ulcers, but appear to be relatively weak predictors, with no clear difference among instruments in diagnostic accuracy. Fair-quality randomized trials consistently found that more advanced static support surfaces were associated with lower risk of pressure ulcers compared with standard mattresses in higher risk patients (relative risk range, 0.20 to 0.60), with no clear differences among 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 that stepped care with dynamic support surfaces was 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 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; corticotropin injections; polarized light therapy; and intraoperative warming therapy for patients undergoing surgery) compared with 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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Executive Summary

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, pressure ulcers were reported in more than 500,000 hospital stays.³ Estimates of pressure ulcer 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 race, lower body weight,^{7,8} 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 successfully 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 21,000.⁹ Estimates of the costs of treatment for pressure ulcers vary, but range between \$37,800 and \$70,000 per case.^{2,10}

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 6 to 23); the Norton scale (5 items; total scores range from 5 to 20); and the Waterlow scale (11 items; total scores range from 1 to 64).^{2,11-13} All three scales include items related to activity, mobility, nutritional status, incontinence, and cognition, although they are weighted differently across studies.¹²

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.¹⁴⁻¹⁶ 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 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.¹⁷

The following Key Questions are the focus of this report:

Key Question 1. For adults in various settings,^a is the use of any risk-assessment tool^b 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. Do the effectiveness and comparative effectiveness of risk-assessment tools differ according to setting?

Key Question 1b. Do the effectiveness and comparative effectiveness of risk-assessment tools differ according to patient characteristics^c 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 are the effectiveness and comparative effectiveness of preventive interventions in reducing the incidence or severity of pressure ulcers?

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

Key Question 3c. Do 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?

^aIncluding acute care hospital, long-term care facility, rehabilitation facility, operating room, home care, and wheelchair users in the community.

^bThe Braden scale, the Norton scale, the Waterlow scale, or others.

^cSuch as age, race or skin tone, physical impairment, body weight, or specific medical comorbidities (e.g., diabetes and peripheral vascular disease).

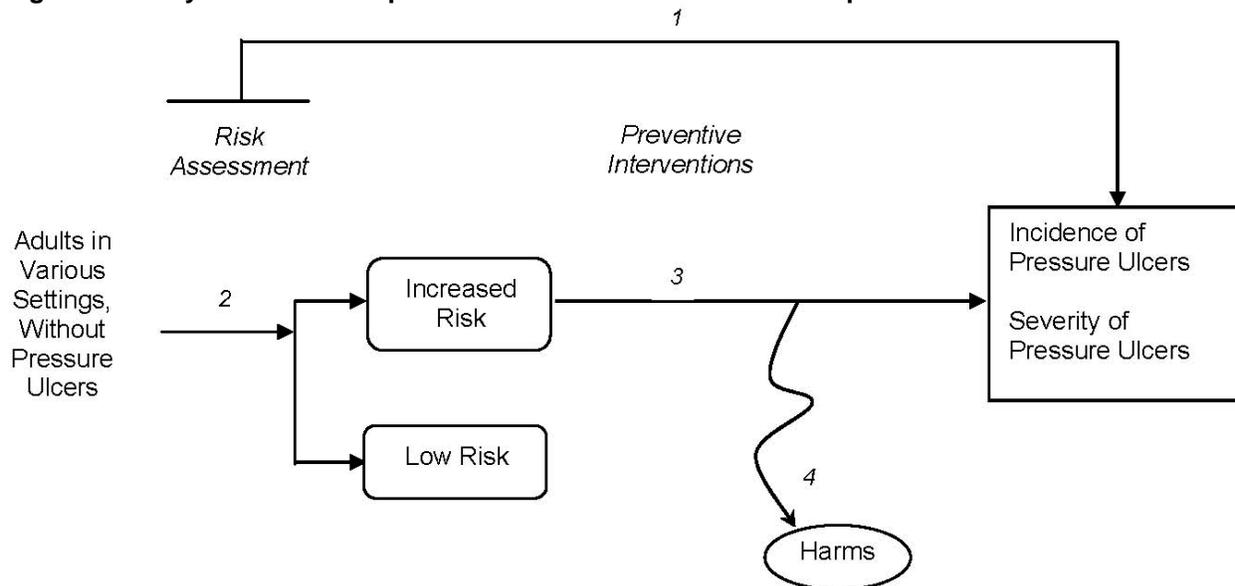
Key Question 4b. Do the harms of preventive interventions differ according to setting?

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

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



Note: The numbers in the analytic framework correspond to the numbers of the Key Questions.

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. AHRQ and the Evidence-based Practice Center agreed on 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 July 2012, CINAHL (EBSCOhost[®]) from 1988 through July 2012, and the Cochrane Central Register of Controlled Trials and Cochrane Database of Systematic Reviews using Evidence-Based Medicine Reviews (Ovid[®]) through July 2012. The search strategies were peer reviewed by another information specialist and revised prior to finalization. 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 were 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, and setting (PICOTS) approach, as well as study designs. 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 restricted inclusion to English-language articles. Studies of nonhuman 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.

For studies of preventive interventions, studies that included patients with pressure ulcers at baseline were included if fewer than 20 percent had stage 2 ulcers and the study reported incident (new) ulcers. For studies of risk-prediction instruments, we excluded studies that enrolled >10 percent of patients with ulcers at baseline, since the presence of ulcers is in itself a marker of high risk. We evaluated patient subgroups defined by age, race, 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 and 4, we included controlled clinical trials and cohort studies. For Key Question 3, we included controlled clinical trials. 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, and 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, and hazards ratio) and the area under the receiver operating characteristic (AUROC) curve.

We assessed the quality of each study based on predefined criteria. The criteria used to assess quality are consistent with the approach recommended by AHRQ in the Methods Guide for Effectiveness and Comparative Effectiveness Reviews.¹⁸

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.¹⁹ For cluster randomized trials, we also evaluated whether the study evaluated cluster effects.²⁰

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.¹⁹ 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.^{19,21} 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.²²

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

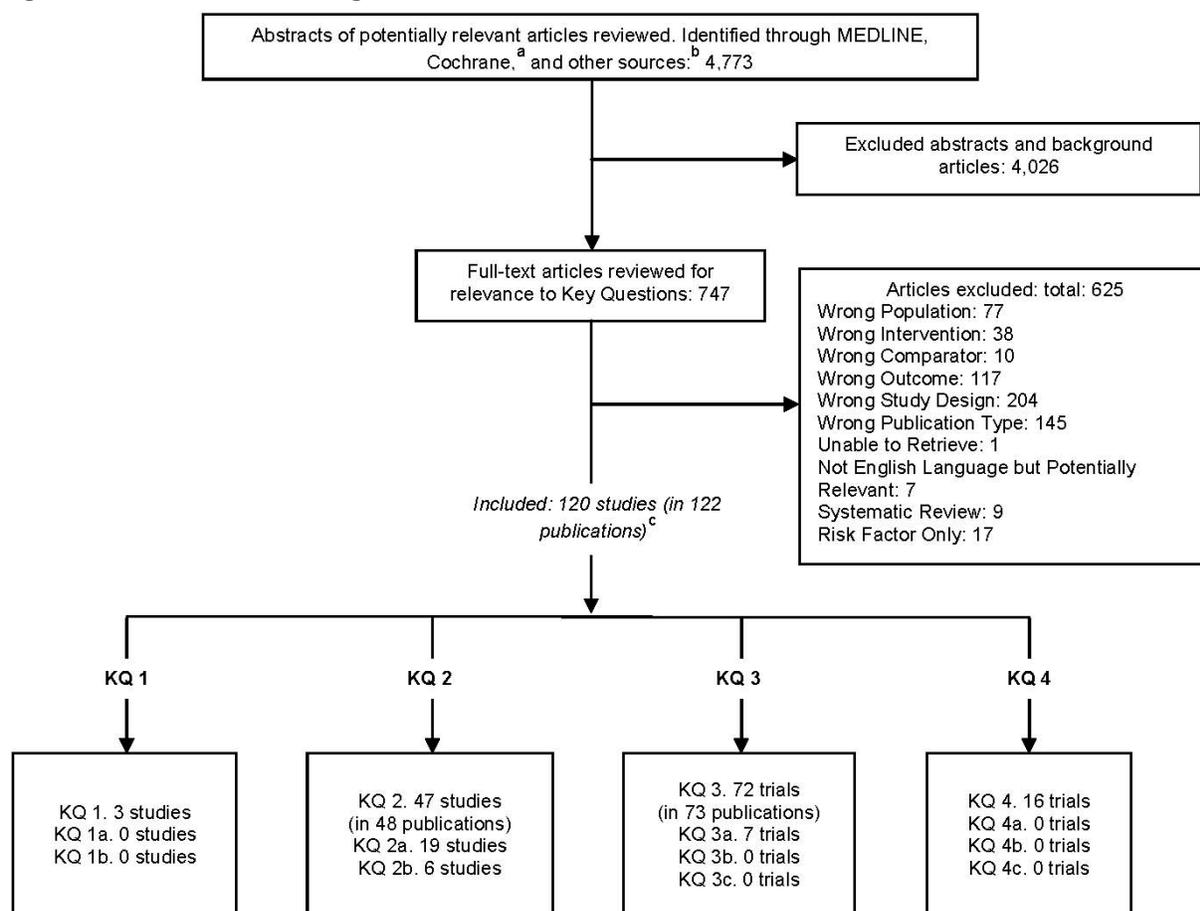
range of cutoffs without a prespecified threshold, we focused on cutoffs for the most common risk instruments (Braden, Norton, and Waterlow) based on recommended thresholds, which may vary depending on the setting and timing of assessments. The total range across studies for the various measures of diagnostic 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 Key Question in accordance with the AHRQ Methods Guide for Effectiveness and Comparative Effectiveness Reviews.²³ 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.²³ 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 that 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



^aCochrane databases include the Cochrane Central Register of Controlled Trials and the Cochrane Database of Systematic Reviews.

^bOther sources include reference lists, peer reviewer suggestions, etc.

^cSome articles are included for more than one Key Question.

Note: KQ = Key Question.

Database searches resulted in 4,773 potentially relevant articles. After dual review of abstracts and titles, 747 articles were selected for full-text review, and 120 studies (in 122 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 nonrandomized study found that use of the modified Norton scale (in conjunction with a standardized intervention protocol based on assessed risk) was 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 and 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 among 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, good- and fair-quality randomized trials consistently found that more advanced static mattresses and overlays were associated with lower risk of pressure ulcers compared with standard mattresses (RR, 0.20 to 0.60), with no clear differences between different advanced static support surfaces. Evidence on the effectiveness and comparative effectiveness of other specific support surfaces, including alternating air mattresses and low-air-loss mattresses, was limited, with most trials showing no clear differences between these types of mattresses and various static mattresses and overlays. One fair-quality trial found that stepped care with alternating air mattresses was associated with substantially decreased risk of ulcers compared with stepped care primarily with static support surfaces. In lower risk populations of patients undergoing surgery, two trials found that use of a foam overlay was associated with an increased risk or trend toward increased risk of pressure ulcers compared with use of a standard operating room mattress. Evidence on effectiveness of other preventive interventions (nutritional supplementation; 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. An exception was repositioning, for which there were three good- or fair-quality trials, although these reported somewhat inconsistent results. One trial found that a repositioning intervention was more effective than usual care in preventing pressure ulcers, although other trials of repositioning did not clearly find decreased risk of pressure ulcers compared with usual care.

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

Table A summarizes the findings of this review.

Table A. Summary of evidence

Key Question and Subcategories	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 = 1,231) found no difference in pressure ulcer incidence between patients assessed with either the Waterlow scale or Ramstadius tool 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 that use of a modified version of the Norton scale to guide use of preventive interventions was 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. Do 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. Do 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 2 good- and 5 fair-quality studies, 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), for a positive likelihood ratio of 2.31 and negative likelihood ratio of 0.38.
Diagnostic accuracy: Norton scale	Moderate	In 3 studies (1 good and 2 fair quality), the median AUROC for the Norton scale was 0.74 (range, 0.56 to 0.75). In 5 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), for a positive likelihood ratio of 1.83 and negative likelihood ratio of 0.42.

Table A. Summary of evidence (continued)

Key Question and Subcategories	Strength of Evidence	Conclusion
Diagnostic accuracy: Waterlow scale	Moderate	In 4 studies (1 good and 3 fair quality), the median AUROC for the Waterlow scale was 0.61 (range, 0.54 to 0.66). In 2 studies, based on a cutoff of ≥ 10 , sensitivities were 0.88 and 1.0, and specificities 0.13 and 0.29, for positive likelihood ratios of 1.15 and 1.24 and negative likelihood ratios of 0.0 and 0.41.
Diagnostic accuracy: Cubbin and Jackson scale	Moderate	In 3 studies (1 good and 2 fair quality), the median AUROC for the Cubbin and Jackson scale was 0.83 (range, 0.72 to 0.90). In 3 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), for positive likelihood ratios that ranged from 1.43 to 5.28 and negative likelihood ratios that ranged from 0.06 to 0.40.
Diagnostic accuracy: direct comparisons between risk-assessment scales	Moderate	In 2 good- and 4 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 that a Braden scale score of ≤ 18 was 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 scale, ICU setting	Low	Two studies (1 good and 1 fair quality) found that the Cubbin and Jackson scale was 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 (1 good and 1 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 and skilled nursing settings.
Diagnostic accuracy: Braden scale, differences according to baseline pressure ulcer risk	Moderate	Three studies (1 good and 2 fair quality) found no clear difference in AUROC estimates based on the presence of higher or lower mean baseline pressure ulcer risk scores.

Table A. Summary of evidence (continued)

Key Question and Subcategories	Strength of Evidence	Conclusion
Key Question 3. In patients at increased risk of developing pressure ulcers, what are the effectiveness and comparative effectiveness of preventive interventions in reducing the incidence or severity of pressure ulcers?		
Pressure ulcer incidence or severity: advanced static mattresses or overlays vs. standard hospital mattress	Moderate	One good-quality trial (n = 1,166) and 4 fair-quality trials (n = 83 to 543) found that a more advanced static mattress or overlay was associated with lower risk of incident pressure ulcers than a standard mattress (RR range, 0.16 to 0.82), although the difference was not statistically significant in 2 trials. Six poor-quality trials reported results that were generally consistent with these findings. Three trials found no difference in length of stay. The static support surfaces evaluated in the trials varied, although a subgroup of 3 trials each found that an Australian medical sheepskin overlay was associated with lower risk of ulcers than a standard mattress (RR, 0.30, 0.58, and 0.58).
Pressure ulcer incidence or severity: advanced static mattress or overlay vs. advanced static mattress or overlay	Moderate	Three fair-quality trials (n = 52 to 100) found no differences between different advanced static support mattresses or overlays in risk of pressure ulcers. One fair-quality trial (n = 40) of nursing home patients found that a foam replaceable-parts mattress was 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). Six poor-quality trials (n = 37 to 407) also found no differences between different advanced static mattresses or overlays.
Pressure ulcer incidence or severity: low-air-loss bed vs. standard hospital mattress	Low	One fair-quality trial (n = 98) found that a low-air-loss bed was associated with lower likelihood of 1 or more pressure ulcers in ICU patients (12% vs. 51%; RR, 0.23; 95% CI, 0.10 to 0.51), but a small (n = 36) poor-quality trial found no difference between a low-air-loss mattress compared with a standard hospital bed following cardiovascular surgery.
Pressure ulcer incidence or severity: low-air-loss mattress compared with dual option (constant low pressure/alternating air) mattress	Low	One fair-quality trial (n = 62) found no clear difference between a low-air-loss mattress compared with the Hill-Rom Duo [®] mattress (options for constant low pressure or alternating air) in risk of ulcers.
Pressure ulcer incidence or severity: alternating air pressure overlay or mattress vs. standard hospital mattress	Low	Three poor-quality trials (n = 108 to 487) found lower incidence of pressure ulcers with use of an alternating air pressure mattress or overlay compared with a standard hospital mattress.
Pressure ulcer incidence or severity: alternating air pressure overlay or mattress vs. advanced static overlay or mattress	Moderate	Six trials (n = 32 to 487; 1 good quality, 1 fair quality, and 4 poor quality) found no difference between an alternating air pressure overlay or mattress compared with various advanced static mattresses or overlays in pressure ulcer incidence or severity.

Table A. Summary of evidence (continued)

Key Question and Subcategories	Strength of Evidence	Conclusion
Pressure ulcer incidence or severity: alternating air pressure overlay or mattress vs. alternating air pressure overlay or mattress	Moderate	Four trials (n = 44 to 1,972; 1 good quality, 2 fair quality, and 1 poor quality) found no clear differences between different alternating air mattresses or overlays. The good-quality (n = 1,972) trial found no difference in risk of stage 2 ulcers between an alternating air pressure overlay and an alternating air pressure mattress (RR, 1.0, 95% CI, 0.81 to 1.3; adjusted OR, 0.94, 95% CI, 0.68 to 1.3).
Pressure ulcer incidence or severity: heel supports or boots vs. usual care	Low	One fair-quality trial (n = 239) of fracture patients found that the Heelift® Suspension Boot was associated with decreased risk of heel, foot, or ankle ulcers compared with usual care without leg elevation (7% vs. 26% for any ulcer, RR, 0.26, 95% CI, 0.12 to 0.53; 3.3% vs. 13.4% for stage 2 ulcers, RR, 0.25, 95% CI, 0.09 to 0.72). 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, although the overall incidence of ulcers was low (5% over 3 years) and results could have been confounded by differential use of cointerventions.
Pressure ulcer incidence or severity: more sophisticated wheelchair cushions vs. standard wheelchair cushions	Low	Four fair-quality trials (n = 32 to 248) of older nursing home patients 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: nutritional supplementation vs. standard hospital diet	Low	Five of 6 trials (1 fair quality and 5 poor quality; n = 59 to 672) found no difference between nutritional supplementation compared with standard hospital diet in risk of pressure ulcers. Four trials evaluated supplementation by mouth and 2 evaluated enteral supplementation.
Pressure ulcer incidence or severity: repositioning intervention vs. usual care	Low	One fair-quality cluster trial (n = 213) found that repositioning at a 30-degree tilt every 3 hours was associated with lower risk of pressure ulcers 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), and 1 fair-quality trial (n = 235) found no difference in risk of pressure ulcers between different repositioning intervals. Two other trials (n = 46 and 838) evaluated repositioning interventions but followed patients for only 1 night or were susceptible to confounding due to differential use of support surfaces.

Table A. Summary of evidence (continued)

Key Question and Subcategories	Strength of Evidence	Conclusion
Pressure ulcer incidence or severity: small unscheduled shifts in body position vs. usual care	Low	Two small (n = 15 and 19) poor-quality trials found that the addition of small unscheduled shifts in body position (using a small rolled towel to designated areas during nurse-patient interactions) to standard repositioning every 2 hours had no effect on risk on pressure ulcers, but the studies reported only 1 or 2 ulcers in each trial.
Pressure ulcer incidence or severity: silicone border foam sacral dressing vs. no silicone border foam dressing	Low	One fair-quality (n = 85) trial of patients undergoing cardiac surgery found that a silicone border foam sacral dressing applied at ICU admission (the Mepilex [®] Border sacrum) was associated with lower likelihood of pressure ulcers compared with standard care (including preoperative placement of a silicone border foam dressing for surgery and use of a low-air-loss bed), but the difference was not statistically significant (2.0% vs. 12%; RR, 0.18; 95% CI, 0.02 to 1.5).
Pressure ulcer incidence or severity: REMOIS pad vs. no pad	Insufficient	One poor-quality randomized trial (n = 37) found that 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 was associated with decreased risk of stage 1 ulcers compared with 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: changing incontinence pad 3 vs. 2 times per day	Low	One fair-quality crossover trial (n = 81) found no statistically significant difference in risk of pressure ulcers between changing incontinence pads 3 times vs. twice after 4 weeks.
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 corticotropin intramuscularly compared with a sham injection.
Pressure ulcer incidence or severity: polarized light	Insufficient	One small poor-quality randomized trial (n = 23) found no statistically significant difference between polarized light compared with standard care in risk of pressure ulcers.
Pressure ulcer incidence or severity: fatty acid cream vs. placebo	Low	One fair-quality trial (n = 331) and 1 poor-quality trial (n = 86) found that creams with fatty acids were associated with decreased risk of new pressure ulcers compared with placebo (RR, 0.42, 95% CI, 0.22 to 0.80; RR, 0.17, 95% CI, 0.04 to 0.70).
Pressure ulcer incidence or severity: other cream or lotion vs. placebo	Insufficient	Evidence from 3 poor-quality trials (n = 79 to 258) was insufficient to determine effectiveness of other creams or lotions for preventing pressure ulcers.

Table A. Summary of evidence (continued)

Key Question and Subcategories	Strength of Evidence	Conclusion
Pressure ulcer incidence or severity: skin cleanser vs. standard soap and water	Low	One fair-quality randomized trial (n = 93) found that the Clinisan™ cleanser was 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. Do 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 (1 good and 1 fair quality; n = 175 and 413) found that use of a static foam overlay was associated with increased risk of pressure ulcers compared with standard care in lower risk surgical patients, although the difference was not statistically significant in 1 trial (OR, 1.9, 95% CI, 1.0 to 3.7; 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 (1 good and 1 poor quality) found that a dry polymer overlay was 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: alternating air vs. static mattress or overlay, lower risk surgical population	Low	Two trials (1 good and 1 poor quality; n = 198 and 217) found no differences between alternating compared with static support surfaces in risk of pressure ulcer incidence or severity.
Key Question 3b. Do 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. Do 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.

Table A. Summary of evidence (continued)

Key Question and Subcategories	Strength of Evidence	Conclusion
Key Question 4. What are the harms of interventions for the prevention of pressure ulcers?		
Harms: support surfaces	Low	<p>Nine of 48 trials of support surfaces reported harms.</p> <ul style="list-style-type: none"> • Three trials (n = 297 to 588) reported cases of heat-related discomfort with sheepskin overlays, with 1 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, and 2 trials (n = 610 and 1,972) found no differences in risk of withdrawal due to discomfort. • One trial (n = 198) reported no differences in risk of adverse events between a multicell 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 that a urethane and gel wheelchair pad (Jay[®] cushion) was associated with increased risk of withdrawal due to discomfort compared with a standard foam wheelchair pad (8% vs. 1%; RR, 6.2; 95% CI, 0.77 to 51).
Harms: nutritional supplementation	Low	<p>One trial of nutritional supplementation found that tube feeds were tolerated poorly, with 54% having the tube removed within 1 week and 67% prior to completing the planned 2-week intervention. Four trials of nutritional supplementation by mouth did not report harms.</p>
Harms: repositioning	Low	<p>Two (n = 46 and 838) of 6 trials of repositioning interventions reported harms. Both trials reported more nonadherence due to intolerability of a 30-degree tilt position compared with standard positioning.</p>
Harms: lotions and creams	Low	<p>Three (n = 93 to 203) of 6 trials of lotions or creams reported harms. One trial found no differences in rash between different creams, and 2 trials each reported 1 case of a wet sore or rash.</p>
Harms: dressings	Low	<p>One (n = 37) of 3 trials of dressings reported harms. It reported that application of the REMOIS pad resulted in pruritus in 1 patient.</p>
Key Question 4a. Do the harms of preventive interventions differ according to the type of intervention?	Insufficient	<p>No study evaluated how harms of preventive interventions vary according to the type of intervention.</p>
Key Question 4b. Do the harms of preventive interventions differ according to setting?	Insufficient	<p>No study evaluated how harms of preventive interventions vary according to care setting.</p>

Table A. Summary of evidence (continued)

Key Question and Subcategories	Strength of Evidence	Conclusion
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

Note: AUROC = area under the receiver operating characteristic; CI = confidence interval; ICU = intensive care unit; 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 noninvasive 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 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. The two poor-quality studies evaluated the modified Norton scale and the Braden scale, with only a nonrandomized study of the Norton scale finding reduced risk of pressure ulcer compared with clinical judgment.

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

About three-quarters of the trials of preventive interventions focused on evaluations of support surfaces. In higher risk populations, good- and fair-quality randomized trials consistently found that more advanced static mattresses and overlays were associated with lower risk of pressure ulcers compared with standard mattresses (RR range, 0.20 to 0.60), with no clear differences between different advanced static support surfaces. Although the mattresses and overlays evaluated in the trials varied, three trials consistently found that an Australian medical sheepskin overlay was associated with lower risk of ulcers than a standard hospital mattress, although the sheepskin was also associated with heat-related discomfort, in some cases resulting in withdrawal. Evidence on the effectiveness and comparative effectiveness of other specific support surfaces, including alternating air mattresses and low-air-loss mattresses, was limited, with most trials showing no clear differences between these types of mattresses and various static mattresses and overlays. One fair-quality trial found that stepped care starting with alternating air mattresses was associated with substantially decreased risk of ulcers compared with stepped care primarily with static mattresses, suggesting that this might be both an effective and efficient approach, since care was initiated with the least expensive alternatives and advanced to more expensive alternatives based on a preset algorithm. In lower risk populations of patients undergoing surgery, two trials found that use of a foam overlay was associated with an increased risk of pressure ulcers compared with a standard operating room mattress. The few trials that evaluated length of stay found no differences among various support surfaces.

Evidence on other preventive interventions (nutritional supplementation; repositioning; pads and dressings; lotions, creams, and cleansers; and intraoperative warming therapy for patients

undergoing surgery) was sparse and insufficient to reach reliable conclusions, in part because most trials had important methodological shortcomings. An exception was repositioning, for which there were three good- or fair-quality trials, although these reported somewhat inconsistent results. One trial found that a repositioning intervention was more effective than usual care in preventing pressure ulcers. 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 vs. usual repositioning, not vs. no repositioning). A recently completed trial of repositioning, consisting of high-risk and moderate-risk arms that were randomized to repositioning at 2-, 3-, or 4-hour intervals, should provide more rigorous evidence on the effectiveness of repositioning.

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 those of other recent systematic reviews.^{24,25} One of these reviews also evaluated the diagnostic accuracy of risk-assessment instruments.²⁵ 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 that review pooled data without regard for differences in cutoff scores and across study settings, and it also included four studies that we excluded due to: retrospective study design,²⁶ inadequate reporting to determine eligibility for inclusion,²⁷ availability only in Spanish language,²⁸ or inability to obtain.²⁹

Our findings on effectiveness of preventive interventions are generally consistent with those of 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,^{10,30} limited evidence on the effectiveness and comparative effectiveness of dynamic support surfaces,^{10,30} and limited evidence on other preventive interventions.^{10,31} 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 higher stage preexisting ulcers and including trials published only as abstracts.

Applicability

The studies included in this review generally enrolled patients at higher risk for pressure ulcers, although eligibility criteria varied among 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.³²

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; and this lack of blinding 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 multicomponent 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, and nursing or other caregiver preferences.

Evidence suggests that more advanced static support surfaces are more effective than standard mattresses for reducing risk of pressure ulcers, although more evidence is needed to understand the effectiveness and comparative effectiveness of dynamic and other support surfaces. Despite limited evidence showing that they are more effective at preventing pressure ulcers compared with static mattresses and overlays, alternating air and low-air-loss mattresses and overlays are used in hospitals in many areas of the United States. Such support surfaces can be quite costly, although 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.³³ 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 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 were 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 interventions not involving complementary or alternative medicine.³⁴ 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 35 of 72 studies of preventive interventions rated poor quality, and only 12 studies of diagnostic accuracy and 6 studies of preventive interventions rated good quality. Few studies of diagnostic accuracy reported measures of discrimination, such as the AUROC; many studies failed to predefine 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 the diagnostic accuracy of risk-assessment instruments or the effectiveness and comparative effectiveness of preventive interventions vary according to care setting, patient characteristics, or other factors. Harms were reported in only 16 of 72 trials of preventive interventions and were 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 government organizations.

Future Research

Future research is needed on the effectiveness of the standardized use of risk-assessment instruments compared with clinical judgment or nonstandardized use in preventing pressure ulcers. Studies should evaluate validated risk-assessment instruments and employ a clearly described protocol for the 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 the 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 should consider reporting adjusted risk estimates to account for such potential confounders. Studies of diagnostic accuracy should also use predefined 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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Introduction

Background

Condition

Pressure ulcers are defined by the United States National Pressure Ulcer Advisory Panel (NPUAP) and the European Pressure Ulcer Advisory Panel (EPUAP) 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.”¹ Pressure ulcers are a common condition, affecting an estimated 1.3 to 3 million adults in the United States (U.S.).² In 2006, there were more than 500,000 hospital stays in which pressure ulcers were reported. Estimates of pressure ulcer 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.²⁻⁴ The variation in estimates is due in part to differences in how ulcers are assessed and defined and in the populations evaluated. The prevalence of facility-acquired pressure ulcers was 6 percent in 2008 and 5 percent in 2009.⁴

Pressure ulcers are often associated with pain and can contribute to decreased function or lead to complications such as infection.⁵ 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 people.⁷ Estimates of the costs of treatment for pressure ulcers vary, but range between \$37,800 and \$70,000 per case.^{6,8}

Most current grading systems for pressure ulcers, including the commonly utilized NPUAP/EPUAP system, assign one of four stages, based on the depth of the ulcer and tissue involvement, with higher stages indicating greater severity (Table 1).¹ In this system, stage 1 is defined as superficial erythema without skin breakdown, stage 2 as partial thickness ulceration, stage 3 as full thickness ulceration, and stage 4 as full thickness with involvement of muscle and bone. When a full thickness (at least stage 3) 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. Another category, suspected deep tissue injury, refers to skin changes suggesting an injury to the tissues underneath the skin’s surface, and most commonly occur in the heel area.

Risk factors for pressure ulcers include older age, cognitive impairment, physical impairments and other comorbidities that affect soft tissue integrity and healing (such as urinary incontinence, edema, impaired microcirculation, hypoalbuminemia, and malnutrition).^{5,9} Given the negative impact and burdens associated with pressure ulcers, interventions that can prevent occurrence or reduce 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.¹⁰

A number of diverse interventions are available as potential preventive interventions for pressure ulcers. However, research indicates that many patients at high risk of pressure ulcers do not receive preventive interventions.¹¹ 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. 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. National Pressure Ulcer Advisory Panel/European Pressure Ulcer Advisory Panel pressure ulcer classification

Stage	Description
1	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.
2	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.
3	Full thickness tissue loss. Subcutaneous 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.
4	Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often includes undermining and tunneling.
Unstageable	Full thickness tissue loss in which the base of the ulcer is covered by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed
Suspected deep tissue injury—depth unknown	Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer, or cooler compared with adjacent tissue.

Source: European Pressure Ulcer Advisory Panel & National Pressure Ulcer Advisory Panel (2009). Prevention and treatment of pressure ulcers: quick reference guide.¹

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.^{1,15,16} 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 race, lower 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 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).^{5,17-19} 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 ulcers²⁰⁻²⁵

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., alternating-air or low-air-loss overlays, mattresses, or bed systems) 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 used older and often poorly standardized methods for describing and classifying support surfaces. In this report, we broadly classified support surfaces as static, alternating air, or low-air-loss.

The use of preventive interventions varies 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 with 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.

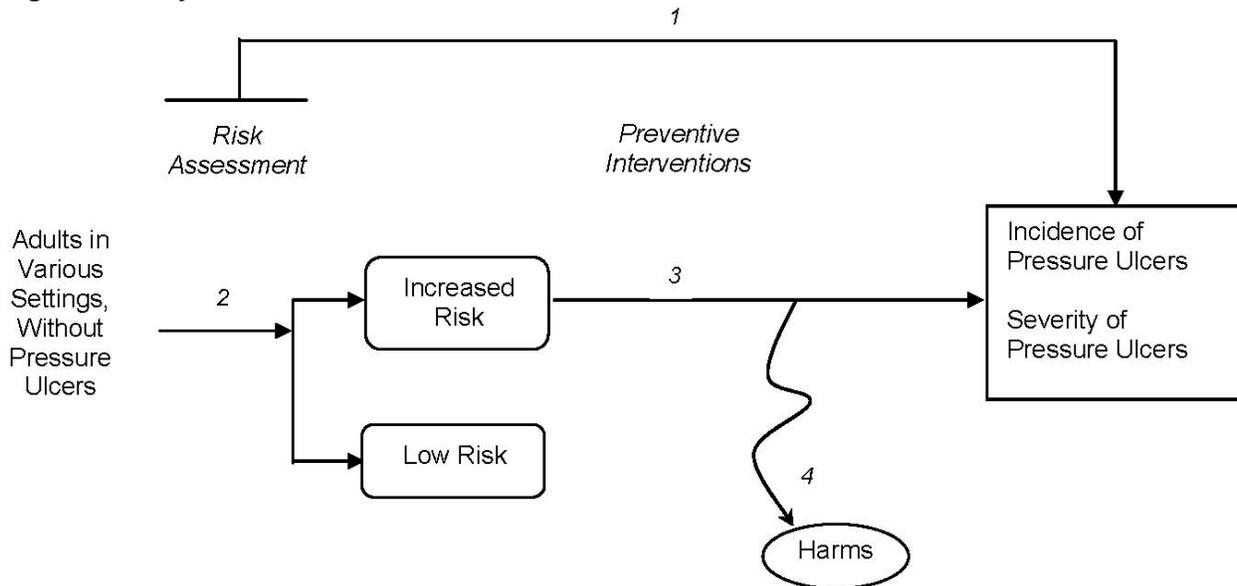
Scope of Review and Key Questions

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, with numbers corresponding to the key questions.

Figure 1. Analytic framework



Note: The numbers in the analytic framework correspond to the numbers of the Key Questions.

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. Do the effectiveness and comparative effectiveness of risk-assessment tools differ according to setting^{*}?

Key Question 1b. Do 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 are the effectiveness and comparative effectiveness of preventive interventions in reducing the incidence or severity of pressure ulcers?

Key Question 3a. Do 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. Do the effectiveness and comparative effectiveness of preventive interventions differ according to setting^{*}?

Key Question 3c. Do 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 pressure ulcer incidence or severity. 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 and/or other interventions. 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 experts in pressure ulcer treatment and research from geriatrics, primary care, hospital medicine, and nursing disciplines.

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 that 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 July, 2012; CINAHL (EBSCOhost) from 1988 through July, 2012; and the Cochrane Central Register of Controlled Trials and Cochrane Database of Systematic Reviews using EBM Reviews (Ovid) through July 2012 (see Appendix A for full search strategies). The search strategies were peer reviewed by another information specialist and revised prior to finalization. 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.

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 the prevention of pressure ulcers, were relevant to a key question, and met the predefined inclusion criteria. We excluded studies of nonhuman 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; 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. For studies of risk prediction instruments, we excluded studies that enrolled >10 percent of patients with ulcers at baseline, since the presence of ulcers is in itself a marker of high risk. For studies of preventive interventions, we included studies that reported incident (new) pressure ulcers and in which fewer than 20 percent of subjects had stage 2 or higher ulcers at baseline. 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 and 4, we included controlled clinical trials and cohort studies. For Key Question 3, we included controlled clinical trials. We amended our protocol to exclude

observational studies for Key Question 3 because over 50 clinical trials were available. For Key Question 2 we included prospective studies that reported diagnostic accuracy of risk prediction instruments. No systematic review met inclusion criteria (because they did not directly address a Key Question, were otherwise outside scope, or were not rated high-quality), though we reviewed reference lists of systematic reviews for potentially relevant 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-health care 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 [OR], hazards ratio [HR]) 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 the condition.^{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 as good, 0.70 to <0.80 as fair, and <0.70 as poor.

For studies of interventions, we calculated relative risks and associated 95 percent confidence intervals for pressure ulcers based on the information provided (sample sizes and incidence in each intervention group). We noted discrepancies between calculated and reported results when present.

Assessing Quality

We assessed the quality of each study based on predefined criteria (Appendix F). 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. Two investigators independently assessed the quality of each study. Discrepancies were resolved through discussion and consensus, with a third investigator making the final decision if necessary.

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 study evaluating the diagnostic accuracy or predictive value of risk prediction instruments 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; assess outcomes blinded to intervention status; 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, and calculated positive and negative likelihood ratios based on the median sensitivities and specificities. Although studies varied in what cutoffs were evaluated, and some evaluated a range of cutoffs without a prespecified 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 tables.

Peer Review and Public Commentary

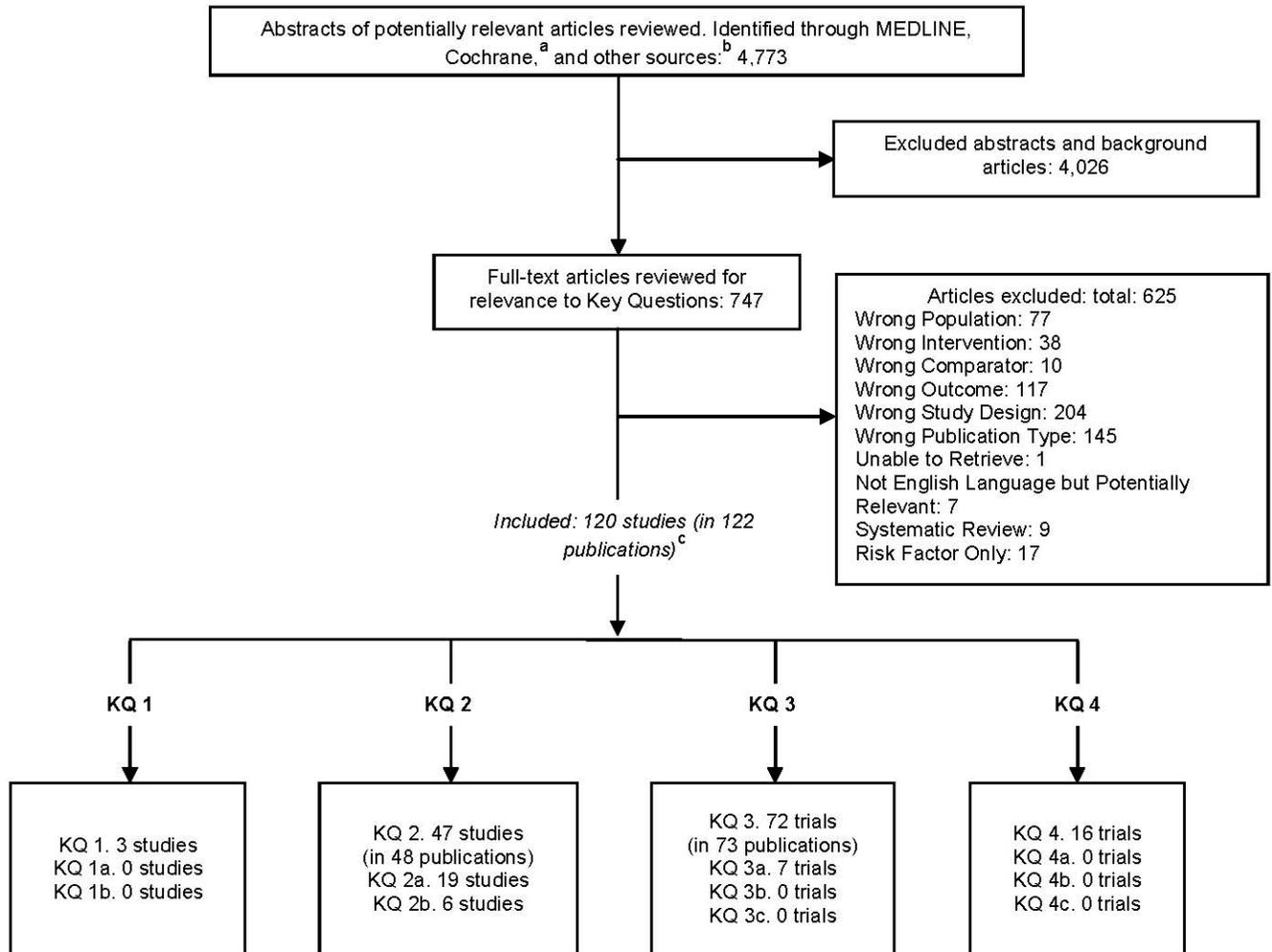
Experts in prevention and management of pressure ulcers, geriatric medicine, wound care research, and epidemiology, as well as individuals representing important stakeholder groups, were invited to provide external peer review of this CER. The AHRQ Task Order Officer and a designated EPC Associate Editor also provided comments and editorial review. To obtain public comment, the draft report was posted on the AHRQ Web site for 4 weeks. A disposition of comments report detailing the authors’ responses to the peer and public review comments 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 4,773 potentially relevant articles. After dual review of abstracts and titles, 747 articles were selected for full-text review, and 120 studies (in 122 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 tables for all included studies per key question are available in Appendix H.

Figure 2. Literature flow diagram



^aCochrane databases include the Cochrane Central Register of Controlled Trials and the Cochrane Database of Systematic Reviews.

^bOther sources include reference lists, peer reviewer suggestions, etc.

^cSome articles are included for more than one Key Question.

Note: KQ = 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=1,231) found no difference in pressure ulcer incidence between patients assessed with either the Waterlow scale or Ramstadius tool 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) (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 Tables H1, H2, and H3).^{13,45,46} The good-quality study was a randomized, controlled trial comparing the Waterlow scale and Ramstadius tool to clinical judgment.¹³ Of the two poor-quality studies, one was a nonrandomized study⁴⁵ that evaluated a modified version of the Norton scale, and the other was a cluster randomized trial⁴⁶ that evaluated the Braden scale. All three studies compared use of standardized instruments against nurses' clinical judgment, which could introduce variability across studies due to differences in experience, training, skills, or other factors.

The good-quality 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 pressure ulcer risk scores were not reported, though 6 percent of patients had a pressure ulcer at baseline (primarily stage 1 or 2). There was no difference between interventions in risk of pressure ulcers after a mean of 9 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 across 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 nonconcurrent 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 stage 1 and about one-third were stage 2. 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 fourth study compared use of the Norton Scale with nurses’ clinical judgment in reducing pressure ulcers, but was excluded because it did not report incident pressure ulcers.⁴⁷

Key Question 1a. Do 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. Do 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), for a positive likelihood ratio of 2.31 and negative likelihood ratio of 0.38 (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), for a positive likelihood ratio of 1.83 and negative likelihood ratio of 0.42 (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, for positive likelihood ratios of 1.15 and 1.24 and negative likelihood ratios of 0.0 and 0.41 (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), for positive likelihood ratios that ranged from 1.43 to 5.28 and negative likelihood ratios that ranged from 0.06 to 0.40 (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 Table 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 Table 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 Tables 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 Table 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} Based on the median sensitivity and specificity at this cutoff, the positive likelihood ratio was 3.67 and negative likelihood ratio 0.74. 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, for a positive likelihood ratio of 2.14 and negative likelihood ratio of 0.36.^{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, for a positive likelihood ratio of 2.31 and negative likelihood ratio of 0.38.^{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. One poor-quality study (n=291) that focused on heel ulcers found a Braden score of ≤ 12 associated with sensitivity of 0.14 and specificity of 0.94 and a Braden of ≤ 16 associated with sensitivity of 0.49 and specificity of 0.76.⁷⁷

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 Table 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. Pressure ulcer risk assessment scales: area under the receiver operator characteristic

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)		

Note: AUROC=area under the receiver operator characteristic, ICU=intensive care unit.

Table 4. Sensitivity and specificity of pressure ulcer risk assessment scales

Cut-off	Number of Studies	Sensitivity	Specificity	PLR ^a	NLR ^a
Braden					
≤10	1 study ⁴⁹	0.91	0.96	22.75	0.09
≤12	2 studies ^{75,77}	0.86, 0.14 ^b	0.65, 0.94 ^b	2.46, 2.33	0.22, 0.91
≤13	1 study ⁷⁵	0.71	0.82	3.94	0.35
≤14	2 studies ^{20,42}	0.93, 0.89	0.70, 0.72	3.10, 3.18	0.10, 0.15
≤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)	3.67	0.74
≤16	9 studies ^{c 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)	2.14	0.36
<17	2 studies ^{41,82}	0.80, 0.59	0.65, 0.41	2.29, 1.00	0.31, 1.00
≤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)	2.31	0.38
≤20	1 study ⁵⁸	0.97	0.05	1.02	0.60
Norton					
<12	1 study ⁴¹	0.62	0.72	2.21	0.53
≤14	5 studies ^{d41,42,65,80,83}	Median 0.75 (range 0 to 0.89)	Median 0.68 (range 0.59 to 0.95)	2.34	0.37
≤16	3 studies ^{18,73,84}	Median 0.75 (range 0.46 to 0.81)	Median 0.59 (range 0.55 to 0.6)	1.83	0.42
Modified Norton					
>10	1 study ^{e45}	1	0.31	1.45	0.00
≤21	1 study ⁵⁸	0.33	0.94	5.50	0.71
≤23	1 study ⁵⁸	0.41	0.88	3.42	0.67
≤25	1 study ⁵⁸	0.58	0.47	1.09	0.89
Waterlow					
>9	1 study ⁷³	0.46	0.60	1.15	0.90
≥10	2 studies ^{25,80}	1.00, 0.88	0.13, 0.29	1.15, 1.24	0.00, 0.41
≥15	2 studies ^{43,81}	0.67, 0.81	0.79, 0.29	3.19, 1.14	0.42, 0.66
≥16	1 study ¹⁸	0.95	0.44	1.70	0.11
≥17	1 study ⁷⁴	0.71	0.67	2.15	0.43
≥20	1 study ⁷⁴	0.86	0.33	1.28	0.42
Cubbin and Jackson					
≤24	1 study ²¹	0.89	0.61	2.28	0.18
≤28	1 study ²⁰	0.95	0.82	5.28	0.06
≤29	1 study ²⁵	0.83	0.42	1.43	0.40

^aLikelihood ratios were calculated based on the median sensitivity and specificity unless there were fewer than three studies, in which case likelihood ratios were calculated for individual studies.

^bThese values are from a study assessing the predictive value of the Braden scale in heel ulcer development

^cIncludes a sensitivity of 0.49 and specificity of 0.76 from one study of heel ulcer development

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

^eThough this study used standard Norton criteria, scoring was reversed so that higher scores indicated increased risk. Thus scores are not directly comparable to other studies using a standard Norton scale.

Norton Scale

The Norton scale was evaluated in 12 studies (Appendix Tables 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 study added skin condition, motivation and age to the five existing items,⁵⁸ and the third study 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, for a positive likelihood ratio of 2.34 and negative likelihood ratio of 0.37 (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 Table 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, for a positive likelihood ratio of 1.83 and negative likelihood ratio of 0.42.^{18,73,84} None of the studies were rated poor-quality. One study reported an unadjusted odds ratios for incident 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 Tables 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, for positive likelihood ratios of 1.15 and 1.24 and negative likelihood ratios of 0 and 0.41.^{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} Associated positive likelihood ratios ranged from 1.43 to 5.28 and negative likelihood ratios from 0.06 to 0.40. 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 at a cutoff of ≤ 24 , for a positive likelihood ratio of 2.28 and negative likelihood ratio of 0.18.²¹ Other risk assessment tools were evaluated in one study each, including the Gosnell,²³ Song and Choi,²⁰ Fraggment,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 Table 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 Tables 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 One poor-quality study (n=291) that focused on heel ulcers found no difference in the AUROC for the Braden scale compared with several alternative, derived scales.⁷⁷

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. Direct comparisons of pressure ulcer risk assessment scales

Author, Year	Setting	Braden	Norton	Waterlow	Cubbin and Jackson	Other	Quality Rating
AUROC							
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	<u>Song/Choi</u> 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	<u>Fragmment</u> 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	<u>Douglas</u> 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

Table 5. Direct comparisons of pressure ulcer risk assessment scales (continued)

Author, Year	Setting	Braden	Norton	Waterlow	Cubbin and Jackson	Other	Quality Rating
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
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	<u>Clinical judgment</u> 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	<u>Dutch CBO</u> Sensitivity: 0.58 Specificity: 0.57	Fair

Note: AUROC=area under the receiver operating characteristic, CI=confidence interval, ICU=intensive care unit.

^aBraden 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 with 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 nonsurgical 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 Table 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 Table 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 patients⁴¹ (Appendix Table H8). Based on a cutoff of ≤ 15 on the Braden Scale, one study performed in an intensive care unit³⁹ reported a higher sensitivity (0.75) and similar specificity (0.67) compared with 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 Table 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 settings. The only study to evaluate hospice patients evaluated a modified version of the Norton scale in which scoring was reversed so that higher scores indicate higher risk and did not report the AUROC.⁴⁵

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 Table H9). One

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, 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 Table 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 Table 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 are the effectiveness and comparative effectiveness of preventive interventions in reducing the incidence or severity of pressure ulcers?

Key Points

Support Surfaces

Mattresses, Overlays, and Bed Systems

- One good-quality trial (n=1166) and four fair-quality trials (n=83 to 543) found a more advanced static mattress or overlay associated with lower risk of incident pressure ulcers than a standard mattress (RR range 0.16 to 0.82), though the difference was not statistically significant in two trials. Six poor-quality trials reported results that were generally consistent with these findings, though one trial found no benefit. Three trials found no difference in length of stay. The static support surfaces evaluated in the trials varied, though a subgroup of three trials each found an Australian medical sheepskin overlay associated with lower risk of ulcers than a standard mattress (RR 0.30, 0.58, and 0.58) (strength of evidence: moderate).
- Three fair-quality trials (n=52 to 100) found no differences between different advanced static support mattresses or overlays 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). Six poor-quality trials (n=37 to 407) also found no differences between different advanced static mattresses or overlays (strength of evidence: moderate).
- One fair-quality trial (n=98) found a low-air-loss bed associated with lower likelihood of one or more pressure ulcers in intensive care unit patients (12 vs. 51 percent, RR 0.23, 95% CI, 0.10 to 0.51), but a small (n=36), poor-quality trial found no difference between a low-air-loss mattress compared with a standard hospital bed following cardiovascular surgery (strength of evidence: low).
- One fair-quality trial (n=62) found no clear difference between a low-air-loss mattress compared with the Hill-Rom Duo mattress (options for constant low pressure or alternating-air) in risk of ulcers (strength of evidence: low).
- Three poor-quality trials (n=108 to 487) found lower incidence of pressure ulcers with use of an alternating air pressure mattress or overlay compared with a standard hospital mattress (strength of evidence: low).
- Six trials (n=32 to 487, one good-quality, one fair-quality, and four poor-quality) found no difference between an alternating air pressure overlay or mattress compared with various advanced static mattresses or overlays in pressure ulcer incidence or severity (strength of evidence: moderate).
- Four trials (n=44 to 1972; one good-quality, two fair-quality, and one poor-quality) found no clear differences between different alternating air mattresses or overlays. The good-quality (n=1972) trial found no difference in risk of stage 2 ulcers between an alternating air pressure overlay and an alternating air pressure mattress (RR 1.0, 95% CI, 0.81 to 1.3; adjusted OR 0.94, 95% CI, 0.68 to 1.3) (strength of evidence: moderate).

Heel Supports/Boots

- 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 without leg elevation (7 vs. 26 percent for any ulcer, RR 0.26, 95% CI, 0.12 to 0.53; 3.3 vs. 13.4 percent for stage 2 ulcers, RR 0.25, 95% CI, 0.09 to 0.72). 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 cointerventions (strength of evidence: insufficient).

Wheelchair Cushions

- Four fair-quality trials (n=32 to 248) of older nursing home patients 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).

Nutritional Supplementation

- Five of six trials (one fair-quality and five poor-quality; n=59 to 672) found no difference between nutritional supplementation compared with standard hospital diet in risk of pressure ulcers. Four trials evaluated supplementation by mouth and two evaluated enteral supplementation (strength of evidence: low).

Repositioning

- One fair-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) and one fair-quality trial (n=235) found no difference in risk of pressure ulcers between different repositioning intervals. 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).
- Two small (n=15 and 19), poor-quality trials found the addition of small, unscheduled shifts in body position (using a small rolled towel to designated areas during nurse-patient interactions) to standard repositioning every 2 hours had no effect on risk of pressure ulcers, but only reported one or two ulcers each. (strength of evidence: low)

Dressings

- One fair-quality (n=85) trial of patients undergoing cardiac surgery found a silicone border foam sacral dressing applied at intensive care unit (ICU) admission (the Mepilex Border sacrum) associated with lower likelihood of pressure ulcers compared with standard care (including preoperative placement of a silicone border foam dressing for

surgery and use of a low air loss bed), but the difference was not statistically significant (2.0 vs. 12 percent, RR 0.18, 95% CI, 0.02 to 1.5) (strength of evidence: low)

- A poor-quality trial of 37 patients 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 stage 1 ulcers compared with 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).
- 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).

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 corticotropin intramuscularly compared with a sham injection (strength of evidence: insufficient).

Polarized Light

- One small, poor-quality randomized trial (n=23) found no statistically significant difference between polarized light compared with standard care in risk of pressure ulcers (strength of evidence: insufficient).

Creams, Lotions and Cleansers

- One fair-quality (n=331) and one poor-quality (n=86) trial found creams with fatty acids associated with decreased risk of new pressure ulcers compared with placebo (RR 0.42, 95% CI 0.22 to 0.80 and RR 0.17, 95% CI, 0.04 to 0.70) (strength of evidence: low)
- Evidence from three poor-quality trials (n=79 to 258) was insufficient to determine effectiveness of other creams or lotions for preventing pressure ulcers (strength of evidence: insufficient).
- One fair-quality trial (n=93) found the 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

Forty-one randomized trials (in forty-two publications) evaluated various types of support surfaces for prevention of pressure ulcers in patients at increased risk⁸⁵⁻¹²⁶ (Appendix Table 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, including alternating-air, low-air-loss, or air-fluidized, and whether the support surface requires power.²⁷ In this report, we classified support surfaces broadly as static, alternating air, or low-air-loss.

Sample sizes ranged from 32 to 1,972 subjects, and followup ranged from 6 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 $\leq 15-18$, Norton $\leq 12-16$, Waterlow $\geq 10-15$, Cubbin and Jackson score < 29 , and others. When reported, mean Braden scores ranged from 9.4 to 15.9,^{86,87,94,95,97,106-108,112,117,123,125,126} Norton scores from 11.5 to 13.4,^{89-91,93,99,111,119} and Waterlow scores from 12.8 to 19.^{92,100,101,103,116,121} Trials of patients at lower baseline risk were typically conducted in surgical settings and are discussed below (see Key Question 3a).¹²⁷⁻¹³³

Three trials were rated good-quality,^{115,116,125} Twenty trials were rated fair-quality^{86,89-91,94-97,100,101,105,107-109,111,113,121,122,124,126} and 18 poor-quality;^{85-88,92,93,98,99,102-104,106,110,112,117-120,123}

(Appendix Table 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 prevent 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 for both high- and low-risk patients 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 air-alternating mattresses or bed systems and some low-air-loss mattresses or bed systems. In addition, the “standard hospital mattress” comparator was not well described in a number of trials and probably differed. Previously, typical hospital mattresses were spring mattresses but more recently, foam mattresses.

Table 6. Types of support surfaces^a

Study Population Assessed	Type of Support Surface	Material (Foam, Air, Gel, Water, Beads, etc.)	Static, Alternating-Air, or Low-Air-Loss	Power Source Required?
Andersen et al, 1982 ⁸⁵ At risk	Alternating-air pressure mattress	Air	Alternating air	Powered
	Water mattress	Water	Static	Nonpowered
	Standard hospital mattress	Unclear	Static	Nonpowered
Aronovitch et al, 1999 ¹²⁷ Low risk	Alternating-air pressure mattress (Micropulse)	Air	Alternating air	Powered
	Gel pad (Action Pad) on operating room table, then replacement hospital mattress (Pressure Guard II)	Gel/Unclear	Static	Nonpowered
Berthe et al, 2007 ¹²⁸ Low risk	Kliniplot mattress system, segmented foam blocks	Foam	Static	Nonpowered
	Standard hospital mattress	Unclear	Static	Nonpowered
Brienza et al, 2010 ⁸⁶ At risk	Solid foam seat cushion	Foam	Static	Nonpowered
	Segmented air seat cushion (Quadro)	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

Table 6. Types of support surfaces^a (continued)

Study Population Assessed	Type of Support Surface	Material (Foam, Air, Gel, Water, Beads, etc.)	Static, Alternating-Air, or Low-Air-Loss	Power Source Required?
Cavicchiloi et al, 2007 ⁸⁷ At risk	Constant low pressure or alternating-air options (Hill Rom Duo)	Air	Alternating air	Powered
	High-specification foam mattress	Foam	Static	Nonpowered
Collier et al, 1996 ⁸⁸ At risk	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 ⁹⁰ At risk	Slab wheelchair cushion	Foam	Static	Nonpowered
	Contoured wheelchair cushion	Foam	Static	Nonpowered
Conine et al, 1994 ⁹¹ At risk	Polyurethane foam wheelchair cushion	Foam	Static	Nonpowered
	Combination foam and gel wheelchair cushion (Jay Cushion)	Foam, Gel	Static	Nonpowered
Conine et al, 1990 ⁸⁹ At risk	Alternating pressure overlay	Air	Alternating air	Powered
	Siliconized hollow fiber overlay	Fiber	Static	Nonpowered
Cooper et al, 1998 ⁹² At risk	Segmented air cell mattress (Sofflex)	Air	Static	Nonpowered
	Segmented air cell mattress (Roho)	Air	Static	Nonpowered
Daechsel & Conine, 1985 ⁹³ At risk	Alternating pressure overlay	Air	Alternating air	Powered
	Siliconized hollow fiber overlay	Fiber	Static	Nonpowered
Demarre, 2012 ⁹⁴ At risk	Clinactiv alternating air mattress with multi-stage inflation and deflation (Hill-Rom)	Air	Alternating air	Powered
	ALPAM alternating air mattress with single stage inflation and deflation (Hill-Rom)	Air	Alternating air	Powered
Donnelly et al, 2011 ⁹⁵ At risk	Heelift Suspension Boot	Foam	Static	Nonpowered
	No boot	Not applicable	Not applicable	Not applicable
Feuchtinger et al, 2006 ¹²⁹ Low risk	Water-filled warming mattress	Water	Static	Powered
	Viscoelastic foam overlay	Foam	Static	Nonpowered

Table 6. Types of support surfaces^a (continued)

Study Population Assessed	Type of Support Surface	Material (Foam, Air, Gel, Water, Beads, etc.)	Static, Alternating-Air, or Low-Air-Loss	Power Source Required?
Gebhardt et al, 1996 ⁹⁶ At risk	Protocol #1: Alternating pressure surfaces: <i>Step 1:</i> Grant Dynacare overlay Alpha X Cell overlay APM 15 overlay Double Bubble Air Floatation overlay Large Cell Ripplebed overlay <i>Step 2:</i> Pegasus Airwave System mattress Nimbus Dynamic Floatation System mattress	Air	Alternating air	Powered
	Protocol #2: Static and low-air-loss support surfaces <i>Step 1:</i> Ultimat Antidecubitis Mattress fibre overlay Slumberland Gold fibre overlay Surgicgood Hollowcore fibre overlay Tendercare Full Bed fibre overlay Universal Polycare fibre overlay Clinifloat mattress Omnifoam 6" mattress Bodigard Critical Flotation overlay Contoured Propad overlay Lyopad mattress Carelite Inflatable static air overlay Sofcare Bed static air overlay Waffle static air overlay <i>Step 2:</i> Roho static overlay Paragon Convertible low-air-loss mattress	Varies	Static; Low-air-loss	Varies
Geyer et al, 2001 ⁹⁷ At risk	Convoluted Foam wheelchair cushion (Sunrise Medical)	Foam	Static	Nonpowered
	Pressure reducing wheelchair cushion	Varies	Varies	Varies
Gilcreast et al, 2005 ⁹⁸ At risk	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 ⁹⁹ At risk	Beaufort Bead Bed system (aka Neumark-Macclesfield Support System)	Bead	Static	Nonpowered
	Standard hospital surfaces	Unclear	Static	Nonpowered
Gray & Campbell, 1994 ¹⁰⁰ At risk	Softform mattress (Medical Support Systems Ltd, now Invacare)	Foam	Static	Nonpowered
	Standard NHS foam mattresses (Recticel Ltd)	Foam	Static	Nonpowered
Gray & Smith, 2000 ¹⁰¹ At risk	Transfoam mattress (Karomed)	Foam	Static	Nonpowered
	Transfoamwave mattress (Karomen)	Foam	Static	Nonpowered
Gunningberg et al, 2000 ¹⁰² At risk	Visco elastic foam mattress (Tempur-Pedic)	Foam	Static	Nonpowered
	Standard hospital mattress	Foam	Static	Nonpowered

Table 6. Types of support surfaces^a (continued)

Study Population Assessed	Type of Support Surface	Material (Foam, Air, Gel, Water, Beads, etc.)	Static, Alternating-Air, or Low-Air-Loss	Power Source Required?
Hampton et al, 1999 ¹⁰³ At risk	Stepped approach on Thermo contour foam mattress (step 1) or an air mattress (step 2)	Foam, air	Static	Unclear
	Stepped approach with usual care (step 1) or an air mattress (step 2)	Foam, air	Static	Unclear
Hofman et al, 1994 ¹⁰⁴ At risk	DeCube Cubed foam mattress (Comfortex)	Foam	Static	Nonpowered
	Standard polypropylene SG40 hospital foam mattress (Vredestein)	Foam	Static	Nonpowered
Hoshowsky et al, 1994 ¹³⁰ Low risk	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
Inman et al, 1993 ¹⁰⁵ At risk	Air suspension bed (KinAir, Kinetic Concepts, Inc.)	Air	Low-air-loss	Powered
	Standard ICU mattress	Unclear	Static	Unclear
Jesurum et al, 1996 ¹⁰⁶ At risk	Standard bed with pressure reducing mattress replacement	Foam	Static	Nonpowered
	Low-air-loss bed	Air	Low-air-loss	Powered
Jolley et al, 2004 ¹⁰⁷ At risk	Australian medical sheepskin overlay	Fiber	Static	Nonpowered
	Standard hospital mattress and other pressure relieving devices as needed	Varies	Varies	Varies
Kemp et al, 1993 ¹⁰⁸ At risk	Convolutated foam overlay	Foam	Static	Nonpowered
	Solid foam overlay	Foam	Static	Nonpowered
Keogh et al, 2001 ¹⁰⁹ At risk	Electrically operated, four-sectioned profiling bed with foam (Pentaflex) pressure relieving/reducing mattress	Profiling bed	Not applicable	Powered
	Nonprofiling, standard hospital bed with variety of pressure relieving/reducing mattresses (alternating air or foam)	Nonprofiling bed	Not applicable	Nonpowered
Lazzara et al, 1991 ¹¹⁰ At risk	Gel mattress	Gel	Static	Nonpowered
	Air-filled overlay	Air	Static	Nonpowered
Lim et al, 1988 ¹¹¹ At risk	Foam slab cushion	Foam	Static	Nonpowered
	Foam contoured cushion	Foam	Static	Nonpowered
McGowan et al, 2000 ¹¹² At risk	Australian medical sheepskin overlay	Fiber	Static	Nonpowered
	Standard hospital mattress and other pressure relieving devices as needed	Varies	Varies	Varies
Mistiaen et al, 2010 ¹¹³ At risk	Australian medical sheepskin overlay (Yellow Earth)	Fiber	Static	Nonpowered
	Standard hospital mattress	Varies	Varies	Varies
Nixon et al, 1998 ¹³¹ Low risk	Visco-elastic polymer pad	Dry polymer	Static	Nonpowered
	Standard operating table mattress	Unclear	Unclear	Unclear
	Gamgee pad heel support	Fiber	Static	Nonpowered
Nixon et al, 2006 ^{114,115} At risk	Alternating pressure mattress	Air	Alternating air	Powered
	Alternating pressure overlay	Air	Alternating air	Powered
Russell et al, 2003 ¹¹⁶ At risk	Viscoelastic and polyurethane foam (CONFOR-Med) mattress	Foam	Static	Nonpowered
	Standard hospital mattress	Foam	Static	Nonpowered

Table 6. Types of support surfaces^a (continued)

Study Population Assessed	Type of Support Surface	Material (Foam, Air, Gel, Water, Beads, etc.)	Static, Alternating-Air, or Low-Air-Loss	Power Source Required?
Russell et al, 2000 ¹³² Low risk	Multi-cell pulsating dynamic mattress system (MicroPulse, Inc)	Air	Alternating air	Powered
	Gel pad (Action Pad) on operating room table, then standard hospital mattress (HillRom)	Gel/Unclear	Static	Nonpowered
Sanada et al, 2003 ¹¹⁷ At risk	Double-layer air cell overlay (Tricell)	Air	Alternating air	Powered
	Single-layer air cell overlay (Air Doctor)	Air	Alternating air	Powered
	Standard hospital mattress (Paracare)	Foam	Static	Nonpowered
Schultz et al, 1999 ¹³³ Low risk	Mattress overlay	Foam	Static	Nonpowered
	Standard care (including gel pads, foam mattresses, ring cushions [donuts] etc)	Varies	Varies	Varies
Sideranko et al, 1992 ¹¹⁸ At risk	Lapidus Airfloat System alternating-air pressure mattress	Air	Alternating air	Powered
	Sofcare Bed Cushion overlay (Gaymar)	Air	Static	Nonpowered
	Lotus water mattress (Connecticut Artcraft Co.)	Water	Static	Nonpowered
Stapleton et al, 1986 ¹¹⁹ At risk	Large Cell Rippled overlay	Air	Alternating air	Powered
	Polyether foam pad	Foam	Static	Nonpowered
	Spenco bed pad	Fiber	Static	Nonpowered
Takala et al, 1996 ¹²⁰ At risk	Carital Air-float System (Carital Optima, Carital Ltd.)	Air	Static	Powered
	Standard hospital mattress (Espe Inc.)	Foam	Static	Nonpowered
Taylor et al, 1999 ¹²¹ At risk	Alternating-air pressure mattress (Pegasus Trinova)	Air	Alternating air	Powered
	Alternating-air pressure mattress (unnamed)	Air	Alternating air	Powered
Theaker et al, 2005 ¹²² At risk	Low-air-loss Therapulse pulsating air suspension mattress (Kinetic Concepts, Inc.)	Air	Low-air-loss	Powered
	Constant low pressure or alternating-air options in same mattress (Hill Rom Duo)	Air	Alternating air	Powered
Tymec et al, 1997 ¹²³ At risk	Foot waffle (EHOB)	Air	Static	Nonpowered
	Hospital pillow	Fabric	Static	Nonpowered
van Leen et al., 2011 ¹²⁴ At risk	Silhouette Cold foam mattress (Comfortex) with static air overlay	Foam/Air	Static	Nonpowered
	Silhouette Cold foam mattress (Comfortex)	Foam	Static	Nonpowered
Vanderwee, 2005 ¹²⁵ At risk	Alpha-X-Cell alternating pressure air mattress (Huntleigh Healthcare)	Air	Alternating air	Powered
	Tempur visco-elastic foam mattress (Tempur-World, Inc)	Foam	Static	Nonpowered
Vyhlidal et al, 1997 ¹²⁶ At risk	Iris 3000 foam overlay (Bio Clinic of Sunrise Medical Co.)	Foam	Static	Nonpowered
	Maxifloat foam mattress replacement (BG Industries)	Foam	Static	Nonpowered

Note: ICU=intensive care unit.

^aTable includes all studies for Key Questions 3 and 3a.

Mattresses, Overlays, and Bed Systems

Static Mattresses, Overlays, and Bed Systems

Twenty-two trials^{85,88,92,99-104,107-113,116,118-120,124,126} (sample sizes 36 to 543) compared static mattresses and/or mattress overlays with each other to prevent pressure ulcers. One was rated

good quality,¹¹⁶ nine fair quality,^{100,101,107-109,111,113,124,126} and the other twelve poor quality.^{85,88,92,99,102-104,110,112,118-120} 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)^{85,88,92,99-104,107-109,112,116,118-121} and long-term care nursing facilities.^{108,110,111,113,124,126}

Twelve trials compared a more advanced static support surface to a standard hospital mattress control.^{85,88,99,100,102,104,107,112,113,116,120,124} One good-quality trial (n=1166) found a more advanced static mattress or overlay associated with lower risk of ulcers than a standard hospital mattress (8.5 vs. 10.9 percent, RR 0.78, 95% CI, 0.55 to 1.1), but the difference was not statistically significant.¹¹⁶ Four fair-quality trials (n=83 to 543) also found the more advanced static mattress or overlay associated with decreased risk of any (primarily stage 1) incident pressure ulcers (RR range 0.16 to 0.82),^{100,107,113,124} though the difference was not statistically significant in one trial (RR 0.28, 95% CI, 0.06 to 1.3) (Table 7).¹²⁴ The static support surfaces evaluated in the trials were a viscoelastic and polyurethane form mattress,¹¹⁶ the Softform mattress,¹⁰⁰ a sheepskin overlay,^{107,113} and an air overlay.¹²⁴ There was no clear difference in results between trials published earlier compared with those published more recently, even though standard mattress comparators have changed over time.

Five poor-quality trials also found a more advanced static mattress or overlay (water mattress, bead overlay, cubed foam mattress, medical sheepskin, or low air pressure mattress) associated with decreased incidence of pressure ulcers compared with a standard hospital mattress (RR 0.08 to 0.32).^{85,99,104,112,120} One poor-quality trial found no difference between a visco-elastic foam mattress compared with a standard hospital mattress¹⁰² and one trial reported no ulcers in patients randomized to various static support surfaces, including a standard hospital mattress.⁸⁸

Three of the trials found no difference between a more advanced static mattress or overlay and a standard mattress in length of stay.^{104,107,116} Three of the trials (two fair quality^{107,113} and one poor quality¹¹²) each found an Australian medical sheepskin overlay associated with lower risk of pressure ulcers compared with a standard mattress (RR 0.30, 0.58, and 0.58).

Eleven trials compared different advanced support surfaces.^{88,92,101,103,108-111,118,119,126} Three fair-quality trials (samples sizes 52 to 100) found no difference between the Transfoamwave and Transfoam mattresses,¹⁰¹ a convoluted compared with solid foam overlay,¹⁰⁸ or a contoured compared with slab foam cushion¹¹¹ 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 1 or 2) 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)¹²⁶ (Table 7). Six poor-quality trials (n=37 to 407) found no differences between different various static support surfaces.^{88,92,103,110,118,119} However, in a subgroup analysis of patients ≥ 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).¹¹⁹

One fair-quality trial (n=70) found no pressure ulcers after a week in patients randomized to a profiling bed with a foam pressure relieving mattress compared with a nonprofiling bed with either a foam (n=25) or alternating air (n=10) mattress.¹⁰⁹

Table 7. Effectiveness of pressure ulcer prevention support surfaces in at-risk patients—static mattresses, overlays, and bed systems

Author, Year Quality Rating	Setting Country Followup	Intervention (N)	Baseline Demographics	Baseline Ulcer Risk Score^a Pressure Ulcers at Baseline	Pressure Ulcer Incidence	Pressure Ulcer Severity	Length of Stay
Andersen et al, 1982 ⁸⁵ 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; >2 indicates at risk) Pressure ulcers at baseline: Excluded	Any pressure ulcer: 4.2% (7/166) vs. 4.5% (7/155) vs. 13.0% (21/161); RR 0.94 (95% CI, 0.34 to 2.6) for A vs. B, RR 0.32 (95% CI, 0.14 to 0.74) for A vs. C, RR 0.35 (95% CI, 0.15 to 0.79) for B vs. C	NR	NR
Collier et al, 1996 ⁸⁸ 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% Age not reported	Waterlow score range: 3 to 25 Pressure ulcers at baseline: Not reported	No patients developed a pressure ulcer of any stage during the study	NR	NR
Cooper et al, 1998 ⁹² Poor	Acute care United Kingdom 7 days	A. Sofflex immersion air mattress (n=41) B. Roho immersion air mattress (n=43)	Mean age: 83 vs. 83 years Percent female: 86% vs. 82% Orthopedic patients	Mean Waterlow score: 17 vs. 16 Pressure ulcers at baseline: Excluded	Any pressure ulcers: 7.3% (3/41) vs. 12% (5/43), RR 0.63 (95% CI, 0.16 to 2.5)	Only 1 pressure ulcer involved a break in the skin (Stirling stage 2.4, Group A Sofflex group)	NR

Table 7. Effectiveness of pressure ulcer prevention support surfaces in at-risk patients—static mattresses, overlays, and bed systems (continued)

Author, Year Quality Rating	Setting Country Followup	Intervention (N)	Baseline Demographics	Baseline Ulcer Risk Score^a Pressure Ulcers at Baseline	Pressure Ulcer Incidence	Pressure Ulcer Severity	Length of Stay
Goldstone et al, 1982 ⁹⁹ 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: All >60 years Percent female: 91% and 84% Fracture patients	Mean Norton score: 13 Pressure ulcers at baseline: Not reported	Any pressure ulcer: 16% (5/32) vs. 49% (21/43), RR 0.32 (95% CI, 0.14 to 0.76) Sacral pressure ulcer: 6.3% (2/32) vs. 26% (11/43), RR 0.24 (95% CI, 0.06 to 1.0) Heel pressure ulcers: 0% (0/32) vs. 33% (14/43), RR 0.05 (95% CI, 0.003 to 0.74)	Maximum ulcer width (mean): 6.4 vs. 30 mm, p=0.03 Buttock ulcer maximum width (mean): 5.7 vs. 24 mm, p=0.018 Sacral ulcer maximum width (mean): 7.5 vs. 56 mm, p=NR	NR
Gray & Campbell, 1994 ¹⁰⁰ 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% vs. 59%	Waterlow score: 18.03 vs. 16.01 Pressure ulcers at baseline: Excluded	Stage 2 or greater ulcer: 7% (5/90) vs. 34% (27/80); RR 0.16 (95% CI, 0.07 to 0.41)	NR	NR
Gray & Smith, 2000 ¹⁰¹ 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 Pressure ulcers at baseline: Excluded	Any pressure ulcer: 4% (2/50) vs. 4% (2/50), RR 1.0 (95% CI, 0.15 to 6.8) Heel ulcer: 0% (0/50) vs. 2% (1/50); RR 0.34 (95% CI, 0.01 to 8.2)	Stage 1: 2% (1/50) vs. 2% (1/50) Stage 2: 2% (1/50) vs. 0% (0/50) Stage 4: 0% (0/50) vs. 2% (1/50)	NR

Table 7. Effectiveness of pressure ulcer prevention support surfaces in at-risk patients—static mattresses, overlays, and bed systems (continued)

Author, Year Quality Rating	Setting Country Followup	Intervention (N)	Baseline Demographics	Baseline Ulcer Risk Score^a Pressure Ulcers at Baseline	Pressure Ulcer Incidence	Pressure Ulcer Severity	Length of Stay
Gunningberg et al, 2000 ¹⁰² Poor	Hospital, surgery Sweden 14 days Post-op	A: Visco-elastic foam mattress (n=48) B: Standard mattress (n=53)	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) Pressure ulcers at baseline: Excluded	Any pressure ulcer: 25% (12/48) vs. 32% (17/53), RR 0.78 (95% CI, 0.42 to 1.5)	Stage 1: 17% (8/48) vs. 17% (9/53), RR 0.98 (95% CI, 0.41 to 2.3) Stage 2: 8% (4/48) vs. 14%, (7/53), RR 0.63 (95% CI, 0.20 to 2.0) Stage 3: 0% (0/48) vs. 0% (0/53) Stage 4: 0% (0/48) vs. 2% (1/53), p=NS Stages 2-4: 8% (4/48) vs. 15% (8/53), RR 0.37 (95% CI, 0.02 to 8.8)	NR
Hampton et al, 1999 ¹⁰³ Poor	Hospital United Kingdom Followup NR	A. Stepped approach on Thermo contour foam mattress (step 1) or an air mattress (step 2) (n=199) B. Stepped approach with usual care (step 1) or an air mattress (step 2) (n=208)	Mean age: 70 vs. 67 years Sex: NR Race: NR	Mean Waterlow score: 14.6 vs. 12.8 Pressure ulcers at baseline: 2.4% (5/208) vs. 1.5% (3/199)	Any pressure ulcer: 2.9% (6/208) vs. 0%; RR 0.08 (95% CI, 0.00 to 1.46)	NR	NR

Table 7. Effectiveness of pressure ulcer prevention support surfaces in at-risk patients—static mattresses, overlays, and bed systems (continued)

Author, Year Quality Rating	Setting Country Followup	Intervention (N)	Baseline Demographics	Baseline Ulcer Risk Score ^a Pressure Ulcers at Baseline	Pressure Ulcer Incidence	Pressure Ulcer Severity	Length of Stay
Hofman et al, 1994 ¹⁰⁴ Poor	Surgery Netherlands 14 days post-op	A. Stepped approach with cubed foam mattress (Comfortex DeCube mattress) - allows removal of small cubes of foam from beneath bony prominences (step 1) or air mattress (step 2) (n=21) B. Stepped approach with standard hospital mattress, polypropylene SG40 hospital foam mattress (step 1) or air mattress (step 2) (n=23)	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) Pressure ulcers at baseline (stage 1): 9.5% vs. 8.7%	Stage 2-4 ulcer: 24% (4/17) vs. 68% (13/19), RR 0.34 (95% CI, 0.14 to 0.85)	Stage 2 ulcer: 5.9% (1/17) vs. 26% (5/19), RR 0.22 (95% CI, 0.03 to 1.7) Stage 3 ulcer: 18% (3/17) vs. 26% (5/19), RR 0.67 (95% CI, 0.19 to 2.4) Stage 4 ulcer: 0% (0/17) vs. 16% (3/19), RR 0.18 (95% CI, 0.01 to 3.3)	Length of stay: 21 vs. 23 days; p=NS
Jolley et al, 2004 ¹⁰⁷ Fair	Hospital Australia 7-7.9 days	A. Sheepskin mattress overlay (n=218) B. Usual care as determined by ward staff. (n=223)	Mean age: 63 vs. 61 years Percent female: 49% vs. 52%	Mean Braden score: 15.7 vs. 15.9 Pressure ulcers at baseline: Excluded	One or more pressure ulcers: 9.6% (21/218) vs. 17% (37/223); RR 0.58 (95% CI, 0.35 to 0.96) Pressure ulcers/patient: 0.12 (27 ulcers/218 patients) vs. 0.26 (58 ulcers/223 patients); rate ratio 0.48 (95% CI, 0.29 to 0.76)	Incidence of pressure ulcers: Number of incident stage 2 ulcers (no stage 3 or 4 ulcers reported): 5.5% (12/218) vs. 9.0% (20/223), RR 0.61 (95% CI, 0.31 to 1.2)	<u>Mean bed days:</u> 7.9 vs. 7.0; p=NS

Table 7. Effectiveness of pressure ulcer prevention support surfaces in at-risk patients—static mattresses, overlays, and bed systems (continued)

Author, Year Quality Rating	Setting Country Followup	Intervention (N)	Baseline Demographics	Baseline Ulcer Risk Score ^a Pressure Ulcers at Baseline	Pressure Ulcer Incidence	Pressure Ulcer Severity	Length of Stay
Kemp et al, 1993 ¹⁰⁸ Fair	Hospital and long-term care United States 1 month	A. Convoluted foam overlay (n=45) B. Solid foam overlay (n=39)	Mean age: 79 vs. 83 years Percent female: 69% vs. 93% Race: 51% vs. 56% Black; 47% vs. 44% White; 2% vs. 0% Hispanic	Mean Braden score: 14 vs. 14 Pressure ulcers at baseline: Excluded	Any pressure ulcer: 47% (21/45) vs. 31% (12/39), RR 1.5 (95% CI, 0.86 to 2.7)	Overall (not reported by intervention group) Stage 1: 10 Stage 2: 47	NR
Keogh et al, 2001 ¹⁰⁹ Fair	Hospital United Kingdom 6-8 days	A: Nonprofiling standard hospital bed with variety of pressure relieving/reducing mattresses (alternating air [n=10] or foam [n=25]) (n=35) B: Electrically operated, four- sectioned profiling bed with foam (Pentaflex) pressure relieving/reducing mattress (n=35)	Mean age: 71 vs. 69 years Sex: 60% vs. 30% female Race: NR	Waterlow score: NR Nutritional assessment score: 11.9 vs. 11.7 Mobility score: 3.4 vs. 3.7 Pressure ulcers at baseline: Grade I ulcers at baseline: 28.5% (10/35) vs. 11.4% (4/35)	Any pressure ulcer: 0% vs. 0%	NR	NR
Lazzara et al, 1991 ¹¹⁰ Poor	Nursing homes United States 6 months	A: Gel mattress (n=33) B: Air-filled overlay (n=33)	NR	All had Norton score >15 Pressure ulcers at baseline: 21% (7/33) vs. 6% (2/33)	Pressure ulcers in patients without ulcers at baseline: 32% (8/26) vs. 32% (10/31); RR 0.95 (95% CI, 0.44 to 2.06)	Improvement in severity: 58% (7/12) vs. 60% (9/15) No differences between groups	NR

Table 7. Effectiveness of pressure ulcer prevention support surfaces in at-risk patients—static mattresses, overlays, and bed systems (continued)

Author, Year Quality Rating	Setting Country Followup	Intervention (N)	Baseline Demographics	Baseline Ulcer Risk Score ^a Pressure Ulcers at Baseline	Pressure Ulcer Incidence	Pressure Ulcer Severity	Length of Stay
Lim et al, 1988 ¹¹¹ Fair	Extended care facility Canada 5 months	A. Contoured foam cushion (n=26) B. Foam slab cushion (n=26)	Mean age: 83 vs. 84.6 years Percent female: 76.9% vs. 69.2%	All patients ≤14 on Norton scale Pressure ulcers at baseline: Excluded	Any pressure ulcer: 69% (18/26) vs. 73% (19/26), RR 0.95 (95% CI, 0.67 to 1.3)	Overall (not reported by intervention group) 60% (44/72) of ulcers were stage 1; none progressed past stage 3 (Exton-Smith scale)	NR
McGowan et al, 2000 ¹¹² Poor	Hospital Australia Post-op	A. Australian Medical Sheepskin overlay (n=155) B. Standard hospital mattress(n=142)	Mean age: 73.6 vs. 74 years Percent female: 54% vs. 61% Orthopedic patients	Mean Braden score: 13.9 vs. 14.0 Pressure ulcers at baseline: Excluded	Any pressure ulcer: 9% (14/155) vs. 30% (43/142), RR 0.30 (95% CI, 0.17 to 0.52) Pressure ulcers/patient: 0.14 (21 ulcers/155 patients) vs. 0.47 (67 ulcers/142 patients); rate ratio 0.29 (95% CI, 0.17 to 0.47)	Stage 2-4 pressure ulcer: 0% (0/155) vs. 3.5% (5/142), RR 0.08 (95% CI, 0.005 to 1.5)	NR
Mistiaen et al, 2010 ¹¹³ Fair	Long-term care facility Netherlands 30 days	A. Australian Medical Sheepskin overlay (buttocks area) (n=271) B. Control (n=272)	Mean age: 78 vs. 78 years Percent female: 71% vs. 67%	Braden score ≤20: 70% vs. 71% Braden score ≤18: 47% vs. 47% Pressure ulcers at baseline: Excluded	Sacral pressure ulcers: 8.9% (24/271) vs. 15% (40/272), RR 0.58 (95% CI, 0.36 to 0.94); adjusted for baseline patient characteristics: OR 0.53 (95% CI, 0.29 to 0.95) Nonsacral pressure ulcers: 16% (44/271) vs. 15% (41/272), RR 1.1 (95% CI, 0.73 to 1.6) Any ulcer: 22% (60/271) vs. 27% (73/272), RR 0.82 (95% CI, 0.61 to 1.1)	Severity, number sacral pressure ulcers (EPUAP stages): Stage 1 = 50 Stage 2 = 12 Stage 3 = 2 p=NS between groups	NR

Table 7. Effectiveness of pressure ulcer prevention support surfaces in at-risk patients—static mattresses, overlays, and bed systems (continued)

Author, Year Quality Rating	Setting Country Followup	Intervention (N)	Baseline Demographics	Baseline Ulcer Risk Score^a Pressure Ulcers at Baseline	Pressure Ulcer Incidence	Pressure Ulcer Severity	Length of Stay
Russell et al, 2003 ¹¹⁶ Good	3 hospitals United Kingdom 11-12 days	A: Viscoelastic and polyurethane foam (CONFOR-Med) mattress (n=562) B: Standard hospital mattress (primarily King's Fund, Linknurse, Softfoam, or Transfoam) (n=604)	Median age: 83 years Sex: 67% female Race: NR	Mean Waterlow score: 17 vs. 17 Grade I ulcers at baseline: 12.4% (145/1168)	Any pressure ulcer (nonblanching erythema or worse), patients without prevalent erythema: 6.9% (34/494) vs. 9.3% (49/527); RR 0.74 (95% CI, 0.49 to 1.1) Any pressure ulcer, all patients: 15% (74/494) vs. 22% (115/527); RR 0.78 (95% CI 0.55 to 1.1)	NR	Mean bed days utilized per patient: 16.7 vs. 17.7 Number of dressings: 44.3 vs. 47.8
Sideranko, 1992 ¹¹⁸ Poor	Surgical intensive care unit United States Mean 9.4 days	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 vs. 63.6 vs. 66.1 years Percent women: 42.1% (24/57)	Baseline risk NR Pressure ulcers at baseline: Excluded	Any pressure ulcer: 25% (5/20) vs. 5% (1/20) vs. 12% (2/17); RR 5.0 (95% CI, 0.64 to 39) for A vs. B, RR 2.1 (95% CI, 0.47 to 9.6) for A vs. C, and RR 0.42 (95% CI, 0.04 to 4.3) for B vs. C	NR	Mean length of stay: 10 vs. 9.4 vs. 8.9 days

Table 7. Effectiveness of pressure ulcer prevention support surfaces in at-risk patients—static mattresses, overlays, and bed systems (continued)

Author, Year Quality Rating	Setting Country Followup	Intervention (N)	Baseline Demographics	Baseline Ulcer Risk Score ^a Pressure Ulcers at Baseline	Pressure Ulcer Incidence	Pressure Ulcer Severity	Length of Stay
Stapleton et al, 1986 ¹¹⁹ 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. 13 vs. 13 Pressure ulcers at baseline: Excluded	Any pressure ulcer: 34% (11/32) vs. 41% (14/34) vs. 35% (12/34); RR 0.84 (95% CI, 0.45 to 1.6) for A vs. B, RR 0.97 (95% CI, 0.50 to 1.9) for A vs. C, RR 1.2 (95% CI, 0.64 to 2.1) for B vs. C Any pressure ulcer, patients >80 years: 45% (9/20) vs. 63% (12/19) vs. 32% (7/22); RR 0.71 (95% CI, 0.39 to 1.3) for A vs. B, RR 1.4 (95% CI, 0.65 to 3.1) for A vs. C, RR 2.0 (95% CI, 0.98 to 4.0) for B vs. C	Stage B-D (Border grading scale): 28% (9/32) vs. 38% (13/34) vs. 29% (10/34); RR 0.74 (95% CI, 0.37 to 1.5) for A vs. B, 0.96 (95% CI, 0.45 to 2.0) for A vs. C, RR 1.3 (95% CI, 0.66 to 2.5) for B vs. C	NR
Takala et al, 1996 ¹²⁰ 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 Pressure ulcers at baseline: Not reported	Any pressure ulcers: 0% (0/21) vs. 37% (7/19);, RR 0.08 (95% CI, 0.005 to 1.4) Heel ulcers: 0% (0/21) vs. 11% (2/19); RR 0.18 (95% CI, 0.009 to 3.6) Pressure ulcers/patient: 0.0 (0 ulcers/21 patients) vs. 0.68 (13 ulcers/19 patients); rate ratio 0 (95% CI, 0 to 0.30)	Stage 1A: 9 Stage 1B: 4 (all in control group)	NR

Table 7. Effectiveness of pressure ulcer prevention support surfaces in at-risk patients—static mattresses, overlays, and bed systems (continued)

Author, Year Quality Rating	Setting Country Followup	Intervention (N)	Baseline Demographics	Baseline Ulcer Risk Score ^a Pressure Ulcers at Baseline	Pressure Ulcer Incidence	Pressure Ulcer Severity	Length of Stay
van Leen et al, 2011 ¹²⁴ 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 >stage 2 occurred	Mean age: 81 vs. 83 years Percent female: 79% vs. 83%	Norton score between 5 to 8: 62% vs. 54% Norton score between 9 to 12: 38% vs. 46% Pressure ulcers at baseline: Excluded	Stage 2 or higher ulcer: 4.8% (2/42) vs. 17% (7/41); RR 0.28 (95% CI, 0.06 to 1.3)	Severity (number patients with ulcers): Stage 2: 2.4% (1/42) vs. 4.9% (2/41), RR 0.49 (95% CI, 0.05 to 5.2) Stage 3: 2.4% (1/42) vs. 12% (5/41), RR 0.20 (95% CI, 0.02 to 1.6)	NR
Vyhlidal et al, 1997 ¹²⁶ 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)	Mean age: 74 vs. 80 years Percent female: 55% vs. 55%	Mean Braden scale: 14.7 vs. 14.5 Pressure ulcers at baseline: Excluded	Any pressure ulcer: 25% (5/20) vs. 60% (12/20); RR 0.42 (95% CI, 0.18 to 0.96)	Stage 2: 15% (3/20) vs. 40% (8/20); RR 0.38 (95% CI, 0.12 to 1.2)	NR

Note: CI=confidence interval, NR=not reported, RR=relative risk.

^aHigher risk for pressure ulcers usually defined as Braden scores <15-18, Cubbin and Jackson scores <29, Norton scores <12-16, or Waterlow scores >10-15. Higher scores indicate higher pressure ulcer risk.

Low-Air-Loss Mattresses, Overlays, and Bed Systems

One fair-quality¹⁰⁵ and one poor-quality¹⁰⁶ trial compared a low-air-loss mattress or bed compared with a standard hospital bed (Table 8). The fair-quality trial (n=98) found a low-air-loss bed associated with lower likelihood of one or more pressure ulcers in intensive care unit patients (12 vs. 51 percent, RR 0.23, 95% CI, 0.10 to 0.51).¹⁰⁵ However, a small (n=36), poor-quality trial found no difference between a low-air-loss mattress compared with a standard hospital bed following cardiovascular surgery.¹⁰⁶

One fair-quality trial (n=62) found a low-air-loss mattress associated with lower risk of pressure ulcer compared with the Hill-Rom Duo mattress (options for constant low pressure or alternating-air), but the difference was not statistically significant (10 vs. 19 percent, RR 0.53, 95% CI, 0.15 to 1.9).¹²²

Table 8. Effectiveness of pressure ulcer prevention support surfaces in at-risk patients—low-air-loss mattresses, overlays, and bed systems

Author, Year Quality Rating	Setting Country Followup	Intervention (N)	Baseline Demographics	Baseline Ulcer Risk Score ^a	Pressure Ulcer Incidence	Pressure Ulcer Severity	Length of Stay
Inman et al, 1993 ¹⁰⁵ Fair	Intensive care Canada 19 days vs. 15	A. Low-air-loss 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 years Percent female: 41% vs. 55	Unclear Pressure ulcers at baseline: Not reported	One or more pressure ulcer: 12% (6/49) vs. 51% (25/49); RR 0.23 (95% CI, 0.10 to 0.51) Multiple pressure ulcers: 2% (1/49) vs. 24% (12/49); RR 0.08 (95% CI, 0.01 to 0.62) Pressure ulcers/patient: Overall: 0.16 (8 ulcers/49 patients) vs. 0.80% (39 ulcers/49 patients); rate ratio 0.21 (95% CI, 0.08 to 0.45) 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 Stage 2 or higher pressure ulcer: 4.1% (2/49) vs. 29% (14/49), RR 0.14 (95% CI, 0.03 to 0.60) Effect of air suspension bed on presence of pressure ulcers: OR 0.16 (0.06-0.44), p=0.0005	Length of stay: 19 days vs. 15

Table 8. Effectiveness of pressure ulcer prevention support surfaces in at-risk patients—low-air-loss mattresses, overlays, and bed systems (continued)

Author, Year Quality Rating	Setting Country Followup	Intervention (N)	Baseline Demographics	Baseline Ulcer Risk Score ^a	Pressure Ulcer Incidence	Pressure Ulcer Severity	Length of Stay
Jesurum et al, 1996 ¹⁰⁶ 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% Nonwhite race: 19% vs. 20% Cardiovascular surgical patients	Mean Braden score: 9.7 vs. 9.4 Pressure ulcers at baseline: Not reported	Pressure ulcers, early post- op: 19% (3/16) vs. 15% (3/20), RR 1.2 (95% CI, 0.29 to 5.4) Heel ulcers, early post-op: 12% (2/16) vs. 5.0% (1/20), RR 2.5 (95% CI, 0.25 to 25) Pressure ulcers, later post- op: 31% (5/16) vs. 20% (4/20), RR 1.6 (95% CI, 0.50 to 4.9)	Severity (early post- op only): Stage 1 or 2: 6.2% (1/16) vs. 15% (3/20), RR 0.42 (95% CI, 0.05 to 3.6) Stage 3 or 4: 12% (2/16) vs. 0% (0/20), RR 6.2 (95% CI, 0.32 to 120)	Length of stay: 17 vs. 21 days; p=NS
Theaker et al, 2005 ¹²² Fair	Hospital, Intensive care United Kingdom 14 days	A. Low-air-loss KCI TheraPulse pulsating air suspension mattress (n=30) B. Hill-Rom Duo, constant low pressure or alternating- air options (n=32) Note: Both beds consist of cells that are connected to a pump that inflate and deflate either at a 5-10 minute cycle or continuously	Mean age: 65 years Percent female: 37% (23/62)	High risk, details NR Pressure ulcers at baseline: Excluded	Any pressure ulcer: 10% (3/30) vs. 19% (6/32); RR 0.53 (95% CI, 0.15 to 1.9)	Stage 2: 8 Stage 3: 1	NR

^aHigher risk for pressure ulcers usually defined as Braden scores <15-18, Cubbin and Jackson scores <29, Norton scores <12-16, or Waterlow scores >10-15. Higher scores indicate higher pressure ulcer risk.

Alternating Air Pressure Mattresses, Overlays, and Bed Systems

Eight trials (n=32 to 487, one good-quality,¹²⁵ two fair-quality,^{89,96} and five poor-quality^{85,87,93,117,118}) compared an alternating-air pressure mattress or overlay with static support surfaces (Table 9). 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.

Three poor-quality trials found alternating air mattresses or overlays associated with lower risk of pressure ulcers compared with standard hospital mattresses.^{85,87,117} One trial (n=108) of stroke, post-operative, or terminally ill patients found an alternating double-layer air cell alternating air pressure overlay associated with decreased risk of pressure ulcers compared with 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 2 ulcers, RR 0.17, 95% CI, 0.02 to 1.3).¹¹⁷ One trial (n=487) found an alternating air-pressure mattress associated with decreased risk of ulcers compared with a standard hospital mattress in risk of any pressure ulcer after 10 days (4.2 vs. 13 percent; RR 0.32, 95% CI, 0.14 to 0.74).⁸⁵ Pressure ulcer severity was not reported in this trial. The third trial found a mattress with options for either alternating low pressure or continuous low pressure (Hill Rom Duo2) associated with lower risk of any new ulcer than a standard mattress (2.1 vs. 36 percent, RR 0.06, 95% CI, 0.02 to 0.20), though only 2 ulcers were higher than stage 1 (stage 2), and both occurred in the Duo2 arm (1.4 vs. 0 percent, RR 1.2, 95% CI, 0.06 to 25).⁸⁷ Among patients in the Duo2 group, there was no difference in risk of pressure ulcers between patients randomized to the alternating compared with continuous low pressure settings (2.9 vs. 1.4 percent, RR 2.1, 95% CI, 0.19 to 22).

Six trials found no difference between an alternating air pressure overlay or mattress compared with various advanced static mattresses or overlays in pressure ulcer incidence or severity.^{85,87,89,93,118,125} The static support surfaces evaluated were a silicone overlay or mattress,^{89,93} water mattress,⁸⁵ air mattress,¹¹⁸ constant low pressure air mattress,⁸⁷ and viscoelastic foam mattress.¹²⁵ In the good-quality trial (n=447), there was no difference in risk of stage 2 or higher ulcers between an alternating pressure air mattress and a visco-elastic foam mattress in hospitalized patients, though the foam mattress group also underwent scheduled turning every four hours (15 vs. 16 percent, RR 0.98, 95% CI, 0.64 to 1.5).¹²⁵ There was also no difference in duration of hospitalization (22 vs. 18 days, p=0.11).

One fair-quality trial (n=43) of intensive care unit patients found stepped care (initial use of less advanced and expensive interventions followed by more advanced and expensive interventions if ulcers began to develop, based on a predefined algorithm) initially with alternating air pressure mattresses associated with decreased risk of pressure ulcers after 11 to 12 days compared with stepped care initially with primarily 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 stage 1 ulcers, RR 0.06, 95% CI, 0.00 to 0.96).⁹⁶ An earlier abstract for the same study that reported results for a larger sample that included intensive care unit as well as nonintensive 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).¹³⁴

Four trials (in five publications) compared different alternating air mattresses or overlays (Table 8).^{94,114,115,117,121} One good-quality (n=1972) trial of hospitalized patients found no difference in risk of incident stage 2 pressure ulcers between an alternating pressure overlay and an alternating pressure mattress (11 vs. 10 percent, RR 1.0, 95% CI, 0.81 to 1.3; adjusted OR 0.94, 95% CI, 0.68 to 1.3).¹¹⁵ Two fair-quality (n=44 and 610) trials of hospitalized patients

found no differences in risk of pressure ulcers between different alternating pressure air mattresses¹²¹ or between a pulsating air suspension mattress compared with an air mattress with options for alternating pressure or constant low pressure.⁹⁴ In both trials, the risk of stage 3 or higher ulcers was <2 percent. One of these trials also found no differences in length of stay.¹²¹ 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, but the difference was not statistically significant (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 2 ulcers; RR 0.28, 95% CI, 0.03 to 2.3).¹¹⁷

Table 9. Effectiveness of pressure ulcer prevention support surfaces in at-risk patients—alternating air pressure mattresses, overlays, and bed systems

Author, Year Quality Rating	Setting Country Followup	Intervention (N)	Baseline Demographics	Baseline Ulcer Risk Score ^a Pressure Ulcers at Baseline	Pressure Ulcer Incidence	Pressure Ulcer Severity	Length of Stay
Andersen et al, 1982 ⁸⁵ 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; >2 indicates at risk) Pressure ulcers at baseline: Excluded	Any pressure ulcer: 4.2% (7/166) vs. 4.5% (7/155) vs. 13.0% (21/161); RR 0.94 (95% CI, 0.34 to 2.6) for A vs. B, RR 0.32 (95% CI, 0.14 to 0.74) for A vs. C, RR 0.35 (95% CI, 0.15 to 0.79) for B vs. C	NR	NR
Cavicchioli et al, 2007 ⁸⁷ Poor	Hospitals Italy 2 weeks	A: Duo2 Hill-Rom mattress (n=140) with options for alternating low pressure or constant low pressure B: Standard mattress (n=33)	Mean age: 78 vs. 77 years Percent female: 72% vs. 73% Race: NR	Mean Braden: 12 vs. 13 Pressure ulcers at baseline: 6.4% (9/140) vs. 18% (6/33)	Any pressure ulcer: 2.1% (3/140) vs. 36% (12/33); RR 17 (95% CI, 5.1 to 57) Alternating low pressure vs. constant low pressure, in patients randomized to Duo2 Hill-Rom mattress Any pressure ulcer: 2.9% (2/69) vs. 1.4% (1/71); RR 2.1 (95% CI, 0.19 to 22)	Stage 1 ulcer: 0.7% (1/140) vs. 36% (12/33); RR 0.02 (95% 0.003 to 0.15) Stage 2 or 3 ulcer: 1.4% (2/140) vs. 0% (0/33); RR 1.2 (95% CI, 0.06 to 24)	NR

Table 9. Effectiveness of pressure ulcer prevention support surfaces in at-risk patients—alternating air pressure mattresses, overlays, and bed systems (continued)

Author, Year Quality Rating	Setting Country Followup	Intervention (N)	Baseline Demographics	Baseline Ulcer Risk Score ^a Pressure Ulcers at Baseline	Pressure Ulcer Incidence	Pressure Ulcer Severity	Length of Stay
Conine et al, 1990 ⁸⁹ Fair	Extended care facility Canada 3 months	A. Alternating air pressure overlay (n=72) B. Spenco silicone overlay (n=76)	Mean age: 39 vs. 36 years Percent female: 57% vs. 62%	Mean Norton score: 12.9 vs. 12.4 Pressure ulcers at baseline: Excluded	One or more pressure ulcers: 54% (39/72) vs. 59% (45/76); RR 0.91 (95% CI, 0.69 to 1.2) Pressure ulcers/patient: 1.8 (133 ulcers/72 patients) vs. 1.9 (148 ulcers/76 patients); rate ratio 0.95 (95% CI, 0.74 to 1.2)	Severity: Stage 1 ulcers/patient: 1.3 (95 ulcers/72 patients) vs. 1.2 (91 ulcers/76 patients); rate ratio 1.1 (95% CI, 0.82 to 1.5) Stages 2-4 ulcers/patient: 0.67 (48 ulcers/72 patients) vs. 0.75 (57 ulcers/76 patients); rate ratio 0.89 (95% CI, 0.59 to 1.3)	NR
Daechsel & Conine, 1985 ⁹³ Poor	Long-term care Canada 3 months	A. Alternating pressure mattress (n=16) B. Silicone-filled mattress (n=16)	Mean age: 43 vs. 38 years Percent female: 38% vs. 62% All chronic neurologic patients	Mean Norton score: 13.4 vs. 13.0 Pressure ulcers at baseline: Excluded	One or more pressure ulcers: 25% (4/16) vs. 25% (4/16); RR 1.0 (95% CI, 0.30 to 3.3) Heel ulcer: 12% (1/16) vs. 0% (0/16); RR 3.0 (95% CI, 0.13 to 69) Pressure ulcers/patient: 0.38 (5 ulcers/16 patients) vs. 0.38 (5 ulcers/16 patients); rate ratio 1.0 (0.23 to 4.3)	Severity: Mean Exton- Smith scores: 2.25 vs. 2.75, p=0.39	NR

Table 9. Effectiveness of pressure ulcer prevention support surfaces in at-risk patients—alternating air pressure mattresses, overlays, and bed systems (continued)

Author, Year Quality Rating	Setting Country Followup	Intervention (N)	Baseline Demographics	Baseline Ulcer Risk Score ^a Pressure Ulcers at Baseline	Pressure Ulcer Incidence	Pressure Ulcer Severity	Length of Stay
Demarre et al, 2012 ⁹⁴ Fair	25 wards of 5 hospitals Belgium 2 weeks	A: Alternating low- pressure air mattress with single-stage inflation and deflation (n=312) B: Alternating low- pressure air mattress with multi-stage inflation and deflation (n=298)	Mean age: 76.5 vs. 76.2 years Sex: 58% vs. 63% female Race: NR	Median Braden score: 14 vs. 14 Pressure ulcers at baseline: Grade I: 15.4% (48/312) vs. 15.4% (46/298)	Pressure ulcer grade II- IV: 5.8% (18/312) vs. 5.7% (17/298); RR 1.01 (95% CI, 0.53 to 1.92); p=0.97 Pressure ulcer grade I: 12.2% (38/312) vs. 17.1% (51/298); RR 0.71 (95% CI, 0.48 to 1.05); p=0.08	NR	NR
Gebhardt et al, 1996 ⁹⁶ Fair	Intensive care unit United Kingdom Mean 11-12 days	A. Stepped care with alternating air pressure mattresses (n=23) B. Stepped care with static or low air loss mattresses (n=20)	Mean age: 55 vs. 60 Percent female: 48% vs. 35%	Norton score >8: n=5 vs. n=1 Norton score ≤8: n=18 vs. n=19 Pressure ulcers at baseline: Excluded	Any pressure ulcer requiring a mattress change: 4.3% (1/23) vs. 55% (11/20); RR 0.08 (95% CI, 0.01 to 0.56)	Stage 1 ulcer: 4.3% (1/23) vs. 15% (3/20); RR 0.29 (95% CI, 0.03 to 2.6) Stage 2 or 3 ulcer: 0% (0/23) vs. 40% (8/20); RR 0.06 (95% CI, 0.003 to 0.92)	NR

Table 9. Effectiveness of pressure ulcer prevention support surfaces in at-risk patients—alternating air pressure mattresses, overlays, and bed systems (continued)

Author, Year Quality Rating	Setting Country Followup	Intervention (N)	Baseline Demographics	Baseline Ulcer Risk Score ^a Pressure Ulcers at Baseline	Pressure Ulcer Incidence	Pressure Ulcer Severity	Length of Stay
Nixon et al, 2006 ^{114,115} Good	Hospital United Kingdom 60 days	A: Alternating- pressure overlay (n=990) B: Alternating- pressure mattress (n=982)	Mean age: 75.4 vs. 75.0 years Sex: 63.1% vs. 64.8% female Race: NR	Mean Braden score: NR Bedfast: 81.3% vs. 76.8% Pressure ulcers at baseline: Grade 1b ulcers: 18.2% (180/989) vs. 14.8% (145/982)	Incidence of grade 2 or greater pressure ulcers: 11% (106/989) vs. 10% (101/982); RR 1.0 (95% CI, 0.81 to 1.3); adjusted OR 0.94 (95% CI, 0.68 to 1.29)	Median ulcer area: 1.2 sq. cm vs. 1.1 sq. cm	NR

Table 9. Effectiveness of pressure ulcer prevention support surfaces in at-risk patients—alternating air pressure mattresses, overlays, and bed systems (continued)

<p>Sanada et al, 2003¹¹⁷ Poor</p>	<p>Hospital Japan Unclear</p>	<p>A. Alternating double-layer air cell overlay (n=37) B. Alternating single-layer air cell overlay (n=36) C. Standard hospital mattress (n=35)</p>	<p>Mean age: 70 vs. 74 vs. 71 years Percent female: 52 vs. 42 vs. 52 All patients required head elevation, including stroke patients, recovering from surgery, and terminally ill</p>	<p>Mean Braden score: 12.5 vs. 12.1 vs. 12.7 Pressure ulcers at baseline: Excluded</p>	<p>Any pressure ulcer: 3.4% (1/26) vs. 19.2% (5/29) vs. 37.0% (10/27); RR 0.22 (95% CI, 0.03 to 1.8) for A vs. B, RR 0.10 (95% CI, 0.01 to 0.76) for A vs. C, RR 0.47 (95% CI, 0.18 to 1.2) for B vs. C Heel ulcer: 0% (0/26) vs. 3.4% (2/29) vs. 7.4% (2/27); RR 0.22 (95% CI, 0.01 to 4.4) for A vs. B, RR 0.21 (95% CI, 0.01 to 4.1) for A vs. C, RR 0.93 (95% CI, 0.14 to 6.2) for B vs. C</p>	<p>Stage 1 ulcers: 0% (0/26) vs. 3% (1/29) vs. 15% (4/27); RR 0.37 (95% CI, 0.02 to 8.7) for A vs. B, RR 0.12 (95% CI, 0.006 to 2.0) for A vs. C, RR 0.23 (95% CI, 0.03 to 2.0) for B vs. C Stage 2 (number ulcers): 4% (1/26) vs. 14% (4/29) vs. 22% (6/27); RR 0.28 (95% CI, 0.03 to 2.3) for A vs. B, RR 0.17 (95% CI, 0.02 to 1.3) for A vs. C, RR 0.62 (95% CI, 0.20 to 2.0) for B vs. C</p>	<p>NR</p>
<p>Sideranko et al, 1992¹¹⁸ Poor</p>	<p>Surgical intensive care unit United States Mean 9.4 days</p>	<p>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)</p>	<p>Mean age: 68 vs. 64 vs. 66 years % women (reported for whole group): 42.1% (24/57)</p>	<p>Baseline risk score: Unclear Pressure ulcers at baseline: Excluded</p>	<p>Any pressure ulcer: 25% (5/20) vs. 5% (1/20) vs. 12% (2/17); RR 5.0 (95% CI, 0.64 to 39) for A vs. B, RR 2.1 (95% CI, 0.47 to 9.6) for A vs. C, RR 0.42 (0.04 to 4.3) for B vs. C</p>	<p>NR</p>	<p>Length of stay: 10 vs. 9.4 vs. 8.9 days; p=NS</p>

Table 9. Effectiveness of pressure ulcer prevention support surfaces in at-risk patients—alternating air pressure mattresses, overlays, and bed systems (continued)

Author, Year Quality Rating	Setting Country Followup	Intervention (N)	Baseline Demographics	Baseline Ulcer Risk Score ^a Pressure Ulcers at Baseline	Pressure Ulcer Incidence	Pressure Ulcer Severity	Length of Stay
Taylor et al, 1999 ¹²¹ Fair	Hospital United Kingdom 11 days (mean)	A. Alternating air pressure mattress (Pegasus Trinova) (n=22) B. Alternating air pressure system (unnamed) (n=22)	Mean age: 66 vs. 70 years Percent female: 46% vs. 41%	Waterlow score: 19 vs. 17 Pressure ulcers at baseline: Excluded	Any pressure ulcer: 0% (0/22) vs. 9% (2/22); RR 0.20 (95% CI, 0.01 to 3.9)	Both ulcers "superficial"	Length of stay: 10.5 vs. 11.6 days; p=NS
Vanderwee et al, 2005 ¹²⁵ Good	7 Hospitals Belgium 20 weeks	A: Alternating- pressure mattress (n=222) B: Viscoelastic foam mattress and repositioning every 4 hours (n=225)	Mean age: 81 vs. 82 years Female sex: 61% vs. 66% Race: NR	Mean Braden score: 14.6 vs. 14.2 Pressure ulcers at baseline: Grade I: 33% vs. 34%	Pressure ulcer grade II- IV: 15% (34/222) vs. 16% (35/225); RR 0.98 (95% CI, 0.64 to 1.5)	Stage 2 ulcer: 12% (26/222) vs. 15% (33/225); RR 0.80 (95% CI, 0.49 to 1.3) Stage 3 or 4 ulcer: 3.6% (8/222) vs. 0.9% (2/225); RR 4.1 (95% CI, 0.87 to 19)	NR

Note: CI=confidence interval, NR=not reported, NS=not significant, RR=relative risk.

^aHigher risk for pressure ulcers usually defined as Braden scores <15-18, Cubbin and Jackson scores <29, Norton scores <12-16, or 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 10).^{95,98,123} 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 without leg elevation (7 vs. 26 percent for any ulcer; RR 0.26, 95% CI, 0.12 to 0.53; 3.3 vs. 13 percent for stage 2 ulcers, RR 0.25, 95% CI, 0.09 to 0.72).⁹⁵ 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).¹²³ 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.⁹⁸ None of the trials evaluated length of stay or measures of resource utilization. Shortcomings in the poor-quality trials included unclear allocation concealment,¹²³ significant differences between groups at baseline,⁹⁸ failure to report attrition,^{98,123} lack of blinding of outcome assessors,^{98,123} and failure to perform intention-to-treat analysis.^{98,123}

Table 10. Effectiveness of static heel supports for pressure ulcer prevention

Author, Year, Quality Rating	Setting, Country, Followup	Intervention (N)	Baseline Demographics	Baseline Ulcer Risk Score ^a , Pressure Ulcers at Baseline	Pressure Ulcer Incidence	Pressure Ulcer Severity	Length of Stay
Donnelly et al, 2011 ⁹⁵ Fair	Hospital United Kingdom 11 to 12 days	A. Heelift Suspension Boot (n=120) B. Usual care (n=119)	Mean age: 81 vs. 81 years Percent female: 79% vs. 75% Fracture patients	Mean Braden score: 15 vs. 15 Heel ulcers at baseline: Excluded	Any pressure ulcer: 7% (8/120) vs. 26% (31/119); RR 0.26 (95% CI, 0.12 to 0.53) Heel, foot, or ankle pressure ulcers: 0% (0/120) vs. 24.4% (29/119); RR 0.25 (95% CI, 0.09 to 0.72)	Stage 2: 4 vs. 16 Unstageable: 5 vs. 5	NR
Gilcreast et al, 2005 ⁹⁸ 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: 64 years Percent female: 42% Race: 68% White, 15% Black, 16% Hispanic, 1% Asian	Braden score \leq 14 Heel or foot ulcers at baseline: Excluded	Heel ulcer: 4% (3/77) vs. 5% (4/87) vs. 7% (5/76), RR 0.84 (95% CI, 0.20 to 3.7) for A vs. B, RR 0.59 (95% CI, 0.15 to 2.4) for A vs. C, RR 0.70 (95% CI, 0.19 to 2.5) for B vs. C	NR	NR
Tymec et al, 1997 ¹²³ 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: 67 years Percent women: 44% Race: 61% Black, 37% White, 2% Asian	Mean Braden score: 11.8 Pressure ulcers at baseline: Excluded	Lower extremity ulcers: 6 vs. 2 ulcers; group sample sizes not reported, p=NS	NR	NR

Note: CI=confidence interval, NR=not reported, NS=not significant, RR=relative risk.

^aHigher risk for pressure ulcers usually defined as Braden scores <15-18, Cubbin and Jackson scores <29, Norton scores <12-16, or 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 11).^{86,90,91,97} All trials were rated fair-quality.^{86,90,91,97} All of the trials were conducted in older patients in extended care facilities or nursing homes and followed patients for three to six months. No trial focused on patients with spinal cord injury.

Results of the trials were somewhat inconsistent and difficult to interpret because the trials evaluated different wheelchair cushion interventions. One (n=248) 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).⁹⁰ 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).⁹⁷ However, a third 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).⁹¹ The Jay cushion was also associated with decreased risk when the analysis was restricted to stage 2 or 3 ulcers (8.8 vs. 26 percent, RR 0.36, 95% CI, 0.15 to 0.85). Another trial (n=232) found various skin protection wheelchair cushions associated with lower risk of ischial tuberosity ulcers (primarily stage 2) compared with a standard segmented foam cushion when used with a fitted wheelchair (9.9 vs. 6.7 percent, RR 0.13, 95% CI, 0.02 to 1.0).⁸⁶ None of the trials evaluated length of stay or measures of resource utilization.

Table 11. Effectiveness of wheelchair cushions for pressure ulcer prevention

Author, Year Quality Rating	Setting Country Followup	Intervention (N)	Baseline Demographics	Baseline Ulcer Risk Score ^a Pressure Ulcers at Baseline	Pressure Ulcer Incidence	Pressure Ulcer Severity	Length of Stay
Brienza et al, 2010 ⁸⁶ Fair	Nursing homes United States 6 months	A: Skin protection wheelchair cushions (n=113) B: Segmented foam wheelchair cushion (SFC) (n=119)	Mean age: 87 vs. 87 years Percent female: 80% vs. 89% Percent nonwhite: 8.8% vs. 6.7%	Mean Braden score: 15.4 (SD ± 1.4) vs. 15.5 (SD ± 1.5) Ischial area pressure ulcers: Excluded	Ischial tuberosity pressure ulcer: 0.9% (1/113) vs. 6.7% (8/119); RR 0.13 (95% CI, 0.02 to 1.04) Ischial tuberosity or sacral pressure ulcers: 11% (12/113) vs. 18% (21/119), RR 0.60 (95% CI, 0.31 to 1.2)	Ischial tuberosity or sacral pressure ulcers (overall, not reported by group) Stage 1: 6 Stage 2: 29 Stage 3: 2 Unstageable: 1	NR
Conine et al, 1993 ⁹⁰ Fair	Extended care facility, wheelchair cushions Canada 3 months	A. Contoured foam cushion (n=123) B. Slab cushion (n=125)	Mean age: 84 vs. 84 years Percent female: 80% vs. 78%	Mean Norton score at baseline: 11.5 vs. 12.1 Pressure ulcers at baseline: Excluded	One or more pressure ulcers: 68% (84/123) vs. 68% (85/125); RR 1.0 (95% CI, 0.84 to 1.2) Pressure ulcers/patient: 1.4 (175 ulcers/123 patients) vs. 1.5 (184 ulcers/125 patients); rate ratio 0.97 (95% CI, 0.78 to 1.2)	Stage 1 ulcers/patient: 0.80 (98 ulcers/123 patients) vs. 0.84 (105 ulcers/125 patients); rate ratio 0.95 (95% CI, 0.71 to 1.3) Stages 2-4: 0.63 (77 ulcers/123 patients) vs. 0.63 (79 ulcers/125 patients); rate ratio 0.99 (95% CI, 0.71 to 1.4)	NR

Table 11. Effectiveness of wheelchair cushions for pressure ulcer prevention (continued)

Author, Year Quality Rating	Setting Country Followup	Intervention (N)	Baseline Demographics	Baseline Ulcer Risk Score ^a Pressure Ulcers at Baseline	Pressure Ulcer Incidence	Pressure Ulcer Severity	Length of Stay
Conine et al, 1994 ⁹¹ 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 Pressure ulcers at baseline: Excluded	One or more pressure ulcers: 25% (17/68) vs. 41% (30/73); RR 0.61, 95% CI, 0.37 to 1.0 Pressure ulcers/patient: 1.5 (26 ulcers/17 patients) vs. 1.4 (42 ulcers/30 patients); rate ratio 1.1 (95% CI, 0.64 to 1.8)	Stage 1 ulcers/patient: 0.29 (20 ulcers/68 patients) vs. 0.33 (24 ulcers/73 patients); rate ratio 0.89 (95% CI, 0.47 to 1.7) Stage 2 or 3 ulcers/patient (no stage 4 ulcers): 0.09 (6 ulcers/68 patients) vs. 0.25 (18 ulcers/73 patients); rate ratio 0.36 (95% CI, 0.12 to 0.94)	NR
Geyer et al, 2001 ⁹⁷ 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 vs. 84 years Percent female: 93% vs. 94%	Initial Braden score, mean: 12.5 vs. 13.4 Sacral pressure ulcers at baseline: Excluded	Any pressure ulcer: 40% (6/15) vs. 59% (10/17); RR 0.68 (95% CI, 0.33 to 1.4)	NR	NR

Note: CI=confidence interval, NR=not reported, NS=not significant, RR=relative risk.

^aHigher risk for pressure ulcers usually defined as Braden scores <15-18, Cubbin and Jackson scores <29, Norton scores <12-16, or Waterlow scores >10-15. Higher scores indicate higher pressure ulcer risk.

Nutritional Supplementation

One fair-quality¹³⁵ and five poor-quality randomized trials (n=59 to 672) examined nutritional interventions for preventing pressure ulcers (Table 12, Appendix Table H13).¹³⁶⁻¹⁴⁰ Four trials compared liquid nutritional supplements by mouth plus standard hospital diet compared with the standard hospital diet alone.¹³⁶⁻¹³⁹ One trial¹⁴⁰ evaluated nutritional supplementation via tube feeding compared with a standard hospital diet by mouth and one trial¹³⁵ a high fat, low-carbohydrate enteral formula enriched with lipids and vitamins compared with the same formulation without the lipid and vitamin supplementation. Methodological limitations in the trials included inadequate description of randomization and allocation concealment (Appendix Table H14). One trial also reported baseline differences between intervention groups in risk factors for pressure ulcers,¹³⁶ and two had high attrition.^{137,138} Only one trial described measures to blind patients and caregivers to the nutritional intervention;¹³⁹ no trial described blinding of outcomes assessors.

The two largest trials of supplementation by mouth reported somewhat inconsistent results. One 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).¹³⁶ 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). Another trial (n=495, 28 percent classified as malnourished at baseline) found no difference between oral liquid nutritional supplements (200 ml twice daily) plus standard hospital diet compared with standard hospital diet alone in risk of pressure ulcers in newly admitted patients to long-term care after up to 6 months of followup (9.9 vs. 12 percent incidence of pressure ulcers in patients without ulcers at baseline, $p > 0.05$).¹³⁸ Two smaller trials also found no effects of a nutritional intervention on risk of pressure 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 stage 1 or 2 pressure ulcers (there were no stage 3 or 4 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 noncaloric water based placebo after 2 weeks (55 vs. 58 percent, RR 0.92, 95% CI, 0.65 to 1.3).¹³⁹ There was also no difference in risk of stage 2 ulcers when they were evaluated separately (18 vs. 27 percent, RR 0.66, 95% CI, 0.31 to 1.4). Another 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.¹³⁷ In this trial, which was the only one to report length of stay, nutritional supplementation was associated with shorter median duration of hospitalization (24 vs. 40 days, $p < 0.04$). Two trials found no clear effects of enteral supplementation on risk of pressure ulcers. One trial of patients with hip fracture (n=129, mean CBO score 9) found no difference between nutritional supplementation via tube feeding compared with standard hospital diet in risk of stage 2 or higher pressure ulcers after two weeks (52 vs. 57 percent, RR 0.92, 95% CI, 0.64 to 1.3) in risk of pressure ulcers.¹⁴⁰ There was also no difference when the analysis was restricted to patients that received tube feeding for at least one week. One other trial of critically ill patients with acute lung injury

(n=95) found no difference between an enteral formula enriched in lipids (eicosapentanoic acid and gamma-linolenic acid) and vitamins (vitamins A, C, and E) compared with without the enrichment in risk of new pressure ulcers after 4 days (11 vs. 18 percent, RR 0.59, 95% CI, 0.21 to 1.6) or 7 days (6.5 vs. 2.0 percent, RR 3.2, 95% CI, 0.34 to 30).¹³⁵

Table 12. Effectiveness of nutritional supplementation for pressure ulcer prevention

Author, Year Duration Quality Rating	Setting	Interventions	Patient Characteristics	Baseline Ulcer Risk Score^b Pressure Ulcers at Baseline	Incident Pressure Ulcers
Bourdel-Marchasson et al, 2000 ¹³⁶ 15 days or until death or discharge Poor	Hospital wards and geriatric inpatient units France	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).	N=672 Mean age: 84 vs. 83 years Percent female: 68% vs. 63% Percent white: NR	Norton Score 5-10: 28% vs. 36% 11-14: 40% vs. 47% >14: 31% vs. 19% Pressure ulcers at baseline: Excluded	Any pressure ulcer (90% stage 1): 40% (118/295) vs. 48% (181/377); RR 0.83 (95% CI, 0.70 to 0.99), adjusted ^a RR 0.64 (95% CI, 0.42 to 0.97)
Delmi et al, 1990 ¹³⁷ Mean duration of supplement 32 days; outcomes assessed though 6 months after discharge Poor	Orthopaedic unit of the University hospital of Geneva and "second (recovery)" hospital Switzerland	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)	N=59 Mean age: 80 vs. 83 years Percent female: 88.9% vs. 90.6%	Pressure ulcer risk score at baseline: NR Pressure ulcers at baseline: NR	Any pressure ulcer at discharge: 7.4% (2/27) vs. 9.4% (3/32); RR 0.79 (95% CI, 0.14 to 4.4) Any pressure ulcer at 6 months: 0% (0/25) vs. 7.4% (2/27); RR 0.22 (95% CI, 0.01 to 4.3)
Ek et al, 1991 ¹³⁸ 26 weeks (mean NR) Poor	Hospital Sweden	A: Nutritional supplement (200 ml; 838 kJ; 8 g protein; 8 g fat; 23.6 g carbohydrates; minerals and vitamins) twice daily in addition to hospital diet B: Standard hospital diet (2200 kcal)	N=495 Mean age: 80.1 years Sex: 62% female Race: NR Demographics not reported by group	Norton score: NR Malnourished at baseline: 28.5% Pressure ulcers at baseline: 14.1%	Pressure ulcers among patients without prevalent ulcers: 9.9% vs. 12%; p=NS (sample size to calculate CI not reported) Second or third pressure ulcer development: 11% vs. 25%; p=NS

Table 12. Effectiveness of nutritional supplementation for pressure ulcer prevention (continued)

Author, Year Duration Quality Rating	Setting	Interventions	Patient Characteristics	Baseline Ulcer Risk Score ^b Pressure Ulcers at Baseline	Incident Pressure Ulcers
Hartgrink et al, 1998 ¹⁴⁰ 2 weeks Poor	Hospital The Netherlands	A: Nasogastric tube feeding (1 liter Nutrison Steriflo Energy-plus; 1500 kcal; 60 g protein) in addition to standard hospital diet B: Standard hospital diet	N=129 Mean age: 84.0 vs. 83.3 Sex: 83.9% vs. 91.0% female Race: NR	Pressure-sore risk score: 9.0 vs. 9.2 Pressure ulcers at baseline (all grade I): 16% (10/62) vs. 15% (10/67)	Incidence of pressure sores (grade II or greater) at 1 week: 37% (20/54) vs. 48% (30/62); RR 0.77 (95% CI, 0.50 to 1.2) Incidence of pressure sores (grade II or greater) at 2 weeks: 52% (25/48) vs. 57% (30/53); RR 0.92 (95% CI, 0.64 to 1.3)
Houwing et al, 2003 ¹³⁹ 28 days or until discharge Poor	3 centers The Netherlands	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: Noncaloric, water-based placebo (n=52)	N=103 Mean age: 82 vs. 80 years Percent female: 78% vs. 84% Percent white: NR	Dutch Consensus Meeting scoring system (CBO-risk assessment tool): 11.1 vs. 11.2 Pressure ulcers at baseline: Not reported	Any pressure ulcer: 55% (27/49) vs. 59% (30/51); RR 0.94 (95% CI, 0.67 to 1.3) Stage 1 ulcers: 37% (18/49) vs. 31% (16/51); RR 1.2 (95% CI, 0.68 to 2.0) Stage 2: 18% (9/49) vs. 28% (14/51); RR 0.67 (95% CI, 0.32 to 1.4)
Theilla et al, 2007 ¹³⁵ 1 week Fair	Hospital Israel	A: High fat, low carbohydrate enteral formula with eicosapentanoic acid, gamma-linolenic acid, and vitamins A, C, and E (n=46) B: High fat, low carbohydrate enteral formula (n=49)	N=95 Mean age: 57 vs. 62 years Sex: 37% vs. 43% female Race: NR	Pressure ulcer risk score at baseline: NR Pressure ulcers at baseline: 15% (7/46) vs. 29% (14/49)	Any pressure ulcer: 33% (15/46) vs. 49% (24/49); RR 0.67 (95% CI, 0.40 to 1.10)

Note: CI=confidence interval, NR=not reported, PU=pressure ulcer, RR=relative risk.

^aAdjusted for intervention group, serum albumin, Kuntzman score, Norton score, and diagnosis.

^bHigher risk for pressure ulcers usually defined as Braden scores <15-18, Cubbin and Jackson scores <29, Norton scores <12-16, or Waterlow scores >10-15. Higher scores indicate higher pressure ulcer risk.

Repositioning

Six randomized trials (n=15 to 838) examined the effectiveness of repositioning interventions for prevention of pressure ulcers (Table 13 and Appendices H15 and H16).¹⁴¹⁻¹⁴⁶ All trials evaluated patients classified as higher-risk for ulcers based on the Braden, Norton or Waterlow scales. One good-quality,¹⁴² two fair-quality,^{143,146} and two poor-quality trials^{141,144} 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.¹⁴⁵ The two poor-quality trials evaluated small, unscheduled shifts in body position plus repositioning every two hours compared with repositioning every two hours without the unscheduled shifts in body position.^{141,144} In the other trials, the repositioning interventions and standard care comparators varied (Appendix Table H15). Standard care always included less structured or frequent 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).¹⁴³ 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.¹⁴⁵

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.¹⁴² It found no difference between groups in risk of stage 1 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 stage 2 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).

One fair-quality trial (n=235) found no difference between different repositioning intervals between the semi-Fowler 30 degree and lateral positions.¹⁴⁶

Two small (n=15 and 19), poor-quality trials found the addition of small, unscheduled shifts in body position (using a small rolled towel to designated areas during nurse-patient interactions) to standard repositioning every 2 hours had no effect on risk of pressure ulcers, but only reported one or two ulcers each.^{141,144} Methodological shortcomings in the trials included inadequate description of randomization or allocation concealment methods, and lack of blinding of outcome assessors.

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

Table 13. Effectiveness of repositioning for pressure ulcer prevention

Author, Year Duration Quality Rating	Setting	Interventions	Patient Characteristics	Baseline Ulcer Risk Score ^a Pressure Ulcers at Baseline	Incident Pressure Ulcers
Brown et al, 1985 ¹⁴¹ 2 weeks Poor	4 nursing homes United States	A: Small shifts of body weight in addition to repositioning every 2 hours B: Repositioning every 2 hours	n = 15 Mean age: 81 vs. 78 years Sex: 75% vs. 67% female Race: NR	High risk: 12.5% (1/8) vs. 50% (3/6) Very high risk: 87.5% (7/8) vs. 50% (3/6)	Any pressure ulcer: 0% vs. 17% (1/6); RR 0.26 (95% CI, 0.01-5.4)
Defloor et al, 2005 ¹⁴² 8 weeks (4 weeks of one intervention, followed by re- randomization and another 4 week intervention) Good	11 elder- care nursing homes Belgium	A: Usual care B: 2-hour turning C: 3-hour turning D: 4-hour turning E: 6-hour turning	n = 838 Mean age: 84 vs. 85 vs. 85 vs. 85 vs. 85 Sex: 78.3% vs. 88.9% vs. 87.9% vs. 81.8% vs. 77.8% female Race: NR	Mean Braden score: 13.2 vs. 13.3 vs. 13.2 vs. vs. 13.1 vs.13.0 Mean Norton score: 10.1 vs. 10.4 vs. 9.6 vs. 9.8 vs. 9.5	Any pressure ulcer: 63% (324/511) vs. 62% (39/63) vs. 69% (40/58) vs. 45% (30/66) vs. 62% (39/63); RR 0.98 (95% CI, 0.80 to 1.2) for B vs. A, RR 1.1 (95% CI, 0.90 to 1.3) for C vs. A, RR 0.72 (95% CI, 0.55 to 0.94) for D vs. A, RR 0.98 (95% CI, 0.80 to 1.2) for E vs. A Stage 1 pressure ulcer: 43% (220/511) vs. 48% (30/63) vs. 45% (26/58) vs. 42% (28/66) vs. 46% (29/63); RR 1.1 (95% CI, 0.84 to 1.5) for B vs. A, RR 1.0 (95% CI, 0.77 to 1.4) for C vs. A, RR 0.99 (95% CI, 0.73 to 1.3) for D vs. A, RR 1.1 (95% CI, 0.79 to 1.4) for E vs. A Stage 2 or greater pressure ulcer: 20% (102/511) vs. 14% (9/63) vs. 24% (14/58) vs. 3% (2/66) vs. 16% (10/63); RR 0.72 (95% CI, 0.38 to 1.3) for B vs. A, RR 1.2 (95% CI, 0.74 to 2.0) for C vs. A, RR 0.15 (95% CI, 0.04 to 0.60) for D vs. A, RR 0.80 (95% CI, 0.44 to 1.4) for E vs. A Stage 3 or 4 pressure ulcer: 5.7% (29/511) vs. 3.2% (2/63) vs. 3.4% (2/58) vs. 0% (0/66) vs. 3.2% (2/63); RR 0.56 (95% CI, 0.14 to 2.3) for B vs. A, RR 0.61 (95% CI, 0.15 to 2.5) for C vs. A, RR 0.12 (95% CI, 0.008 to 2.1) for D vs. A, RR 0.56 (95% CI, 0.14 to 2.3) for E vs. A
Moore et al, 2011 ¹⁴³ 28 days Fair	12 long- term care facilities Ireland	A: Repositioning at 30 degree tilt every 3 hours during the night B: Repositioning at 90 degree lateral every 6 hours during the night	n = 213 Age: 53% between 81 and 90 years, 13% between 91 and 100 years Sex: 79% female	NR	Any pressure ulcer: 3.0% (3/99) vs. 11.4% (13/114); RR 0.27 (95% CI, 0.08 to 0.91)

Table 13. Effectiveness of repositioning for pressure ulcer prevention (continued)

Author, Year Duration Quality Rating	Setting	Interventions	Patient Characteristics	Baseline Ulcer Risk Score^a Pressure Ulcers at Baseline	Incident Pressure Ulcers
Smith et al, 1990 ¹⁴⁴ 2 weeks Poor	A single long-term care facility United States	A: Repositioning every 2 hours, and small shifts in body position using a rolled hand towel during unscheduled interactions (n=9) B: Repositioning every 2 hours (n=10)	n = 26 Mean age: 79 vs. 82 years Sex: NR Race: NR	Mean Norton score: 10.3 vs. 12	Any pressure ulcer: 11% (1/9) vs. 10% (1/10); RR 1.1 (95% CI, 0.08 to 15)
Vanderwee et al, 2007 ¹⁴⁶ 5 weeks Fair	16 nursing homes Belgium	A: Repositioning with unequal time intervals (4 hours in semi-Fowler 30 degree, 2 hours in right-side later position 30 degree, 4 hours in semi- Fowler 30 degree, 2 hours in left-side lateral 30 degree (n=122) B: Same positions but for equal 4-hour intervals (n=113)	n = 235 Median age: 87 vs. 87 years Sex: 83 vs. 84% female Race: NR	Mean Braden score: 15.1 vs. 15.0	Any pressure ulcer: 16% (20/122) vs. 21% (24/113); RR 0.66 (95% CI, 0.37-1.2)
Young et al, 2004 ¹⁴⁵ 1 night Fair	Hospital (acute ward) United Kingdom	A: 30 degree tilt repositioning B: Standard repositioning	n = 46 Mean age: 70 vs. 70 years Sex: 50% vs.50% female Race: 100% White	Mean Waterlow score: 20 vs.20	Nonblanching erythema: 13% (3/23) vs. 9% (2/23); RR 1.5 (95% CI, 0.28-8.2)

^aHigher risk for pressure ulcers usually defined as Braden scores <15-18, Cubbin and Jackson scores <29, Norton scores <12-16, or Waterlow scores >10-15. Higher scores indicate higher pressure ulcer risk.

Dressings and Pads

Two fair-quality^{147,148} and one poor-quality¹⁴⁹ trials evaluated dressings or pads for prevention of pressure ulcers (Appendix Tables H17 and H18). One trial compared a silicone border foam dressing with standard ICU care,¹⁴⁷ one trial compared more with less frequent incontinence pad changes in women with incontinence,¹⁴⁸ and the third trial compared use of a dressing (the REMOIS Pad) with no dressing.¹⁴⁹ Methodological shortcomings in the trials included inadequate randomization^{147,149} or allocation concealment^{148,149} or failure to report intention-to-treat analysis.¹⁴⁷ None of the trials reported length of stay or measures of resource utilization. A fair-quality randomized trial of cardiac surgery ICU patients (n=85, mean Braden 11 at baseline) found a silicone border foam sacral dressing applied at ICU admission (the Mepilex Border sacrum) associated with lower likelihood of pressure ulcers compared with standard ICU care (mean followup about 25 days), but the difference was not statistically significant (2.0 vs. 12 percent, RR 0.18, 95% CI, 0.02 to 1.5).¹⁴⁷ Other components of standard care in both groups included preoperative placement of a silicone border foam dressing for surgery, and use of a low air loss bed. 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 with 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).¹⁴⁹

A fair-quality cross-over trial of incontinent female nursing home patients (n=81, mean Braden 13 at baseline) found no statistically significant difference in risk of stage 2 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).¹⁴⁸

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 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 Tables H19 and H20).¹⁵⁰ 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 corticotropin intramuscularly compared with a sham injection (12 vs. 28 percent, RR 0.43, 95% CI, 0.16 to 1.1) (Appendix Tables H19 and H20).¹⁵¹ 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.

Polarized Light

One small, poor-quality randomized trial (n=23) of ICU patients found no statistically significant difference between polarized light compared with standard care (including use of a viscoelastic or low-air-loss mattress, repositioning, and viscoelastic pillow) in risk of any pressure ulcer (RR 0.43, 95% CI, 0.16 to 1.2) or stage 2 or greater ulcers (RR 0.08, 95% CI, 0.01 to 1.3).¹⁵² Methodological limitations included unclear randomization, high loss to followup, and lack of intention-to-treat analysis.

Creams, Lotions, and Cleansers

Two fair-quality^{153,154} and four poor-quality randomized trials (reported in five publications)¹⁵⁵⁻¹⁵⁹ evaluated lotions, creams, or cleansers in various settings, including nursing homes, long-term care facilities, and acute care hospitals (Table 14; Appendix Tables H21 and H22). None of the poor-quality trials¹⁵⁵⁻¹⁵⁹ reported adequate methods for randomization and/or allocation concealment, only two trials reported blinding of care providers or patients,^{155,157} and only one trial reported low loss to followup.¹⁵⁵ In addition, one cluster randomized trial^{158,159} failed to assess cluster effects. Five 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.^{153-156,158,159} The sixth trial evaluated younger (mean age 60 years) patients (proportion of female not reported) in an intensive care unit.¹⁵⁷ Four trials compared a lotion or cream with placebo^{154,155,157-159} and a fifth¹⁵⁶ compared two lotions. The creams and lotions evaluated in the trials varied (Table 13). The sixth trial compared a foam cleanser (Clinisan) to standard hospital soap.¹⁵³

One fair-quality trial (n=331) found a hyperoxygenated fatty acid cream (Mepentol) associated with lower risk of new pressure ulcers (severity not reported) compared with placebo after 30 days (7.3 vs. 17 percent, RR 0.42, 95% CI, 0.22 to 0.80).¹⁵⁴ 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 1 or stage 2, 4.7 vs. 28 percent, RR 0.17, 95% CI, 0.04 to 0.70; stage 2 only 0 vs. 28 percent, RR 0.04, 95% CI, 0.002 to 0.66).¹⁵⁷

A 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 repellent]) associated with lower risk of any pressure ulcer (Barbarel score) after 24 weeks compared with placebo cream, though the difference was not statistically significant (27 vs. 36 percent, RR 0.74, 95% CI, 0.52 to 1.1).¹⁵⁵

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 that is not approved by the Food and Drug Administration for treatment of ulcers) or a placebo cream (Vaseline-cetomacrogol) compared with neither cream in severity or incidence of pressure ulcers (any location) after 4 weeks (incidence 62, 31, and 39 percent), though the DMSO cream was associated with greater risk of ulcers than the placebo cream (RR 2.0, 95% CI, 1.1 to 3.6).^{158,159} 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. The DMSO cream was also associated with greater risk of heel or ankle ulcers than either the placebo cream (RR 3.5, 95% CI, 1.5 to 8.4) or no cream (RR 3.3, 95% CI, 1.1 to 9.8).¹⁵⁹

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).¹⁵⁶

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 (18 vs. 42 percent; RR 0.43, 95% CI, 0.19 to 0.98).¹⁵³ Three-quarters of the ulcers were stage 1.

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

Table 14. Effectiveness of lotions and cleansers for pressure ulcer prevention

Author, Year Duration Quality Rating	Setting	Interventions	Patient Characteristics	Baseline Ulcer Risk^a Pressure Ulcers at Baseline	Pressure Ulcer Incidence
Cooper et al, 2001 ¹⁵³ Fair	5 long-term care facilities	A: Clinisan cleanser (includes silicone, triclosan, benzylicum and emollients) B: Standard hospital soap	n=66 with intact skin at baseline Mean age 85 vs. 79 years 80% vs. 55% female	All patients had incontinence Results reported separately for patients with no pressure ulcers at baseline	Any pressure ulcer: 18% (6/33) vs. 42% (14/33); RR 0.43 (95% CI, 0.19 to 0.98) Stage 2 ulcer: 3.0% (1/33) vs. 12% (4/33); RR 0.25 (95% CI, 0.03 to 2.1)
Declair et al, 1997 ¹⁵⁷ Mean 21 days Poor	Intensive care unit Brazil	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	n = 86 Mean age: 60 years Sex, race not reported	Mean Norton score: 9 (whole sample) Pressure ulcers at baseline: Not reported	Any pressure ulcer: 4.7% (2/43) vs. 28% (12/43); RR 0.17 (95% CI, 0.04 to 0.70) PU incidence according to severity: Stage 1 ulcer: 4.6% (2/43) vs. 0% (0/43); RR 5.0 (95% CI, 0.25 to 101) Stage 2: 0% (0/43) vs. 28% (12/43); RR 0.04 (95% CI, 0.002 to 0.66)
Houwing et al, 2008 ¹⁵⁹ 4 weeks (Same study population as Duimel- Peeters et al, 2007 ¹⁵⁸) Poor	8 nursing homes Holland	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	n = 79 Median age 81 vs. 85 vs. 82 years 62% vs. 75% vs. 72% female Race not reported	Incontinence (sometimes/always): 100% vs. 94% vs. 83% Pressure ulcers at baseline: Excluded	Any pressure ulcer: 62% (18/29) vs. 31% (10/32) vs. 39% (7/18); RR 2.0 (95% CI, 1.1 to 3.6) for A vs. B, RR 1.6 (0.84 to 3.0) for A vs. C, and RR 0.80 (95% CI, 0.37 to 1.7) for B vs. C Buttock ulcer: 38% (11/29) vs. 22% (7/32) vs. 33% (6/18); RR 1.7 (95% CI, 0.78 to 3.9) for A vs. B, RR 1.1 (95% CI, 0.51 to 2.5) for A vs. C, RR 0.66 (95% CI, 0.26 to 1.7) for B vs. C Heel/ankle ulcers: 55% (16/29) vs. 16% (5/32) vs. 17% (3/18); RR 3.5 (95% CI, 1.5 to 8.4) for A vs. B, RR 3.3 (95% CI, 1.1 to 9.8) for A vs. C, RR 0.94 (95% CI, 0.25 to 3.5) for B vs. C
Smith et al, 1986 ¹⁵⁵ 24 weeks Poor	6 Long-term care facilities United Kingdom	A: Conotrane (20% dimethicone 350 and 0.05% hydrargaphen) B: Unguentum (description NR)	n = 258 Mean age: 82 vs. 83 years 81% vs. 82% female Race not reported	Baseline ulcer risk not reported Pressure ulcers at baseline: Excluded	One or more ulcers: 27% (35/129) vs. 36% (47/129); RR 0.74 (95% CI, 0.52 to 1.1) Grade 3 or 4 (Barbareil et al system): 3.9% (5/129) vs. 3.9% (5/129); RR 1.0 (95% CI, 0.30 to 3.4)

Table 14. Effectiveness of lotions and cleansers for pressure ulcer prevention (continued)

Author, Year Duration Quality Rating	Setting	Interventions	Patient Characteristics	Baseline Ulcer Risk ^a Pressure Ulcers at Baseline	Pressure Ulcer Incidence
Torra I Bou et al, 2005 ¹⁵⁴ 30 days Fair	13 centers (hospitals and long-term care) Spain	A: Mepentol (hyperoxygenated fatty acids compound of oleic, stearic, palmitic, palmitoleic, linoleic, gamma linoleic, arachidonic, and eicosanoic acids and extracts of Equisetum arvense and Hypericum perforatum) (n=164) B: Inert lotion (triosostearin and perfume) (n=167)	n = 380 Mean age: 84 vs. 84 years Sex: 75% vs. 72% female Race: NR	Mean Braden score: 12.4 vs. 12.4 Pressure ulcer at admission: 24.4% vs. 21.6%	Incidence of pressure ulcer development: 7.3% (12/164) vs. 17.4% (29/167); p<0.006; RR 0.42 (95% CI, 0.22 to 0.80)
van der Cammen et al, 1987 ¹⁵⁶ 3 weeks Poor	Hospital (geriatric wards) United Kingdom	A: Prevasore cream B: Dermalax cream	n = 104 Mean age: 82 vs. 83 years 74% female in both groups Race not reported	Mean Norton score at entry: 11.4 vs. 11.5 Pressure ulcers at baseline: Excluded	Deterioration in skin condition: 13% (7/54) vs. 22% (11/50); RR 0.59 (95% CI, 0.25 to 1.4)

Note: CI=confidence interval, DMSO=dimethyl sulfoxide, NR=not reported, NS=not significant, OR=odds ratio, PU=pressure ulcer, RR=relative risk.

^aHigher risk for pressure ulcers usually defined as Braden scores <15-18, Cubbin and Jackson scores <29, Norton scores <12-16, or Waterlow scores >10-15. Higher scores indicate higher pressure ulcer risk.

Key Question 3a. Do 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 of pressure ulcers compared with standard care in lower-risk surgical patients, though the difference was not statistically significant in one trial (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).

Alternating Support Surfaces

- Two trials (one good- and one poor-quality; n=198 and 217) found no differences between alternating 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 preventive 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 15; Appendix Tables H11 and H12).¹²⁷⁻¹³³ Patients were lower-risk based on pressure ulcer risk assessment scores, using the Braden (score ≥ 20),^{131,133} Norton (score ≥ 20),¹²⁹ modified Knoll (score ≤ 4)^{127,132} or modified Ek (score 3-4) scales.¹²⁸ Interventions were given in the operating room in all studies except one,¹²⁸ in which it was unclear if interventions were given in the operating room and post-operatively, or just post-operatively. Two studies continued interventions into the post-operative period.^{127,132} Post-operative followup ranged from 5 to 8 days, apart from one study that only evaluated patients in the immediate post-operative period¹³⁰ and one study that did not report mean study duration.¹²⁸ Four trials^{129-131,133} compared various static mattresses or overlays compared with standard operating room care and two compared an alternating air mattress to a static mattress.^{127,132} Two trials were rated good-quality,^{132,133} two fair-quality,^{129,131} and three poor-quality.^{127,128,130} 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 15. Effectiveness of pressure ulcer prevention support surfaces in lower-risk patients

Author, Year Quality Rating	Setting Followup	Intervention	Baseline Demographics	Baseline Ulcer Risk ^a Pressure Ulcers at Baseline	Pressure Ulcer Incidence
Static vs. Static Support Surfaces					
Berthe et al, 2007 ¹²⁸ 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 Pressure ulcers at baseline: Excluded	Any pressure ulcer: 3.2% (21/657) vs. 1.9% (21/1072); RR 1.6 (95% CI, 0.90 to 3.0)
Feuchtinger et al, 2006 ¹²⁹ Fair	Operating room 5 days post- op	A: Water-filled warming mattress + 4-cm thermoactive viscoelastic foam overlay (n=85) B: Water-filled warming mattress alone (n=90)	n=175 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 Pressure ulcers at baseline: 2.3% (all stage 1)	Any pressure ulcer: 18% (15/85) vs. 11% (10/90); RR 1.6 (CI, 0.76 to 3.3) Stage 1 ulcers: 15% (13/85) vs. 10% (9/90); RR 1.5 (CI, 0.68 to 3.4) Stage 2 ulcers: 2.4% (2/85) vs. 1.1% (1/90); RR 2.1 (CI, 0.20 to 23)
Hoshowsky et al, 1994 ¹³⁰ Poor	Operating room Immediate post-op period	A: Viscoelastic dry polymer mattress overlay (n=unclear) B: Nylon fabric covered 2-inch thick foam and gel OR table mattress (n=unclear) C: 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 (<i>Demographic data not stratified by intervention group</i>)	Hemphill's Guidelines for Assessment of Pressure Sore Potential (score 0-12= low risk) Mean not reported Pressure ulcers at baseline: Not reported	Any pressure ulcer (all stage 1): Adjusted OR 0.40 (95% CI, 0.21 to 0.77); number of ulcers in each group and sample sizes not reported

Table 15. Effectiveness of pressure ulcer prevention support surfaces in lower-risk patients (continued)

Author, Year Quality Rating	Setting Followup	Intervention	Baseline Demographics	Baseline Ulcer Risk ^a Pressure Ulcers at Baseline	Pressure Ulcer Incidence
Nixon et al, 1998 ¹³¹ Fair	Operating room 8 days post- op	A. Dry visco-elastic polymer pad + standard operating table mattress (n=222) B. Standard operating table mattress+ heel support (n=224)	n=416 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 ≥20: 91% (202/222) vs. 89% (200/224) Pressure ulcers at baseline: Excluded if stage 2 or higher, (proportion with stage 1 ulcers not reported)	Any pressure ulcer: 11% (22/205) vs. 20% (43/211); RR 0.53 (95% CI, 0.33 to 0.85)
Schultz et al, 1999 ¹³³ Good	Operating room 6 days post- op	A. Foam overlay + heel and elbow protectors (n=206) B. Standard perioperative care (n=207)	n=413 Mean age: 66 vs. 66 years 35% vs. 36% women Mean BMI 27.06 vs. 27.03 Past smoker: 50% vs. 52% Current smoker: 23% vs. 22% Diabetes: 22% vs. 24%	Braden: mean 22 for both groups Pressure ulcers at baseline: Excluded	Any pressure ulcer: 27% (55/206) vs. 16% (34/207); RR 1.6 (95% CI, 1.1 to 2.4) ≥Stage 2 ulcer: 3% (6/206) vs. 1% (3/207); RR 2.0 (95% CI, 0.51 to 7.9)
Alternating vs. Static Support Surfaces					
Aronovitch et al, 1999 ¹²⁷ Poor	Operating room 7 days post- op	A: Alternating pressure system (n=105) B: Conventional care (n=112)	n=217 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 Pressure ulcers at baseline: Excluded	Any pressure ulcer: 1% (1/112) vs. 6.7% (7/105); RR 0.13 (95% CI, 0.02 to 1.1) Heel ulcer: 0% (0/112) vs. 1.9% (2/105); RR 0.18 (95% C(0.009 to 3.9)

Table 15. Effectiveness of pressure ulcer prevention support surfaces in lower-risk patients (continued)

Author, Year Quality Rating	Setting Followup	Intervention	Baseline Demographics	Baseline Ulcer Risk ^a Pressure Ulcers at Baseline	Pressure Ulcer Incidence
Russell et al, 2000 ¹³² Good	Operating room 7 days post- op	A: MicroPulse alternating air system in the OR and postoperatively (n=98) B: Conventional care (foam overlay) (n=100)	n=198 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 Pressure ulcers at baseline: Excluded	Any pressure ulcer: 2% (2/98) vs. 7% (7/100); RR 0.29 (CI, 0.06 to 1.4) Stage 1 pressure ulcer: 0% (0/98) vs. 2% (2/100); RR 0.20 (95% CI, 0.01 to 4.2) Stage 2 pressure ulcer: 2% (2/98) vs. 5% (5/100); RR 0.41 (95% CI, 0.08 to 2.1) Stage 3 pressure ulcer: 0% (0/98) vs. 3% (3/100); RR 0.15 (95% CI, 0.008 to 2.8) Heel ulcer: 0% (0/98) vs. 1.0% (1/100); RR 0.34 (95% CI, 0.01 to 8.2)

Note: CI=confidence interval, NR=not reported, RR=relative risk.

^aHigher risk for pressure ulcers usually defined as Braden scores <15-18, Cubbin and Jackson scores <29, Norton scores <12-16, or Waterlow scores >10-15. Higher scores indicate higher pressure ulcer risk.

Static Mattresses, Overlays, or Bed Systems

Static mattresses or overlays were compared with standard operating room mattresses in one good-quality,¹³³ two fair-quality^{129,131} and two poor-quality trials (Table 15).^{128,130} 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 3.7¹³³ and 18 vs. 11 percent, RR 1.6, 95% CI, 0.76 to 3.3¹²⁹) after five to six days, compared with a standard operating mattress alone, though the difference was not statistically significant in one of the trials. In both trials, about 90 percent of the ulcers were stage 1 and the remainder stage 2, 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.¹³¹ 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.¹³⁰

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).¹²⁸

Alternating Air Mattresses, Overlays, and Bed Systems

One good-quality trial¹³² and one poor-quality trial¹²⁷ compared alternating support surfaces in the operating room with static, usual care surfaces and followed patients for 7 days post-operatively (Table 15). The good-quality trial found no statistically significant difference in pressure ulcer incidence or severity between the MicroPulse alternating air mattress system (in the operating room and continued post-operatively) compared with standard care, though results favored the alternating system (2 vs. 7 percent for any ulcer, RR 0.29, 95% CI, 0.06 to 1.4; 2 vs. 5 percent for stage 2 ulcer, RR 0.41, 95% CI, 0.08 to 2.0).¹³² A poor-quality trial similarly found an alternating pressure system associated with decreased risk of pressure ulcers compared with standard operating room care, though again results did not reach statistical significance (1 vs. 7 percent, RR 0.14, 95% CI, 0.02 to 1.1).¹²⁷

Key Question 3b. Do 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.¹⁵⁰

Key Question 3c. Do 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

- Nine of 48 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 and two trials (n=610 and 1972) found no differences in risk of withdrawal due to discomfort.
 - 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 that a urethane and gel wheel chair pad was associated with an increased risk of withdrawal due to discomfort compared with a standard foam wheel chair pad. (8 vs. 1 percent, RR 6.2, 95% CI 0.77 to 51).
- One trial of nutritional supplementation found that tube feeds were tolerated poorly, with 54 percent having the tube removed within 1 week, and 67 percent prior to completing the planned 2 week intervention. Four trials of nutritional supplementation by mouth did not report harms (strength of evidence: low).
- Two (n=46 and 838) of six 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 six 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 three trials of dressings reported harms. One trial reported that application of the REMOIS pad resulted in pruritus in one patient (strength of evidence: low).

Detailed Synthesis

Harms were reported in only 16^{91,94,95,107,112,113,115,132,140,142,145,149,153,155,156,160} of 72 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.

Support Surfaces

Nine^{91,94,95,107,112-115,132,160} trials (in 10 publications) of 48 trials of support surfaces reported harms (Table 16; Appendix Tables H11 and H12). Three trials reported cases of heat-related discomfort with a sheepskin overlay, leading to some withdrawals in two trials.^{107,112,113} The only trial to report quantitative data found the sheepskin overlay associated with increased risk of withdrawal due to discomfort compared with a standard mattress (5 vs. 0 percent; RR 21, 95% CI, 1.3 to 364).¹⁰⁷

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.¹⁶⁰ 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.¹³²

Two trials that compared different alternating pressure mattresses or overlays found no difference in rate of withdrawal due to discomfort (5.1 vs. 3.7 percent in one study⁹⁴ and 23 vs. 19 percent in the other¹¹⁵).

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).⁹⁵

One trial reported that a urethane and gel wheelchair pad (Jay cushion) was associated with an increased risk of withdrawal due to discomfort compared with a standard foam wheelchair pad (8 vs. 1 percent, RR 6.2, 95% CI 0.77 to 51).⁹¹

Nutritional Supplementation

One trial of nutritional supplementation found that patients tolerated tube feeds poorly. Six and a half percent (4/62) of patients removed the tube immediately, 54 percent (29/54) had the tube removed within 1 week, and 67 percent (32/48) had the tube removed prior to completing the planned two week intervention.¹⁴⁰ Four trials that evaluated nutritional supplementation by mouth did not report harms.¹³⁶⁻¹³⁹

Repositioning

Two^{142,145} of three trials of repositioning reported harms (Table 16; Appendix Tables 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).¹⁴⁵ 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.¹⁴²

Creams, Lotions, and Cleansers

Three^{153,155,156} of six trials of lotions reported harms (Table 16; Appendix Tables 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).¹⁵⁵ Two other trials of lotions or creams reported blisters or a wet sore in one patient each.^{153,156}

Dressings

One of three trials of dressings reported harms. It reported pruritus in one patient following application of the REMOIS pad (Table 16; Appendix Tables H19 and H20).¹⁴⁹

Table 16. Harms of pressure ulcer prevention interventions

Author, Year Quality Rating	Population	Intervention	Harms
Support Surfaces			
Conine et al, 1994 ⁹¹ 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/m ³ density foam bevelled at the bottom to prevent sling effect	Withdrawals due to discomfort: 8% (6/80) vs. 1% (1/83); RR 6.2, 95% CI 0.77 to 51
Demarre et al, 2012 ⁹⁴ Fair	n=610 Hospital acute care patients	A: Alternating low-pressure air mattress with single-stage inflation and deflation (n=312) B: Alternating low-pressure air mattress with multi-stage inflation and deflation (n=298)	Discontinued intervention due to discomfort: 5.1% (16/312) vs. 3.7% (11/298)
Donnelly et al, 2011 ⁹⁵ Good	n=239 Hospital acute care patients	A: Heelift Suspension Boot B: Usual care	Total adverse events: 20 ^a vs. 23 ^a ; p=0.69
Jolley et al, 2004 ¹⁰⁷ Fair	n=441 Hospital acute care patients	A. Sheepskin mattress overlay: leather-backed with a dense, uniform 25 mm wool pile B. Usual care	Withdrawals due to heat-related discomfort: 5% (10/218) vs. 0% (0/223); RR 21, 95% CI 1.3 to 364
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)
Mistiaen et al, 2010 ¹¹³ 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)
Nixon et al, 2006 ^{114,115} Good	n=1,972 Hospital acute care patients	A: Alternating-pressure overlay (n=990) B: Alternating-pressure mattress (n=982)	23% (230/990) vs. 19% (186/982) discontinued intervention for comfort or device-related reasons
Pring et al, 1998 ¹⁶⁰ Fair	n=39 Long-term care patients	A: Nimbus II mattress B: Pegasus Airwave mattress C: Quattro DC2000 mattress	Pain: A (p<0.05) and C (p<0.01) < B Sleep disturbance: C < A (p<0.05) and B (p<0.01)
Russell et al, 2000 ¹³² 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)	Adverse events: no difference between groups; no adverse events were treatment-related (no data reported)
Nutrition			
Hartgrink et al, 1998 ¹⁴⁰ Poor	n=129 Hospital acute care patients	A: Nasogastric tube feeding (1 liter Nutrison Steriflo Energy-plus; 1500 kcal; 60 g protein) in addition to standard hospital diet B: Standard hospital diet	Death: 7 vs. 0 Most patients did not accept tube feeding

Table 16. Harms of pressure ulcer prevention interventions (continued)

Author, Year Quality Rating	Population	Intervention	Harms
Repositioning			
Defloor et al, 2005 ¹⁴² 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 ¹⁴⁵ Fair	n=46 Hospital acute care patients	A: 30 degree tilt repositioning B: Standard repositioning	Difficulty tolerating positioning: 87% (20/23) vs. 24% (5/21); RR 0.17, 95% CI, 0.06 to 0.51
Lotions, Creams and Cleansers			
Cooper et al, 2001 ¹⁵³ Fair	n=93 Long-term care patients	A. Clinisan cleanser (includes silicone, triclosan, benzylicum and emollients) B. Standard hospital soap	Withdrawals: 7% (3/44) vs. 6% (3/49) Withdrawals due to adverse events: 2% (1/44) vs. 0% (0/49)
Smith et al, 1986 ¹⁵⁵ Poor	n=203 Long-term care patients	A: 20% dimethicone 350 and 0.05% hydrargaphen (Conotrane) B: placebo (Unguentum)	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 ¹⁵⁶ Poor	n=128 Wheelchair users	A: Prevasore cream B: Dermalex cream	Development of wet sore: 2% (1/60) vs. 0% (0/60)
Dressings			
Nakagami et al, 2007 ¹⁴⁹ 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)	Pruritus: 3% (1/37) vs. (0/37)

Note: CI=confidence interval, RR=relative risk.

^aDenominator unclear; text reported 45 adverse events but only accounted for 43.

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 17 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 noninvasive 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 scale⁴⁵ and the Braden scale,⁴⁶ with only a nonrandomized study of the Norton scale⁴⁵ 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 help identify patients at increased risk for ulcers who might benefit from more intense or targeted interventions, but appear to be relatively weak predictors, based on likelihood ratios at commonly used cutoffs. However, diagnostic accuracy may have been underestimated in these studies if patients at higher risk were more likely to receive effective interventions to prevent ulcers. Studies of diagnostic accuracy rarely reported risk estimates, and 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, good- and fair-quality randomized trials consistently found more advanced static mattresses and overlays associated with lower risk of pressure ulcers compared with standard mattresses in higher-risk patients (relative risk [RR] range 0.20 to 0.60),^{100,107,113,116,124} with no clear differences between different advanced static support surfaces.^{88,92,101,103,108,110,111,118,119,126} Although the mattresses and overlays evaluated in the trials varied, three trials consistently found an Australian medical sheepskin overlay associated with lower risk of ulcers than a standard hospital mattress, though the sheepskin was also associated with heat-related discomfort, in some cases resulting in withdrawal.^{107,112,113} Evidence on the effectiveness and comparative effectiveness of other specific support surfaces, including alternating air mattresses and low-air-low mattresses, was limited, with most

trials^{85,87,89,93,106,118,125} showing no clear differences between these types of mattresses and various static mattresses and overlays. One fair-quality trial found stepped care starting with alternating air mattresses associated with substantially decreased risk of ulcers compared with stepped care primarily with static mattresses,⁹⁶ suggesting that this might be both an effective as well as efficient approach, since care was initiated with the least expensive alternatives and advanced to more expensive alternatives based on a preset algorithm. In lower-risk populations of patients undergoing surgery, two trials found use of a foam overlay associated with an increased risk of pressure ulcers compared with a standard operating room mattress.^{129,133} The few trials that evaluated length of stay found no differences between various support surfaces.^{104-107,118,121,122}

Evidence on other preventive interventions (nutritional supplementation; repositioning; pads and dressings; lotions, creams, and cleansers; and intraoperative warming therapy for patients undergoing surgery) was sparse and insufficient to reach reliable conclusions, in part because most trials had important methodological shortcomings. An exception was repositioning, for which there were three good- or fair-quality trials, though these reported somewhat inconsistent results.^{142,143,146} One trial found a repositioning intervention was more effective than usual care in preventing pressure ulcers.¹⁴³ 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.¹⁶¹

Table 17. Summary of evidence

Key Question and Subcategories	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 = 1,231) found no difference in pressure ulcer incidence between patients assessed with either the Waterlow scale or Ramstadius tool 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 that use of a modified version of the Norton scale to guide use of preventive interventions was 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. Do 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. Do 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 2 good- and 5 fair-quality studies, 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), for a positive likelihood ratio of 2.31 and negative likelihood ratio of 0.38.
Diagnostic accuracy: Norton scale	Moderate	In 3 studies (1 good and 2 fair quality), the median AUROC for the Norton scale was 0.74 (range, 0.56 to 0.75). In 5 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), for a positive likelihood ratio of 1.83 and negative likelihood ratio of 0.42.

Table 17. Summary of evidence (continued)

Key Question and Subcategories	Strength of Evidence	Conclusion
Diagnostic accuracy: Waterlow scale	Moderate	In 4 studies (1 good and 3 fair quality), the median AUROC for the Waterlow scale was 0.61 (range, 0.54 to 0.66). In 2 studies, based on a cutoff of ≥ 10 , sensitivities were 0.88 and 1.0, and specificities 0.13 and 0.29, for positive likelihood ratios of 1.15 and 1.24 and negative likelihood ratios of 0.0 and 0.41.
Diagnostic accuracy: Cubbin and Jackson scale	Moderate	In 3 studies (1 good and 2 fair quality), the median AUROC for the Cubbin and Jackson scale was 0.83 (range, 0.72 to 0.90). In 3 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), for positive likelihood ratios that ranged from 1.43 to 5.28 and negative likelihood ratios that ranged from 0.06 to 0.40.
Diagnostic accuracy: direct comparisons between risk-assessment scales	Moderate	In 2 good- and 4 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 that a Braden scale score of ≤ 18 was 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 scale, ICU setting	Low	Two studies (1 good and 1 fair quality) found that the Cubbin and Jackson scale was 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 (1 good and 1 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 and skilled nursing settings.
Diagnostic accuracy: Braden scale, differences according to baseline pressure ulcer risk	Moderate	Three studies (1 good and 2 fair quality) found no clear difference in AUROC estimates based on the presence of higher or lower mean baseline pressure ulcer risk scores.

Table 17. Summary of evidence (continued)

Key Question and Subcategories	Strength of Evidence	Conclusion
Key Question 3. In patients at increased risk of developing pressure ulcers, what are the effectiveness and comparative effectiveness of preventive interventions in reducing the incidence or severity of pressure ulcers?		
Pressure ulcer incidence or severity: advanced static mattresses or overlays vs. standard hospital mattress	Moderate	One good-quality trial (n = 1,166) and 4 fair-quality trials (n = 83 to 543) found that a more advanced static mattress or overlay was associated with lower risk of incident pressure ulcers than a standard mattress (RR range, 0.16 to 0.82), although the difference was not statistically significant in 2 trials. Six poor-quality trials reported results that were generally consistent with these findings. Three trials found no difference in length of stay. The static support surfaces evaluated in the trials varied, although a subgroup of 3 trials each found that an Australian medical sheepskin overlay was associated with lower risk of ulcers than a standard mattress (RR, 0.30, 0.58, and 0.58).
Pressure ulcer incidence or severity: advanced static mattress or overlay vs. advanced static mattress or overlay	Moderate	Three fair-quality trials (n = 52 to 100) found no differences between different advanced static support mattresses or overlays in risk of pressure ulcers. One fair-quality trial (n = 40) of nursing home patients found that a foam replaceable-parts mattress was 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). Six poor-quality trials (n = 37 to 407) also found no differences between different advanced static mattresses or overlays.
Pressure ulcer incidence or severity: low-air-loss bed vs. standard hospital mattress	Low	One fair-quality trial (n = 98) found that a low-air-loss bed was associated with lower likelihood of 1 or more pressure ulcers in ICU patients (12% vs. 51%; RR, 0.23; 95% CI, 0.10 to 0.51), but a small (n = 36) poor-quality trial found no difference between a low-air-loss mattress compared with a standard hospital bed following cardiovascular surgery.
Pressure ulcer incidence or severity: low-air-loss mattress compared with dual option (constant low pressure/alternating air) mattress	Low	One fair-quality trial (n = 62) found no clear difference between a low-air-loss mattress compared with the Hill-Rom Duo® mattress (options for constant low pressure or alternating air) in risk of ulcers.
Pressure ulcer incidence or severity: alternating air pressure overlay or mattress vs. standard hospital mattress	Low	Three poor-quality trials (n = 108 to 487) found lower incidence of pressure ulcers with use of an alternating air pressure mattress or overlay compared with a standard hospital mattress.
Pressure ulcer incidence or severity: alternating air pressure overlay or mattress vs. advanced static overlay or mattress	Moderate	Six trials (n = 32 to 487; 1 good quality, 1 fair quality, and 4 poor quality) found no difference between an alternating air pressure overlay or mattress compared with various advanced static mattresses or overlays in pressure ulcer incidence or severity.

Table 17. Summary of evidence (continued)

Key Question and Subcategories	Strength of Evidence	Conclusion
Pressure ulcer incidence or severity: alternating air pressure overlay or mattress vs. alternating air pressure overlay or mattress	Moderate	Four trials (n = 44 to 1,972; 1 good quality, 2 fair quality, and 1 poor quality) found no clear differences between different alternating air mattresses or overlays. The good-quality (n = 1,972) trial found no difference in risk of stage 2 ulcers between an alternating air pressure overlay and an alternating air pressure mattress (RR, 1.0, 95% CI, 0.81 to 1.3; adjusted OR, 0.94, 95% CI, 0.68 to 1.3).
Pressure ulcer incidence or severity: heel supports or boots vs. usual care	Low	One fair-quality trial (n = 239) of fracture patients found that the Heelift® Suspension Boot was associated with decreased risk of heel, foot, or ankle ulcers compared with usual care without leg elevation (7% vs. 26% for any ulcer, RR, 0.26, 95% CI, 0.12 to 0.53; 3.3% vs. 13.4% for stage 2 ulcers, RR, 0.25, 95% CI, 0.09 to 0.72). 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, although the overall incidence of ulcers was low (5% over 3 years) and results could have been confounded by differential use of cointerventions.
Pressure ulcer incidence or severity: more sophisticated wheelchair cushions vs. standard wheelchair cushions	Low	Four fair-quality trials (n = 32 to 248) of older nursing home patients 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: nutritional supplementation vs. standard hospital diet	Low	Five of 6 trials (1 fair quality and 5 poor quality; n = 59 to 672) found no difference between nutritional supplementation compared with standard hospital diet in risk of pressure ulcers. Four trials evaluated supplementation by mouth and 2 evaluated enteral supplementation.
Pressure ulcer incidence or severity: repositioning intervention vs. usual care	Low	One fair-quality cluster trial (n = 213) found that repositioning at a 30-degree tilt every 3 hours was associated with lower risk of pressure ulcers 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), and 1 fair-quality trial (n = 235) found no difference in risk of pressure ulcers between different repositioning intervals. Two other trials (n = 46 and 838) evaluated repositioning interventions but followed patients for only 1 night or were susceptible to confounding due to differential use of support surfaces.

Table 17. Summary of evidence (continued)

Key Question and Subcategories	Strength of Evidence	Conclusion
Pressure ulcer incidence or severity: small unscheduled shifts in body position vs. usual care	Low	Two small (n = 15 and 19) poor-quality trials found that the addition of small unscheduled shifts in body position (using a small rolled towel to designated areas during nurse-patient interactions) to standard repositioning every 2 hours had no effect on risk on pressure ulcers, but the studies reported only 1 or 2 ulcers in each trial.
Pressure ulcer incidence or severity: silicone border foam sacral dressing vs. no silicone border foam dressing	Low	One fair-quality (n = 85) trial of patients undergoing cardiac surgery found that a silicone border foam sacral dressing applied at ICU admission (the Mepilex® Border sacrum) was associated with lower likelihood of pressure ulcers compared with standard care (including preoperative placement of a silicone border foam dressing for surgery and use of a low-air-loss bed), but the difference was not statistically significant (2.0% vs. 12%; RR, 0.18; 95% CI, 0.02 to 1.5).
Pressure ulcer incidence or severity: REMOIS pad vs. no pad	Insufficient	One poor-quality randomized trial (n = 37) found that 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 was associated with decreased risk of stage 1 ulcers compared with 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: changing incontinence pad 3 vs. 2 times per day	Low	One fair-quality crossover trial (n = 81) found no statistically significant difference in risk of pressure ulcers between changing incontinence pads 3 times vs. twice pafter 4 weeks.
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 corticotropin intramuscularly compared with a sham injection.
Pressure ulcer incidence or severity: polarized light	Insufficient	One small poor-quality randomized trial (n = 23) found no statistically significant difference between polarized light compared with standard care in risk of pressure ulcers.
Pressure ulcer incidence or severity: fatty acid cream vs. placebo	Low	One fair-quality trial (n = 331) and 1 poor-quality trial (n = 86) found that creams with fatty acids were associated with decreased risk of new pressure ulcers compared with placebo (RR, 0.42, 95% CI, 0.22 to 0.80; RR, 0.17, 95% CI, 0.04 to 0.70).
Pressure ulcer incidence or severity: other cream or lotion vs. placebo	Insufficient	Evidence from 3 poor-quality trials (n = 79 to 258) was insufficient to determine effectiveness of other creams or lotions for preventing pressure ulcers.

Table 17. Summary of evidence (continued)

Key Question and Subcategories	Strength of Evidence	Conclusion
Pressure ulcer incidence or severity: skin cleanser vs. standard soap and water	Low	One fair-quality randomized trial (n = 93) found that the Clinisan™ cleanser was 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. Do 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 (1 good and 1 fair quality; n = 175 and 413) found that use of a static foam overlay was associated with increased risk of pressure ulcers compared with standard care in lower risk surgical patients, although the difference was not statistically significant in 1 trial (OR, 1.9, 95% CI, 1.0 to 3.7; 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 (1 good and 1 poor quality) found that a dry polymer overlay was 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: alternating air vs. static mattress or overlay, lower risk surgical population	Low	Two trials (1 good and 1 poor quality; n = 198 and 217) found no differences between alternating compared with static support surfaces in risk of pressure ulcer incidence or severity.
Key Question 3b. Do 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. Do 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.

Table 17. Summary of evidence (continued)

Key Question and Subcategories	Strength of Evidence	Conclusion
Key Question 4. What are the harms of interventions for the prevention of pressure ulcers?		
Harms: support surfaces	Low	<p>Nine of 48 trials of support surfaces reported harms.</p> <ul style="list-style-type: none"> • Three trials (n = 297 to 588) reported cases of heat-related discomfort with sheepskin overlays, with 1 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, and 2 trials (n = 610 and 1,972) found no differences in risk of withdrawal due to discomfort. • One trial (n = 198) reported no differences in risk of adverse events between a multicell 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 that a urethane and gel wheelchair pad (Jay® cushion) was associated with increased risk of withdrawal due to discomfort compared with a standard foam wheelchair pad (8% vs. 1%; RR, 6.2; 95% CI, 0.77 to 51).
Harms: nutritional supplementation	Low	<p>One trial of nutritional supplementation found that tube feeds were tolerated poorly, with 54% having the tube removed within 1 week and 67% prior to completing the planned 2-week intervention. Four trials of nutritional supplementation by mouth did not report harms.</p>
Harms: repositioning	Low	<p>Two (n = 46 and 838) of 6 trials of repositioning interventions reported harms. Both trials reported more nonadherence due to intolerability of a 30-degree tilt position compared with standard positioning.</p>
Harms: lotions and creams	Low	<p>Three (n = 93 to 203) of 6 trials of lotions or creams reported harms. One trial found no differences in rash between different creams, and 2 trials each reported 1 case of a wet sore or rash.</p>
Harms: dressings	Low	<p>One (n = 37) of 3 trials of dressings reported harms. It reported that application of the REMOIS pad resulted in pruritus in 1 patient.</p>
Key Question 4a. Do the harms of preventive interventions differ according to the type of intervention?	Insufficient	<p>No study evaluated how harms of preventive interventions vary according to the type of intervention.</p>
Key Question 4b. Do the harms of preventive interventions differ according to setting?	Insufficient	<p>No study evaluated how harms of preventive interventions vary according to care setting.</p>
Key Question 4c. Do the harms of preventive interventions differ according to patient characteristics?	Insufficient	<p>No study evaluated how harms of preventive interventions vary in subgroups defined by patient characteristics</p>

Note: AUROC=area under the receiver operating characteristic, CI=confidence interval, ICU=intensive care unit, 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.^{162,163} One of these reviews also evaluated the diagnostic accuracy of risk assessment tools.¹⁶³ 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,¹⁶⁴ inadequate details to determine eligibility for inclusion,¹⁶⁵ availability only in Spanish,¹⁶⁶ or that we were unable to obtain.¹⁶⁷

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,^{168,169} limited evidence on the effectiveness and comparative effectiveness of dynamic support surfaces,^{168,169} and limited evidence on other preventive interventions.^{169,170} 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 higher stage 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, patients at end of life, and spinal cord injury patients. 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.¹⁷¹

Some interventions evaluated in older trials may no longer be available, and the control interventions (e.g., standard hospital mattresses) have also changed over time. However, conclusions were unchanged when analyses were restricted to trials conducted more recently. In addition, many trials of support surfaces evaluated specific brand name products and it might be difficult to generalize results to other products in the same class. This problem is compounded by the constantly changing nature of products sold and marketed by support surface manufacturers.

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 (blinding might be difficult for ethical reasons), 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 decreased incidence of pressure ulcers, thus affecting estimates of diagnostic accuracy. For trials of preventive interventions, usual care varied and was not always well described, but generally 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. In addition, the applicability of trial findings to clinical practice could be limited by delays in use of preventive interventions or differences in the quality of care between research and typical clinical settings.

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.

Although the studies included in this review generally enrolled patients in whom pressure ulcer risk assessment and preventive interventions would typically be considered and evaluated clinically relevant usual care comparison arms, they frequently did not meet a number of other criteria for effectiveness studies, such as assessment of adverse events, adequate sample sizes to detect clinically important differences, and use of intention-to-treat analysis.¹⁷²

The results of this CER are not applicable to populations excluded from the review, including patients with higher stage pressure ulcers at baseline, or patients with lower stage pressure ulcers 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. In some populations, such as spinal cord injured patients, risk assessment instruments have not been well studied, but may not be highly relevant since all patients may be considered to be at risk.

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. Despite limited evidence showing that they are more effective at preventing pressure ulcers compared with static mattresses and overlays, alternating air and low-air-loss mattresses and overlays are used in hospitals in many areas of the United States. Such support surfaces can be quite costly, though 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.⁹⁶ 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 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 noncomplementary or alternative medicine interventions.¹⁷³ 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.¹⁷⁴ Inclusion of two studies of preventive interventions published only as conference abstracts would not have changed our results.^{134,175}

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 35 of 72 studies of preventive interventions rated poor-quality, and only 12 studies of diagnostic accuracy and six studies of preventive interventions rated good-quality. Few studies of diagnostic accuracy reported measures of discrimination such as the AUROC, many studies failed to predefine 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 16 of 72 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 nonstandardized 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 predefined, standardized cutoffs and routinely report measures of discrimination such as the AUROC. Research is also needed to understand how the different components of risk assessment instruments contribute to predictive utility, and on whether the addition of aspects not addressed well in standard risk assessments (such as decreased perfusion) improves diagnostic accuracy, in order to refine prediction instruments. Studies are also needed to understand how risk prediction instruments perform in specific patient populations and settings and whether the diagnostic accuracy of risk prediction instruments varies for different types of ulcers (e.g., heel ulcers vs. sacral or other ulcers).

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 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 operating 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

Appendix A. Search Strategies

Overall

Database: EBM Reviews - Cochrane Database of Systematic Reviews

- 1 ((pressure or decubitus) and ulcer\$.ti,ab.
- 2 ((pressure or decubitus) and sore\$.ti,ab.
- 3 (bed sore\$ or bedsore\$.ti,ab.
- 4 or/1-3

Risk Assessment

Database: Ovid MEDLINE® and Ovid OLDMEDLINE®

- 1 Pressure Ulcer/
- 2 ((pressure or decubitus) and ulcer\$.mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]
- 3 ((pressure or decubitus) and sore\$.mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]
- 4 (bed sore\$ or bedsore\$.mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]
- 5 or/1-4
- 6 Risk Assessment/
- 7 Risk Factors/
- 8 Nursing Assessment/
- 9 “Predictive Value of Tests”/
- 10 ROC Curve/
- 11 “Sensitivity and Specificity”/
- 12 “Reproducibility of Results”/
- 13 or/6-12
- 14 (risk adj2 (factor\$ or assess\$)).mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]
- 15 13 or 14
- 16 5 and 15
- 17 “Severity of Illness Index”/
- 18 5 and 17
- 19 16 or 18
- 20 limit 19 to “all adult (19 plus years)”
- 21 limit 20 to humans

Database: EBM Reviews - Cochrane Central Register of Controlled Trials

- 1 Pressure Ulcer/
- 2 ((pressure or decubitus) and ulcer\$.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]

- 3 ((pressure or decubitus) and sore\$).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
- 4 (bed sore\$ or bedsore\$).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
- 5 or/1-4
- 6 Risk Assessment/
- 7 Risk Factors/
- 8 Nursing Assessment/
- 9 "Predictive Value of Tests"/
- 10 ROC Curve/
- 11 "Sensitivity and Specificity"/
- 12 "Reproducibility of Results"/
- 13 or/6-12
- 14 (risk adj2 (factor\$ or assess\$)).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
- 15 13 or 14
- 16 5 and 15
- 17 "Severity of Illness Index"/
- 18 5 and 17
- 19 16 or 18

Database: EBSCO CINAHL Plus[®]

- S1 (MH "Pressure Ulcer")
- S2 "pressure ulcer*"
- S3 "decubitus ulcer*"
- S4 "bedsore*"
- S5 "bed sore*"
- S6 S1 or S2 or S3 or S4 or S5
- S7 (MH "Risk Assessment") OR "risk assessment"
- S8 (MH "Risk Factors") OR "risk factors"
- S9 (MH "Nursing Assessment")
- S10 (MH "Predictive Value of Tests")
- S11 (MH "Sensitivity and Specificity")
- S12 (MH "Reproducibility of Results")
- S13 (MH "ROC Curve")
- S14 S7 or S8 or S9 or S10 or S11 or S12 or S13
- S15 "risk factor*"
- S16 "risk assess*"
- S17 S14 or S15 or S16
- S20 Limiters - Exclude MEDLINE records
- S19 Limiters - Age Groups: All Adult
- S18 S6 and S17
- S21 S18 and S19
- S22 S18 and S20
- S23 S21 and S22

Risk Assessment—Prognosis

Database: Ovid MEDLINE® and Ovid OLDMEDLINE®

- 1 Pressure Ulcer/
- 2 ((pressure or decubitus) and ulcer\$.mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]
- 3 ((pressure or decubitus) and sore\$.mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]
- 4 (bed sore\$ or bedsores\$.mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]
- 5 or/1-4
- 6 Risk Assessment/
- 7 Risk Factors/
- 8 Nursing Assessment/
- 9 “Predictive Value of Tests”/
- 10 ROC Curve/
- 11 “Sensitivity and Specificity”/
- 12 “Reproducibility of Results”/
- 13 or/6-12
- 14 (risk adj2 (factor\$ or assess\$)).mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]
- 15 13 or 14
- 16 5 and 15
- 17 “Severity of Illness Index”/
- 18 5 and 17
- 19 16 or 18
- 20 limit 19 to “all adult (19 plus years)”
- 21 limit 20 to humans
- 22 Prognosis/
- 23 16 and 22
- 24 limit 23 to “all adult (19 plus years)”

Prevention

Database: Ovid MEDLINE® and Ovid OLDMEDLINE®

- 1 Pressure Ulcer/
- 2 ((pressure or decubitus) and ulcer\$.mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]
- 3 ((pressure or decubitus) and sore\$.mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]

- 4 (bed sore\$ or bedsore\$).mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]
- 5 or/1-4
- 6 5 and pc.fs.
- 7 5 and prevent\$.mp.
- 8 6 or 7
- 9 limit 8 to “all adult (19 plus years)”
- 10 limit 9 to humans

Database: EBM Reviews - Cochrane Central Register of Controlled Trials

- 1 Pressure Ulcer/
- 2 ((pressure or decubitus) and ulcer\$).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
- 3 ((pressure or decubitus) and sore\$).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
- 4 (bed sore\$ or bedsore\$).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
- 5 or/1-4
- 6 5 and pc.fs.
- 7 5 and prevent\$.mp.
- 8 6 or 7

Database: EBSCO CINAHL Plus[®]

- S1 (MH “Pressure Ulcer”)
- S2 “pressure ulcer*”
- S3 “decubitus ulcer*”
- S4 “bedsore*”
- S5 “bed sore*”
- S6 S1 or S2 or S3 or S4 or S5
- S7 “prevent*”
- S8 S6 and S7
- S9 S6 and S7 Limiters - Exclude MEDLINE records
- S10 S6 and S7 Limiters - Age Groups: All Adult

Appendix B. Inclusion and Exclusion Criteria by Key Question

	Include	Exclude
KQ 1		
Population	All adult patients, ages ≥ 18 years old in the following settings: acute care hospital, long-term care facility, rehabilitation facility, operating room, home care, and wheelchair users in the community	Children and adolescents
Patient characteristics	Such as age, race or skin tone, physical impairment, body weight, specific medical comorbidities (e.g., diabetes, peripheral vascular disease)	Baseline pressure ulcers (>10%)
Interventions	Pressure ulcer risk-assessment tools, including Braden Scale, Norton Scale, Waterlow Scale, other tools	Individual predictors/risk factors
Comparators	Clinical judgment and/or usual care Different risk-assessment tools and reference standard	
Outcomes	Incidence of pressure ulcers, further examining effects of setting and patient characteristics on incidence Severity/stage of pressure ulcers, further examining effects of setting and patient characteristics on severity/stage Resource utilization (e.g., length of stay, number of hospitalizations)	
Settings	Acute care hospital, long-term care facility, rehabilitation facility, operating room, home care, and wheelchair users in the community	
Study designs	Controlled or comparative randomized and nonrandomized trials and controlled or comparative observational studies	
KQ 2		
Population	All adult patients, ages ≥ 18 years old in the following settings: acute care hospital, long-term care facility, rehabilitation facility, operating room, home care, and wheelchair users in the community	Children and adolescents
Patient characteristics	Such as age, race or skin tone, physical impairment, body weight, specific medical comorbidities (e.g., diabetes, peripheral vascular disease)	Baseline pressure ulcers (>10%)
Interventions	Pressure ulcer risk-assessment tools, including Braden Scale, Norton Scale, Waterlow Scale, other tools	Individual predictors/risk factors
Comparators	Different risk-assessment tools and reference standard	
Outcomes	Predictive validity of tools, further examining effects of setting and patient characteristics on predictive validity. E.g., diagnostic accuracy = sensitivity, specificity, positive and negative likelihood ratios, positive and negative predictive values; measures of risk = HR, OR, RR; calibration; discrimination = area under receiver operating characteristic (ROC) curve, etc.	Inter-rater reliability
Settings	Acute care hospital, long-term care facility, rehabilitation facility, operating room, home care, and wheelchair users in the community	
Study designs	Studies of predictive validity; Prospective studies	Retrospective studies; Case-control studies
KQ 3		
Population	Adult patients, ages ≥ 18 years old	Children and adolescents
Patient characteristics	Such as age, race or skin tone, physical impairment, body weight, specific medical comorbidities (e.g., diabetes, peripheral vascular disease)	>20% stage 2 ulcers at baseline, or proportion with ulcers at baseline not reported and includes patients with stage 2 or higher ulcers

	Include	Exclude
Interventions	Interventions to prevent pressure ulcers: Support surfaces (e.g., beds, overlays for mattresses), Dressings, Nutritional support, Nursing interventions (e.g., turning, repositioning), Self-care education, Wheelchair features, Combined treatment modalities	Non-preventive treatment interventions (covered in a separate review) Nursing education
Comparators	Usual care, placebo, no treatment, different preventive interventions (including different preventive interventions within the same category; e.g., alternating pressure mattress vs. foam overlay)	
Outcomes	Incidence of pressure ulcers, further examining effects of risk level, setting, and patient characteristics on incidence Severity/stage of pressure ulcers, further examining effects of risk level, setting, and patient characteristics on severity/stage Resource utilization (e.g., length of stay, number of hospitalizations) More specific measures of comfort: sleep deprivation, quality of life, etc.	Comfort
Settings	Acute care hospital, long-term care facility, rehabilitation facility, operating room, home care, and wheelchair users in the community	
Study designs	Randomized controlled trials	Observational studies
KQ 4		
Population	Adult patients, ages ≥ 18 years old	Children and adolescents
Patient characteristics	Such as age, race or skin tone, physical impairment, body weight, specific medical comorbidities (e.g., diabetes, peripheral vascular disease)	>20% stage 2 ulcers at baseline, or proportion with ulcers at baseline not reported and includes patients with stage 2 or higher ulcers
Interventions	Interventions to prevent pressure ulcers: Support surfaces (e.g., beds, overlays for mattresses), Dressings, Nutritional support, Nursing interventions (e.g., turning, repositioning), Self-care education, Wheelchair features, Combined treatment modalities	Non-preventive treatment interventions (covered in a separate review)
Comparators	Usual care, placebo, no treatment, different preventive interventions (including different preventive interventions within the same category; e.g., alternating pressure mattress vs. foam overlay)	
Outcomes	Harms of preventive interventions/strategies, such as dermatologic reactions, pain, or infection, further examining effects of categories of impairment, setting, and patient characteristics	
Settings	Acute care hospital, long-term care facility, rehabilitation facility, operating room, home care, and wheelchair users in the community	
Study designs	Randomized controlled trials, cohort studies, and other observational studies.	

Appendix C. Included Studies List

Andersen KE, Jensen O, Kvorning SA, Bach E. Decubitus prophylaxis: a prospective trial on the efficiency of alternating-pressure air-mattresses and water-mattresses. *Acta Derm Venereol.* 1982;63(3):227-30. PMID: 6192636.

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Appendix D. Excluded Studies List

Wrong Population

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Wrong Study Design for Key Question

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Appendix E. Non-English Language Titles and Abstracts

Titles

Blumel JE, Tirado K, Schiele C, Schonffeldt G, Sarra S. [Prediction of the pressure ulcer development in elderly women using the Braden scale]. *Rev Med Chil.* 2004;132(5):595-600. PMID: 15279146

Cadue JF, Karolewicz S, Tardy C, Barrault C, Robert R, Pourrat O. [Prevention of heel pressure sores with a foam body-support device. A randomized controlled trial in a medical intensive care unit]. *Presse Med.* 2008;37(1 Pt 1):30-6. PMID: 18037257

Feuchtinger J. [Preventing decubitus ulcer in heart surgery interventions: visco-elastic foam layer on the operating room table--a study]. *Pflege Z.* 2006;59(8):498-501. PMID: 16955593

Gallart E, Fuentelsaz C, Vivas G, Garnacho I, Font L, Aran R. Experimental study to test the effectiveness of hyperoxygenated fatty acids in the prevention of pressure sores in hospitalized patients [Spanish]. *Enferm Clin.* 2001;11(5):179-83

Matsui Y, Miyake S, Kawasaki T, Konya C, Sugama J, Sanada H. Randomized controlled trial of a two layer type air cell mattress in the prevention of pressure ulcers. *Japan J Pressure Ulcers.* 2001;3(3):331-7

Torra i Bou JE, Rueda Lopez J, Camanes G, Herrero Narvaez E, Blanco Blanco J, Martinez-Esparza EH, et al. [Heel pressure ulcers. Comparative study between heel protective bandage and hydrocellular dressing with special form for the heel]. *Rev Enferm.* 2002;25(5):50-6. PMID: 14508939

Segovia Gomez T, Verdu Soriano J, Nolasco Bonmati A, Rueda Lopez J. The effectiveness of a hyperoxygenated fatty acid compound in preventing pressure ulcers. *EWMA Journal.* 2005;5(2):27-31. PMID: 15779642

Abstracts (When Available)

Blumel, J. E., K. Tirado, et al. (2004). "[Prediction of the pressure ulcer development in elderly women using the Braden scale]." *Rev Med Chil.* 132(5): 595-600.

BACKGROUND: Pressure ulcers are a common complication among elderly patients confined to bed for long periods. The Braden scale is a commonly used risk assessment tool. **AIM:** To evaluate the use of Braden scale. **PATIENTS AND METHODS:** Seventy women aged 61 to 96 years, admitted to the Internal Medicine Service of Barros Luco-Trudeau Hospital, were studied. Their risk was evaluated using the Braden scale. The presence of pressure ulcer was diagnosed according to the National Pressure Ulcer Advisory Panel on admission, two weeks later and at discharge. **RESULTS:** On admission, mean Braden scale score was 16.6+/-2.8 and 34 women had a score of 16 or less, that is considered of risk. Twenty five women (20 with a score of 16 or less) developed pressure ulcers, mostly superficial. The odds ratio of a score of 16 or less for the development of ulcers was 4.2 (95% CI 1.8-11.7, p <0.001). The sensitivity and specificity of such score were 80 and 69% respectively. **CONCLUSIONS:** The Braden scale predicts the risk of developing pressure ulcers with a good sensitivity and specificity in female elderly patients.

Cadue, J. F., S. Karolewicz, et al. (2008). “[Prevention of heel pressure sores with a foam body-support device. A randomized controlled trial in a medical intensive care unit].” *Presse Med.* 37(1 Pt 1): 30-36.

BACKGROUND: To assess in a prospective controlled study the efficacy and safety of a specific foam body-support device designed as to prevent heel pressure ulcers. **METHODS:** A randomization table was used to allocate 70 patients into 2 groups. The control group was treated with our standard pressure sore prevention protocol (half-seated position, water-mattress and preventive massages 6 times a day); the experimental group was treated with the same standard protocol as well as with the foam body-support device being evaluated. Patients were included if their Waterlow score was >10, indicating a high risk of developing pressure ulcers and if they had no skin lesion on the heels. Foam devices, covered with jersey, were constructed for the legs and allowed the heels to be free of any contact with the bed; another foam block was arranged perpendicularly to the first, in contact with the soles, to prevent ankles from assuming an equinus position (to prevent a dropfoot condition). The principal criterion for efficacy was the number of irreversible skin lesions on the heel (that is, beyond the stage of blanching hyperemia, reversible after finger pressure); these lesions were assessed every day until the end of the study (up to 30 days). **FINDINGS:** The number of irreversible heel pressure ulcers was lower in the experimental (3 patients, 8.6%) than in the control group (19 patients, 55.4%) ($p < 0.0001$). Mean time without any pressure ulcer was higher in the experimental group (5.6 days, compared with 2.8 days, $p = 0.01$). The groups did not differ in the number of pressure sores on the sacrum and leg. **CONCLUSION:** An anatomical foam body-support is effective in preventing heel pressure ulcers in patients on a medical intensive care unit and is well tolerated.

Gallart, E., C. Fuentelsaz, et al. (2001). “Experimental study to test the effectiveness of hyperoxygenated fatty acids in the prevention of pressure sores in hospitalized patients [Spanish].” *Enferm Clin.* 11(5): 179-183.

Aim: To identify whether there are differences in the incidence of pressure sores in patients receiving preventive and those not undergoing this therapy. **Design:** A randomized, experimental study including a control and experimental group of patients. **Study site:** Hospital General Vall d’Hebron, Barcelona (Spain) from December 1999 to May 2000. **Subjects:** After calculation of the sample size required, 192 patients admitted to hospital without pressure sores and with mobility and altered activities (according to the EMINA risk scale) were included in the study. The sampling technique used was accidental including successive patients admitted to hospital. The patients were then randomly divided into two groups of 96 patients each. **Intervention:** In the control group the routine preventive therapy for pressure sores used in the hospital was applied. In addition to this preventive treatment, the experimental group also received hyperoxygenated fatty acids according to the protocol established for the study. **Results:** The incidence of pressure sores in the control group was of 35% (CI 95%; 27%-47%) and 19% (CI 95%; 12%-29%) in the experimental group; with the difference being statistically significant (chi square=6.8; $gl=1$; $p=0.007$). **Conclusions:** The incidence of pressure sores was lower in the group receiving preventive treatment with hyperoxygenated fatty acids thereby indicating the this therapy may be useful in the prevention of the development of pressure ulcers in hospitalized patients.

Segovia Gomez, T., J. Verdu Soriano, et al. (2005). "The effectiveness of a hyperoxygenated fatty acid compound in preventing pressure ulcers." *EWMA Journal* 5(2): 27-31.

Objective: To compare the effects of Mepentol, a hyperoxygenated fatty acid preparation, with a placebo treatment in preventing the development of pressure ulcers. **Method:** The research study consisted of a multicentre double-blind randomised clinical trial. The incidence of pressure ulcers, relative risk (RR), preventable fraction and number necessary to treat (NNT) were calculated. In addition, Kaplan-Meier survival curves, with log-rank test, and Cox's proportional hazards regression model were used to compare both groups. **Results:** A total of 331 patients completed the study: 167 in the control group and 164 in the study group. Pressure-ulcer incidence during the study was 7.32% in the intervention group versus 17.37% in the placebo group ($p=0.006$). These results show that for each 10 patients treated with Mepentol one pressure ulcer was prevented (NNT = 9.95). Survival curves and the regression model showed a significant statistical difference for both groups ($p<=0.001$). The average cost of Mepentol during the study was euro 7.74. **Conclusion:** Mepentol is an effective measure for pressure ulcer prevention. It was more effective than a greasy placebo product, and was found to be cost-effective.

Torra i Bou, J. E., J. Rueda Lopez, et al. (2002). "[Heel pressure ulcers. Comparative study between heel protective bandage and hydrocellular dressing with special form for the heel]." *Rev Enferm.* 25(5): 50-56.

INTRODUCTION: The heels, together with the sacra area, are one of the most frequent spots where pressure sores appear here in Spain. Any preventive measure against pressure sores on heels needs be oriented towards two main objectives: effective relief of pressure and its compatibility with localized care and skin inspection in order to detect lesions early on at least once a day. **PATIENTS, MATERIALS AND METHODS:** The authors planned a comparative, multi-centered, open, labeled and controlled study in which patients were assigned to two groups receiving these treatments: one received traditional preventive pressure sore treatment and a protective bandage on their heels while the other used a special Allevyn Heel hydrocellular dressing to protect their heels. The patients took part in this study over an eight week period. The response variable used to determine the effectiveness of the preventive measure in this study was the appearance of pressure sores. **RESULTS:** At the beginning, 130 patients were included in this study, 65 in each one of the treatment groups. In the bandage group, 50 patients finished this study while 61 in the dressing group finished this study. The appearance of pressure sores in the protective bandage group occurred in 44% of the patients, 22 out of 50, while in the dressing group, the occurrence rate was 3.3%, 2 out of 61 patients with a value of "ji" squared $p < 0.001$. The risk factor to develop a pressure sore brought us a value of relative risk of 13.42 (IC 95%: 3.31-54.3) in the group wearing the protective bandage compared to the group wearing the dressing. **COMMENTS:** The results of this study allow us to accept as valid the alternate hypothesis that there exist significant statistical differences between both treatment methods in favor of the Allevyn Heel dressing instead of the protective heel bandage. The use of this dressing, even though it is more expensive a priori than the protective bandage, in terms of unit cost for the product, has proven to be more effective in preventing pressure sores, and cheaper than the protective bandage if we bear in mind these combination of variables: time of usage, application and removal.

Appendix F. Quality Assessment Methods

Individual studies were rated as “good,” “fair” or “poor” as defined below:

For Controlled Trials:

Each criterion was give an assessment of yes, no, or unclear.

1. Was the assignment to the treatment groups really random?
Adequate approaches to sequence generation:
 Computer-generated random numbers
 Random numbers tables
Inferior approaches to sequence generation:
 Use of alternation, case record numbers, birth dates or week days
Randomization reported, but method not stated
Not clear or not reported
Not randomized
2. Was the treatment allocation concealed?
Adequate approaches to concealment of randomization:
 - Centralized or pharmacy-controlled randomization (randomization performed without knowledge of patient characteristics).
 - Serially-numbered identical containers
 - On-site computer based system with a randomization sequence that is not readable until allocation
 - Sealed opaque envelopesInferior approaches to concealment of randomization:
 - Use of alternation, case record numbers, birth dates or week days
 - Open random numbers lists
 - Serially numbered non- opaque envelopes
 - Not clear or not reported
3. Were the groups similar at baseline in terms of prognostic factors?
4. Were the eligibility criteria specified?
5. Were outcome assessors and/or data analysts blinded to the treatment allocation?
6. Was the care provider blinded?
7. Was the patient kept unaware of the treatment received?
8. Did the article include an intention-to-treat analysis, or provide the data needed to calculate it (i.e., number assigned to each group, number of subjects who finished in each group, and their results)?
9. Did the study maintain comparable groups?
10. Did the article report attrition, crossovers, adherence, and contamination?
11. Is there important differential loss to followup or overall high (>20%) loss to followup?

For Cohort Studies:

Each criterion was give an assessment of yes, no, or unclear.

1. Did the study attempt to enroll all (or a random sample of) patients meeting inclusion criteria, or a random sample (inception cohort)?
2. Were the groups comparable at baseline on key prognostic factors (e.g., by restriction or matching)?

3. Did the study use accurate methods for ascertaining exposures, potential confounders, and outcomes?
4. Were outcome assessors and/or data analysts blinded to treatment?
5. Did the article report attrition?
6. Did the study perform appropriate statistical analyses on potential confounders?
7. Is there important differential loss to followup or overall high (>20%) loss to followup?
8. Were outcomes pre-specified and defined, and ascertained using accurate methods?

For Studies of Diagnostic Accuracy:

Each criterion was given an assessment of yes, no, or unclear.

1. Did the study evaluate a representative spectrum of patients?
2. Did the study enroll a random or consecutive sample of patients meeting pre-defined criteria?
3. Did the study evaluate a credible reference standard?
4. Did the study apply the reference standard to all patients, or to a random sample?
5. Did the study apply the same reference standard to all patients?
6. Was the reference standard interpreted independently from the test under evaluation?
7. If a threshold was used, was it pre-specified?

Appendix F References

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Whiting PF, Rutjes AW, Westwood ME, et al. QUADAS-2. A revised toll for the quality assessment of diagnostic accuracy studies. *Ann Intern Med.* 2011;155(8):529-536.

Appendix G. Overall Strength of Evidence Tables

Appendix Table G1. Strength of evidence for Key Question 1

Details	Number of studies	Quality (Good, Fair, Poor)	Consistency (High, Moderate, Low)	Directness (Direct or indirect)	Precision (High, Moderate, Low)	Number of subjects	Strength of evidence
<i>Pressure ulcer incidence or severity: Waterlow scale vs. clinical judgment</i>	1	Good	Not applicable (1 study)	Direct	Low	1,231	Low
<i>Pressure ulcer incidence or severity: Norton scale vs. clinical judgment</i>	1	Poor	Not applicable (1 study)	Direct	Low	240	Insufficient
<i>Pressure ulcer incidence or severity: Braden scale vs. clinical judgment</i>	1	Poor	Not applicable (1 study)	Direct	Low	521	Insufficient

Note: 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?

Appendix Table G2. Strength of evidence for Key Question 1a

Details	Number of studies	Quality (Good, Fair, Poor)	Consistency (High, Moderate, Low)	Directness (Direct or indirect)	Precision (High, Moderate, Low)	Number of subjects	Strength of evidence
<i>Not relevant</i>	0	No evidence	No evidence	No evidence	No evidence	No evidence	Insufficient

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

Appendix Table G3. Strength of evidence for Key Question 1b

Details	Number of studies	Quality (Good, Fair, Poor)	Consistency (High, Moderate, Low)	Directness (Direct or indirect)	Precision (High, Moderate, Low)	Number of subjects	Strength of evidence
<i>Not relevant</i>	0	No evidence	No evidence	No evidence	No evidence	No evidence	Insufficient

Note: 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?

Appendix Table G4. Strength of evidence for Key Question 2

Details	Number of studies	Quality (Good, Fair, Poor)	Consistency (High, Moderate, Low)	Directness (Direct or indirect)	Precision (High, Moderate, Low)	Number of subjects	Strength of evidence
<i>Diagnostic accuracy: Braden Scale</i>	AUROC: 7 Sensitivity/specificity, cutoff ≤18: 16; all cut-offs: 32	Fair	Moderate	Direct	Moderate	AUROC: 4,811 Sensitivity/specificity, cutoff ≤18: 5,462; all cut-offs: 11,596	Moderate
<i>Diagnostic accuracy: Norton scale</i>	AUROC: 3 Sensitivity/specificity, cutoff ≤14: 5; all cut-offs: 12	Fair	Moderate	Direct	Low	AUROC: 4,191 Sensitivity/specificity: Cutoff ≤14: 2,809 All cut-offs: 5,910	Moderate
<i>Diagnostic accuracy: Waterlow scale</i>	AUROC: 4 Sensitivity/specificity, cutoff ≥10: 2; all cut-offs: 10	Fair	Moderate	Direct	Low	AUROC: 2,559 Sensitivity/specificity, cutoff ≥10: 419 all cut-offs: 3,979	Moderate
<i>Diagnostic accuracy: Cubbin and Jackson scale</i>	AUROC: 3 Sensitivity/specificity, cutoff ≤24 to 29: 3	Fair	Moderate	Direct	Low	AUROC: 865 Sensitivity/specificity, cutoff ≤24 to 29: 865	Moderate
<i>Diagnostic accuracy: Direct comparisons between risk assessment scales</i>	AUROC: 6 Sensitivity/specificity, all scales, common cut-offs: 8; all scales, all cut-offs: 14	Fair	Moderate	Direct	Moderate	AUROC: 5,921 Sensitivity/specificity, all scales, common cut-offs: 4,637 all scales, all cut-offs: 6,528	Moderate

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

Appendix Table G5. Strength of evidence for Key Question 2a

Details	Number of studies	Quality (Good, Fair, Poor)	Consistency (High, Moderate, Low)	Directness (Direct or indirect)	Precision (High, Moderate, Low)	Number of subjects	Strength of evidence
<i>Diagnostic accuracy: Braden scale, across settings (direct evidence)</i>	29	Fair	Moderate	Indirect	Low	10,705	Low
<i>Diagnostic accuracy: Cubbin and Jackson, ICU setting</i>	2	Fair	Moderate	Direct	Low	646	Low
<i>Diagnostic accuracy: Braden scale, optimal cutoff in different settings</i>	9	Fair	Moderate	Indirect	Low	3,654	Low

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

Appendix Table G6. Strength of evidence for Key Question 2b

Details	Number of studies	Quality (Good, Fair, Poor)	Consistency (High, Moderate, Low)	Directness (Direct or indirect)	Precision (High, Moderate, Low)	Number of subjects	Strength of evidence
<i>Diagnostic accuracy: Braden scale, differences according to race</i>	2	Fair	Low	Direct	Low	917	Low
<i>Diagnostic accuracy: Braden scale, differences according to baseline pressure ulcer risk</i>	3	Fair	Moderate	Direct	Low	3,535	Moderate

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

Appendix Table G7. Strength of evidence for Key Question 3

Details	Number of studies	Quality (Good, Fair, Poor)	Consistency (High, Moderate, Low)	Directness (Direct or indirect)	Precision (High, Moderate, Low)	Number of subjects	Strength of evidence
<i>Pressure ulcer incidence or severity: Advanced static mattresses or overlays vs. a standard hospital mattress</i>	12	Fair	High	Direct	Moderate	2,533	Moderate
<i>Pressure ulcer incidence or severity: Advanced static mattress or overlay vs. advanced static mattress or overlay</i>	11	Fair	Moderate	Direct	Moderate	1,170	Moderate
<i>Pressure ulcer incidence or severity: Low-air-loss bed vs. standard hospital mattress</i>	2	Fair	Low	Direct	Low	134	Low
<i>Pressure ulcer incidence or severity: Low-air-loss mattresses versus dual option (constant low pressure/alternating air) mattress</i>	1	Fair	Not applicable (1 study)	Direct	Low	62	Low
<i>Pressure ulcer incidence or severity: Alternating air pressure overlay or mattress vs. standard hospital mattress</i>	3	Poor	High	Direct	Moderate	768	Low
<i>Pressure ulcer incidence or severity: Alternating air pressure overlay or mattress vs. advanced static overlay or mattress</i>	6	Fair	Moderate	Direct	Moderate	1,339	Moderate

Details	Number of studies	Quality (Good, Fair, Poor)	Consistency (High, Moderate, Low)	Directness (Direct or indirect)	Precision (High, Moderate, Low)	Number of subjects	Strength of evidence
<i>Pressure ulcer incidence or severity: Alternating air pressure overlay or mattress vs. alternating air pressure overlay or mattress</i>	4	Fair	Moderate	Direct	Moderate	2,734	Moderate
<i>Pressure ulcer incidence or severity: Heel ulcer supports or boots vs. usual care</i>	2	Fair	Low	Direct	Low	291	Low
<i>Pressure ulcer incidence or severity: Heel ulcer preventive intervention vs. heel ulcer preventive intervention</i>	1	Poor	Not applicable (1 study)	Direct	Low	240	Insufficient
<i>Pressure ulcer incidence or severity: More sophisticated wheelchair cushions vs. standard wheelchair cushions</i>	4	Fair	Low	Direct	Moderate	653	Low
<i>Pressure ulcer incidence or severity: Nutritional supplementation vs. standard hospital diet</i>	6	Poor	Moderate	Direct	Low	1,553	Low
<i>Pressure ulcer incidence or severity: Repositioning intervention vs. usual care</i>	4	Fair	Moderate	Direct	Low	1,332	Low
<i>Pressure ulcer incidence or severity: Small, unscheduled shifts in body position vs. usual care</i>	2	Poor	High	Direct	Low	34	Low
<i>Pressure ulcer incidence or severity: Silicone border foam sacral dressing vs. no silicone border foam dressing</i>	1	Fair	Not applicable (1 study)	Direct	Low	85	Low
<i>Pressure ulcer incidence or severity: REMOIS pad vs. no pad</i>	1	Poor	Not applicable (1 study)	Direct	Low	37	Insufficient
<i>Pressure ulcer incidence or severity: Changing incontinence pad three vs. two times daily</i>	1	Fair	Not applicable (1 study)	Direct	Low	81	Low
<i>Pressure ulcer incidence or severity: Intraoperative warming vs. usual care</i>	1	Fair	Not applicable (1 study)	Direct	Low	324	Low
<i>Pressure ulcer incidence or severity: Corticotropin vs. sham</i>	1	Poor	Not applicable (1 study)	Direct	Low	85	Insufficient

Details	Number of studies	Quality (Good, Fair, Poor)	Consistency (High, Moderate, Low)	Directness (Direct or indirect)	Precision (High, Moderate, Low)	Number of subjects	Strength of evidence
<i>Pressure ulcer incidence or severity: Polarized light</i>	1	Poor	Not applicable (1 study)	Direct	Low	23	Insufficient
<i>Pressure ulcer incidence or severity: Fatty acid cream vs. placebo</i>	2	Fair	Moderate	Direct	Moderate	417	Low
<i>Pressure ulcer incidence or severity: Other cream or lotion vs. placebo</i>	3	Poor	Moderate	Direct	Low	534	Insufficient
<i>Pressure ulcer incidence or severity: Skin cleanser vs. standard soap and water</i>	1	Fair	Not applicable (1 study)	Direct	Low	93	Low

Note: 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?

Appendix Table G8. Strength of evidence for Key Question 3a

Details	Number of studies	Quality (Good, Fair, Poor)	Consistency (High, Moderate, Low)	Directness (Direct or indirect)	Precision (High, Moderate, Low)	Number of subjects	Strength of evidence
<i>Pressure ulcer incidence or severity: Static foam overlay vs. standard care, lower-risk surgical population</i>	2	Good	High	Direct	Low	588	Moderate
<i>Pressure ulcer incidence or severity: Static dry polymer overlay vs. standard care, lower-risk surgical population</i>	2	Fair	High	Direct	Low	921	Low
<i>Pressure ulcer incidence or severity: Static foam block mattress vs. standard care, lower-risk surgical population</i>	1	Poor	Not applicable (1 study)	Direct	Low	1,729	Insufficient
<i>Pressure ulcer incidence or severity: Alternating air vs. static mattress or overlay, lower-risk surgical population</i>	2	Fair	High	Direct	Low	415	Low

Note: 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?

Appendix Table G9. Strength of evidence for Key Question 3b

Details	Number of studies	Quality (Good, Fair, Poor)	Consistency (High, Moderate, Low)	Directness (Direct or indirect)	Precision (High, Moderate, Low)	Number of subjects	Strength of evidence
<i>Not relevant</i>	No evidence	No evidence	No evidence	No evidence	No evidence	No evidence	Insufficient

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

Appendix Table G10. Strength of evidence for Key Question 3c

Details	Number of studies	Quality (Good, Fair, Poor)	Consistency (High, Moderate, Low)	Directness (Direct or indirect)	Precision (High, Moderate, Low)	Number of subjects	Strength of evidence
<i>Not relevant</i>	No evidence	No evidence	No evidence	No evidence	No evidence	No evidence	Insufficient

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

Appendix Table G11. Strength of evidence for Key Question 4

Details	Number of studies	Quality (Good, Fair, Poor)	Consistency (High, Moderate, Low)	Directness (Direct or indirect)	Precision (High, Moderate, Low)	Number of subjects	Strength of evidence
<i>Harms: Support surfaces</i>	9	Fair	Moderate	Direct	Low	4,524	Low*
<i>Harms: Nutritional supplementation</i>	1	Fair	Not applicable (1 study)	Direct	Low	129	Low*
<i>Harms: Repositioning</i>	2	Fair	Moderate	Direct	Low	884	Low*
<i>Harms: Lotions, creams and cleansers</i>	3	Fair	Moderate	Direct	Low	424	Low*
<i>Harms: Dressings</i>	1	Poor	Not applicable (1 study)	Direct	Low	37	Low*

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

Appendix Table G12. Strength of evidence for Key Question 4a

Details	Number of studies	Quality (Good, Fair, Poor)	Consistency (High, Moderate, Low)	Directness (Direct or indirect)	Precision (High, Moderate, Low)	Number of subjects	Strength of evidence
<i>Not relevant</i>	No evidence	No evidence	No evidence	No evidence	No evidence	No evidence	Insufficient

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

Appendix Table G13. Strength of evidence for Key Question 4b

Details	Number of studies	Quality (Good, Fair, Poor)	Consistency (High, Moderate, Low)	Directness (Direct or indirect)	Precision (High, Moderate, Low)	Number of subjects	Strength of evidence
<i>Not relevant</i>	No evidence	No evidence	No evidence	No evidence	No evidence	No evidence	Insufficient

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

Appendix Table G14. Strength of evidence for Key Question 4c

Details	Number of studies	Quality (Good, Fair, Poor)	Consistency (High, Moderate, Low)	Directness (Direct or indirect)	Precision (High, Moderate, Low)	Number of subjects	Strength of evidence
<i>Not relevant</i>	No evidence	No evidence	No evidence	No evidence	No evidence	No evidence	Insufficient

*Selective reporting of harms also noted.

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

Appendix G Reference

Owens D, Lohr KN, Atkins D, et al. AHRQ Series Paper 5: Grading the strength of a body of evidence when comparing medical interventions—Agency for Healthcare Research and Quality and the Effective Health Care Program. *J Clin Epidemiol* 2010;63(5):513-23. PMID: 19595577.

Appendix H. Evidence Tables and Quality Assessment Tables

Appendix Table H1. Key Question 1: data extraction of pressure ulcer screening and clinical outcome studies

Author, Year	Study Design	Setting Country	Eligibility Criteria and Exclusions	Study Duration of Followup	Number Screened/ Enrolled/ Analyzed	Withdrawals	Loss to Followup	Baseline Demographics (Age, Sex, Race)	Ulcer Risk
Bale, 1995 ¹	Nonrandomized trial	Hospice, Wales (presumed)	All patients admitted to hospice from May 1991 to Dec 1993	Mean (SD) A: 12 days (6) B: 13 days (5)	240/240/240	0	0	Mean age 67 vs. 67 years 45 % vs. 59% women Race not reported	Norton score (“adapted version”) by percent per score range (A vs. B): ≤ 10: 30% vs. 29% 11—15: 41% vs. 51% ≥ 16: 29% vs. 20%
Saleh, 2009 ²	Cluster randomized trial (randomized by hospital ward)	Hospital, Saudi Arabia	Braden score ≤ 18 No other criteria described	8 weeks	NR/719/521	198 (excluded due to hospital discharge < 8 weeks)	None reported	Not reported (study conducted in a Saudi military hospital, so presumably subjects were Saudi males)	All subjects had Braden score ≤18. Details of Braden score not reported for the 3 pre-test groups or the 3 post-test groups. Reports statistically significant differences in Braden score between 3 groups, with B higher than A and C, but only p values reported (no Braden scores).
Webster, 2011 ³	Randomized trial	Hospital, Australia	Admitted between April 2009 to December 2009; excluded hospital stay less than 3 days or hospitalization more than 24 hours before baseline assessment	Mean 9 days	1,524/1,231/1,231	293	None reported	Mean age 63 vs. 63 vs. 62 years 51% vs. 50% vs. 48% female Race not reported	Baseline scores not reported; 6% had pressure ulcer at baseline

Author, year	Intervention	Results	Harms	Quality rating	Funding source
Bale, 1995 ¹	<p>A: Mattresses allocated based on risk score, and re-allocated if score changed: ≤ 10: Pressure-reducing hollow core fiber overlay (Superdown) 11—15: Basic alternating air mattress overlay (Alpha Xcell) ≥ 16: “More sophisticated” alternating pressure mattress replacement (Nimbus) B: Pressure reducing hollow core fiber overlay (Spenco), unless patient requested special overlay used before admission. Alternating pressure mattress replacement (Nimbus) based on nurses’ clinical judgment of high risk.</p>	<p>Incidence of pressure ulcers: 2.5% (2/79) vs. 22.4% (36/161); RR 0.11; 95% CI, 0.03 to 0.46</p>	Not reported	Poor	HNE Huntleigh (manufacturer of the alternating pressure mattress used in the study)
Saleh, 2009 ²	<p>A: a) Wound care education; b) PU prevention training, with specific training in use of Braden scale; c) Required to implement Braden scale in post-intervention period. B: Same as group A, except not required to implement Braden scale. C: a) Wound care education; b) Asked to use a 5-level clinical judgment (CJ) scale devised for the study.</p>	<p>Pre-intervention: Incidence of “nosocomial” pressure ulcer: 33.0 vs. 29.7 vs. 31.6 (chi square, p = 0.90) Post-intervention: Incidence of “nosocomial” pressure ulcer: 21.6 vs. 22.4 vs. 15.1 (chi square, p = 0.38)</p>	Not reported	Poor	Not reported
Webster, 2011 ³	<p>A. Assessment with Waterlow scale B. Assessment with Ramstadius scale C. Clinical judgment</p>	<p>Incidence of pressure ulcers: 8% (31/411) vs. 5% (22/410) vs. 7% (28/410) A vs. B: RR 1.41 (95% CI 0.82 to 2.39) A vs. C: RR 1.10 (95% CI 0.68 to 1.81) B vs. C: RR 0.79 (95% CI 0.46 to 1.35)</p>	Not reported	Good	Queensland Nursing Council, Royal Brisbane and Women’s Hospital Private Practice and Research Foundation funds, Queensland Health Nursing Research Grant

Appendix Table H2. Key Question 1: quality assessment of pressure ulcer screening and clinical outcome trials

Author, Year	Randomization adequate?	Allocation concealment adequate?	Groups similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Care provider masked?	Patient masked?	Reporting of attrition	Loss to followup: differential/high	Intention-to-treat analysis	Quality rating	Comment
Saleh, 2009 ²	Unclear	Unclear	No	Unclear	No	No	No	Unclear	No.	No	Poor	This cluster randomized trial did not report a cluster correlation coefficient
Webster, 2011 ³	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Good	

Appendix Table H3. Key Question 1: quality assessment of pressure ulcer screening and clinical outcome cohort studies

Author, Year	Did the study attempt to enroll a random sample or consecutive patients meeting inclusion criteria (inception cohort)?	Were the groups comparable at baseline?	Did the study use accurate methods for ascertaining exposures, potential confounders, and outcomes?	Were outcome assessors and/or data analysts blinded to treatment?	Did the article report attrition?	Did the study perform appropriate statistical analyses on potential confounders?	Is there important differential loss to followup or overall high loss to followup?	Were outcomes pre-specified and defined, and ascertained using accurate methods?	Quality rating
Bale, 1995 ¹	Yes	No. (sex and ulcer risk differed)	Unclear (Although they report that they used Torrance's scoring system to assess skin status, they did not report the times and intervals of assessment or who made the assessments)	No	Yes	No	No	Unclear (See previous comment)	Poor

Appendix Table H4. Key Question 2: data extraction of pressure ulcer risk assessment studies

Author, year	Study Design	Screening Test/Scale	Setting Country	Inclusion Criteria	Study excluded: Symptomatic patients? Patients with history of PUs? Patients with specific findings	Number Screened/ Eligible/ Enrolled/ Analyzed	Baseline Demographics	Mean Risk Score at Baseline	Mean Followup
Multiple scales									
Boyle, 2001 ⁴	Prospective cohort	Cubbin and Jackson Waterlow	Hospital inpatient; ICU Australia	Not reported	Symptomatic: excluded from analysis History of PUs: unclear Specific findings: unclear	NR/ NR/ 534/ 534	Mean age 58 years 37% female Race not reported	Cubbin and Jackson: 33 (SE 0.4) Waterlow: 29 (SE 0.4)	Unclear; mean length of stay in ICU 4 days
DeFloor, 2005 ⁵	Prospective cohort	Braden Norton	Long-term care facilities (n=11) Belgium	Not reported	Symptomatic: included History of PUs: included Specific findings: if pressure ulcers present at baseline, patient included but those pressure ulcers excluded from analysis	NR/ NR/ 1,772/ 1,772	Mean age 85 years (SD 8) 79% female Race not reported	Braden: 17 (SD 4) Norton: 14 (SD 4)	4 weeks
Feuchtinger, 2007 ⁶	Prospective cohort	Braden Modified Norton 4-factor model (sensory perception, moisture, friction/shear, age)	Hospital inpatient; cardiac ICU Germany	Admitted to the cardiac ICU with a length of stay ≥24 hours	Symptomatic: excluded History of PUs: unclear Specific findings: unclear	NR/ NR/ 53/ 53	Mean age 62 years (range 25-83) 42% female Race not reported	Mean not reported	Mean 3 days (range 1-8 years)

Author, year	Study Design	Screening Test/Scale	Setting Country	Inclusion Criteria	Study excluded: Symptomatic patients? Patients with history of PUs? Patients with specific findings	Number Screened/ Eligible/ Enrolled/ Analyzed	Baseline Demographics	Mean Risk Score at Baseline	Mean Followup
Jalali, 2005 ⁷	Prospective cohort	Braden Gosnell Norton Waterlow	Hospital inpatient Iran	Age ≥21 years; admitted to hospital within 48 hours of study entry; expected hospital stay ≥= 14 days; no PU	Symptomatic: excluded History of PU: unclear Specific findings: no pressure ulcers on admission	NR/ NR/ 230/ 230	Mean age 60 years (range 21-89 years) 57% women Race not reported	Not reported for all scales	Not reported (minimum followup 14 days)
Kim, 2009 ⁸	Prospective cohort	Braden Cubbin and Jackson Song and Choi	Hospital inpatient; surgical ICU South Korea	Age ≥16 years; no pressure ulcer on admission to surgical ICU	Symptomatic: excluded History of PUs: unclear Specific findings: unclear	NR/ NR/ 219/ 219	Mean age 58 years (SD 1.2) 34% female Race not reported	Mean not reported	11.3 days (range 3-90 days)
Kwong, 2005 ⁹	Prospective cohort	Braden Modified Braden Norton	Hospital inpatient (acute care) China	Admitted to any ward of one of two acute care hospitals within 24 hours of study entry, no pressure ulcers	Symptomatic: excluded History of PU: unclear Specific findings: no pressure ulcers on admission	NR/ NR/ 429/ 429	Mean age 54 years (SD 17; range 5-93) 41% female Race not reported	Mean not reported	11 days (range 5-21 days)
Pang, 1998 ¹⁰	Prospective cohort	Braden Norton Waterlow	Hospital inpatient Hong Kong	Age ≥21 years, newly admitted to medical or orthopedic unit, no history of psychiatric illness; no pressure sore; expected stay at least 14 days	Symptomatic: excluded History of PU: unclear Specific findings: no incidence of grade I-IV PU according to Torrance Developmental Classification of Pressure Sores	NR/ NR/ 138/ 106	Mean age not reported; range 45-92 years, 84% ≥years 51% female 100% Chinese	Mean not reported	11.7 days (range 2-17 days)

Author, year	Study Design	Screening Test/Scale	Setting Country	Inclusion Criteria	Study excluded: Symptomatic patients? Patients with history of PUs? Patients with specific findings	Number Screened/ Eligible/ Enrolled/ Analyzed	Baseline Demographics	Mean Risk Score at Baseline	Mean Followup
Perneger, 2002 ¹¹	Prospective cohort	Fragmment Scale (score 0-9: friction, age, mobility, mental status; lower score=lower risk) Braden Norton	Hospital inpatient Switzerland	Admitted between March and June 1997	Symptomatic: included History of PU: unclear Specific findings: 2% had pressure ulcers on admission but those patients were excluded from analysis	NR/ NR/ 1,190/ 1,190	Mean age 61 years (range 16-96 years)	Fragmment 2.0 (SD 2.1) Braden, Norton mean not reported	9 days (based on 10,415 total patient-days)
Salvadalena, 1992 ¹²	Prospective cohort	Braden Clinical judgment	Hospital inpatient (acute care) United States	Admission <48 hours prior to study enrollment, expected duration of stay at least 2-3 days after initial data collection, no existing pressure ulcers	Symptomatic: excluded History of PU: unclear Specific findings: no pressure ulcers on admission	NR/ NR/ 99/ 99	Mean age 72 years 64% female 80% white 7% non-white 13% no data	Mean 18.1 (SD 3.3)	Mean not reported; mean duration of stay 5.2 days
Schoonhoven, 2002 ¹³	Prospective cohort	Braden Norton Waterlow	Hospital inpatient The Netherlands	Age ≥18 years admitted to the surgical, internal, neurological or geriatric wards of 2 hospitals in the Netherlands; expected stay at least 5 days; no PU on admission	Symptomatic: excluded History of PUs: unclear Specific findings: unclear	6,000/ 1,536/ 1,431/ 1,229	Mean age 60 years 55% women Race not reported 62% surgical 22% internal medicine 10% neurology 6% geriatric 5% used preventive measures	Braden: 19.6 Norton:16.8 Waterlow: 13.0	4 weeks

Author, year	Study Design	Screening Test/Scale	Setting Country	Inclusion Criteria	Study excluded: Symptomatic patients with history of PUs? Patients with specific findings	Number Screened/ Eligible/ Enrolled/ Analyzed	Baseline Demographics	Mean Risk Score at Baseline	Mean Followup
Seongsook, 2004 ¹⁴	Prospective cohort	Braden Cubbin and Jackson Douglas	Hospital inpatient; surgical, internal or neurological ICU South Korea	Age ≥21 years; admitted to ICU	Symptomatic: unclear History of PUs: unclear Specific findings: unclear	NR/ 125/ 112/ 112	Mean age 62 years 43% female Race not reported	Mean not reported	Unclear; duration 2 months
van Marum, 2000 ¹⁵	Mixed (Norton data prospective, CBO data retrospective)	Norton Dutch CBO	Nursing home The Netherlands	Age >64 years; newly-admitted; not admitted for psychogeriatric care; examined for pressure sores within 48 hours of admission	Symptomatic: excluded History of PUs: unclear Specific findings: unclear	NR/ NR/ 319/ 267	Mean age 79 years Race not reported 64% female (based on 220/267 patients with CBO data)	Mean not reported	Mean not reported; total duration 4 weeks
VandenBosch, 1996 ¹⁶	Prospective cohort	Braden Clinical judgment	Hospital inpatient (general care, ICU, inpatient rehab) United States	Age ≥18 years, randomly selected with expected hospital stay at least 1 week	Symptomatic: excluded History of PU: unclear Specific findings: no pressure ulcers on admission	NR/ NR/ 103/ 103	Mean age 64 years 52% female 86% white 12% black 2% other	18; among patients who developed PU mean score 16.6, patient with no PU mean score 18.2	Up to 2 weeks or until discharge
Wai-Han, 1997 ¹⁷	Prospective cohort	Norton Waterlow	Geriatric care facility Hong Kong	Age >70 years, hospital stay at least 24 hours	Symptomatic: excluded History of PU: unclear Specific findings: no pressure ulcers on admission	NR/ NR/ 185/ 185	Mean age 80 years 56% female Race not reported	Not reported	Mean not reported; study duration 4 weeks

Author, year	Study Design	Screening Test/Scale	Setting Country	Inclusion Criteria	Study excluded: Symptomatic patients? Patients with history of PUs? Patients with specific findings	Number Screened/ Eligible/ Enrolled/ Analyzed	Baseline Demographics	Mean Risk Score at Baseline	Mean Followup
Braden scale									
Baldwin, 1998 ¹⁸	Prospective cohort	Braden	Hospital inpatient (trauma center) United States	Age 15-60 years, previously healthy, hospitalized as a result of severe trauma but not requiring burn fluid resuscitation, expected hospitalization of at least 1 week	Symptomatic: unclear History of PU: unclear Specific findings: unclear	NR/ NR/ 36/ 36	Mean age 32 years 28% female 42% white 39% Latino 11% black 8% Asian	Mean not reported	27 days (range 8-65 days)
Barnes, 1993 ¹⁹	Prospective cohort	Braden	Hospital inpatient United States	Age ≥50 years, no pressure sores, not receiving chemotherapy or radiotherapy	Symptomatic: excluded History of PU: unclear Specific findings: no pressure ulcers on admission	NR/ NR/ 361/ 361	Mean age not reported (range 50 to 90 years) 49% female Race not reported	Not reported	Up to 15 days
Bergstrom, 1987a ²⁰	Prospective cohort	Braden	Hospital inpatient United States	Admitted to one of two hospital nursing units with on pressure ulcer	Symptomatic: excluded History of PU: unclear Specific findings: no pressure ulcers on admission	NR/ NR/ 200/ 199 (reported in 2 studies)	Study 1 - Mean age 57 years 49% female 74% white 26% other Study 2 - Mean age 50 years 49% female 77% white 23% other	Study 1: 20 Study 2: 17	Mean not reported; total follow-up Study 1: 6 weeks, Study 2: 12 weeks

Author, year	Study Design	Screening Test/Scale	Setting Country	Inclusion Criteria	Study excluded: Symptomatic patients? Patients with history of PUs? Patients with specific findings	Number Screened/ Eligible/ Enrolled/ Analyzed	Baseline Demographics	Mean Risk Score at Baseline	Mean Followup
Bergstrom, 1987b ²¹	Prospective cohort	Braden	Hospital inpatient; adult ICU United States	Consecutively admitted to ICU with no pressure sore on admission	Symptomatic: excluded History of PU: unclear Specific findings: no pressure ulcers on admission	NR/ NR/ 60/ 60	Mean age 59 years 53% female 88% white 10% black 2% other	Mean 16; among patients who developed PU mean score 13.8, patients without PU mean score 16.9	2 weeks
Bergstrom, 1992 ²²	Prospective cohort	Braden	Skilled nursing facility United States	Age >65 years, Braden score <17, no pressure ulcers, expected duration of stay >10 days	Symptomatic: excluded History of PU: unclear Specific findings: no pressure ulcers on admission	1,913/ 681/ 200/ 200	Mean age 80 years 70% female 95% white 5% other	Total cohort: 19 Patients with PU: 14 Patients without PU: 16	Mean not reported; followup was up to 12 weeks; 49% had follow up of 4 weeks; 15% of original cohort followed to study's end
Bergstrom, 1998 ²³ Other publications: Bergstrom, 2002 ²⁴	Prospective cohort	Braden	Tertiary care, VA medical centers, skilled nursing facilities (SNF) USA	Age >19 years, free of existing pressure ulcers, admitted within the previous 72 hours; participants randomly selected	Symptomatic: excluded History of PU: unclear Specific findings: no pressure ulcers on admission	NR/ NR/ NR/ 843	Mean age 62 years (range 19-102 years) 37% female 21% non-white	Mean not reported	1 to 4 weeks

Author, year	Study Design	Screening Test/Scale	Setting Country	Inclusion Criteria	Study excluded: Symptomatic patients with history of PUs? Patients with specific findings	Number Screened/ Eligible/ Enrolled/ Analyzed	Baseline Demographics	Mean Risk Score at Baseline	Mean Followup
Bergstrom, 2002 ²⁴ Other publications: Bergstrom, 1998 ²³	Prospective cohort, subgroup analysis	Braden	Tertiary care, VA medical centers, skilled nursing facilities (SNF) USA	Age >19 years, free of existing pressure ulcers, admitted within the previous 72 hours; participants randomly selected	Symptomatic: excluded History of PU: unclear Specific findings: no pressure ulcers on admission	NR/ 843/ 825/ 821	Mean age 62 years (range 19-102 years) 37% female 21% non-white	Total cohort: 19 Patients with PU: 16 Patients without PU: 20	1 to 4 weeks
Braden, 1994 ²⁵	Prospective cohort	Braden	Hospital, skilled nursing facility (extended care) United States	Age ≥19 years, no pressure ulcers, admitted within previous 72 hours	Symptomatic: excluded History of PU: unclear Specific findings: no pressure ulcers on admission	453/ 177/ 123/ 102	Mean age 75 years 72% female Race not reported	Mean score - Patients with PU: 16 Patients without PU 20	4 weeks
Capobianco 1996 ²⁶	Prospective cohort	Braden	Hospital inpatient United States	Medical or surgical inpatients with no preexisting skin ulcerations	Symptomatic: excluded History of PU: unclear Specific findings: no pressure ulcers on admission	NR/ NR/ 50/ 50	Mean age 66 years (SD 19; range 20-95) 64% female 86% white 10% black 4% Hispanic Mean duration of stay 8 days (SD 3; range 3 to 14)	Not reported; among patients who developed PU mean score 16 (SD 8; range 9 to 23)	Not reported for entire cohort; among patients who developed PUs: mean 9 days (SD 5; range 3 to 14)

Author, year	Study Design	Screening Test/Scale	Setting Country	Inclusion Criteria	Study excluded: Symptomatic patients? Patients with history of PUs? Patients with specific findings	Number Screened/ Eligible/ Enrolled/ Analyzed	Baseline Demographics	Mean Risk Score at Baseline	Mean Followup
Chan, 2005 ²⁷	Prospective cohort	Braden	Hospital inpatient Singapore	Age ≥18 years, newly admitted with no pressure ulcers	Symptomatic: excluded History of PU: unclear Specific findings: no pressure ulcers on admission	NR/ NR/ 666/ 666	Mean age 64 years (SD 18) 48% female 77% Chinese 10% Malaysian 9% Indian 4% other	Mean 18.3 (SD 3.8) Low-risk (Braden 16-23): 75% Moderate risk (Braden 12-15): 17% High-risk (Braden 6-11): 8%	Mean duration of hospital stay 13 days; maximum 28 days
Chan, 2009 ²⁸	Prospective cohort	Braden Modified Braden	Hospital inpatient (orthopedic unit) Hong Kong	Age ≥18 years, Chinese, expected stay of at least 5 days, not ambulant, no pressure ulcer	Symptomatic: excluded History of PU: unclear Specific findings: no pressure ulcers on admission	NR/ NR/ 197/ 197	Mean age 79 years 85% female 100% Chinese	Mean not reported	Mean not reported; mean duration of hospitalization 11 days (range 5-53 days)
Goodridge 1998 ²⁹	Prospective cohort	Braden	Hospital and long-term facility inpatients Canada	Age ≥65 years, newly admitted with no dermal ulcers.	Symptomatic: excluded History of PU: unclear Specific findings: no pressure ulcers on admission	NR/ NR/ 330/ 330	Mean age 79 years (SD 9) Gender not reported Race not reported	Mean 18 (SD 3; range 6-24)	2 months
Hagisawa, 1999 ³⁰		Braden	Hospital inpatient Japan	Admitted to internal medical ward; short-stay patients excluded	Symptomatic: included History of PU: unclear Specific findings: >1% had pressure sores at baseline	NR/ NR/ 275/ 275	Not reported	Not reported; 87% Braden >17 at baseline	Not reported; study duration 1 year

Author, year	Study Design	Screening Test/Scale	Setting Country	Inclusion Criteria	Study excluded: Symptomatic patients? Patients with history of PUs? Patients with specific findings	Number Screened/ Eligible/ Enrolled/ Analyzed	Baseline Demographics	Mean Risk Score at Baseline	Mean Followup
Halfens, 2000 ³¹	Prospective cohort	Braden Extended Braden	Hospital inpatient The Netherlands	No pressure sore on admission, Caucasian, probably stay of at least 10 days	Symptomatic: excluded History of PU: unclear Specific findings: no pressure ulcers on admission	NR/ NR/ 320/ 320	Mean age 61 years 48% female 100% white	Not reported	Not reported; 10-day or more anticipated stay inclusion criteria
Langemo, 1991 ³²	Prospective cohort	Braden	Mixed inpatient and outpatient settings: acute care, skilled care, rehabilitation facility, home care and hospice United States	Age ≥18 years, medical or surgical patients, enrollment within 24-72 hours of admission, no pressure ulcers	Symptomatic: excluded History of PU: unclear Specific findings: no pressure ulcers on admission	NR/ NR/ 190/ 190 (Acute care n=74; skilled care n=25; rehabilitation n=40; home care n=30; hospice n=20)	Mean age 66 years (range 21-99) 56% female 96% white 4% Native American	Mean 18 (SD 3)	Means not reported; duration varied according to setting - Acute care: At least 5 days, maximum 2 weeks Skilled care, rehabilitation, home care, hospice: up to four weeks or until discharge
Lewicki, 2000 ³³	Prospective cohort	Braden	Acute care hospital (undergoing cardiac surgery) USA	Age ≥21 years undergoing cardiac surgery between February and March 1995 and no pressure ulcer on enrollment	Symptomatic: excluded History of PU: unclear Specific findings: no pressure ulcers on admission	NR/ NR/ NR/ 337	Mean age 62 years 25% female Race not reported	Not reported	5 days

Author, year	Study Design	Screening Test/Scale	Setting Country	Inclusion Criteria	Study excluded: Symptomatic patients with history of PUs? Patients with specific findings	Number Screened/ Eligible/ Enrolled/ Analyzed	Baseline Demographics	Mean Risk Score at Baseline	Mean Followup
Lyder, 1998 ³⁴	Prospective cohort	Braden	Hospital inpatient (general medical and surgical units) United States	Age ≥60 years, consecutively admitted, black or Latino/Hispanic, expected duration of stay ≥5 days, no pressure ulcer	Symptomatic: excluded History of PUs: included (3/36) Specific findings: no pressure ulcer on admission	43/ 43/ 43/ 36	Mean age 71 years (SD 7) 58% female 72% black 28% Latino/Hispanic	Not reported	Mean not reported
Lyder, 1999 ³⁵	Prospective cohort	Braden	Hospital inpatient United States	Age ≥60 years, consecutively admitted, black or Latino/Hispanic, expected duration of stay ≥5 days, no pressure ulcer	Symptomatic: excluded History of PUs: unclear Specific findings: no pressure ulcer on admission	NR/ 84/ 74/ 74	Mean age 72 years (range 60-99) 66% female 70% black 30% Hispanic/Latino	Not reported	Not reported
Olson, 1998 ³⁶	Prospective cohort	Braden	Hospital inpatient (oncology) Canada	All adult patients admitted to oncology nursing unit between January and May 1993; subsequent study enrolled patients between October 1994 and June 1995	Symptomatic: excluded History of PU: unclear Specific findings: no pressure ulcers on admission	Study 1 (1993 results) - 186/ 142/ 128/ 128 Study 2 (1996 results) - 508/ 488/ 488/ 418	Study 1 - Mean age 55 years Gender not reported Race not reported Study 2 - Mean age 56 years Gender not reported Race not reported	Not reported	Not reported

Author, year	Study Design	Screening Test/Scale	Setting Country	Inclusion Criteria	Study excluded: Symptomatic patients? Patients with history of PUs? Patients with specific findings	Number Screened/ Eligible/ Enrolled/ Analyzed	Baseline Demographics	Mean Risk Score at Baseline	Mean Followup
Ramundo, 1995 ³⁷	Prospective cohort	Braden	Home care United States	Unable to leave bed or chair	Symptomatic: unclear History of PU: unclear Specific findings: free of "skin breakdown"	NR/ NR/ 48/ 48	Not reported	Total cohort: 18 Patients with a PU: 17 Patients without PU: 18	Mean not reported; followup up to 4 weeks or until discharge or development of pressure ulcer
Serpa, 2011 ³⁸	Prospective cohort (post-hoc analysis of data from another prospective study)	Braden	Hospital ICU Brazil	Age ≥18 years, no pressure ulcer on first assessment, hospitalized for at least 24 hours but no more than 48 hours, Braden score ≤18	Symptomatic: excluded History of PU: unclear Specific findings: no pressure ulcers on admission	82/ 72/ 72/ 72	Mean age 61 years (SD 17) 36% female Race not reported	Mean not reported; 31% characterized as low-risk, 40% as moderate risk, 29% as high-risk at baseline	Unclear; mean duration of hospitalization 17 days (range 6 to >31 days) but only data from 3 consecutive assessment included in analysis
Tourtual, 1997 ³⁹	Prospective cohort (results of 2 studies reported; see comments)	Braden	Hospital inpatient United States	Admitted to one of four hospital nursing units	Symptomatic: included (4% prevalence at baseline) History of PUs: unclear Specific findings: unclear	Study 2: 609/ NR/ 291/ 291	Mean age 68 years 58% female Race not reported	Mean 17.6; among patients who developed PU mean score 16.2, patients without PU mean score 18.4	Unclear; mean duration of hospitalization for entire cohort 10 days; 17 days for patients who developed a PU vs. 8 days for patients who did not develop a PU

Author, year	Study Design	Screening Test/Scale	Setting Country	Inclusion Criteria	Study excluded: Symptomatic patients? Patients with history of PUs? Patients with specific findings	Number Screened/ Eligible/ Enrolled/ Analyzed	Baseline Demographics	Mean Risk Score at Baseline	Mean Followup
Norton scale									
Bale, 1995 ¹	Prospective cohort	Modified Norton (Norton scale customized for this study, higher score represented higher pressure ulcer risk)	Hospice England	Entered hospice care between December 1992 and December 1993 (Phase 2)	Symptomatic: excluded History of PU: unclear Specific findings: analysis limited to patients with no pressure ulcers on admission	NR/ NR/ 79/ 79* <i>*Subgroup of patients with no pressure ulcer on admission to Phase 2</i>	Mean age 67 years 45% female Race not reported	Mean not reported; 30% ≤10 32% 11-15 29% ≥16	Not reported
Lincoln, 1986 ⁴⁰	Prospective cohort	Norton	Hospital inpatient (medical or surgical) United States	Age >65 years, no pressure sores on admission	Symptomatic: excluded History of PU: unclear Specific findings: no pressure ulcers on admission	NR/ NR/ 50/ 36	Mean age 72 years (range 65-89) 54% female Race not reported	Mean not reported; 34/36 (94%) score ≥15	Mean not reported; mean duration of stay 8 days (range 2-26 days)
Stotts, 1988 ⁴¹	Prospective cohort	Modified Norton (same items as the standard Norton scale, with clarification regarding specific operational definitions)	Hospital inpatient (surgical) United States	Age >18 years, electively admitted to cardiovascular of neurosurgery surgical service	Symptomatic: unclear History of PU: unclear Specific findings: unclear	NR/ NR/ 387/ 387	Mean age 53 years (range 17-86 years) 47% female Race not reported	Mean 19 (SD 2.5)	Mean not reported; followup up to 3 weeks

Author, year	Study Design	Screening Test/Scale	Setting Country	Inclusion Criteria	Study excluded: Symptomatic patients? Patients with history of PUs? Patients with specific findings	Number Screened/ Eligible/ Enrolled/ Analyzed	Baseline Demographics	Mean Risk Score at Baseline	Mean Followup
Waterlow scale									
Compton, 2008 ⁴²	Prospective cohort	Waterlow	Hospital inpatient (ICU) Germany	Admitted to medical ICU between April 2001 and December 2004 with no pressure ulcer with ICU stay >72 hours	Symptomatic: excluded History of PU: unclear Specific findings: no pressure ulcers on admission	NR/ 713/ 698/ 698	Median age 66 years 44% female Race not reported	Not reported	Mean not reported; median length of ICU stay 6 days
Edwards, 1995 ⁴³	Prospective cohort	Waterlow	Home care England	Patients being visited by community health nurses in a South London district health authority, no pressure sores	Symptomatic: excluded History of PU: unclear Specific findings: no pressure ulcers on admission	80/ NR/ 31/ 31	Mean age 83 years (SD 6; range 71-96) 65% female 97% white 3% Asian	Mean 17	Unclear
Serpa, 2009 ⁴⁴	Prospective cohort	Waterlow	Hospital inpatient (ICU) Brazil	Age ≥18 years, admitted from January to July 2006 within 24-48 hours, no pressure ulcer, Braden score ≤18, Waterlow score ≥16, at least 3 consecutive measures	Symptomatic: excluded History of PU: unclear Specific findings: no pressure ulcers on admission	187/ 113/ 98/ 98	Mean age 71 years (SD 16) Proportion female not reported; text states gender distribution was even Race not reported 40% hypertensive 25% diabetic	Not reported; study protocol required Waterlow score ≥16 at time of study entry	Not reported; patients assessed every 48 hours until development of a pressure ulcer, discharge or transfer or death
Webster, 2010 ⁴⁵	Prospective cohort	Waterlow	Hospital inpatient Australia	Admitted to any internal medicine ward	Symptomatic: included (6%) History of PU: included Specific findings: unclear	NR/ NR/ 274/ 200	Mean age 65 years (SD 18) 50% female Race not reported	Not reported	Not reported

Author, year	Study Design	Screening Test/Scale	Setting Country	Inclusion Criteria	Study excluded: Symptomatic patients with history of PUs? Patients with specific findings	Number Screened/ Eligible/ Enrolled/ Analyzed	Baseline Demographics	Mean Risk Score at Baseline	Mean Followup
Westrate, 1998 ⁴⁶	Prospective cohort	Waterlow	Hospital inpatient (ICU) The Netherlands	Admitted to surgical ICU in 1994, with stay at least 24 hours and no pressure sores or use of preventive measure (mattress)	Symptomatic: excluded History of PU: unclear Specific findings: no pressure ulcers on admission	686/ 594/ 594/ 594	Mean age 59 years (range 9 to 96) 35% female Race not reported	Mean 17	Mean not reported; mean length of stay in ICU 6 days
Other scales									
Andersen, 1982 ⁴⁷	Prospective cohort	Risk assessment based on age ≥ 70 years, reduced mobility, incontinence, pronounced emaciation, redness over bony prominence	Hospital inpatient (acute care) Denmark	Admitted to acute care ward between January 17 and August 18, 1977, no pressure ulcers on admission	Symptomatic: excluded History of PU: unclear Specific findings: no pressure ulcers on admission	3,571/ 3,516/ 3,398/ 3,398	Not reported	Mean not reported; 14% had a risk score ≥ 2 , indicating increased PU risk	10 days in-hospital observation; 3-months total observation
Hatanaka, 2008 ⁴⁸	Prospective cohort	Novel indicator consisting of hemoglobin, CRP, albumin, age, gender	Hospital inpatient Japan	Bedridden patients hospitalized for a respiratory disorder with no pressure ulcer	Symptomatic: excluded History of PU: unclear Specific findings: no pressure ulcers on admission	NR/ NR/ 149/ 149	Mean age 72 years (SD 11) 30% female Race not reported	Mean Braden 15	Mean 33 days (range 5-79 days)

Author, year	Study Design	Screening Test/Scale	Setting Country	Inclusion Criteria	Study excluded: Symptomatic patients with history of PUs? Patients with specific findings	Number Screened/ Eligible/ Enrolled/ Analyzed	Baseline Demographics	Mean Risk Score at Baseline	Mean Followup
Lindgren, 2002 ⁴⁹	Prospective cohort	Risk Assessment Pressure Sore Scale (RAPS)	Hospital inpatient Sweden	Age ≥17 years; newly admitted to medical, surgical, infection, orthopedic, rehabilitation or geriatric ward; expected hospital stay of at least 5 days; for surgical patients, expected duration of surgery at least 1 hour	Symptomatic: excluded History of PU: unclear Specific findings: no pressure ulcers on admission	NR/ 588/ 530/ 488	Mean age 70 years (SD 14 years) 50% female Race not reported	Mean not reported	Mean not reported; maximum followup 12 weeks; 50% of patients had ≤8 days followup
Page, 2010 ⁵⁰	Prospective cohort	Northern Hospital Pressure Ulcer Prevention Plan (TNH-PUPP)	Hospital general ward, critical care or emergency department Australia	Acute care patients	Symptomatic: unclear History of PU: unclear Specific findings: unclear	NR/ NR/ 165/ 165	Mean age 68 years (SD 18) 47% female Race not reported	Mean not reported	Mean not reported; mean length of hospital stay 15 days

Author, year	Study Design	Screening Test/Scale	Setting Country	Inclusion Criteria	Study excluded: Symptomatic patients with history of PUs? Patients with specific findings	Number Screened/ Eligible/ Enrolled/ Analyzed	Baseline Demographics	Mean Risk Score at Baseline	Mean Followup
Towey, 1988 ⁵¹	Prospective cohort	Knoll Decubitus Ulcer Potential Scale (incorporates general health, mental health, activity, mobility, incontinence, oral nutrition intake, oral fluid intake, predisposing diseases)	Long-term care facility United States	Age >65 years admitted to long-term care facility, no pressure ulcer on admission	Symptomatic: excluded History of PU: unclear Specific findings: no pressure ulcers on admission	NR/ NR/ 60/ 60	Mean age 81 years (range 65-97 years) 80% female 72% white 15% black 2% Asian 11% unknown	Mean 14 (range 3 to 23)	28 days

Author, year	Outcome Assessment Method	Risk Factor Adjustment	Interventions to Prevent Pressure Ulcers (n if reported)	Prevalence of Pressure Ulcers	Timing of risk Assessment	Type of Analysis	Analyzed by
Multiple scales							
Boyle, 2001 ⁴	Stirling Pressure Sore Severity Scale - Stage 0: no evidence of pressure sore Stage 1: Discoloration of intact skin Stage 2: Partial-thickness skin loss or damage involving epidermis or dermis Stage 3: Full thickness skin loss extending to subcutaneous tissue Stage 4: Full thickness skin loss extending to bone, tendon or joint	None; no adjusted analyses conducted	Routine preventive care given, including turning every 2-4 hours and mattress overlay or special mattress	5% (28/534)	Unclear	None	Cubbin and Jackson ≤ 29 Waterlow ≥ 10
DeFloor, 2005 ⁵	EPUAP - Grade 1: non-blanchable erythema Grade 2: partial-thickness skin loss or damage involving epidermis and/or dermis Grade 3: full-thickness skin loss with necrosis of epidermis or dermis Grade 4: full-thickness skin loss involving damage or necrosis of epidermis and/or dermis extending to the underlying bone, tendon or capsule	None; no adjusted analyses conducted incorporating risk scores	18% (314/1,772) turning every 2-4 hours + pressure reducing mattress; other patients (n=1,458) received water mattresses (11%; 188/1,772), small cell alternating mattresses (4%; 63/1,1772), sheepskins (8% 139/1,772), gel cushions (2%; 40/1,772) or no preventive interventions (58%; 1,028/1,772) as deemed clinically appropriate	Nonblanchable erythema: 20% (363/1,772) Grade 2 or higher pressure ulcer: 11% (187/1,772)	Unclear	None	Braden <17, <18 Norton <12, <14 Clinical judgment risk vs. no-risk

Author, year	Outcome Assessment Method	Risk Factor Adjustment	Interventions to Prevent Pressure Ulcers (n if reported)	Prevalence of Pressure Ulcers	Timing of risk Assessment	Type of Analysis	Analyzed by
Feuchtinger, 2007 ⁶	EPUAP - Grade 1: non-blanchable erythema Grade 2: partial-thickness skin loss or damage involving epidermis and/or dermis Grade 3: full-thickness skin loss with necrosis of epidermis or dermis Grade 4: full-thickness skin loss involving damage or necrosis of epidermis and/or dermis extending to the underlying bone, tendon or capsule	None; no adjusted analyses conducted	Unclear	49% (26/53)	Preop, postop and once each of the four following days	None	Braden ≤16; ≤20 Modified Norton ≤21; ≤23; ≤25 4-factor model ≥2
Jalali, 2005 ⁷	Stage 1: nonblanchable erythema of intact skin Stage 2: partial-thickness skin loss Stage 3: full-thickness skin loss Stage 4: full-thickness skin loss with tissue necrosis, bone damage, etc.	None; no adjusted analyses conducted	Preventive measures (not described)	32% (74/230)	Once a day for up to 14 days	None	Cutoffs unclear
Kim, 2009 ⁸	AHRQ 4-stage criteria	None; no adjusted analyses conducted	"Ordinary" nursing interventions	18% (40/219)	Once daily until discharge from surgical ICU	None	Braden ≤14 Cubbin and Jackson ≤28 Song/Choi ≤21

Author, year	Outcome Assessment Method	Risk Factor Adjustment	Interventions to Prevent Pressure Ulcers (n if reported)	Prevalence of Pressure Ulcers	Timing of risk Assessment	Type of Analysis	Analyzed by
Kwong, 2005 ⁹	NPUAP staging- Stage 0: no redness or breakdown Stage I: non-blanching erythema Stage II: partial thickness skin loss involving epidermis or derma Stage III: full thickness skin loss involving damage or necrosis of subcutaneous tissue Stage IV: full thickness skin loss extending to muscle or bone	None; no adjusted analyses conducted	Turning 39% (168/429); pressure reducing item, e.g. cushion, air ring, etc. 35% (152/429); clean/dry bedding 34% (148/429); clean/dry skin 48% (205/429); positioning 40% (170/429); use of draw sheet for lifting 21% (91/429); massage 23% (97/429)	2% (9/429)	On admission, then daily until development of a pressure ulcer, transfer/discharge, or 21 days of followup	None	Braden ≤14 Modified Braden ≤16 Norton ≤14
Pang, 1998 ¹⁰	Torrance Developmental Classification of Pressure Sores: Grade I: discoloration of skin with persistent erythema Grade II: loss of skin layer involving epidermis and penetrating into dermis Grade III; IV: NR; participant removed from study once identified	None; no adjusted analyses conducted	Turning, positioning, use of pillows, bed cradles, sheepskin pads, clean sheets, footboard, water mattress, air mattress and/or Stryker frame, massage; rates not reported	20% (21/106)	Once daily for up to 14 days	None	Braden ≤18 Norton ≤16 Waterlow ≥16
Perneger, 2002 ¹¹	NPUAP staging- Stage 0: no redness or breakdown Stage I: non-blanching erythema Stage II: partial thickness skin loss involving epidermis or dermis Stage III: full thickness skin loss involving damage or necrosis of subcutaneous tissue Stage IV: full thickness skin loss extending to muscle or bone	Adjustment for individual risk factors but not for total risk score (except for Fragmment scale)	24% (288/1,190) received special pillow, mattress or bed or regular change in position	15% (182/1,190)	On admission, then twice a week for up to 3 weeks	Univariate and multivariate logistic regression for individual risk factors	Fragmment >3 Not reported for Braden, Norton

Author, year	Outcome Assessment Method	Risk Factor Adjustment	Interventions to Prevent Pressure Ulcers (n if reported)	Prevalence of Pressure Ulcers	Timing of risk Assessment	Type of Analysis	Analyzed by
Salvadalena, 1992 ¹²	Braden and Bergstrom criteria	None; no adjusted analyses conducted	Preventive measures given but not described	20% (20/99)	On admission, then every Monday, Wednesday and Friday until discharge	None	Braden cutoff ≤15, ≤18 Clinical judgment:
Schoonhoven, 2002 ¹³	Nurse assessed using individual risk factors from all three scales	None; no adjusted analyses conducted	Preventive measures (not described) used; text states that use of preventive measures did not affect risk score or subsequent development of pressure ulcers	Total cohort: 11% (135/1229)	Within 48 hours of admission, then weekly for up to 12 weeks	None	Braden <18 Norton <16 Waterlow >9
Seongsook, 2004 ¹⁴	NPUAP staging- Stage 0: no redness or breakdown Stage I: non-blanching erythema Stage II: partial thickness skin loss involving epidermis or dermis Stage III: full thickness skin loss involving damage or necrosis of subcutaneous tissue Stage IV: full thickness skin loss extending to muscle or bone	None; no adjusted analyses conducted	Water mattresses; massage; position change every 2 hours	31% (35/112)	Within 24-72 hours of admission, followed by afternoon observations on Monday, Wednesday and Friday of each week	None	Braden ≤16 Cubbin and Jackson ≤24 Douglas ≤18
van Marum, 2000 ¹⁵	NPUAP staging- Stage 0: no redness or breakdown Stage I: non-blanching erythema Stage II: partial thickness skin loss involving epidermis or dermis Stage III: full thickness skin loss involving damage or necrosis of subcutaneous tissue Stage IV: full thickness skin loss extending to muscle or bone	None; no adjusted analyses conducted	Preventive measures given but not described	20% (54/267)	Within 48 hours of admission, then weekly (some patients assessed more frequently, but details not provided)	None	Norton ≤16 Dutch CBO ≤10

Author, year	Outcome Assessment Method	Risk Factor Adjustment	Interventions to Prevent Pressure Ulcers (n if reported)	Prevalence of Pressure Ulcers	Timing of risk Assessment	Type of Analysis	Analyzed by
VandenBosch, 1996 ⁵²	Stage I: nonblanchable erythema that does not disappear for 24 hours after pressure relief Stage II: break in the skin, i.e. blisters or abrasions Stage III: break in skin exposing subcutaneous tissue Stage IV: break in the skin extending through tissue exposing muscle or bone	None; no adjusted analyses conducted	Preventive measures given but not described	28% (29/103)	On admission, then every Monday, Wednesday and Friday until time of discharge; maximum number of observations=6	None	Braden ≤17 Clinical judgment risk vs. no risk
Wai-Han, 1997 ¹⁷	Not described	None; no adjusted analyses conducted	Preventive measures given but not described	4% (8/185)	On admission, then weekly until discharge or death	None	Norton ≤14 Waterlow ≥10
Braden scale							
Baldwin, 1998 ¹⁸	NPUAP staging- Stage 0: no redness or breakdown Stage I: non-blanching erythema Stage II: partial thickness skin loss involving epidermis or dermis Stage III: full thickness skin loss involving damage or necrosis of subcutaneous tissue Stage IV: full thickness skin loss extending to muscle or bone	No adjusted analyses incorporating Braden score	All patients received pressure reducing mattresses; 58% (21/36) also received additional pressure relieving or reducing support (not described)	31% (11/36)	Within 24 hours of admission, then biweekly until discharge	None	Braden ≤10, ≤15
Barnes, 1993 ¹⁹	Grade I: erythema that does not resolve within 30 minutes of pressure relief while epidermis remains intact (presence of Grade I pressure ulcer resulted in discharge from study)	None; no adjusted analyses conducted	Not reported	6% (22/361)	Daily, until time of discharge, development of Grade I pressure ulcer or 15 days	None	Braden ≤16

Author, year	Outcome Assessment Method	Risk Factor Adjustment	Interventions to Prevent Pressure Ulcers (n if reported)	Prevalence of Pressure Ulcers	Timing of risk Assessment	Type of Analysis	Analyzed by
Bergstrom, 1987a ²⁰	Stage I: erythema only Stage II: break in skin, e.g. blisters, abrasions Stage III: break in skin exposing subcutaneous tissue Stage IV: break in skin extending through tissue and subcutaneous layers exposing muscle and bone	None; no adjusted analyses conducted	Standard care given but not described	Study 1: 7% (7/99) Study 2: 9% (9/100)	Within 72 hours of admission, then weekly until discharge from unit or death	None	Braden ≤16
Bergstrom, 1987b ²¹	Skin assessment tool, comprising scores from 0 (no redness or breakdown) to 4 (break in skin extending through subcutaneous layers and into muscle)	None; no adjusted analyses conducted	Egg crate mattress, turning, special bed, elbow protectors, heel protectors, other	40% (24/60)	Within 24-72 hours of study admission, then every 48 hours for 2 weeks	None	Braden ≤15, ≤18
Bergstrom, 1992 ²²	NPUAP staging- Stage 0: no redness or breakdown Stage I: non-blanching erythema Stage II: partial thickness skin loss involving epidermis or dermis Stage III: full thickness skin loss involving damage or necrosis of subcutaneous tissue Stage IV: full thickness skin loss extending to muscle or bone	Age, SBP, DBP, temperature, protein intake, caloric intake, serum albumin, BMI, Braden score	Egg crate foam 61% (121/200); turning every 2 hours 44% (88/200); heel, elbow and/or sacral pad 14% (28/200); foot cradle 4% (8/200); jelly pad 3% (6/200); other 3% (6/200)	74% (147/200)	On admission, weekly for the first 4 weeks, then bi-weekly for remainder of time on study	Logistic regression	Braden <14

Author, year	Outcome Assessment Method	Risk Factor Adjustment	Interventions to Prevent Pressure Ulcers (n if reported)	Prevalence of Pressure Ulcers	Timing of risk Assessment	Type of Analysis	Analyzed by
Bergstrom,, 1998 ²³ Other publications: Bergstrom, 2002 ²⁴	NPUAP staging- Stage 0: no redness or breakdown Stage I: non-blanching erythema Stage II: partial thickness skin loss involving epidermis or dermis Stage III: full thickness skin loss involving damage or necrosis of subcutaneous tissue Stage IV: full thickness skin loss extending to muscle or bone	None; no adjusted analyses conducted	Not reported	Any pressure ulcer: 13% (108/843) <u>By severity</u> Stage I: 4% (35/843) Stage II: 9% (73/842) <u>By setting</u> Tertiary care: 9% (26/306) VA: 7% (21/282) SNF: 24% (61/255)	On admission (time point A) and 48 to 72 hours after admission (time point B)	None	Braden ≤15, ≤18 Results stratified by time point, setting
Bergstrom, 2002 ²⁴ Other publications: Bergstrom, 1998 ²³	NPUAP staging- Stage 0: no redness or breakdown Stage I: non-blanching erythema Stage II: partial thickness skin loss involving epidermis or dermis Stage III: full thickness skin loss involving damage or necrosis of subcutaneous tissue Stage IV: full thickness skin loss extending to muscle or bone	Braden score, age, sex, DBP, SBP, temperature	Not reported	Total cohort: 13% (108/843) Blacks: 5% (8/159) Whites: 15% (98/662*) *data missing for 4 patients	Unclear, from time of admission to discharge	Logistic regression	Braden ≤15, ≤18 Results stratified according to race
Braden, 1994 ²⁵	Stage 1: nonblanchable erythema for 2 consecutive study days Stage 2: blisters, abrasions, etc. Stage 3: break in skin exposing subcutaneous tissue Stage 4: break in skin exposing or extending into muscle or bone	None; no adjusted analyses conducted	Not reported	28% (28/102)	Every 48-72 hours	None	Braden ≤15, ≤18 at last observation (either prior to PU development or end of follow up)

Author, year	Outcome Assessment Method	Risk Factor Adjustment	Interventions to Prevent Pressure Ulcers (n if reported)	Prevalence of Pressure Ulcers	Timing of risk Assessment	Type of Analysis	Analyzed by
Capobianco, 1996 ²⁶	Assessment by observer blinded to Braden score; PUs staged 1-4	None; no adjusted analyses conducted	Preventive measures given but not described	28% (14/50)	On admission, then every Monday, Wednesday and Friday until time of discharge (final assessment at time of discharge)	None	Braden ≤18
Chan, 2005 ²⁷	NPUAP staging- Stage 0: no redness or breakdown Stage I: non-blanching erythema Stage II: partial thickness skin loss involving epidermis or dermis Stage III: full thickness skin loss involving damage or necrosis of subcutaneous tissue Stage IV: full thickness skin loss extending to muscle or bone	Braden score, age, race, gender, length of hospital stay, medical diagnosis, risk factors	Not reported	12% (81/666)	On admission to study, then twice weekly until discharge or 28 days of followup	Logistic regression	Low, moderate or high risk according to Braden score
Chan, 2009 ²⁸	NPUAP staging- Stage 0: no redness or breakdown Stage I: non-blanching erythema Stage II: partial thickness skin loss involving epidermis or dermis Stage III: full thickness skin loss involving damage or necrosis of subcutaneous tissue Stage IV: full thickness skin loss extending to muscle or bone	None; no adjusted analyses conducted	Preventive measures given but not described	9% (18/197)	Daily	None	Braden ≤16 Modified Braden ≤19

Author, year	Outcome Assessment Method	Risk Factor Adjustment	Interventions to Prevent Pressure Ulcers (n if reported)	Prevalence of Pressure Ulcers	Timing of risk Assessment	Type of Analysis	Analyzed by
Goodridge, 1998 ²⁹	Unblinded assessment by research assistants not involved in patient care	Unclear; text states adjustment but doesn't report results	Turning, ambulation, exercise, positioning, padding, seating assessment, pressure reducing, relieving mattress, lotions, incontinence management, nutrition management; 3-11 interventions used depending on baseline Braden score	10% (32/330)	Bi-weekly	None	Braden ≤15, ≤18
Hagisawa, 1999 ³⁰	NPUAP staging- Stage 0: no redness or breakdown Stage I: non-blanching erythema Stage II: partial thickness skin loss involving epidermis or dermis Stage III: full thickness skin loss involving damage or necrosis of subcutaneous tissue Stage IV: full thickness skin loss extending to muscle or bone	None; no adjusted analyses conducted	Varied by protocol based on Braden score	5% (14/275; includes 2 patients with pressure ulcer on admission)	On admission, one week later, then varied according to Braden score (>23 assessed monthly; <23 assessed weekly)	None	Braden ≤16

Author, year	Outcome Assessment Method	Risk Factor Adjustment	Interventions to Prevent Pressure Ulcers (n if reported)	Prevalence of Pressure Ulcers	Timing of risk Assessment	Type of Analysis	Analyzed by
Halfens, 2000 ³¹	Pressure sore incidence - Stage 1: non-blanching erythema of intact skin Stage 2: partial-thickness skin loss or damage involving epidermis and/or blister and shallow ulcer Stage 3: full-thickness skin loss involving damage or necrosis of epidermis and/or dermis, not extending to underlying bone, tendon or joint capsule Stage 4: full-thickness skin loss involving damage or necrosis of epidermis and/or dermis extending to underlying bone, tendon or capsule	Urine incontinence, fecal incontinence, extreme sweating, diabetes, Quetlet index, physical health, mental health, smoker, pressure sore in past, age evaluated in univariate analysis Age, moisture included in logistic regression model	Anti-decubitus mattress, mobilization or position change: 55% (177/320)	All: 15% (47/320) Among patients using preventive treatments (high-risk): 21% (38/177)	On admission and every 5 days	Stepwise logistic regression	Braden ≤15, ≤18 Extended Braden ≤15, ≤18
Langemo, 1991 ³²	NPUAP staging- Stage 0: no redness or breakdown Stage I: non-blanching erythema Stage II: partial thickness skin loss involving epidermis or dermis Stage III: full thickness skin loss involving damage or necrosis of subcutaneous tissue Stage IV: full thickness skin loss extending to muscle or bone	None; no adjusted analyses conducted	Unclear; "normal" procedures followed according to each unit's policies	Total cohort: 9% (18/190) Acute care: 15% (11/74) Skilled care: 28% (7/25)	On admission, then varied according to setting - Acute care: 3 times per week Skilled care: weekly Rehabilitation: 2 times per week Home care: weekly Hospice: weekly	None	Braden ≤15 (acute care), ≤18 (skilled care)
Lewicki, 2000 ³³	Wound, Ostomy and Continence Nurses Society 4-stage criteria	None; no adjusted analyses conducted	Varied by protocol based on Braden score	5% (16/337)	Preoperatively, POD 1, POD 3, POD 5	None	Braden cutoff ≤15, ≤18 Results stratified by time point

Author, year	Outcome Assessment Method	Risk Factor Adjustment	Interventions to Prevent Pressure Ulcers (n if reported)	Prevalence of Pressure Ulcers	Timing of risk Assessment	Type of Analysis	Analyzed by
Lyder, 1998 ³⁴	Stage I: nonblanchable erythema for more than 24 hours Stage II: superficial break in skin, blisters or abrasions, epidermal or dermal layer exposed Stage III: break in skin exposing subcutaneous tissue Stage IV: break in skin exposing muscle or bone	None; no adjusted analyses conducted	Not reported	39% (14/36)	Within 48-72 hours of study admission, then Mondays, Wednesdays and Fridays until time of discharge	None	Braden ≤16
Lyder, 1999 ³⁵	NPUAP staging- Stage 0: no redness or breakdown Stage I: non-blanching erythema Stage II: partial thickness skin loss involving epidermis or dermis Stage III: full thickness skin loss involving damage or necrosis of subcutaneous tissue Stage IV: full thickness skin loss extending to muscle or bone	None; no adjusted analyses conducted	Not reported	32% (24/74)	Within 24-48 hours of study admission, then Mondays, Wednesdays and Fridays until time of discharge	None	Braden ≤16 (in patients age ≤74 years) ≤18 (in patients age ≥75 years)
Olson, 1998 ³⁶	NPUAP staging- Stage 0: no redness or breakdown Stage I: non-blanching erythema Stage II: partial thickness skin loss involving epidermis or dermis Stage III: full thickness skin loss involving damage or necrosis of subcutaneous tissue Stage IV: full thickness skin loss extending to muscle or bone	None; no adjusted analyses conducted	Preventive measures given to patients with Braden score ≤16, including sensory perception awareness, moisture, mobility/activity, nutrition, friction/shear	Study 1 - 9% (11/128) Study 2 - 10% (43/418)	Daily	None	Braden ≤15, ≤18
Ramundo, 1995 ³⁷	Braden criteria (see Bergstrom 1987)	None; no adjusted analyses conducted	Unclear	17% (7/48)	On admission, then weekly	None	Braden ≤15, ≤18

Author, year	Outcome Assessment Method	Risk Factor Adjustment	Interventions to Prevent Pressure Ulcers (n if reported)	Prevalence of Pressure Ulcers	Timing of risk Assessment	Type of Analysis	Analyzed by
Serpa, 2011 ³⁸	Method not described	None; no adjusted analyses conducted	Preventive measures given but not described	11% (8/72)	On admission and every 48 hours until development of PU, discharge from ICU or death; only patients with 3 consecutive assessments included in analysis	None	Braden ≤ 12 , ≤ 13 Results stratified according to 1st, 2nd or 3rd assessment
Tourtual, 1997 ³⁹	NPUAP staging- Stage 0: no redness or breakdown Stage I: non-blanching erythema Stage II: partial thickness skin loss involving epidermis or dermis Stage III: full thickness skin loss involving damage or necrosis of subcutaneous tissue Stage IV: full thickness skin loss extending to muscle or bone	Presence of pressure ulcer at baseline, incontinence, limb weakness, pulses, diagnosis of circulatory problem in lower extremity, diagnosis of CHF	Preventive measures given but not described	Study 2: 22% (63/291)	Daily	Logistic regression	Incidence of heel pressure ulcer only, Braden ≤ 12 , ≤ 16
Norton scale							
Bale, 1995 ¹	Torrance Developmental Classification of Pressure Sores: Stage 1: blanching erythema Stage 2: non-blanching erythema, superficial skin damage Stage 3: dermis ulceration Stage 4: ulceration extending to subcutaneous fat Stage 5: infective necrosis extending to muscle	None; no adjusted analyses conducted	All patients received preventive interventions, either mattress overlay (71%) or alternating pressure mattress (21%)	Phase 2: 3% (2/79)	Every other day until death or discharge	None	Modified Norton >10

Author, year	Outcome Assessment Method	Risk Factor Adjustment	Interventions to Prevent Pressure Ulcers (n if reported)	Prevalence of Pressure Ulcers	Timing of risk Assessment	Type of Analysis	Analyzed by
Lincoln, 1986 ⁴⁰	5-point scale - 0: no skin change 1: erythema 2: superficial skin opening 3: lesion extending into underlying tissue 4: involvement of muscle and bone	None; no adjusted analyses conducted	Preventive measures given but not described	14% (5/36)	On admission, then every 3 days until discharge	None	Norton ≤ 14
Stotts, 1988 ⁴¹	Grade I: redness of skin without vesicle formation Grade II: excoriation, vesiculation or skin break Grade III: tissue disruption that extends into muscle Grade IV: ulcer through skin, fat and muscle extending to bone	None; no adjusted analyses conducted	Not reported	17% (67/387)	On admission, then every 3 days for up to 3 weeks	None	Modified Norton ≤ 14
Waterlow scale							
Compton, 2008 ⁴²	EPUAP - Grade 1: non-blanchable erythema Grade 2: partial-thickness skin loss or damage involving epidermis and/or dermis Grade 3: full-thickness skin loss with necrosis of epidermis or dermis Grade 4: full-thickness skin loss involving damage or necrosis of epidermis and/or dermis extending to the underlying bone, tendon or capsule	No adjusted analyses incorporating Waterlow score (used as a comparator)	Not reported	17% (121/698)	Unclear	Logistic regression for individual risk factors	Unclear cutoff

Author, year	Outcome Assessment Method	Risk Factor Adjustment	Interventions to Prevent Pressure Ulcers (n if reported)	Prevalence of Pressure Ulcers	Timing of risk Assessment	Type of Analysis	Analyzed by
Edwards, 1995 ⁴³	Torrance Developmental Classification of Pressure Sores: Stage 1: blanching erythema Stage 2: non-blanching erythema, superficial skin damage Stage 3: Dermis ulceration Stage 4: Ulceration extending to subcutaneous fat Stage 5: Infective necrosis extending to muscle	None; no adjusted analyses conducted	Preventive measures in 10% (3/31) of patients	6% (2/31)	Unclear	None	Unclear cutoff
Serpa, 2009 ⁴⁴	Not described	None; no adjusted analyses conducted	Not reported	7% (7/98)	Every 48 hours	None	Waterlow ≥ 17 , ≥ 20
Webster, 2010 ⁴⁵	NPUAP staging- Stage 0: no redness or breakdown Stage I: non-blanching erythema Stage II: partial thickness skin loss involving epidermis or dermis Stage III: full thickness skin loss involving damage or necrosis of subcutaneous tissue Stage IV: full thickness skin loss extending to muscle or bone	None; no adjusted analyses conducted	Not reported	4% (12/274)	On admission, then every other day until development of pressure ulcer or discharge	None	Waterlow ≥ 15
Westrate, 1998 ⁴⁶	NPUAP staging- Stage 0: no redness or breakdown Stage I: non-blanching erythema Stage II: partial thickness skin loss involving epidermis or dermis Stage III: full thickness skin loss involving damage or necrosis of subcutaneous tissue Stage IV: full thickness skin loss extending to muscle or bone	None; no adjusted analyses conducted	Turning, nursing alternate sides of the bed at least 1 hour continuously, mobilizing patient from bed to standing or chair sitting	8% (47/594)	Daily	None	Waterlow ≥ 15

Author, year	Outcome Assessment Method	Risk Factor Adjustment	Interventions to Prevent Pressure Ulcers (n if reported)	Prevalence of Pressure Ulcers	Timing of risk Assessment	Type of Analysis	Analyzed by
Other scales							
Andersen, 1982 ⁴⁷	Unclear; presence of bullae, black necrosis or skin defects indicated presence of pressure ulcer	None; no adjusted analyses conducted	Preventive measures given but not described	1% (40/3,398)	Every other day for 10 days	None	Risk assessment score cutoff 2
Hatanaka, 2008 ⁴⁸	Pressure ulcers graded 1 (closed, persistent erythema) to 5	Age, Braden score, gender, laboratory values	All patients given standard pressure relieving mattress	26% (38/149)	Unclear	Logistic regression for individual risk factors	Novel indicator (combination of individual risk factors hemoglobin, CRP, albumin, age and gender) cutoff 0.28 (possible range 0-1)
Lindgren, 2002 ⁴⁹	Stage 1: persistent discoloration with intact skin surface Stage 2: epithelial damage (abrasion or blister) Stage 3: damage to the full thickness of the skin without a deep cavity Stage 4: damage to the full thickness of the skin with a deep cavity	None; no adjusted analyses conducted	Not reported	12% (62/530)		None	RPS ≤36
Page, 2010 ⁵⁰	Unclear	No adjusted analyses relevant to TNH-PUPP	Not reported	4% (7/165)	Unclear	Univariate and multivariate logistic regression for individual risk factors	TNH-PUPP cutoff 3
Towey, 1988 ⁵¹	Unclear	None; no adjusted analyses conducted	Preventive measures given but not described	47% (28/60)	On admission, 14 days and 28 days later	None	Knoll cutoff 12

Author, year	True Positives (n)	False Negatives (n)	True Negatives (n)	False Positives (n)	Sensitivity	Specificity	PLR (95% CI)
Multiple scales							
Boyle, 2001 ⁴	Cubbin and Jackson: 23 Waterlow: 28	Cubbin and Jackson: 5 Waterlow: 0	Cubbin and Jackson: 213 Waterlow: 66	Cubbin and Jackson: 293 Waterlow: 440	Cubbin and Jackson: 0.83 (23/28) Waterlow: 1.0 (28/28)	Cubbin and Jackson: 0.42 (213/506) Waterlow: 0.13 (66/506)	Cubbin and Jackson: 0.08 Waterlow: 0.06
DeFloor, 2005 ⁵	<i>Nonblanchable erythema</i> - Braden 17: 290 Braden 18: 301 Norton 12: 225 Norton 14: 298 Clinical judgment: 269 <i>Grade 2 or higher pressure ulcer</i> - Braden 17: 148 Braden 18: 159 Norton 12: 123 Norton 14: 151 Clinical judgment: 77	<i>Nonblanchable erythema</i> - Braden 17: 73 Braden 18: 62 Norton 12: 138 Norton 14: 65 Clinical judgment: 94 <i>Grade 2 or higher pressure ulcer</i> - Braden 17: 39 Braden 18: 28 Norton 12: 64 Norton 14: 36 Clinical judgment: 110	<i>Nonblanchable erythema</i> - Braden 17: 916 Braden 18: 817 Norton 12: 1,014 Norton 14: 831 Clinical judgment: 705 <i>Grade 2 or higher pressure ulcer</i> - Braden 17: 951 Braden 18: 856 Norton 12: 1,094 Norton 14: 872 Clinical judgment: 1,411	<i>Nonblanchable erythema</i> - Braden 17: 493 Braden 18: 592 Norton 12: 395 Norton 14: 578 Clinical judgment: 704 <i>Grade 2 or higher pressure ulcer</i> - Braden 17: 634 Braden 18: 729 Norton 12: 491 Norton 14: 713 Clinical judgment: 174	<i>Nonblanchable erythema</i> - Braden 17: 0.8 (290/363) Braden 18: 0.83 (301/363) Norton 12: 0.62 (225/363) Norton 14: 0.82 (298/363) Clinical judgment: 0.74 (269/363) <i>Grade 2 or higher pressure ulcer</i> - Braden 17: 0.79 (148/187) Braden 18: 0.85 (159/187) Norton 12: 0.66 (123/187) Norton 14: 0.81 (151/187) Clinical judgment: 0.41 (77/187)	<i>Nonblanchable erythema</i> - Braden 17: 0.65 (916/1,409) Braden 18: 0.58 (817/1,409) Norton 12: 0.72 (1,014/1,409) Norton 14: 0.59 (831/1,409) Clinical judgment: 0.5 (705/1,409) <i>Grade 2 or higher pressure ulcer</i> - Braden 17: 0.6 (951/1,585) Braden 18: 0.54 (856/1,585) Norton 12: 0.69 (1,094/1,585) Norton 14: 0.55 (872/1,585) Clinical judgment: 0.89 (1,411/1,585)	<i>Nonblanchable erythema</i> - Braden 17: 0.57 Braden 18: 0.49 Norton 12: 0.55 Norton 14: 0.5 Clinical judgment: 0.37 <i>Grade 2 or higher pressure ulcer</i> - Braden 17: 0.24 Braden 18: 0.23 Norton 12: 0.26 Norton 14: 0.22 Clinical judgment: 0.46

Author, year	True Positives (n)	False Negatives (n)	True Negatives (n)	False Positives (n)	Sensitivity	Specificity	PLR (95% CI)
Feuchtinger, 2007 ⁶	Braden 16: 20 Braden 20: 25 Modified Norton 21: 9 Modified Norton 23: 11 Modified Norton 25: 15 4-factor model: 22	Braden 16: 6 Braden 20: 1 Modified Norton 21: 17 Modified Norton 23: 15 Modified Norton 25: 11 4-factor model: 4	Braden 16: 8 Braden 20: 26 Modified Norton 21: 25 Modified Norton 23: 24 Modified Norton 25: 19 4-factor model: 8	Braden 16: 19 Braden 20: 1 Modified Norton 21: 2 Modified Norton 23: 3 Modified Norton 25: 8 4-factor model: 16	Braden 16: 0.78 (20/26) Braden 20: 0.97 (25/26) Modified Norton 21: 0.33 (9/26) Modified Norton 23: 0.41 (11/26) Modified Norton 25: 0.58 (15/26) 4-factor model: 0.85 (22/26)	Braden 16: 0.29 (8/27) Braden 20: 0.05 (26/27) Modified Norton 21: 0.94 (25/27) Modified Norton 23: 0.88 (24/27) Modified Norton 25: 0.47 (19/27) 4-factor model: 0.31 (8/27)	Braden 16: 0.7 [0.51] Braden 20: 0.69 [0.5] Modified Norton 21: 0.92 [0.84] Modified Norton 23: 0.88 [0.76] Modified Norton 25: 0.7 [0.65] 4-factor model: 0.7 [0.540]
Jalali, 2005 ⁷	Braden: 39 Gosnell: 63 Norton: 36 Waterlow: 47	Braden: 35 Gosnell: 11 Norton: 38 Waterlow: 27	Braden: 156 Gosnell: 129 Norton: 156 Waterlow: 129	Braden: 0 Gosnell: 27 Norton: 0 Waterlow: 27	Braden: 0.53 (39/74) Gosnell: 0.85 (63/74) Norton: 0.49 (36/74) Waterlow: 0.63 (47/74)	Braden: 1.0 (156/156) Gosnell: 0.83 (129/156) Norton: 1.0 (156/156) Waterlow: 0.83 (129/156)	Braden: ∞ Gosnell: 2.35 Norton: ∞ Waterlow: 1.74
Kim, 2009 ⁸	Braden: 37 Cubbin and Jackson: 38 Song/Choi: 38	Braden: 3 Cubbin and Jackson: 2 Song/Choi: 2	Braden: 125 Cubbin and Jackson: 147 Song/Choi: 124	Braden: 54 Cubbin and Jackson: 32 Song/Choi: 55	Braden: 0.93 (37/40) Cubbin and Jackson: 0.95 (38/40) Song/Choi: 0.95 (38/40)	Braden: 0.7 (125/179) Cubbin and Jackson: 0.82 (147/179) Song/Choi: 0.69 (124/179)	Braden: 0.68 Cubbin and Jackson: 1.15 Song/Choi: 0.67
Kwong, 2005 ⁹	Braden: 8 Modified Braden: 8 Norton: 8	Braden: 1 Modified Braden: 1 Norton: 1	Braden: 302 Modified Braden: 315 Norton: 256	Braden: 118 Modified Braden: 105 Norton: 164	Braden: 0.89 (8/9) Modified Braden: 0.89 (8/9) Norton: 0.89 (8/9)	Braden: 0.72 (302/420) Modified Braden: 0.75 (315/420) Norton: 0.61 (256/420)	Braden: 0.06 Modified Braden: 0.07 Norton: 0.05
Pang, 1998 ¹⁰	Braden: 19 Norton: 17 Waterlow: 20	Braden: 2 Norton: 4 Waterlow: 1	Braden: 53 Norton: 50 Waterlow: 37	Braden: 32 Norton: 35 Waterlow: 48	Braden: 0.91 (19/21) Norton: 0.81 (17/21) Waterlow: 0.95 (20/21)	Braden: 0.62 (53/85) Norton: 0.59 (50/85) Waterlow: 0.44 (37/85)	Braden: 0.6 Norton: 0.49 Waterlow: 0.42

Author, year	True Positives (n)	False Negatives (n)	True Negatives (n)	False Positives (n)	Sensitivity	Specificity	PLR (95% CI)
Perneger, 2002 ¹¹	Fragmment: 113 Not calculable for Braden, Norton	Fragmment: 69 Not calculable for Braden, Norton	Fragmment: 857 Not calculable for Braden, Norton	Fragmment: 151 Not calculable for Braden, Norton	Fragmment: 0.62 (113/182) Not calculable for Braden, Norton	Fragmment: 0.85 (857/1,008) Not calculable for Braden, Norton	Fragmment: 0.73 Not calculable for Braden, Norton
Salvadalena, 1992 ¹²	Braden 15: 6 Braden 18: 12 Clinical judgment: 10	Braden 15: 14 Braden 18: 8 Clinical judgment: 10	Braden 15: 61 Braden 18: 43 Clinical judgment: 60	Braden 15: 18 Braden 18: 36 Clinical judgment: 16	Braden 15: 0.3 (6/20) Braden 18: 0.6 (12/20) Clinical judgment: 0.5 (10/20)	Braden 15: 0.77 (61/79) Braden 18: 0.54 (43/79) Clinical judgment: 0.79 (60/76)	Braden 15: 0.33 Braden 18: 0.33 Clinical judgment: 0.63
Schoonhoven, 2002 ¹³	Braden: 59 Norton: 62 Waterlow: 122	Braden: 76 Norton: 73 Waterlow: 13	Braden: 744 Norton: 656 Waterlow: 241	Braden: 350 Norton: 438 Waterlow: 853	Braden: 0.44 (59/135) Norton: 0.46 (62/135) Waterlow: 0.9 (122/135)	Braden: 0.68 (744/1,094) Norton: 0.6 (656/1,094) Waterlow: 0.22 (241/1,094)	Braden: 0.17 Norton: 0.14 Waterlow: 0.14
Seongsook, 2004 ¹⁴	Braden: 34 Cubbin/Jackson: 31 Douglas: 35	Braden: 1 Cubbin/Jackson: 4 Douglas: 0	Braden: 20 Cubbin/Jackson: 47 Douglas: 14	Braden: 57 Cubbin/Jackson: 30 Douglas: 63	Braden: 0.97 (34/35) Cubbin/Jackson: 0.89 (31/35) Douglas: 1.00 (35/35)	Braden: 0.26 (20/77) Cubbin/Jackson: 0.61 (47/77) Douglas: 0.18 (14/77)	Braden: 0.59 Cubbin/Jackson: 1.03 Douglas: 0.55
van Marum, 2000 ¹⁵	Not calculable	Not calculable	Not calculable	Not calculable	Norton: 0.75 Dutch CBO: 0.55	Norton: 0.55 Dutch CBO: 0.75	Not calculable
VandenBosch, 1996 ¹⁶	Braden: 17 Clinical judgment: 15	Braden: 12 Clinical judgment: 14	Braden: 44 Clinical judgment: 43	Braden: 30 Clinical judgment: 29	Braden: 0.59 (17/29) Clinical judgment: 0.52 (15/29)	Braden: 0.41 (44/74) Clinical judgment: 0.59 (43/74)	Braden: 0.39 Clinical judgment: 0.5
Wai-Han, 1997 ¹⁷	Norton: 6 Waterlow: 7	Norton: 2 Waterlow: 1	Norton: 120 Waterlow: 51	Norton: 57 Waterlow: 126	Norton: 0.75 (6/8) Waterlow: 0.88 (7/8)	Norton: 0.68 (120/177) Waterlow: 0.29 (51/177)	Norton: 0.11 Waterlow: 0.03
Braden scale							
Baldwin, 1998 ¹⁸	Braden 10: 10 Braden 15: 1	Braden 10: 1 Braden 15: 10	Braden 10: 24 Braden 15: 18	Braden 10: 1 Braden 15: 7	Braden 10: 0.91 (10/11) Braden 15: 0.09 (1/11)	Braden 10: 0.96 (24/25) Braden 15: 0.71 (18/25)	Braden 10: 10.2 Braden 15: 0.14
Barnes, 1993 ¹⁹	16	6	32	307	0.73 (16/22)	0.91 (32/339)	0.52

Author, year	True Positives (n)	False Negatives (n)	True Negatives (n)	False Positives (n)	Sensitivity	Specificity	PLR (95% CI)
Bergstrom, 1987a ²⁰	Study 1: 7 Study 2: 9	Study 1: 0 Study 2: 0	Study 1: 83 Study 2: 58	Study 1: 9 Study 2: 6	Study 1: 1.0 (7/7) Study 2: 1.0 (9/9)	Study 1: 0.9 (83/92) Study 2: 0.64 (58/64)	Study 1: 0.75 Study 2: 0.27
Bergstrom, 1987b ²¹	Braden 15: 18 Braden 18: 22	Braden 15: 6 Braden 18: 2	Braden 15: 24 Braden 18: 14	Braden 15: 12 Braden 18: 22	Braden 15: 0.75 (18/24) Braden 18: 0.92 (22/24)	Braden 15: 0.67 (24/36) Braden 18: 0.39 (14/36)	Braden 15: 1.5 Braden 18: 1.0
Bergstrom, 1992 ²²	146	1	Not calculable	Not calculable	Not calculable	Not calculable	Not calculable
Bergstrom, 1998 ²³ Other publications: Bergstrom, 2002 ²⁴	<i>Time 1:</i> <u>Tertiary care</u> Braden 15: 10 Braden 18: 10 <u>VA</u> Braden 15: 4 Braden 18: 6 <u>SNF</u> Braden 15: 19 Braden 18: 45 <i>Time 2:</i> <u>Tertiary care</u> Braden 15: 12 Braden 18: 23 <u>VA</u> Braden 15: 4 Braden 18: 13 <u>SNF</u> Braden 15: 20 Braden 18: 44	<i>Time 1:</i> <u>Tertiary care</u> Braden 15: 16 Braden 18: 16 <u>VA</u> Braden 15: 17 Braden 18: 15 <u>SNF</u> Braden 15: 42 Braden 18: 16 <i>Time 2:</i> <u>Tertiary care</u> Braden 15: 14 Braden 18: 3 <u>VA</u> Braden 15: 17 Braden 18: 8 <u>SNF</u> Braden 15: 41 Braden 18: 17	<i>Time 1:</i> <u>Tertiary care</u> Braden 15: 269 Braden 18: 221 <u>VA</u> Braden 15: 258 Braden 18: 235 <u>SNF</u> Braden 15: 182 Braden 18: 116 <i>Time 2:</i> <u>Tertiary care</u> Braden 15: 252 Braden 18: 190 <u>VA</u> Braden 15: 245 Braden 18: 211 <u>SNF</u> Braden 15: 180 Braden 18: 132	<i>Time 1:</i> <u>Tertiary care</u> Braden 15: 11 Braden 18: 59 <u>VA</u> Braden 15: 3 Braden 18: 26 <u>SNF</u> Braden 15: 12 Braden 18: 78 <i>Time 2:</i> <u>Tertiary care</u> Braden 15: 28 Braden 18: 90 <u>VA</u> Braden 15: 16 Braden 18: 50 <u>SNF</u> Braden 15: 14 Braden 18: 62	<i>Time 1:</i> <u>Tertiary care</u> Braden 15: 0.39 (10/26) Braden 18: 0.38 (10/26) <u>VA</u> Braden 15: 0.20 (4/21) Braden 18: 0.30 (6/21) <u>SNF</u> Braden 15: 0.31 (19/61) Braden 18: 0.74 (45/61) <i>Time 2:</i> <u>Tertiary care</u> Braden 15: 0.46 (12/26) Braden 18: 0.88 (23/26) <u>VA</u> Braden 15: 0.20 (4/21) Braden 18: 0.60 (13/21) <u>SNF</u> Braden 15: 0.33 (20/61) Braden 18: 0.72 (44/61)	<i>Time 1:</i> <u>Tertiary care</u> Braden 15: 0.96 (269/280) Braden 18: 0.79 (221/280) <u>VA</u> Braden 15: 0.99 (258/261) Braden 18: 0.90 (235/261) <u>SNF</u> Braden 15: 0.94 (182/194) Braden 18: 0.60 (116/194) <i>Time 2:</i> <u>Tertiary care</u> Braden 15: 0.90 (252/280) Braden 18: 0.68 (190/280) <u>VA</u> Braden 15: 0.94 (245/261) Braden 18: 0.81 (211/261) <u>SNF</u> Braden 15: 0.93 (180/194) Braden 18: 0.68 (132/194)	<i>Time 1:</i> <u>Tertiary care</u> Braden 15: 0.9 Braden 18: 0.17 <u>VA</u> Braden 15: 1.6 Braden 18: 0.24 <u>SNF</u> Braden 15: 1.63 Braden 18: 0.58 <i>Time 2:</i> <u>Tertiary care</u> Braden 15: 0.43 Braden 18: 0.26 <u>VA</u> Braden 15: 0.27 Braden 18: 0.25 <u>SNF</u> Braden 15: 1.48 Braden 18: 0.71

Author, year	True Positives (n)	False Negatives (n)	True Negatives (n)	False Positives (n)	Sensitivity	Specificity	PLR (95% CI)
Bergstrom, 2002 ²⁴ Other publications: Bergstrom, 1998 ²³	Blacks - Braden 15: 3 Braden 18: 6 Whites - Braden 15: 31 Braden 18: 69	Blacks - Braden 15: 5 Braden 18: 2 Whites - Braden 15: 67 Braden 18: 29	Blacks - Braden 15: 140 Braden 18: 115 Whites - Braden 15: 536 Braden 18: 434	Blacks - Braden 15: 11 Braden 18: 36 Whites - Braden 15: 28 Braden 18: 130	Blacks - Braden 15: 0.38 (3/8) Braden 18: 0.75 (6/8) Whites - Braden 15: 0.32 (31/98) Braden 18: 0.7 (69/98)	Blacks - Braden 15: 0.92 (140/151) Braden 18: 0.76 (115/151) Whites - Braden 15: 0.95 (536/564) Braden 18: 0.77 (434/564)	Blacks - Braden 15: 0.25 Braden 18: 0.16 Whites - Braden 15: 1.13 Braden 18: 0.54
Braden, 1994 ²⁵	Braden 15: 12 Braden 18: 22	Braden 15: 16 Braden 18: 6	Braden 15: 70 Braden 18: 50	Braden 15: 4 Braden 18: 24	Braden 15: 0.32 (12/28) Braden 18: 0.79 (22/28)	Braden 15: 0.95 (70/74) Braden 18: 0.74 (50/74)	Braden 15: 2.49 Braden 18: 0.94
Capobianco, 1996 ²⁶	10	4	30	6	0.71 (10/14)	0.83 (30/36)	1.62
Chan, 2005 ²⁷	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported
Chan, 2009 ²⁸	Braden: 12 Modified Braden: 16	Braden: 6 Modified Braden: 2	Braden: 115 Modified Braden: 111	Braden: 64 Modified Braden: 68	Braden: 0.67 (12/18) Modified Braden: 0.89 (16/18)	Braden: 0.64 (115/179) Modified Braden: 0.62 (111/179)	Braden: 0.18 Modified Braden: 0.23
Goodridge, 1998 ²⁹	Braden 15: 3 Braden 18: 15	Braden 15: 29 Braden 18: 17	Braden 15: 271 Braden 18: 203	Braden 15: 27 Braden 18: 95	Braden 15: 0.09 (3/32) Braden 18: 0.47 (15/32)	Braden 15: 0.91 (271/298) Braden 18: 0.68 (203/298)	Braden 15: 0.11 Braden 18: 0.16
Hagisawa, 1999 ³⁰	14	22	239	0	0.39 (14/36)	1.0 (239/239)	∞
Halfens, 2000 ³¹	Braden 15: 10 Braden 18: 24 Extended Braden 15: 3 Extended Braden 18: 11	Braden 15: 37 Braden 18: 23 Extended Braden 15: 44 Extended Braden 18: 36	Braden 15: 259 Braden 18: 235 Extended Braden 15: 270 Extended Braden 18: 259	Braden 15: 14 Braden 18: 38 Extended Braden 15: 3 Extended Braden 18: 14	Braden 15: 0.22 (10/47) Braden 18: 0.51 (24/47) Extended Braden 15: 0.07 (3/47) Extended Braden 18: 0.24 (11/47)	Braden 15: 0.95 (259/273) Braden 18: 0.86 (235/273) Extended Braden 15: 0.99 (270/273) Extended Braden 18: 0.95 (259/273)	Braden 15: 0.76 Braden 18: 0.63 Extended Braden 15: 1.21 Extended Braden 18: 0.83
Langemo, 1991 ³²	Braden 15: 6 Braden 18: 4	Braden 15: 5 Braden 18: 3	Braden 15: 59 Braden 18: 11	Braden 15: 4 Braden 18: 7	Braden 15: 0.55 (6/11) Braden 18: 0.57 (4/7)	Braden 15: 0.94 (59/63) Braden 18: 0.61 (11/18)	Braden 15: 1.62 Braden 18: 0.57

Author, year	True Positives (n)	False Negatives (n)	True Negatives (n)	False Positives (n)	Sensitivity	Specificity	PLR (95% CI)
Lewicki, 2000 ³³	<p><i>POD 1</i> Braden 15: 11 Braden 18: no data</p> <p><i>POD 3</i> Braden 15: 9 Braden 18: 9</p> <p><i>POD 5</i> Braden 15: 5 Braden 18: 5</p>	<p><i>POD 1</i> Braden 15: 5 Braden 18: no data</p> <p><i>POD 3</i> Braden 15: 7 Braden 18: 7</p> <p><i>POD 5</i> Braden 15: 11 Braden 18: 11</p>	<p><i>POD 1</i> Braden 15: 35 Braden 18: no data</p> <p><i>POD 3</i> Braden 15: 289 Braden 18: 257</p> <p><i>POD 5</i> Braden 15: 295 Braden 18: 273</p>	<p><i>POD 1</i> Braden 15: 286 Braden 18: no data</p> <p><i>POD 3</i> Braden 15: 32 Braden 18: 64</p> <p><i>POD 5</i> Braden 15: 26 Braden 18: 48</p>	<p><i>POD 1</i> Braden 15: 0.67 (11/16) Braden 18: no data</p> <p><i>POD 3</i> Braden 15: 0.57 (9/16) Braden 18: 0.57 (9/16)</p> <p><i>POD 5</i> Braden 15: 0.33 (5/16) Braden 18: 0.33 (5/16)</p>	<p><i>POD 1</i> Braden 15: 0.11 (35/321) Braden 18: no data</p> <p><i>POD 3</i> Braden 15: 0.9 (289/321) Braden 18: 0.8 (257/321)</p> <p><i>POD 5</i> Braden 15: 0.92 (295/321) Braden 18: 0.85 (273/321)</p>	<p><i>POD 1</i> Braden 15: 0.04 Braden 18: no data</p> <p><i>POD 3</i> Braden 15: 0.29 Braden 18: 0.14</p> <p><i>POD 5</i> Braden 15: 0.19 Braden 18: 0.11</p>
Lyder, 1998 ³⁴	5	9	22	0	0.35 (5/14)	1.0 (22/22)	∞
Lyder, 1999 ³⁵	Not calculable	Not calculable	Not calculable	Not calculable	Braden 16 (blacks): 0.77 Braden 16 (Hispanics): 0.9 Braden 18 (blacks): 0.81	Braden 16 (blacks): 0.5 Braden 16 (Hispanics): 0.14 Braden 18 (blacks): 1	Not calculable
Olson, 1998 ³⁶	<p>Study 1 - Braden 15: 9 Braden 18: 10</p> <p>Study 2 - Braden 15: 18 Braden 18: 31</p>	<p>Study 1 - Braden 15: 2 Braden 18: 1</p> <p>Study 2 - Braden 15: 25 Braden 18: 12</p>	<p>Study 1 - Braden 15: 103 Braden 18: 83</p> <p>Study 2 - Braden 15: 338 Braden 18: 266</p>	<p>Study 1 - Braden 15: 14 Braden 18: 34</p> <p>Study 2 - Braden 15: 37 Braden 18: 109</p>	<p>Study 1 - Braden 15: 0.82 (9/11) Braden 18: 0.91 (10/11)</p> <p>Study 2 - Braden 15: 0.42 (18/43) Braden 18: 0.72 (31/43)</p>	<p>Study 1 - Braden 15: 0.88 Braden 18: 0.71</p> <p>Study 2 - Braden 15: 0.9 (338/375) Braden 18: 0.71 (266/109)</p>	<p>Study 1 - Braden 15: 0.68 Braden 18: 0.31</p> <p>Study 2 - Braden 15: 0.47 Braden 18: 0.28</p>
Ramundo, 1995 ³⁷	Braden 15: 6 Braden 18: 7	Braden 15: 1 Braden 18: 0	Braden 15: 34 Braden 18: 14	Braden 15: 7 Braden 18: 27	Braden 15: 0.14 (6/7) Braden 18: 1.0 (7/7)	Braden 15: 0.83 (34/41) Braden 18: 0.34 (14/27)	Braden 15: 0.17 Braden 18: 0.31

Author, year	True Positives (n)	False Negatives (n)	True Negatives (n)	False Positives (n)	Sensitivity	Specificity	PLR (95% CI)
Serpa, 2011 ³⁸	Braden 12; 1st assessment: 7 Braden 13; 2nd assessment: 6 Braden 13; 3rd assessment: 6	Braden 12; 1st assessment: 1 Braden 13; 2nd assessment: 2 Braden 13; 3rd assessment: 2	Braden 12; 1st assessment: 42 Braden 13; 2nd assessment: 52 Braden 13; 3rd assessment: 53	Braden 12; 1st assessment: 22 Braden 13; 2nd assessment: 12 Braden 13; 3rd assessment: 11	Braden 12; 1st assessment: 0.86 (7/8) Braden 13; 2nd assessment: 0.71 (6/8) Braden 13; 3rd assessment: 0.71 (6/8)	Braden 12; 1st assessment: 0.65 (42/66) Braden 13; 2nd assessment: 0.82 (52/66) Braden 13; 3rd assessment: 0.83 (53/66)	Braden 12; 1st assessment: 2.42 (1.55 to 3.79) Braden 13; 2nd assessment: 3.87 (1.93 to 7.74) Braden 13; 3rd assessment: 4.22 (2.07 to 8.62)
Tourtual, 1997 ³⁹	Braden 12: 9 Braden 16: 31	Braden 12: 54 Braden 16: 32	Braden 12: 214 Braden 16: 173	Braden 12: 14 Braden 16: 55	Braden 12: 0.14 (9/63) Braden 16: 0.49 (31/63)	Braden 12: 0.94 (214/228) Braden 16: 0.76 (173/228)	Braden 12: 0.66 Braden 16: 0.58
Norton scale							
Bale, 1995 ¹	2	0	24	53	1.0 (2/2)	0.31 (24/77)	3.2
Lincoln, 1986 ⁴⁰	0	2	29	5	0.0 (0/2)	0.85 (29/34)	0.0
Stotts, 1988 ⁵³	11	56	305	15	0.16 (11/67)	0.95 (305/320)	0.67
Waterlow scale							
Compton, 2008 ⁴²	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported
Edwards, 1995 ⁴³	2	0	3	26	1.0 (2/2)	0.1 (3/29)	0.07
Serpa, 2009 ⁴⁴	Waterlow 17, 1st assessment: 5 Waterlow 20, 2nd assessment: 6 Waterlow 20, 3rd assessment: 6	Waterlow 17, 1st assessment: 2 Waterlow 20, 2nd assessment: 1 Waterlow 20, 3rd assessment: 1	Waterlow 17, 1st assessment: 61 Waterlow 20, 2nd assessment: 37 Waterlow 20, 3rd assessment: 30	Waterlow 17, 1st assessment: 30 Waterlow 20, 2nd assessment: 54 Waterlow 20, 3rd assessment: 61	Waterlow 17, 1st assessment: 0.71 (5/7) Waterlow 20, 2nd assessment: 0.86 (6/7) Waterlow 20, 3rd assessment: 0.86 (6/7)	Waterlow 17, 1st assessment: 0.67 (61/91) Waterlow 20, 2nd assessment: 0.41 (37/91) Waterlow 20, 3rd assessment: 0.33 (30/91)	Waterlow 17, 1st assessment: 2.17 (CI 1.25 to 3.77) Waterlow 20, 2nd assessment: 1.44 (CI 1.02 to 2.04) Waterlow 20, 3rd assessment: 1.28 (CI 0.91 to 1.79)
Webster, 2010 ⁴⁵	6	39	152	3	0.67 (6/45)	0.79 (152/155)	0.15
Westrate, 1998 ⁴⁶	38	9	156	391	0.81 (38/47)	0.29 (156/547)	0.1
Other scales							
Andersen, 1982 ⁴⁷	35	5	2,911	447	0.88 (35/40)	0.87 (2,911/3,358)	0.08
Hatanaka, 2008 ⁴⁸	28	10	78	33	0.73 (28/38)	0.7 (78/111)	0.85
Lindgren, 2002 ⁴⁹	35	27	271	197	0.57 (35/62)	0.58 (271/468)	0.19
Page, 2011 ⁵⁰	6	1	115	43	0.86 (6/7)	0.73 (115/158)	0.13
Towey, 1988 ⁵¹	24	4	18	14	0.86 (24/28)	0.56 (18/32)	1.71

Author, year	NLR (95% CI)	PPV (calculated value, if different from reported value)	NPV (calculated value, if different from reported value)	OR (95% CI)	AUROC (95% CI)	Other Results/Comments	Quality Rating
Multiple scales							
Boyle, 2001 ⁴	Cubbin and Jackson: 0.02 Waterlow: 0.0	Cubbin and Jackson: 0.07 Waterlow: 0.06	Cubbin and Jackson: 0.98 Waterlow: 1.0	Not reported	Cubbin and Jackson: 0.72 Waterlow: 0.66	PLR, NLR, PPV, NPV calculated based on data in text	Fair
DeFloor, 2005 ⁵	<i>Nonblanchable erythema</i> - Braden 17: 0.08 Braden 18: 0.07 Norton 12: 0.13 Norton 14: 0.08 Clinical judgment: 0.13 <i>Grade 2 or higher pressure ulcer</i> - Braden 17: 0.04 Braden 18: 0.03 Norton 12: 0.06 Norton 14: 0.04 Clinical judgment: 0.08	<i>Nonblanchable erythema</i> - Braden 17: 0.36 Braden 18: 0.33 Norton 12: 0.36 Norton 14: 0.33 Clinical judgment: 0.27 <i>Grade 2 or higher pressure ulcer</i> - Braden 17: 0.2 Braden 18: 0.19 Norton 12: 0.21 Norton 14: 0.18 Clinical judgment: 0.32	<i>Nonblanchable erythema</i> - Braden 17: 0.93 Braden 18: 0.93 Norton 12: 0.88 Norton 14: 0.67 Clinical judgment: 0.73 <i>Grade 2 or higher pressure ulcer</i> - Braden 17: 0.96 Braden 18: 0.97 Norton 12: 0.94 Norton 14: 0.96 Clinical judgment: 0.92	<i>Nonblanchable erythema</i> - Braden 17: 7.22 Braden 18: 6.86 Norton 12: 4.2 Norton 14: 6.58 Clinical judgment: 2.83 <i>Grade 2 or higher pressure ulcer</i> - Braden 17: 5.62 Braden 18: 6.94 Norton 12: 4.3 Norton 14: 5.34 Clinical judgment: 5.77	<i>Nonblanchable erythema</i> - Braden: 0.77 Norton: 0.75 <i>Grade 2 or higher pressure ulcer</i> - Braden: 0.75 Norton: 0.74 No data for clinical judgment		Fair

Author, year	NLR (95% CI)	PPV (calculated value, if different from reported value)	NPV (calculated value, if different from reported value)	OR (95% CI)	AUROC (95% CI)	Other Results/Comments	Quality Rating
Feuchtinger, 2007 ⁶	Braden 16: 0.76 Braden 20: 0.58 Modified Norton 21: 0.68 Modified Norton 23: 0.64 Modified Norton 25: 0.58 4-factor model: 0.46	Braden 16: 0.7 [0.51] Braden 20: 0.69 [0.5] Modified Norton 21: 0.92 [0.84] Modified Norton 23: 0.88 [0.76] Modified Norton 25: 0.7 [0.65] 4-factor model: 0.7 [0.540]	Braden 16: 0.38 [0.58] Braden 20: 0.5 [0.63] Modified Norton 21: 0.4 [0.59] Modified Norton 23: 0.42 [0.61] Modified Norton 25: 0.35 [0.63] 4-factor model: 0.38 [0.68]	Not reported	Not reported		Fair
Jalali, 2005 ⁷	Braden: 0.22 Gosnell: 0.09 Norton: 0.24 Waterlow: 0.21	Braden: 1.0 Gosnell: 0.59 [0.7] Norton: 1.0 Waterlow: 0.61 [0.64]	Braden: 0.58 [0.82] Gosnell: 0.95 [0.92] Norton: 0.52 [0.81] Waterlow: 0.84 [0.83]	Not reported	Not reported	Youden's index (measures diagnostic value; values range from -1 to 1; J=0 indicates no diagnostic value) Braden: 0.53 Gosnell: 0.68 Norton: 0.49 Waterlow: 0.47	Fair
Kim, 2009 ⁸	Braden: 0.02 Cubbin and Jackson: 0.01 Song/Choi: 0.02	Braden: 0.41 Cubbin and Jackson: 0.56 [0.54] Song/Choi: 0.41 [0.4]	Braden: 0.98 Cubbin and Jackson: 0.99 Song/Choi: 0.98	Not reported	Braden: 0.881 Cubbin and Jackson: 0.902 Song/Choi: 0.89	73% of patients that developed a PU used artificial respirator	Fair
Kwong, 2005 ⁹	Braden: 0.003 Modified Braden: 0.001 Norton: 0.004	Braden: 0.05 [0.06] Modified Braden: 0.07 Norton: 0.05	Braden: 1.0 Modified Braden: 1.0 Norton: 1.0	Not reported	Not reported		Good
Pang, 1998 ¹⁰	Braden: 0.04 Norton: 0.08 Waterlow: 0.03	Braden: 0.37 Norton: 0.33 Waterlow: 0.29 [0.3]	Braden: 0.96 Norton: 0.97 [0.93] Waterlow: 0.93 [0.97]	Not reported	Not reported		Good

Author, year	NLR (95% CI)	PPV (calculated value, if different from reported value)	NPV (calculated value, if different from reported value)	OR (95% CI)	AUROC (95% CI)	Other Results/Comments	Quality Rating
Perneger, 2002 ¹¹	Fragmment: 0.08 Not calculable for Braden, Norton	Fragmment: 0.34 [0.42] Not calculable for Braden, Norton	Fragmment: 0.95 [0.93] Not calculable for Braden, Norton	Fragmment: RR 1.6 (CI 1.4 to 1.7) per 1 point increase in score	Fragmment: 0.79 (CI 0.75 to 0.82) Braden: 0.74 (CI 0.70 to 0.78; p=0.004 vs. Fraggmment) Norton: 0.74 (CI 0.70 to 0.78; p=0.006 vs. Fraggmment)	Fragmment + preventive measures: HR 1.3 (CI 1.2 to 1.5) per one-point difference Fragmment score + no preventive measures: HR 1.7 (CI 1.6 to 1.9) per one-point difference Unadjusted HR/1 SD increase from baseline: Braden: range 2.4 (for days 0-2) to 1.0 (Day ≥11) Norton: range 2.3 (days 0-2) to 1.1 (Day ≥11)	Fair
Salvadalena, 1992 ¹²	Braden 15: 0.23 Braden 18: 0.19 Clinical judgment: 0.17	Braden 15: 0.25 Braden 18: 0.25 Clinical judgment: 0.39	Braden 15: 0.81 Braden 18: 0.84 Clinical judgment: 0.86	Not reported	Not reported		Fair
Schoonhoven, 2002 ¹³	Braden: 0.12 Norton: 0.11 Waterlow: 0.06	Braden: 0.08 (0.06 to 0.1) [0.15] Norton: 0.07 (0.06 to 0.09) [0.12] Waterlow: 0.07 (0.06 to 0.08) [0.12]	Braden: 0.95 (0.94 to 0.96) [0.91] Norton: 0.95 (0.93 to 0.96) [0.89] Waterlow: 0.98 (0.95 to 0.99) [0.95]	Not reported	Braden: 0.55 (0.49 to 0.6) Norton: 0.56 (0.51 to 0.61) Waterlow: 0.61 (0.56 to 0.66)		Good
Seongsook, 2004 ¹⁴	Braden: 0.05 Cubbin/Jackson: 0.08 Douglas: 0.0	Braden: 0.37 Cubbin/Jackson: 0.51 Douglas: 0.34	Braden: 0.95 Cubbin/Jackson: 0.92 Douglas: 1.00	Not reported	Braden: 0.707 Cubbin/Jackson: 0.826 Douglas: 0.791		Good

Author, year	NLR (95% CI)	PPV (calculated value, if different from reported value)	NPV (calculated value, if different from reported value)	OR (95% CI)	AUROC (95% CI)	Other Results/Comments	Quality Rating
van Marum, 2000 ¹⁵	Not calculable	Not calculable	Not calculable	Not reported	Not reported	CBO data for 220/267 patients with Norton data	Fair
VandenBosch, 1996 ⁵²	Braden: 0.39 Clinical judgment: 0.33	Braden: 0.28 Clinical judgment: 0.33	Braden: 0.72 Clinical judgment: 0.75	Not reported	Not reported		Good
Wai-Han, 1997 ¹⁷	Norton: 0.02 Waterlow: 0.02	Norton: 0.01 Waterlow: 0.05	Norton: 0.98 Waterlow: 0.98	Not reported	Not reported		Fair
Braden scale							
Baldwin, 1998 ¹⁸	Braden 10: 0.04 Braden 15: 0.58	Braden 10: 0.91 Braden 15: 0.12	Braden 10: 0.96 Braden 15: 0.63	Not reported	Not reported	Other Braden cutoffs also evaluated, ranging from 9-16 PLR, NLR, PPV, NPV calculated from reported data	Fair
Barnes, 1993 ¹⁹	0.02	0.34	0.98	Not reported	Not reported		Fair
Bergstrom, 1987a ²⁰	Study 1: 0 Study 2: 0	Study 1: 0.43 Study 2: 0.23	Study 1: 1.0 Study 2: 1.0	Not reported	Not reported		Good
Bergstrom, 1987b ²¹	Braden 15: 0.25 Braden 18: 0.14	Braden 15: 0.6 Braden 18: 0.5	Braden 15: 0.8 Braden 18: 0.88	Not reported	Not reported	Other Braden cutoffs also evaluated, ranging from 9-22	Good
Bergstrom, 1992 ²²	Not calculable	Not calculable	Not calculable	Not reported	Not reported		Good

Author, year	NLR (95% CI)	PPV (calculated value, if different from reported value)	NPV (calculated value, if different from reported value)	OR (95% CI)	AUROC (95% CI)	Other Results/Comments	Quality Rating
Bergstrom, 1998 ²³ Other publications: Bergstrom, 2002 ²⁴	<p><i>Time 1:</i> <u>Tertiary care</u> Braden 15: 0.06 Braden 18: 0.07 <u>VA</u> Braden 15: 0.06 Braden 18: 0.06 <u>SNF</u> Braden 15: 0.23 Braden 18: 0.12</p> <p><i>Time 2:</i> <u>Tertiary care</u> Braden 15: 0.06 Braden 18: 0.02 <u>VA</u> Braden 15: 0.07 Braden 18: 0.04 <u>SNF</u> Braden 15: 0.23 Braden 18: 0.13</p>	<p><i>Time 1:</i> <u>Tertiary care</u> Braden 15: 0.40 [0.48] Braden 18: 0.14 <u>VA</u> Braden 15: 0.60 [0.62] Braden 18: 0.19 <u>SNF</u> Braden 15: 0.61 [0.62] Braden 18: 0.37</p> <p><i>Time 2:</i> <u>Tertiary care</u> Braden 15: 0.31 [0.30] Braden 18: 0.21 <u>VA</u> Braden 15: 0.20 [0.21] Braden 18: 0.18 [0.2] <u>SNF</u> Braden 15: 0.61 [0.6] Braden 18: 0.42 [0.41]</p>	<p><i>Time 1:</i> <u>Tertiary care</u> Braden 15: 0.94 Braden 18: 0.93 <u>VA</u> Braden 15: 0.94 Braden 18: 0.94 <u>SNF</u> Braden 15: 0.81 Braden 18: 0.88</p> <p><i>Time 2:</i> <u>Tertiary care</u> Braden 15: 0.94 [0.95] Braden 18: 0.93 [0.98] <u>VA</u> Braden 15: 0.94 Braden 18: 0.96 <u>SNF</u> Braden 15: 0.81 [0.82] Braden 18: 0.88 [0.89]</p>	Not reported	Not reported	Other Braden cutoffs also evaluated	Fair
Bergstrom, 2002 ²⁴ Other publications: Bergstrom, 1998 ²³	<p>Blacks - Braden 15: 0.04 Braden 18: 0.02 Whites - Braden 15: 0.13 Braden 18: 0.07</p>	<p>Blacks - Braden 15: 0.23 Braden 18: 0.17 [0.14] Whites - Braden 15: 0.57 [0.53] Braden 18: 0.41 [0.35]</p>	<p>Blacks - Braden 15: 0.96 Braden 18: 0.98 Whites - Braden 15: 0.86 [0.89] Braden 18: 0.92 [0.94]</p>	Blacks - OR 2.06; p=0.03 Whites - OR 1.3; p=0.0001	Blacks - 0.82 (SE 0.07) Whites - 0.75 (SE 0.03)	Other cutoffs also evaluated, ranging from 6-23	Fair

Author, year	NLR (95% CI)	PPV (calculated value, if different from reported value)	NPV (calculated value, if different from reported value)	OR (95% CI)	AUROC (95% CI)	Other Results/Comments	Quality Rating
Braden, 1994 ²⁵	Braden 15: 0.28 Braden 18: 0.12	Braden 15: 0.69 [0.71] Braden 18: 0.54	Braden 15: 0.79 [0.78] Braden 18: 0.9	Not reported	Not reported		Fair
Capobianco, 1996 ²⁶	0.14	0.63 [0.62]	0.88	Not reported	Not reported		Good
Chan, 2005 ²⁷	Not reported	Not reported	Not reported	Moderate risk vs. low risk: OR 7.7 (CI 3.5 to 17.1) High-risk vs. low-risk: OR 12.5 (CI 4.5-34.6)	Not reported	Mean Braden score in patients with ulcers (54/666) 14 vs. patients without ulcers (612/666) 19	Fair
Chan, 2009 ²⁸	Braden: 0.05 Modified Braden: 0.02	Braden: 0.16 Modified Braden: 0.19	Braden: 0.95 Modified Braden: 0.98	Not reported	Braden: 0.68 (CI 0.51 to 0.79) Modified Braden: 0.74 (CI 0.63 to 0.84)	PLR, NLR, PPV, NPV calculated from data in text	Fair
Goodridge, 1998 ²⁹	Braden 15: 0.11 Braden 18: 0.09	Braden 15: 0.10 Braden 18: 0.14	Braden 15: 0.90 Braden 18: 0.92	Not reported	Not reported	Sensitivity, specificity, PPV and NPV reported for Braden scores 11-20	Fair
Hagisawa, 1999 ³⁰	0.09	1.0	0.92	Not reported	Not reported		Fair
Halfens, 2000 ³¹	Braden 15: 0.14 Braden 18: 0.1 Extended Braden 15: 0.16 Extended Braden 18: 0.14	Braden 15: 0.43 Braden 18: 0.39 Extended Braden 15: 0.55 Extended Braden 18: 0.45	Braden 15: 0.88 Braden 18: 0.91 Extended Braden 15: 0.86 Extended Braden 18: 0.88	OR 3.0 (1.8 to 5.0)	Not reported	Unclear comparison used in OR calculation PPV, NPV, PLR, NLR not reported in text - values calculated	Fair
Langemo, 1991 ³²	Braden 15: 0.08 Braden 18: 0.27	Braden 15: 0.62 Braden 18: 0.36	Braden 15: 0.92 Braden 18: 0.78	Not reported	Not reported	No pressure ulcers developed in rehab, home care or hospice patients; estimated ideal cutoffs were 18, 20 and 18, respectively	Good

Author, year	NLR (95% CI)	PPV (calculated value, if different from reported value)	NPV (calculated value, if different from reported value)	OR (95% CI)	AUROC (95% CI)	Other Results/Comments	Quality Rating
Lewicki, 2000 ³³	<i>POD 1</i> Braden 15: 0.15 Braden 18: no data <i>POD 3</i> Braden 15: 0.02 Braden 18: 0.03 <i>POD 5</i> Braden 15: 0.04 Braden 18: 0.04	<i>POD 1</i> Braden 15: 0.03 Braden 18: no data <i>POD 3</i> Braden 15: 0.22 Braden 18: 0.12 <i>POD 5</i> Braden 15: 0.16 Braden 18: 0.1	<i>POD 1</i> Braden 15: 0.87 Braden 18: no data <i>POD 3</i> Braden 15: 0.98 Braden 18: 0.97 <i>POD 5</i> Braden 15: 0.97 Braden 18: 0.96	Not reported	Not reported	Other Braden cutoffs also evaluated	Good
Lyder, 1998 ³⁴	0.41	1.0	0.71	Not reported	Not reported	PLR, NLR, PPV, NPV calculated from data in text	Good
Lyder, 1999 ³⁵	Not calculable	Braden 16 (blacks): 0.77 Braden 16 (Hispanics): 0.6 Braden 18: 1	Braden 16 (blacks): 0.6 Braden 16 (Hispanics): 0.5 Braden 18: 0.5	Not reported	Not reported		Good
Olson, 1998 ³⁶	Study 1 - Braden 15: 0.02 Braden 18: 0.01 Study 2 - Braden 15: 0.07 Braden 18: 0.04	Study 1 - Braden 15: 0.4 Braden 18: 0.24 Study 2 - Braden 15: 0.32 Braden 18: 0.22	Study 1 - Braden 15: 0.98 Braden 18: 0.99 Study 2 - Braden 15: 0.93 Braden 18: 0.96	Not reported	Not reported	Other Braden cutoffs also evaluated, ranging from 12-20 PLR, NLR, PPV, NPV calculated from data in text	Fair
Ramundo, 1995 ³⁷	Braden 15: 0.21 Braden 18: 0.0	Braden 15: 0.14 Braden 18: 0.24	Braden 15: 0.82 Braden 18: 1.0	Not reported	Not reported		Poor

Author, year	NLR (95% CI)	PPV (calculated value, if different from reported value)	NPV (calculated value, if different from reported value)	OR (95% CI)	AUROC (95% CI)	Other Results/Comments	Quality Rating
Serpa, 2011 ³⁸	Braden 12; 1st assessment: 0.22 (0.04 to 1.37) Braden 13; 2nd assessment: 0.35 (0.11 to 1.14) Braden 13; 3rd assessment: 0.34 (0.11 to 1.12)	Braden 12; 1st assessment: 0.21 [0.23] Braden 13; 2nd assessment: 0.29 [0.33] Braden 13; 3rd assessment: 0.31 [0.34]	Braden 12; 1st assessment: 0.98 Braden 13; 2nd assessment: 0.96 Braden 13; 3rd assessment: 0.96	Not reported	Braden 12; 1st assessment: 0.79 (0.29 to 1.0) Braden 13; 2nd assessment: 0.79 (0.27 to 1.0) Braden 13; 3rd assessment: 0.8 (0.28 to 1.0)	PLR, NLR reported in text	Fair
Tourtual, 1997 ³⁹	Braden 12: 0.26 Braden 16: 0.19	Braden 12: 0.4 Braden 16: 0.37	Braden 12: 0.79 Braden 16: 0.84	Not reported for Braden (RRs for individual risk factors reported)	Not reported	Results from Study 1 not included; prevalence of pressure ulcers at baseline 14% PLR, NLR, PPV and NPV calculated from data in text	Poor
Norton scale							
Bale, 1995 ¹	0	0.04	1.0	Not reported	Not reported	Sensitivity, specificity, PLR, NLR, PPV, NPV calculated from reported data	Fair
Lincoln, 1986 ⁴⁰	0.07	0.0	0.94	Not reported	Not reported	Sensitivity, specificity, PLR, NLR, PPV, NPV calculated from reported data	Fair
Stotts, 1988 ⁴¹	0.18	0.4	0.85	Not reported	Not reported	Sensitivity, specificity, PLR, NLR, PPV, NPV calculated from reported data	Fair
Waterlow scale							
Compton, 2008 ⁴²	Not reported	Not reported	Not reported	Not reported	0.58 (CI 0.54 to 0.65)	Other results not reported	Fair

Author, year	NLR (95% CI)	PPV (calculated value, if different from reported value)	NPV (calculated value, if different from reported value)	OR (95% CI)	AUROC (95% CI)	Other Results/Comments	Quality Rating
Edwards, 1995 ⁴³	0.0	0.07	1.0				Fair
Serpa, 2009 ⁴⁴	Waterlow 17, 1st assessment: 0.43 (CI 0.13 to 1.39) Waterlow 20, 2nd assessment: 0.35 (CI 0.06 to 2.19) Waterlow 20, 3rd assessment: 0.43 (0.07 to 2.72)	Waterlow 17, 1st assessment: 0.14 Waterlow 20, 2nd assessment: 0.1 Waterlow 20, 3rd assessment: 0.9	Waterlow 17, 1st assessment: 0.97 Waterlow 20, 2nd assessment: 0.97 Waterlow 20, 3rd assessment: 0.97	Not reported	Waterlow 17, 1st assessment: 0.64 (CI 0.35 to 0.93) Waterlow 20, 2nd assessment: 0.59 (CI 0.34 to 0.83) Waterlow 20, 3rd assessment: 0.54 (0.35 to 0.74)	PLR, NLR, PPV, NPV reported in text	Fair
Webster, 2010 ⁴⁵	0.02	0.13 (0.07 to 0.24)	0.98 (0.94 to 0.99)	5.37 (1.76 to 16.42) (unadjusted)	Not reported	Mean length of stay: 8.8 vs. 9.4 vs. 8.5 days	Fair
Westrate, 1998 ⁴⁶	0.06	0.09	0.95	Not reported	Not reported	Sensitivity, specificity, PLR, NLR, PPV, NPV calculated from data in text	Fair
Other scales							
Andersen, 1982 ⁴⁷	0.02	0.07	1.0	Not reported	Not reported	PLR, NLR, PPV, NPV calculated from data in text	Fair
Hatanaka, 2008 ⁴⁸	0.14	0.46	0.88	Not reported	Novel indicator: 0.79 Braden: 0.56	Sensitivity, specificity for Braden score not reported PLR, NLR, PPV, NPV calculated from data in text	Fair
Lindgren, 2002 ⁴⁹	0.10	0.14 [0.16]	0.92 [0.91]	Not reported	Not reported		Poor
Page, 2010 ⁵⁰	0.01	0.13 (0.05 to 0.25) [0.12]	0.99 (0.95 to 1.0)	Not reported	0.9 (CI 0.82 to 0.99)	An unclear proportion of patients may have had pressure ulcers at baseline, though these results are not included in the report	Fair

Author, year	NLR (95% CI)	PPV (calculated value, if different from reported value)	NPV (calculated value, if different from reported value)	OR (95% CI)	AUROC (95% CI)	Other Results/Comments	Quality Rating
Towey, 1988 ⁵¹	0.22	0.63	0.82	Not reported	Not reported		Fair

Note: AUROC=area under the receiver operating characteristic, CI=confidence interval, ICU=intensive care unit, NLR=negative likelihood ratio, NPV=negative predictive value, NR=not reported, OR=odds ratio, PLR=positive likelihood ratio, PPV=positive predictive value, PU=pressure ulcer, SD=standard deviation.

Appendix Table H5. Key Question 2: quality assessment of pressure ulcer risk assessment scales

Author, year	Representative spectrum?	Evaluated a population other than the one used to derive the screening instrument?	Random or consecutive sample?	Study reported that groups received comparable interventions?	Test cutoffs predefined?	Credible reference standard?	Reference standard applied to all patients, or a random subset?	Low attrition?	Same reference standard applied to all patients?	Blinding: Reference standard interpreted independently from test under evaluation?	Quality Rating
Andersen, 1982 ⁴⁷	Yes	No	Unclear	No	No	Unclear	Yes	Yes	Yes	Unclear	Poor
Baldwin, 1998 ¹⁸	Yes	Yes	Unclear	No	No	Yes	Yes	Yes	Yes	Yes	Fair
Bale, 1995 ¹	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Unclear	Fair
Barnes, 1993 ¹⁹	Yes	Yes	Unclear	No	Yes	Yes	Yes	Yes	Yes	Unclear	Fair
Bergstrom, 1987a ²⁰	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Unclear	Good
Bergstrom, 1987b ²¹	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Good
Bergstrom, 1992 ²²	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Good
Bergstrom, 2002 ²⁴ Other publications: Bergstrom, 1998 ²³	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Unclear	Fair

Author, year	Representative spectrum?	Evaluated a population other than the one used to derive the screening instrument?	Random or consecutive sample?	Study reported that groups received comparable interventions?	Test cutoffs predefined?	Credible reference standard?	Reference standard applied to all patients, or a random subset?	Low attrition?	Same reference standard applied to all patients?	Blinding: Reference standard interpreted independently from test under evaluation?	Quality Rating
Bergstrom, 1998 ²³ Other publications: Bergstrom, 2002 ²⁴	Yes	Yes	Unclear	No	Yes	Yes	Yes	Yes	Yes	Unclear	Fair
Boyle, 2001 ⁴	Yes	Yes	Unclear	Yes	Yes	Unclear	Yes	Yes	Yes	Unclear	Fair
Braden, 1994 ²⁵	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Unclear	Fair
Capobianco, 1996 ²⁶	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Good
Chan, 2005 ²⁷	Yes	Yes	Unclear	No	Yes	Yes	Yes	Yes	Yes	Unclear	Fair
Chan 2009 ²⁸	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Unclear	Fair
Compton, 2008 ⁴²	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Unclear	Fair
DeFloor, 2005 ⁵	Yes	Yes	Unclear	No	Yes	Yes	Yes	Yes	Yes	Yes	Fair
Edwards, 1995 ⁴³	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Unclear	Fair
Feuchtinger, 2007 ⁶	Yes	Yes, for 2/3 scales	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Fair
Goodridge, 1998 ²⁹	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Fair
Hagisawa, 1999 ³⁰	Unclear	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Unclear	Fair
Halfens, 2000 ³¹	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Fair
Hatanaka, 2008 ⁴⁸	Yes	No	Unclear	Yes	No	Unclear	Yes	Yes	Yes	Unclear	Fair
Jalali, 2005 ⁷	Yes	Yes	Unclear	No	Yes	Yes	Yes	Yes	Yes	Unclear	Fair

Author, year	Representative spectrum?	Evaluated a population other than the one used to derive the screening instrument?	Random or consecutive sample?	Study reported that groups received comparable interventions?	Test cutoffs predefined?	Credible reference standard?	Reference standard applied to all patients, or a random subset?	Low attrition?	Same reference standard applied to all patients?	Blinding: Reference standard interpreted independently from test under evaluation?	Quality Rating
Kim, 2009 ⁸	Yes	Yes	Unclear	No	Yes	Yes	Yes	Yes	Yes	Unclear	Fair
Kwong, 2005 ⁹	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Good
Langemo, 1991 ³²	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Good
Lewicki, 2000 ³³	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Good
Lincoln, 1986 ⁴⁰	Yes	Yes	Unclear	No	Yes	Yes	Yes	Yes	Yes	Yes	Fair
Lindgren, 2002 ⁴⁹	Yes	No	Unclear	No	No	Yes	Yes	No	Yes	Unclear	Poor
Lyder, 1998 ³⁴	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Good
Lyder, 1999 ³⁵	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Good
Olson, 1998 ³⁶	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Fair
Page, 2011 ⁵⁰	Yes	Yes (validity results)	Unclear	No	No	Unclear	Yes	Yes	Yes	Unclear	Fair
Pang, 1998 ¹⁰	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Unclear	Good
Perneger, 2002 ¹¹	Yes	No (for Fragment scale)	Yes	No	No	Yes	Yes	Yes	Yes	Unclear	Fair
Ramundo, 1995 ³⁷	Unclear	Yes	Unclear	No	No	Yes	Yes	Yes	Yes	No	Poor
Salvadarena, 1992 ¹²	Yes	Yes	Unclear	No	No	Yes	Yes	Yes	Yes	Yes	Fair
Schoonhoven, 2002 ¹³	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good
Seongsook, 2004 ¹⁴	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Good
Serpa, 2009 ⁴⁴	Yes	Yes	Yes	No	No	Unclear	Yes	Yes	Yes	Unclear	Fair

Author, year	Representative spectrum?	Evaluated a population other than the one used to derive the screening instrument?	Random or consecutive sample?	Study reported that groups received comparable interventions?	Test cutoffs predefined?	Credible reference standard?	Reference standard applied to all patients, or a random subset?	Low attrition?	Same reference standard applied to all patients?	Blinding: Reference standard interpreted independently from test under evaluation?	Quality Rating
Serpa, 2011 ³⁸	Yes	Yes	Yes	No	Yes	Unclear	Yes	Yes	Yes	Unclear	Fair
Stotts, 1988 ⁴¹	Yes	Yes	Unclear	No	No	Yes	Yes	Yes	Yes	No	Fair
Tourtual, 1997 ³⁹	Unclear	Yes	Unclear	No	No	Yes	Yes	Unclear	Yes	Unclear	Poor
Towey, 1988 ⁵¹	Yes	Unclear	Yes	No	Yes	Unclear	Yes	Yes	Yes	Unclear	Fair
van Marum, 2000 ¹⁵	Yes	Yes	Unclear	No	No	Yes	Unclear	Yes	Unclear	Unclear	Fair
VandenBosch, 1996 ⁵²	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Good
Wai-Han, 1997 ¹⁷	Yes	Yes	Yes	No	Yes	Unclear	Yes	Yes	Yes	Unclear	Fair
Webster, 2010 ⁴⁵	Yes	Yes	Unclear	No	Yes	Yes	Yes	No	No	Unclear	Fair
Westrate, 1998 ⁴⁶	Unclear (some children included)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Fair

Appendix Table H6. Key Question 2: sensitivity and specificity of pressure ulcer risk assessment scales

Study	Cutoff	Sensitivity	Specificity
Braden			
Baldwin, 1998 ¹⁸	≤10	0.91	0.96
Serpa, 2011 ³⁸	≤12	0.86	0.65
Tortual, 1997 ³⁹	≤12	0.14	0.94
Serpa, 2011 ³⁸	≤13	0.71	0.82
Kim, 2009 ⁵	≤14	0.93	0.7
Kwong, 2005 ⁹	≤14	0.89	0.72
Baldwin, 1998 ¹⁸	≤15	0.09	0.71
Bergstrom, 1987a ²⁰	≤15 (Study 1)	0.71	0.95
Bergstrom, 1987a ²⁰	≤15 (Study 2)	0.8	0.74
Bergstrom, 1987b ²¹	≤15	0.75	0.67
Bergstrom, 1998 ²³	≤15 (Tertiary care units)	0.46	0.9
Bergstrom, 1998 ²³	≤15 (VAMC units)	0.2	0.94
Bergstrom, 1998 ²³	≤15 (Skilled nursing facility)	0.33	0.93
Braden, 1994 ²⁵	≤15	0.32	0.95
Goodridge, 1998 ²⁹	≤15	0.09	0.91
Halfens, 2000 ³¹	≤15	0.22	0.95
Langemo, 1991 ³²	≤15	0.55	0.94
Lewicki, 2000 ³³	≤15	0.33	0.92
Olson, 1998 ³⁶	≤15 (Study 1)	0.82	0.88
Olson, 1998 ³⁶	≤15 (Study 2)	0.42	0.9
Ramundo, 1995 ³⁷	≤15	0.14	0.83
Salvadalena, 1992 ¹²	≤15	0.3	0.77
	Median: ≤15	0.33 (0.09 to 0.82)	0.9 (0.67 to 0.95)
Bergstrom, 1987a ²⁰	≤16 (Study 1)	1	0.9
Bergstrom, 1987a ²⁰	≤16 (Study 2)	1	0.64
Chan, 2005 ²⁷	≤16	0.67	0.64
Hagisawa, 1999 ³⁰	≤16	0.39	1
Seongsook, 2004 ¹⁴	≤16	0.97	0.26
Barnes, 1993 ¹⁹	≤16	0.73	0.91
Feuchtinger, 2007 ⁶	≤16	0.78	0.29
Lyder, 1998 ³⁴	≤16	0.35	1
Lyder, 1999 ³⁵	≤16 (blacks)	0.77	0.5
Lyder, 1999 ³⁵	≤16 (Hispanics)	0.9	0.14
Tortual, 1997 ³⁹	≤16	0.49	0.76
	Median: ≤16	0.77 (0.35 to 1)	0.64 (0.14 to 1)
	Excluding poor quality study	0.78 (0.35 to 1)	0.64 (0.14 to 1)
DeFloor, 2005 ⁵	<17	0.8	0.65
VandenBosch, 1996 ¹⁶	≤17	0.59	0.41
DeFloor, 2005 ⁵	<18	0.83	0.58
Schoonhoven, 2002 ¹³	<18	0.44	0.68
Bergstrom, 1987a ²⁰	≤18 (Study 1)	1.0	0.83
Bergstrom, 1987a ²⁰	≤18 (Study 2)	1.0	0.51
Bergstrom, 1987b ²¹	≤18	0.92	0.39
Bergstrom, 1998 ²³	≤18 (Tertiary care units)	0.88	0.68
Bergstrom, 1998 ²³	≤18 (VAMC units)	0.6	0.81
Bergstrom, 1998 ²³	≤18 (Skilled nursing facility units)	0.72	0.68
Braden, 1994 ²⁵	≤18	0.79	0.74
Capobianco, 1996 ²⁶	≤18	0.71	0.83
Goodridge, 1998 ²⁹	≤18	0.47	0.68
Halfens, 2000 ³¹	≤18	0.51	0.86
Langemo, 1991 ³²	≤18	0.57	0.61

Study	Cutoff	Sensitivity	Specificity
Lewicki, 2000 ³³	≤18	0.33	0.85
Lyder, 1999 ³⁵	≤18	0.81	1
Olson, 1998 ³⁶	≤18 (Study 1)	0.91	0.71
Olson, 1998 ³⁶	≤18 (Study 2)	0.72	0.71
Pang, 1998 ¹⁰	≤18	0.91	0.62
Ramundo, 1995 ³⁷	≤18	1	0.34
Salvadalena, 1992 ¹²	≤18	0.6	0.54
	Median: ≤18	0.74 (0.33 to 1)	0.68 (0.34 to 0.86)
	Excluding poor quality study	0.72 (0.33 to 1)	0.68 (0.39 to 0.86)
Feuchtinger, 2007 ⁶	≤20	0.97	0.05
Jalali, 2005 ⁷	Unclear	0.53	1
Extended/Modified Braden			
Halfens, 2000 ³¹	≤15 (extended Braden)	0.07	0.99
Halfens, 2000 ³¹	≤18 (extended Braden)	0.24	0.95
Kwong, 2005 ⁹	≤16 (modified Braden)	0.89	0.75
Norton			
DeFloor, 2005 ⁵	<12	0.62	0.72
DeFloor, 2005 ⁵	<14	0.82	0.59
Wai-Han, 1997 ¹⁷	≤14	0.75	0.68
Kwong, 2005 ⁹	≤14	0.89	0.61
Lincoln, 1986 ⁴⁰	≤14	0	0.85
Stotts, 1988 ^{*53}	≤14	0.16	0.95
	Median: ≤14	0.75 (0 to 0.89)	0.61 (0.59 to 0.95)
	Excluding Lincoln 1986	0.78 (0.16 to 0.89)	0.65 (0.59 to 0.95)
	Excluding Stott 1988	0.78 (0 to 0.89)	0.65 (0.59 to 0.85)
	Excluding Lincoln 1986 and Stott 1988	0.82 (0.75 to 0.89)	0.61 (0.59 to 0.68)
Schoonhoven, 2002 ¹³	<16	0.46	0.6
Pang, 1998 ¹⁰	≤16	0.81	0.59
van Marum, 2000 ¹⁵	≤16	0.75	0.55
	Median ≤16	0.75 (0.46 to 0.81)	0.59 (0.55 to 0.6)
Jalali, 2005 ⁷	Unclear	0.49	1
Modified Norton			
Bale, 1995 ^{a1}	>10	1.0	0.31
Feuchtinger, 2007 ⁶	≤21	0.33	0.94
Feuchtinger, 2007 ⁶	≤23	0.41	0.88
Feuchtinger, 2007 ⁶	≤25	0.58	0.47
Waterlow			
Schoonhoven, 2002 ¹³	>9	0.46	0.6
Boyle, 2001 ⁴	≥10	1	0.13
Wai-Han, 1997 ¹⁷	≥10	0.88	0.29
Webster, 2010 ⁴⁵	≥15	0.67	0.79
Westrate, 1998 ⁴⁶	≥15	0.81	0.29
Pang, 1998 ¹⁰	≥16	0.95	0.44
Serpa, 2009 ⁴⁴	≥17	0.71	0.67
Serpa, 2009 ⁴⁴	≥20	0.86	0.33
Edwards, 1995 ⁴³	Unclear	1	0.1
Jalali, 2005 ⁷	Unclear	0.63	0.83
Jackson and Cubbin			
Seongsook, 2004 ¹⁴	≤24	0.89	0.61
Kim, 2009 ⁸	≤28	0.95	0.82
Boyle, 2001 ⁴	≤29	0.83	0.42

Study	Cutoff	Sensitivity	Specificity
<i>Clinical Judgment</i>			
Defloor, 2005 ⁵	Risk vs. no risk	0.74	0.5
Salvadalena, 1992 ¹²	Risk vs. no risk	0.5	0.79
van den Bosch, 1996 ¹⁶	Risk vs. no risk	0.52	0.59
	Median: risk vs. no risk	0.52	0.59

^aUsed a slightly modified version of the Norton scale.

^bThough this study used standard Norton criteria, scoring was reversed so that higher scores indicated increased risk. Thus scores are not directly comparable to other studies using a standard Norton scale.

Appendix Table H7. Key Question 2: sensitivity and specificity of pressure ulcer risk assessment scales—setting

Study	Scale	Cutoff	Sensitivity	Specificity	Notes
Home care					
Ramundo, 1995 ³⁷	Braden	≤15	0.14	0.83	
		≤18	1	0.34	
Edwards, 1995 ⁴³	Waterlow	Unclear	1	0.1	
Hospice					
Bale, 1995 ¹	Modified Norton	>10	1	0.31	Modified Norton: scoring reversed and additional risk factors included
Hospital, acute care					
Baldwin, 1998 ¹⁸	Braden	≤10	0.91	0.96	
Tortual, 1997 ³⁹	Braden	≤12	0.14	0.94	
Kwong, 2005 ⁹	Braden	≤14	0.89	0.72	
Baldwin, 1998 ¹⁸	Braden	≤15	0.09	0.71	
Bergstrom, 1987 ²¹	Braden	≤15	0.75	0.67	
Bergstrom, 1998 ²³	Braden	≤15	0.46	0.9	Time 2 assessment, tertiary care units
		≤15	0.2	0.94	Time 2 assessment, VAMC units
Goodridge, 1998 ²⁹	Braden	≤15	0.09	0.91	
Halfens, 2000 ³¹	Braden	≤15	0.22	0.95	
Olson, 1998 ³⁶	Braden	≤15	0.82	0.88	
		≤15	0.42	0.9	
Salvadalena, 1992 ¹²	Braden	≤15	0.3	0.77	
	Median	≤15	0.26 (0.09 to 0.82)	0.9 (0.67 to 0.95)	
Barnes, 1993 ¹⁹	Braden	≤16	0.73	0.91	
Feuchtinger, 2007 ⁶	Braden	≤16	0.78	0.29	
Lyder, 1998 ³⁴	Braden	≤16	0.35	1	
Lyder, 1999 ³⁵	Braden	≤16	0.77	0.5	black patients
Lyder, 1999 ³⁵	Braden	≤16	0.9	0.14	Hispanic/Latino patients
Seongsook, 2004 ¹⁴	Braden	≤16	0.97	0.26	
Tortual, 1997 ³⁹	Braden	≤16	0.49	0.76	
	Median	≤16	0.77 (0.35 to 0.97)	0.5 (0.14 to 1)	
Chan, 2005 ²⁷	Braden	≤17	0.67	0.64	
Hagisawa, 1999 ³⁰	Braden	≤17	0.39	1	
VandenBosch, 2001 ⁵²	Braden	≤17	0.59	0.41	
	Median	≤17	0.59 (0.39 to 0.67)	0.64 (0.41 to 1)	
Bergstrom, 1987 ²¹	Braden	≤18	0.92	0.39	
Bergstrom, 1998 ²³	Braden	≤18	0.88	0.68	Time 2 assessment, tertiary care units
		≤18	0.6	0.81	Time 2 assessment, VAMC units
Capobianco, 1996 ²⁶	Braden	≤18	0.71	0.83	

Study	Scale	Cutoff	Sensitivity	Specificity	Notes
Goodridge, 1998 ²⁹	Braden	≤18	0.47	0.68	
Halfens, 2000 ³¹	Braden	≤18	0.51	0.86	
Lyder, 1999 ³⁵	Braden	≤18	0.81	1	
Olson, 1998 ³⁶	Braden	≤18	0.72	0.71	
	Braden	≤18	0.91	0.71	
Pang, 1998 ¹⁰	Braden	≤18	0.91	0.62	
Salvadalena, 1992 ¹²	Braden	≤18	0.6	0.54	
	Median	≤18	0.72 (0.47 to 0.92)	0.71 (0.39 to 1)	
Feuchtinger, 2007 ⁶	Braden	≤20	0.97	0.05	
Jalali, 2005 ⁷	Braden	unclear	0.53	1	
Seongsook, 2004 ¹⁴	Cubbin and Jackson	≥24	0.89	0.61	
Boyle, 2001 ⁴	Cubbin and Jackson	≥29	0.83	0.42	
Kwong, 2005 ⁹	Norton	≤14	0.89	0.61	
Lincoln, 1986 ⁴⁰	Norton	≤14	0	0.85	
Schoonhoven, 2002 ¹³	Norton	<16	0.46	0.6	
Pang, 1998 ¹⁰	Norton	≤16	0.81	0.59	
Feuchtinger, 2007 ⁶	Modified Norton	≤21	0.33	0.94	Modified Norton: Includes skin condition, motivation and age
		≤23	0.41	0.88	Modified Norton: Includes skin condition, motivation and age
		≤25	0.58	0.47	Modified Norton: Includes skin condition, motivation and age
Jalali, 2005 ⁷	Norton	unclear	0.49	1	
Perneger, 2002 ¹¹	Norton	unclear	no data	no data	
Schoonhoven, 2002 ¹³	Waterlow	>9	0.46	0.6	
Boyle, 2001 ⁴	Waterlow	≥10	1	0.13	
Webster, 2010 ⁴⁵	Waterlow	≥15	0.67	0.79	
Westrate, 1998 ⁴⁶	Waterlow	≥15	0.81	0.29	
Pang, 1998 ¹⁰	Waterlow	≥16	0.95	0.44	
Serpa, 2009 ⁴⁴	Waterlow	≥17	0.71	0.67	
		≥20	0.86	0.33	
Jalali, 2005 ⁷	Waterlow	unclear	0.63	0.83	
ICU					
Serpa, 2011 ³⁸	Braden	≤12	0.86	0.65	1st assessment
		≤13	0.71	0.82	2nd assessment
		≤13	0.71	0.83	3rd assessment
Bergstrom, 1987b ²¹	Braden	≤15	0.75	0.67	
Seongsook, 2004 ¹⁴	Braden	≤16	0.97	0.26	
Bergstrom, 1987b ²¹	Braden	≤18	0.92	0.39	
Seongsook, 2004 ¹⁴	Cubbin and Jackson	≤24	0.89	0.61	
Boyle, 2001 ⁴	Cubbin and Jackson	≤29	0.83	0.42	
Boyle, 2001 ⁴	Waterlow	≥10	1	0.13	

Study	Scale	Cutoff	Sensitivity	Specificity	Notes
Long-term care					
Bergstrom, 1998 ²³	Braden	≤15	0.31	0.94	Time 2 assessment
Braden, 1994 ²⁵	Braden	≤15	0.32	0.95	
Defloor, 2005 ⁵	Braden	≤17	0.8	0.65	
Bergstrom, 1998 ²³	Braden	≤18	0.72	0.68	Time 2 assessment
Braden, 1994 ²⁵	Braden	≤18	0.79	0.74	
Defloor, 2005 ⁵	Braden	≤18	0.83	0.58	
Langemo, 1991 ³²	Braden	≤18	0.57	0.61	
	Median	≤18	0.76 (0.57 to 0.83)	0.65 (0.58 to 0.74)	
Defloor, 2005 ⁵	Norton	≤12	0.62	0.72	
		≤14	0.82	0.59	
Surgical					
Kim, 2009 ⁸	Braden	≤14	0.93	0.7	
Lewicki, 2000 ³³	Braden	≤15	0.33	0.92	
Feuchtinger, 2007 ⁶	Braden	≤16	0.78	0.29	
Lewicki, 2000 ³³	Braden	≤18	0.33	0.85	
Feuchtinger, 2007 ⁶	Braden	≤20	0.97	0.05	
Kim, 2009 ⁸	Cubbin and Jackson	≤28	0.95	0.82	
Stotts, 1988 ⁴¹	Modified Norton	≤14	0.16	0.95	Modified Norton: Includes clarification on rating category definitions
Feuchtinger, 2007 ⁶	Modified Norton	≤21	0.33	0.94	Modified Norton: Includes skin condition, motivation and age
		≤23	0.41	0.88	Modified Norton: Includes skin condition, motivation and age
		≤25	0.58	0.47	Modified Norton: Includes skin condition, motivation and age
Westrate, 1998 ⁴⁶	Waterlow	≥15	0.81	0.29	

Appendix Table H8. Key Question 2: pressure ulcer risk assessment scales area under the receiver operating characteristic curve—setting

Study	Scale	Setting	AUROC	Quality Rating	Notes
Hospital, acute care					
Chan, 2009 ²⁸	Braden	Hospital inpatient n=197	0.68	Fair	
Perneger, 2002 ¹¹	Braden	Hospital inpatient n=1,190	0.74	Fair	
Schoonhoven, 2002 ¹³	Braden	Hospital inpatient n=1,229	0.55	Good	
Perneger, 2002 ¹¹	Norton	Hospital inpatient n=1,190	0.74	Fair	
Schoonhoven, 2002 ¹³	Norton	Hospital inpatient n=1,229	0.56	Good	
Serpa, 2009 ⁴⁴	Waterlow	Hospital inpatient n=98	0.64	Fair	1st assessment
		Hospital inpatient n=98	0.54	Fair	2nd assessment
ICU					
Seongsook, 2004 ¹⁴	Braden	Hospital inpatient; ICU n=112	0.71	Good	
Serpa, 2011 ³⁸	Braden	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
Boyle, 2001 ⁴	Waterlow	Hospital inpatient; ICU n=534	0.66	Fair	
Compton, 2008 ⁴²	Waterlow	Hospital inpatient; ICU n=698	0.58	Fair	
Boyle, 2001 ⁴	Cubbin and Jackson	Hospital inpatient; ICU n=534	0.72	Fair	
Seongsook, 2004 ¹⁴	Cubbin and Jackson	Hospital inpatient; surgical, internal or neurological ICU n=112	0.83	Good	
Surgical					
Kim, 2009 ⁸	Braden	Post-surgery inpatient n=219	0.88	Fair	
	Cubbin and Jackson	Hospital inpatient; surgical ICU n=219	0.9	Fair	
Long-term care					
DeFloor, 2005 ⁵	Braden	Long-term care facilities n=1,772	0.77	Fair	
	Norton	Long-term care facilities n=1,772	0.75	Fair	

Appendix Table H9. Key Question 2: optimal pressure ulcer risk assessment scale cutoffs

Study	Scale	Setting	Optimal Cutoff*	Notes
Langemo, 1991 ³²	Braden	Acute care	15	
Chan, 2009 ²⁸	Braden	Acute care	16	
Capobianco, 1996 ²⁶	Braden	Acute care	18	
Olson, 1998 ³⁶	Braden	Acute care	19	
Serpa, 2011 ³⁸	Braden	ICU	13	
Braden, 1994 ²⁵	Braden	Long term care	18	
Defloor, 2005 ⁵	Braden	Long term care	18	Noted poor predictive value; still performed better than clinical judgment alone
Langemo, 1991 ³²	Braden	Skilled care	18	
Bergstrom, 1992 ²²	Braden	Skilled care	16 or 17	
Kim, 2009 ⁸	Braden	Surgical	14	
Lewicki, 2000 ³³	Braden	Surgical	13, 14, 20	Optimal cutoff depended on timing of risk assessment
Kim, 2009 ⁸	Cubbin and Jackson	Surgical	28	
Chan, 2009 ²⁸	Modified Braden	Acute care	19	
Defloor, 2005 ⁵	Norton	Long term care	14	Noted poor predictive value; still performed better than clinical judgment alone
Serpa, 2009 ⁴⁴	Waterlow	Acute care	17	

*Optimal cutoffs were determined based on the best balance of sensitivity and specificity or by maximizing sensitivity.

Appendix Table H10. Key Question 2: area under the receiver operating characteristic curve by baseline risk score

Study	Mean Baseline Score	Setting	AUROC	Quality Rating	Comments
Braden					
DeFloor, 2005 ⁵	17	Long-term care facilities n=1,772	0.77	Fair	
Schoonhoven, 2002 ¹³	20	Hospital inpatient n=1,229	0.55	Good	
Chan, 2009 ²⁸	Not reported	Hospital inpatient n=197	0.68	Fair	
Perneger, 2002 ¹¹	Not reported	Hospital inpatient n=1,190	0.74	Fair	
Kim, 2009 ⁸	Not reported	Hospital inpatient; ICU n=219	0.88	Fair	
Seongsook, 2004 ¹⁴	Not reported	Hospital inpatient; ICU n=112	0.71	Good	
Serpa, 2011 ³⁸	Not reported	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
Norton					
DeFloor, 2005 ⁵	14	Long-term care facilities n=1,772	0.75	Fair	
Schoonhoven, 2002 ¹³	17	Hospital inpatient n=1,229	0.56	Good	
Perneger, 2002 ¹¹	Not reported	Hospital inpatient n=1,190	0.74	Fair	
Waterlow					
Schoonhoven, 2002 ¹³	13	Hospital inpatient n=1,229	0.61	Good	
Boyle, 2001 ⁴	29	Hospital inpatient; ICU n=534	0.66	Fair	
Compton, 2008 ⁴²	Not reported	Hospital inpatient; ICU n=698	0.58	Fair	
Serpa, 2009 ⁴⁴	Not reported	Hospital inpatient n=98	0.64	Fair	1st assessment
		Hospital inpatient n=98	0.54	Fair	2nd assessment
Cubbin and Jackson					
Boyle, 2001 ⁴	33	Hospital inpatient; ICU n=534	0.72	Fair	
Kim, 2009 ⁸	Not reported	Hospital inpatient; surgical ICU n=219	0.9	Fair	
Seongsook, 2004 ¹⁴	Not reported	Hospital inpatient; surgical, internal or neurological ICU n=112	0.83	Good	

Appendix Table H11. Key Questions 3 and 4: data extraction of support surfaces trials

Author, Year Notes About Study Design, Publication Status	Setting Country	Eligibility Criteria and Exclusions	Patient Followup	Number Screened/ Enrolled/ Analyzed	Withdrawals	Loss to Followup	Intervention (Ns)	Baseline Demographics (Age, Percent Women, Race, etc.), p value
Andersen, 1982 ⁵⁴	Acute care Denmark	Patients at risk of pressure ulcer development using a simple risk score system, without existing sores	10 days	3,571/600/482	118 (prior to randomization); ~35% became ineligible during the course of the study	None	A. Alternating-air pressure mattress (n=166) B. Water mattress (camping mattress filled with lukewarm water) (n=155) C. Ordinary hospital mattress (n=166)	Mean age: NR (age reported by ranges within groups, majority >60 years) % Female: 63% vs. 56% vs. 53%

Author, Year Notes About Study Design, Publication Status	Setting Country	Eligibility Criteria and Exclusions	Patient Followup	Number Screened/ Enrolled/ Analyzed	Withdrawals	Loss to Followup	Intervention (Ns)	Baseline Demographics (Age, Percent Women, Race, etc.), p value
Aronovitch, 1999 ⁵⁵ Quasi-randomized trial (comparative, parallel study with weekly randomization)	Surgical units (cardiothoracic, ENT, urology, and vascular surgery) United States	Patients ≥ 18 years of age undergoing a scheduled surgery with general anesthesia for at least 4 hours (actual operative time of ≥ 3 hours). Excluded patients if they participated in a clinical trial within 30 days of baseline visit or if they had a pressure ulcer at baseline visit (n=4 patients excluded because they were discharged home before postop day 4). Patients removed from study if they requested discontinuation, experienced adverse event that precluded continued treatment, or if investigator felt it was not in the best interest of the patient to continue in the study	7 days or until discharge (median NR)	NR/234/217	None	None	A. Alternating pressure system intra and postoperatively (Micropulse). Micropulse is thin pad with over 2,500 small air cells in rows; 50% cells inflated at any time (n=112) B. Conventional management (gel pad in operating room and replacement mattress postoperatively) (n=105)	Mean age, years: 63.5+/-11.9 vs. 64.7+/-11.8 Age distribution: < 50 years 12.7% vs. 16.3% 50-60 years 21.8% vs. 17.3% 61-70 37.3% vs. 27.9% > 70 years 28.2% vs. 38.5% % female: 28.2% (31/110) vs. 26% (27/104) Race distribution: Caucasian 95.5% vs. 92% Black 3.6% vs. 7% Hispanic 0 vs. 1% Other 0.9% vs. 0 Mean weight, pounds: 178.7+/-40.35 vs. 168.1+/-39.79 Mean height, inches: 66.23+/-17.51 vs. 68.12+/-4.248 Smoking status: Smoker 23.8% (25/105) vs. 30.4% (21/102) Never smoked 20.0% (21/105) vs. 17.6% (18/102) Ex-smoker 56.2% (59/105) vs. 52.0% (53/102) Baseline skin risk assessment score for both groups <4 (range: 0-13) *All data not available for all patients (p=NS for all)
Berthe, 2007 ⁵⁶ Randomized trial	Hospital (medical and surgical wards) Belgium	Patients admitted for at least 24 hours, free of bed sores	Until PU incidence (median and length without PU unclear)	NR/1729/1729	0	0	A: Kliniplot foam block mattress (n=657) B: Standard hospital mattress (n=1072)	NR

Author, Year Notes About Study Design, Publication Status	Setting Country	Eligibility Criteria and Exclusions	Patient Followup	Number Screened/ Enrolled/ Analyzed	Withdrawals	Loss to Followup	Intervention (Ns)	Baseline Demographics (Age, Percent Women, Race, etc.), p value
Brienza, 2010 ⁵⁷	Nursing homes United States	Inclusion: nursing home resident, aged 65+, Braden score ≤ 18, combined Braden Activity and Mobility subscale ≤ 5, absence of ischial area PU, tolerance for daily wheel chair sitting 6+ hours, ability to accommodate seating and positioning needs with the wheelchairs selected for study use. Exclusion: body weight > 113kg, hip width > 51 cm, various wheelchair seating requirements, current use of wheelchair cushions other than segmented foam cushions (SFCs) or their equivalent or lower-quality	6 months or until PU incidence, discharge, or death (median NR)	NR/232/232	Did not receive intervention: 5.3% (6/113) vs. 3.4% (4/119) Death: 11.5% (13/113) vs. 12.6% (15/119) Voluntary withdrawal: 4.4% (5/113) vs. 5.0 % (6/119)	18.6% (21/113) vs. 17.6% (21/119)	A: Skin Protection Cushions (SPC), including Quadtro (Roho, Inc.), J2 Deep Contour (Sunrise Medical, Inc.), Infinity MC (Invacare Corporation) (n=113) B: Cross-cut 7.6cm thick, Segmented Foam Cushion (SFC) (Span-America Medical Systems, Inc., Greenville, SC) - standard care (n=119)	KiSha

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Cavicchioli, 2007 ⁵⁸	Hospitals Italy	Admission expected to last at least 2 weeks; had up to one grade I pressure ulcer Exclude: not at risk according to Braden scale; more than one pressure ulcer at study entry; prevalent pressure ulcer of grade 2 or greater	2 weeks	203 enrolled/173 analyzed		0 9 died, 12 were discharged before study completion, 9 could not tolerate interventions	A: Alternating-low- pressure option on Duo2 Hillrom mattress (n=69) B: Constant-low- pressure option on Duo2 Hillrom mattress (n=71) C: Standard mattress (n=33)	Mean age: 77 vs. 78 vs. 77 years Sex: 71% vs. 72% vs. 73% female Race: NR
Collier, 1996 ⁵⁹	Hospital United Kingdom	Patients with a low Waterlow score (low risk) were not excluded	Length of hospital stay (median NR)	NR/NR/90	9 due to one mattress manufacturer's decision to remove the mattress from the study	NR	Comparison of 8 foam mattresses: A. New Standard Hospital Mattress (Relyon) (130 mm) (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)	% women: 60% (59/99)

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Conine, 1990 ⁶⁰ Modified sequential randomized trial	Extended care facility Canada	Patients aged 18 to 55 years, with no evidence of skin breakdown for at least 2 weeks prior to the study, who were at high risk of developing pressure ulcers according to the Norton's scale (score<14). Excluded patients if their high risk status changed during the study.	3 months (median NR)	NR/187/148	Discomfort: 20% (19/93) vs. 18% (17/94) Transferred: 0 vs. 1% (1/94) Total dropouts: 22% (21/93) vs. 19% (18/94)* *includes 2 deaths in group A Note: Above patients were not included in analysis	See withdrawals	A. Alternating- pressure overlay, 10- cm air cells that alternately inflate and deflate by electronic pump (cycle time not reported, nor the make of overlay) (n=72) B. Silicore (Spenco) overlay; siliconized hollow fibers in waterproofed cotton placed over standard hospital mattress (spring or foam) (n=76) Note: Both groups received usual care (2-3 hourly turning; daily bed baths; weekly bath/shower; use of heel, ankle and other protectors)	Mean age, years (SD; range): 38.8 (13.0;19-55) vs. 35.6 (13.0;21-55) % female: 56.9%(41/72) vs. 61.8% (47/76) (p=NS for all)

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Conine, 1993 ⁶¹	Extended care facility, wheelchair cushions Canada	Patients >60 years, free of any skin breakdown for at least 2 weeks prior to study, considered to be at high risk of pressure sores (Norton score <14), sitting in wheelchair for minimum of 4 consecutive hours for normal daily activities, and free of progressive disease which could confine them to bed. Excluded patients if they had diabetes or peripheral vascular disease, if they became confined to bed during trial for >120 consecutive hours due to reasons other than pressure sores, or if their status of high risk improved.	3 months (median NR)	NR/288/248	Discomfort: 1% (2/144) vs. 1% (2/144) Transferred: 3% (4/144) vs. 2% (3/144) Score change (Norton score>15): 2% (3/144) vs. 3% (4/144) Total dropouts: 13% (19/144) vs. 15% (21/144)* *includes 10 deaths in group A and 12 deaths in group B Note: Above patients were not included in analysis	See withdrawal	A. Contoured foam cushion individually customized by seating specialist, with a posterior cut out in the area of ischial tuberosities and an anterior ischial bar (n=123) B. Slab cushion made of medium-high density polyurethane foam, bevelled at base to prevent seat sling (n=125) Note: Both cushions were covered by the identical polyester covers with laminated waterproof inside. Patients assigned to wheelchairs by institutions' personnel. All patients given equal medical, nursing, nutritional and rehabilitation care.	Mean age: 84 vs. 83.5 years % female: 79.6 (98/123) vs. 77.6% (97/125) (p>0.05 for all)

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Conine, 1994 ⁶² Modified sequential randomized trial	Extended care facility, wheelchair cushions Canada	Patients aged >60 years, assessed at high risk of pressure sores (Norton score >14), free of pressure ulcer for at least 2 weeks prior to the study, sitting in a wheelchair daily for minimum of four consecutive hours, free of any progressive disease which could confine them to bed. Excluded patients if they had diabetes, or peripheral vascular disease, became confined to bed for more than 120 consecutive hours due to reasons other than pressure ulcer, or had change in high risk status during the study	3 months (median NR)	NR/163/141	Discomfort: 1% (1/83) vs. 7% (6/80), p=0.05 Transferred: 2% (2/83) vs. 1% (1/80) Score change (Norton score>15): 4% (3/83) vs. 3% (2/80) Total dropouts: 12% (10/83) vs. 15% (12/80)* *includes 4 deaths in group A and 3 deaths in group B Note: Above patients were not included in analysis	See withdrawal	A. Jay cushion; the Jay cushion is a contoured urethane foam base with gel pad over top (n=68) B. Foam cushion; 32 kg/m3 density foam bevelled at the bottom to prevent sling effect (n=73)	Mean age 82 years % female: 85%

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Cooper, 1998 ⁶³	Acute care United Kingdom	Patients > 65 years, no existing pressure ulcers, and a Waterlow score >15	7 days	NR/100/100	16	0	A: Sofflex immersion air mattress, 2 separate air sections and a foam section for the head, larger cells (n=51) B: Roho immersion air mattress, 3 separate air sections and a foam section for the head, smaller cells (n=49) Note: Both mattress systems are constructed with flexible interconnecting air cells manufactured from neoprene and have protective covers	Mean age: 83 vs. 83 years % female: 86% (44/51) vs. 82% (40/49) Orthopedic patients
Daechsel, 1985 ⁶⁴	Long-term care Canada	Patients between 19 and 60 years old, free of skin deterioration two weeks prior to study, and considered to be high risk according to Norton Scale and independent clinical judgment	3 months	NR/32/32	0	0	A. Alternating- pressure mattress (n=16) B. Silicone-filled mattress (n=16)	Mean age: 42.6 vs. 38.5 years Sex: 37.5% (6/16) vs. 62.5% (10/16) All chronic neurologic patients

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Demarre, 2012 ⁶⁵	25 wards of 5 hospitals Belgium	Patients ≥ 18 years of age, with a Braden score of < 17 , an expected stay of ≥ 3 days Exclude: Patients with prevalent ulcers of grade II-IV, a "do not resuscitate" code, or weight less than 30 kg or more than 160 kg	2 weeks	7393 screened/796 eligible/610 enrolled	227 withdrawn prior to study completion due to transfer to another ward (37), discharge to home (81) or another institution (79), death (29) or withdrawal of consent (1)	41 lost to follow-up due to technical problems (6), discomfort (27), or reason not defined (8)	A: Alternating low- pressure air mattress with single-stage inflation and deflation (n=312) B: Alternating low- pressure air mattress with multi-stage inflation and deflation (n=298)	Mean age: 76.5 vs. 76.2 years Sex: 58% vs. 63% female Race: NR
Donnelly, 2011 ⁶⁶	Hospital (fracture trauma unit) United Kingdom	Patients aged > 65 with a hip fracture in the prior 48 hours Exclude: Existing heel pressure damage and/or a history of pressure ulcers	10.8 days (control) vs. 12.2 days (intervention)	705/239/239	12 (3 in control group and 9 in intervention group)	2 (1 in each group)	A. Heelift Suspension Boot (n=120) B. Usual care (n=119)	Mean age: 80.9 vs. 80.8 years Sex: 79.2% vs. 74.8% female Race: NR Fracture patients
Feuchtinger, 2006 ⁶⁷	Surgical unit Germany	Patients scheduled for cardiac surgery with extracorporeal circulation, aged > 18 years, not included in another study, and written informed consent obtained.	5 days	NR/175/175	None	None	A. Standard configuration; Operating room (OR) table with water filled warming mattress (n=90) B. Test configuration; OR table with water filled warming mattress and a 4-cm thermo active viscoelastic foam overlay (n=85) Note: Both tables also covered with moisture keeping disposable sheet and cotton sheet	Mean age, years (SD; range): 67.6 (10.8;33-92) vs. 68 (11;34-92) Number female: 23/90 vs. 27/85 BMI, mean (SD; range): 26.6 (4.2;18.6-40.1) vs. 27.2 (4.7;19.1- 48.2) (p > 0.05 for all) Cardiac surgery patients

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Gebhardt, 1996 ⁶⁸ Cluster trial	Intensive care unit United Kingdom	Patients with Norton score <13 who had been in the unit for <3 days and had no sores. Excluded patients if condition improved so that Norton score >12 and no sore was present, if they were discharged or transferred to another ward or hospital, or if they died	Mean followup: 11 vs. 12 days	NR/52/43	Transferred or died before 2nd assessment: n=2 vs. n=3 Note: Above 5 patients plus 4 used to trial equipment were not included in analysis Note: n=6 deaths per group during trial	None	A. Alternating- pressure air mattress (shallow small cell overlays, medium depth large cell overlays, and deep mattresses) (n=23) B. Static support surfaces (foam mattresses/overlays, fiber-, air-, gel-, water-, and bead- overlays) (n=20) C. Low-air-loss mattresses (n=7, but grouped in with static support surfaces)	Mean age (range), years: 55 (23- 83) vs. 60 (21-83) % female: 47.8% (11/23) vs. 35% (7/20)
Geyer, 2001 ⁶⁹ Pilot randomized trial	Nursing homes United States	Residents >65 years with Braden score <18, combined Braden Activity and Mobility subscale score of <5, an absence of sitting- surface pressure ulcers, tolerance for total daily wheelchair sitting time >6 hours and sitting needs that could be accommodated by the ETAC Twin wheelchair (including body weight <250 lbs)	Mean days to endpoint 99.9 vs. 76.3 days	NR/32/32	Transferred or discharged: n=2 vs. n=3 Note: one subject per group died during study Note: all participants included in ITT analysis	See withdrawals	A. Pressure-reducing wheelchair cushion and fitted incontinence cover. No single make of cushion specified, rather this could be selected by the nurse from a group of cushions based on the participants' clinical status (n=15) B. Generic 3-inch convoluted foam (eggcrate) cushion (Bioclinic Standard, Sunrise Medical), fitted incontinence cover, and solid seat insert (n=17)	Mean age: 85.2 vs. 84.1 years % female: 93.3% (14/15) vs. 94% (16/17) p=NS for all

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Gilcreast, 2005 ⁷⁰	Military tertiary-care academic medical centers United States	Patients with Braden score <14, and able to read and write English (or surrogate able). Excluded patients with hip surgery, patients anticipated to be admitted for < 72 h, patients (or surrogates) unable to provide informed consent, and patients with preexisting pressure ulcer on foot or foot deformity. Hospital discharge, changes in enrollment criteria (i.e. Braden score >14) resulted in ending subjects participation in study. Occurrence of pressure ulcer also ended enrollment.	Mean time in study 7.5 days (SD 7.4)	5475/338/240	15% (36/240) said they no longer wanted to participate after 48 hours in the study	35% (84/240) ended study because they were discharged, 24% (57/240) no longer met study criteria, 15% (36/240) said they no longer wanted to participate after 48 hours in the study, 13% (32/240) died and 5.0% (12/240) developed pressure ulcers	A. Bunny Boot (fleece) high cushion heel protector (n=77) B. Egg crate heel lift positioner (holds the foot suspended above the bed surface with heel through a window) (n=87) C. Foot waffle air cushion (felt coated plastic inflatable plastic pillow that encircles the foot) (n=76) Note: Nurses added pillows to the bunny boot group	Mean age (SD; range), years: 63.9 (19.94;18-97) % female: 42% (101/240), p=.008; Race: 68% (163/240) White, 15.4% (37/240) Black, 16.3% Hispanic (39/240), 1% (1/240) Asian

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Goldstone, 1982 ⁷¹	Hospital United Kingdom	Patients aged >60 y who arrived in the accident and emergency department with a suspected femur fracture	Unclear	NR/NR/75 Patients who did not suffer a fracture, or who requested to be removed from the intervention mattress, or who died before reaching the post operative ward were excluded from the analysis	NR	NR	A. Beaufort bead bed system overlay, renamed as "Neumark- Macclesfield Support System" (includes polystyrene bead- filled mattress on A&E trolley; bead- filled operating table overlay; bead-filled sacral cushion for operating table; bead-filled boots to protect heels on operating table (n=32) B. Standard supports in A&E, operating room, ward (n=43)	Age: >60 y % women: 90.6% and 83.7% Fracture patients
Gray, 1994 ⁷²	Hospital United Kingdom	Patients were recruited from the following specialties: orthopaedic trauma, vascular and medical oncology. To be included, patients had to be assessed using the Waterlow Score and have a score >15 (high risk) and were required to have intact skin on admission	10 days	NR/NR/170	NR	NR	A. Softform mattress (n=90) B. Standard 130 mm NHS foam mattress (n=80)	Mean age: 76 vs. 74 years % women: 63.3% vs. 58.8% p=NS for all

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Gray, 2000 ⁷³	Surgical, orthopedic, and medical wards United Kingdom	Emergency or list admission for bed rest or surgery, less than 353 lbs, skin intact, no existing skin conditions, no terminal illness	10 days	NR/100/98	0	2 (post- randomization exclusions due to torn mattresses)	A. Transfoamwave pressure-reducing mattress - trial (n=50) B. Transfoam pressure-reducing mattress (n=50)	Mean age: 69 vs. 61 years % women: 40% vs. 38%
Gunningberg, 2000 ⁷⁴	Hospital, surgery Sweden	Patients aged over 65 years with a suspected hip fracture on arrival in assessment and emergency (A&E)	Until discharge, or 14 days postoperative	119/101/101	None	None	A: Visco-elastic foam mattress (A&E 10cm; Ward 7cm) (n=48) B: Standard mattress (A&E 5cm; Ward 10cm) (n=53) Note: While all patients received standard prevention protocols, those with grade I pressure ulcers in the usual care group received more preventive interventions than those in the intervention group (confound); results not reported for other pressure ulcer grades so unknown	Mean age: 84 years vs. 85 years % women: 79% vs. 81% p=NS for all Fracture patients
Hampton, 1999 ⁷⁵	Hospital United Kingdom	Patients without pressure damage, with a Waterlow score of less than 25	NR (study ran 6 months, but no comment on length of stay)	407 enrolled	NR	NR	A. Stepped approach on Thermo contour foam mattress (step 1) or an air mattress (step 2) (n=199) B. Stepped approach with usual care (step 1) or an air mattress (step 2) (n=208)	Mean age: 70 vs. 67 years Sex: NR Race: NR

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Hofman, 1994 ⁷⁶ Randomized trial, stopped early	Surgery Netherlands	Patients with femoral neck fracture and concomitant high risk (score >8 per 1985 Dutch consensus meeting criteria) for the development of pressure sores. Patients with existing pressure sores of > grade 2 were excluded.	Post- operative period of 14 days	46/44/42 at week 1; 36 at week 2 2 excluded due to inadequate randomization	3 deceased; 5 discharged	None	A. Cubed foam mattress (Comfortex DeCube mattress) - allows removal of small cubes of foam from beneath bony prominences (n=21) B. Standard hospital mattress, polypropylene SG40 hospital foam mattress (n=23)	Age: 85.0 years vs. 83.9 years % women: 76.2% (16/21) vs. 95.7% (22/23) p=NS for all Fracture patients
Hoshowsky, 1994 ⁷⁷ Quasi- experimental study	Surgery United States	Patients from weekday operative schedule of a large university teaching hospital. Placement in the supine or prone positions while undergoing surgery, older than 12 years of age, and possession of symmetrical lower limbs	Post- operative	NR/NR/505 people (1,010 legs)	None	None	Six combinations of the below mattresses using patients right and left heels or knees as controls; each person served as their own control: - Standard vinyl covered 2-inch thick foam OR table mattress (SFM) - Nylon fabric covered 2-inch thick foam and gel OR table mattress (FGM - Akros®, American Sterilizer Co.) - Viscoelastic dry polymer mattress overlay (VEO- Action®, Action Products Inc.) A. SFM vs. FGM (n=91) B. VEO above SFM vs. FGM (n=92)	Mean age: 47 years (17.1 SD) % women: 63.6% (321/505) Preexisting vascular disease: 6.3% (32/505) Preexisting hypertension: 20.4% (103/505) Preexisting diabetes mellitus: 7.5% (35/505) Current smokers: 23.8% (120/505) Past smokers: 2.4% (12/505)

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							C. SFM vs. VEO above FGM (n=62) D. VEO above SFM vs. VEO above FGM (n=113) E. SFM vs. VEO above SFM (n=73) F. FGM vs. VEO above FGM (n=74)	
Inman, 1993 ⁷⁸	Intensive care Canada	Critically ill patients admitted to the Critical Care Trauma Centre of Victoria Hospital, London, Ontario from March 1989 to November 1990. Eligible patients were >17 years of age, had an admission Acute Physiology and Chronic Health Evaluation II (APACHE II) score >15, and had an expected stay in the ICU of at least 3 days. Excluded patients with myocardial infarction, vascular and cardiac surgery, and drug overdoses	18.8+18.1 days vs. 15.4+13.9 days	NR/NR/100	None	None	A. Air suspension bed, (KinAir, Kinetic Concepts, Inc, San Antonio, Texas); smooth, low-friction, low shear surface with a high moisture vapor transmission rate; each section of the bed has separate air-controlled settings (n=49) B. Standard ICU bed (undefined), plus repositioning every 2 hours (n=49)	Age: 63.4+14.4 years vs. 65.4+13.9 years % women: 40.8% (20/49) vs. 55.1% (27/49)

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Jesurum, 1996 ⁷⁹ Quasi- experimental pilot study	Hospital United States	Adult cardiovascular surgery patients with intra-aortic balloon pump	Post- operative period	NR/NR/39	0	5 eligible patients missed due to protocol breach	A. Low-air-loss mattress, 16 compartmentalized, separately controlled air sacs with a nylon quilted fabric cover (n=16) B. Standard foam mattress (n=20)	Mean age: 67 vs. 69 years % 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

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Jolley, 2004 ⁸⁰ Open label randomized trial	Hospital Australia	Patients admitted to hospital during study period at low to moderate risk of developing a pressure ulcer on Braden scale. Excluded patients if they were assessed at "no risk" (requiring no intervention) or "high risk" (requiring more complex intervention), had any pre-existing ulcer, were <18 years old, had expected length of stay <48 hours, had darkly pigmented skin, making Stage 1 ulcer difficult to detect	7-7.9 days average	~1900/539/441	14/270 vs. 8/269 requested withdrawal after receiving intervention; 0 vs. 2 withdrew before receiving intervention Note: 10 patients in group A complained about discomfort and requested removal of sheepskin The following were followed up and included in analysis: 178/218 vs. 194/223 discharged; 2/218 vs. 5/223 died; 7/218 vs. 1/223 became high risk; 6/218 vs. 5/223 ward staff intervention; 11/218 vs. 10/223 other reason (e.g. Incontinence)	52/270 vs. 46/269 were randomized but did not receive intervention Note: Above were not included in analysis	A. Sheepskin mattress overlay: leather-backed with a dense, uniform 25 mm wool pile. Used as a partial mattress overlay. Pressure points that were not covered by sheepskin were protected by a second sheepskin, or specific sheepskin elbow and heel protectors. Overlays were changed 3 times a week (unless required). Received usual care including repositioning (n=218) B. Usual care as determined by ward staff. Included repositioning and any other PRD or prevention strategy with/without low-tech constant pressure relieving devices (n=223)	Mean age (range), years: 63.2 (18-97) vs. 61.1 (18-99) % female: 49% vs. 52% Note: Groups differed substantially by admission type with more emergency admissions in group A, but did not differ on other baseline demographic and clinical characteristics

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Kemp, 1993 ⁸¹	Hospital and long-term care United States	Patients without pressure ulcers, at least 65 years old, with Braden score <16 (increased likelihood of developing pressure ulcer)	1 month	994/84/84	None	None	A. Convoluted foam overlay, 3 or 4 inches thick, depending on acute care or long- term care setting (n=45) B. Solid foam overlay, 4 inches thick, sculptured (n=39) Note: Standard nursing practice was to reposition patient every 2 hours if at risk of pressure ulcers and to apply moisture repelling ointments to protect skin of incontinent patients. Hospital setting used disposable under pads for incontinent patients while long term facility used reusable cloth under pads	Mean age (SD), years: 79.31 (7.54) vs. 82.64 (8.60) % women: 68.8% (31/45) vs. 93.1% (27/29) Race: 23/45 vs. 22/39 black, 21/45 vs. 17/39 white, 1/45 vs. 0/39 Hispanic p=NS for all

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Keogh, 2001 ⁸²	Hospital United Kingdom	Patients age >18 years, with a Waterlow score of 15-25, no tissue damage greater than grade I, and expected to stay in bed at least 12 hours/day Exclude: Patients with terminal illness, weighing more than 120 kg, or posing a manual-handling risk	Mean follow- up: 7.4 vs. 6.8 days	100 eligible/70 randomized	30 recruited patients excluded due to stays <5 days (13), Waterlow score exceeding 25 (2), discharged or transferred (10), or refused to complete questionnaire (5)	0	A: Non-profiling standard hospital bed with variety of pressure relieving/reducing mattresses (alternating air [n=10] or foam [n=25]) (n=35) B: Electrically operated, four- sectioned profiling bed with foam (Pentaflex) pressure relieving/reducing mattress (n=35)	Mean age: 71 vs. 69 years Sex: 60% vs. 30% female Race: NR
Lazzara, 1991 ⁸³	Nursing homes United States	Residents determined to be at risk for pressure ulcer development	6 months	74 enrolled	0	2 refused to give consent, 19 died *Numbers do not add up	A: Gel mattress (n=33) B: Air-filled overlay (n=33)	NR

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Lim, 1988 ⁸⁴	Extended care facility Canada	Residents >60 years, free of any pressure ulcer for at least 2 weeks prior to the study, considered to be at high risk for developing ulcers (Norton Scale <14), using a wheelchair for >3 hours daily. Excluded residents if they had a progressive disease that could confine them to bed or if they became confined to bed for >120 consecutive hours due to reasons other than pressure ulcer	5 months	NR/62/52	n=1 in group A refused to continue Note: patient was not included in analysis	n=1 in group B transferred Note: 8 deaths during trial (2 in group A, 6 in group B) Note: Above were not included in analysis	A. Contoured foam cushion, cut into a customized shape to relieve pressure on ischial tuberosities (n=26) B. Foam slab cushion, 2.5 cm medium density foam glued to 5 cm firm chipped foam (n=26) Note: Both groups also received usual care	Mean age (SD; range), years: 83.0 (7.7;65-103) vs. 84.6 (8.2;70-104) % female: 76.9% (20/26) vs. 69.2% (18/26) p=NS for all

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McGowan, 2000 ⁸⁵	Hospital (orthopedic wards) Australia	Patients aged >60 years, admitted with an orthopedic diagnosis, assessed at low or moderate risk of developing a pressure ulcer on the Braden scale, patient or significant other able to give informed consent. Excluded patients if patients assessed as no risk (requiring no intervention) or high risk (requiring more complex intervention) for developing pressure ulcers, patients with pre- existing pressure ulcer, non-English speaking patients (unless interpreter present), patients with anticipated stay <48 hours, colored skin patients where stage 1 ulcer detection is difficult	Post- operative period until discharge	NR/297/290 (unclear)	n=2 (one from each group) withdrew prior to data collection; n=6 in group A withdrew before completion of data collection due to discomfort; n=7 in group B vs. n=3 in group A withdrawn due to protocol violations Note: above included in ITT analysis	See withdrawals	A. Australian Medical Sheepskin overlay; sheepskin heel and elbow protectors as required on top of standard hospital mattress and sheet. Sheepskins were changed as required (at least every 3 days) (n=155) B. Standard hospital mattress and sheet with or without other low tech constant pressure devices as required (n=142)	Mean age: 73.6 vs. 74 years % female: 54% (83/155) vs. 61% (87/142) Note: More patients in Group A were male and more were admitted for total knee replacement compared to Group B Orthopedic patients

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Mistiaen, 2010 ⁸⁶	Long-term care facility Netherlands	Newly admitted to one of eight nursing homes for primarily physical impairments, age ≥ 18 years, expected stay > 1 week, free of PU on sacrum Exclusion: darkly pigmented skin, allergy to wool, admitted for a primarily psycho- geriatric reason	30 days	1066/588/543	NR	8.1% (24/295) vs. 7.2% (21/293)	A. Australian Medical Sheepskin on top of the mattress in the area of the buttocks (n=271) B. Control (n=272) Note: Both groups received usual care (includes all other pressure-reducing interventions; varied per group)	Mean age: 78 (26-97) years vs. 78 (27-98) years % women: 71% vs. 67% (p=NS for all) Somatic nursing home patients 40.5% cardiovascular disease 38% fracture patients

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Nixon, 1998 ⁸⁷	Hospital United Kingdom	Patients scheduled for elective major general, gynecological, or vascular surgery, >55 years old and position to be supine or lithotomy. Excluded patients with pressure damage of > Grade 2a pre-operatively, ward staff provision of pre-operative alternating pressure mattress, dark skin pigmentation which precludes reliable identification of Grade 1 and Grade 2a skin assessments, and skin conditions over the sacrum, buttocks, or heels which preclude reliable identification of Grade 1 and Grade 2a skin assessments	8 days	720/446/416	30	30	A. Dry visco-elastic polymer pad (torso area and heels) on standard operating table mattress (n=222) B. Standard operating table mattress plus heel support (Gamgee pad) (n=224) Note: Both groups received usual care (warming mattress)	Aged 55-69: 56% (124/222) vs. 57% (128/224) Aged >70: 44% (98/222) vs. 43% (96/224) % women: 45% (101/222) vs. 48% (107/224) <90 min operation: 23% (50/222) vs. 18% (40/224) 90-179 min operation: 49% (108/222) vs. 49% (110/224) >180 min operation: 28% (62/222) vs. 33% (73/224) p=NR

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<p>Nixon, 2006⁸⁸ RCT</p> <p>Same data as in Nixon, 2006 Health Technology Report</p>	<p>Hospital United Kingdom</p>	<p>Aged ≥ 55 years; admitted to vascular orthopaedic, medical, or care of elderly wards; expected length of stay \geq seven days; limited mobility or activity or an existing grade 2 pressure ulcer. Elective surgical patients without limitation of activity or mobility also included if average length of stay for their type of surgery ≥ 7 days or expected Braden activity or mobility scores of 1 or 2 for at least 3 days post- operatively Exclude: pressure ulcers of grade 3 or greater; planned admission to intensive care after surgery; admitted to hospital >4 days prior to surgery; slept at night in a chair; or weighed more than 140 kg or less than 45 kg</p>	<p>60 days</p>	<p>6,155 screened/1,972 randomized/1,971 analyzed</p>	<p>1 patient randomized twice</p>	<p>6.6% (66/990) vs. 5.2% (51/982)</p>	<p>A: Alternating- pressure overlay (n=990) B: Alternating- pressure mattress (n=982)</p>	<p>Mean age: 75.4 vs. 75.0 years Sex: 63.1% vs. 64.8% female Race: NR</p>

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Russell, 2000 ⁸⁹	Hospital and Surgery Canada	Patients > 18 years, undergoing cardiothoracic surgery under general anesthesia, surgery of > 4 hours duration, and free of pressure ulcers	7 days	NR/198/198	2	None	A. MicroPulse system (multi-cell dynamic mattress) in the OR and postoperatively (n=98) B. Conventional care (gel pad in OR, standard mattress postoperatively) (n=100)	Mean age: 65.2 (10.9 SD) vs. 65.2 (10.6 SD) % women: 23.5% (23/98) vs. 25% (25/100) Smoker: Never 37.1% (36/98) vs. 33.3% (33/100), Past 45.4% (44/98) vs. 51.5% (51/100), Current 17.5% (17/98) vs. 15.2% (15/100) Race: Caucasian 94.9% (93/98) vs. 87.0% (87/100), African- American 0 vs. 1.0% (1/100), Asian 2.0% (2/98) vs. 2.0% (2/100), Hispanic 0 vs. 3.0% (3/100), Other 3.1% (3/98) vs. 7.0% (7/100) Mean hours in surgery: 4.1 (1.0 SD) vs. 4.2 (1.1 SD) p=NR for all Cardiovascular surgery patients
Russell, 2003 ⁹⁰	3 hospitals United Kingdom	Patients aged ≥65 years, with a Waterlow score of 15 to 20 Exclude: Patients weighing >155 kg	Median follow-up: 12 vs. 11 days	1168 enrolled/1166 analyzed	2 excluded post- randomization due to placement on incorrect mattress	0	A: Standard hospital mattress (primarily King's Fund, Linknurse, Softfoam, or Transfoam) (n=604) B: Viscoelastic and polyurethane foam (CONFOR-Med) mattress (n=562)	Median age: 83 years Sex: 67% female Race: NR

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Sanada, 2003 ⁹¹	Hospital Japan	Braden score < 16, bed bound, free of pressure ulcers at study admission, and required head elevation	Unclear	123/108/82	41	NR	<p>A. Double-layer air cell overlay (Tri cell): two layers consisting of 24 narrow cylinder air cells, cell pressure alternated at 5 minute intervals (n=37)</p> <p>B. Single-layer air cell overlay (Air doctor): single layer consisting of 20 round air cells, cell pressures alternated at 5 minute intervals (n=36)</p> <p>C. Standard hospital mattress (Paracare) (n=35)</p> <p>Notes: All groups had change of body position every 2 h, and special skin care to guard against friction and shear. Nutritional intervention was given where required</p>	<p>Mean age: 69.5 (14.7 SD) vs. 73.9 (10.4 SD) vs. 70.6 (10.7 SD), p=NS</p> <p>% women: 51.7 (15/29) vs. 42.3 (11/26) vs. 51.9 (14/27), p=NS</p> <p>All patients required head elevation, including stroke patients, recovering from surgery, and terminally ill</p>

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Schultz, 1999 ⁹²	Operating room United States	Patients scheduled for inpatient care, >18 years old, with surgery scheduled to last longer than 2 hours in the lithotomy or supine position. Excluded patients with an existing pressure ulcer, patients with severe chronic skin problems, or patients receiving only local anesthesia.	6 days	NR/NR/413	None	None	A. Experimental mattress overlay in operating room made of foam with a 25% indentation load deflection (ILD) of 30 lb and density of 1.3 cubic feet (n=206) B. Standard perioperative care (padding as required, including gel pads, foam mattresses, ring cushions [donuts] etc.) (n=207)	Mean age: 65.68 (11.66 SD) vs. 65.73 (12.87 SD) % women: 35.4% (73/206) vs. 35.7% (74/207) BMI: 27.06 (4.97 SD) vs. 27.03 (4.51 SD) Smoker: Never 26.2% (54/206) vs. 24.6% (51/207), Past 49.5% (102/206) vs. 52.2% (108/207), Current 23.3% (48/206) vs. 22.2% (46/207) Diabetes: 21.8% (45/206) vs. 24.1% (50/207) (p=NS for all) Without pressure ulcers vs. with pressure ulcers: No significant difference for patient type (same day admit vs. inpatient), gender, smoking status, preoperative albumin levels, OR time, or time to first position change.
Sideranko, 1992 ⁹³	Surgical intensive care unit United States	Patients with surgical ICU stay >48h, presence of ventilatory support or some form of hemodynamic support on admission to surgical ICU. Exclude any evidence of existing skin breakdown upon admission to the surgical ICU.	Mean followup: 9.4 days	NR/NR/57	NR	NR	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)

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Stapleton, 1986 ⁹⁴	Hospital United Kingdom	Female patients aged >65 years with fractured femur, without existing pressure ulcers, with a Norton score of <14	Unclear	NR/100/98	2	2	A. Large Cell Ripple (canvas or plastic) pads ("Talley") (n=32) B. Polyether foam pad 2 feet x 2 feet x 3-inch thickness (n=34) C. Spenco pad (n=34) Note: these materials were all already in use, but not systematically	Mean age: 60 years vs. 63 years % female: 43% vs. 32% Acute respiratory organ failure patients
Takala, 1996 ⁹⁵	Hospital Intensive care unit Finland	Admitted to hospital with expected stay in ICU exceeding five days Exclude: patients with accidental injuries	14 days	1,489/40/24	0	16 (10 patients excluded due to early discharge or death, 6 patients excluded due to unavailable intervention mattress)	A. Carital Air-float System (Carital Optima, Carital Ltd.): constant, static low pressure mattress comprising 21 double air bags (one inside the other), which can be adjusted for the head, middle, and feet areas (n=21) B. Standard hospital foam mattress: 10 cm thick foam density 35 kg/m3 (n=19)	Mean age: 60 years vs. 63 years % female: 43% vs. 32% Acute respiratory organ failure patients

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Taylor, 1999 ⁹⁶	Hospital United Kingdom	Inpatients aged >16 years, with intact skin, requiring a pressure-relieving support, and expected hospital stay of >7 days	Mean days: 10.5 vs. 11.6 days	NR/44/44	None	None	A. Alternating air pressure mattress (Pegasus Trinova), 19 cells that inflate and deflate in a 3-cell cycle over a 7.5 minute period; along with alternating air pressure redistributing chair cushion, 4 cells inflating and deflating over a 7.5 minute cycle (n=22) B. Alternating air pressure system (unnamed), cells inflating and deflating over a 10 minute cycle - control (n=22)	Mean age: 66.50 (2.20 SD) vs. 70.27 (2.73 SD), p=NS % women: 45.5% (10/22) vs. 40.9% (9/22), p=NS
Theaker, 2005 ⁹⁷	Hospital, Intensive care United Kingdom	Patients in ICU aged > 18 years, deemed at high risk of pressure ulcer development (based on 5 factors, no details provided). Excluded those with pressure sores on admission and those transferred from hospitals or other ward areas and had been nursed on a pressure-relieving device other than the control mattress	14 days	68/62/62	None	None	A. KCI TheraPulse pulsating air suspension mattress (n=30) B. Hill-Rom Duo, constant low pressure or alternating-air options in same mattress (n=32) Note: Both consist of cells that are connected to a pump that inflate and deflate either a at a 5-10 minute time cycle or continuously	Mean age: 53 (range: 38-75) vs. 57 (range: 35-77) vs. 59 (range: 26-80) vs. 66 (range: 30-85) % women: 33% (10/30) vs. 41% (13/32)

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Tymec, 1997 ⁹⁸	Hospital United States	Patients of select nursing units, with a Braden score <16 and intact skin on the heels	Unclear	NR/NR/52	NR	NR	A. Foot Waffle ([EHOB Inc.] FDA approved, non- abrasive vinyl boot with built-in foot cradle and inflated air chamber). B. Hospital pillow under both legs from below knee to the Achilles tendon (n=52 total)	Mean age: 66.6 (16.5 SD) years % women: 44% (23/52) Race: 61% (32/52) African American, 37% (19/52) Caucasian, 2% (1/52) Asian
van Leen, 2011 ⁹⁹	Long-term care nursing facility Netherlands	Patients aged > 65 years, living in the nursing home with a Norton score < 13 Exclude: Pressure ulcer in the previous 6 months	6 months	NR/83/83	9 (died, 5 in cold foam group and 4 in the static air group, for reasons not related to the study [none developed ulcers])	None	A. Static air overlay on top of cold foam mattress (n=41) B. Standard cold foam mattress - control (n=42) Note: Repositioning was only begun when signs of developing a pressure ulcer of >grade 2 occurred	Mean age: 81.1 vs. 83.1 years % women: 78.6% vs. 82.9% p=NS for all Dementia: 73.8% vs. 75.6%

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Vanderwee, 2005 ¹⁰⁰	7 Hospitals Belgium	Patients aged >18 years, with an expected stay of ≥ 3 days, no grade II or greater pressure ulcers, no contraindication for turning, body weight <140 kg, and in need of pressure ulcer prevention (judged by Braden score <17 or presence of non- blanchable erythema)	20 weeks	2608 screened/570 eligible/447 enrolled	0	0	B: Alternating- pressure mattress (n=222) A: Viscoelastic foam mattress and repositioning every 4 hours (n=225)	Mean age: 81 vs. 82 years Sex: 61% vs. 66% female Race: NR

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Vyhldal, 1997 ¹⁰¹	Skilled nursing facility United States	Patients newly admitted to the skilled nursing facility with an estimated stay of at least 10 days, free of existing pressure ulcers, at- risk for pressure ulcer development (Braden score <18 with a subscale score of <3 in sensory perception, mobility, or activity levels)	10-21 days	492/40/40	None	None	A. MAXIFLOAT (BG Industries, Northridge, CA), a foam replaceable parts mattress with 4 primary parts: a water repellent antibacterial cover, a 1.5-inch thick 2.4 lb antimicrobial foam dual indentation force load deflection, a foam center core with heel pillow, and waterproof antibacterial bottom cover (n=20) B. IRIS 3000 (Bio Clinic of Sunrise Medical Group, Ontario, CA), a 4- inch thick 1.8 lb foam overlay with a dimpled surface (n=20) Note: Subjects in both groups received standards of care according to the protocols of the organization	Mean age: 74.3 vs. 80.2 years, p=0.19 % women: 55% (11/20) vs. 55% (11/20), p=1.0 Most common admitting diagnoses: musculoskeletal 45%, cardiovascular disease 27.5%

Author, Year Notes About Study Design, Publication Status	Baseline Ulcer Risk Score, p- value	Risk Level, Per General Cutoffs*	Baseline Pressure Ulcers, Defined as ≥10% of Population? (Y/N/unclear)	Results - Incidence and Characteristics (Number patients with Ulcers or Number Ulcers, varies)	Results – Severity (Number Patients with Ulcers or Number Ulcers, varies)	Results – Resource Utilization	Harms	Quality	Funding Source
Andersen, 1982 ⁵⁴	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	At risk	No	Incidence (number pressure ulcers): 4.2% (7/166) vs. 4.5% (7/155) vs. 13.0% (21/161), p<0.01 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	NR	Poor	NR

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Aronovitch, 1999 ⁵⁵ Quasi-randomized trial (comparative, parallel study with weekly randomization)	Modified Knoll Risk Scores for both groups: <4 (range 0-13) Modified Knoll Risk Assessment Tool ranges from 0-33, with a score of >12 indicating a greater risk for the development of alternations in skin integrity	Low risk	No	Incidence: 1% (1/112) vs. 7% (7/105); p<0.005 Note: For patients that developed ulcers in group B vs. group A, there was significant differences between groups on vascular surgery (p=0.02), previous history of pressure ulcer (p=0.02) and age (p=0.03). Significant difference in incidence of pressure ulcers between groups, even when these factors were controlled (p=0.04). Note: Analysis with only vascular surgery patients, controlled for age and baseline skin assessment and looking at type of device, found a statistical significance associated with device and presence of pressure ulcers (p=0.023)	Severity: 7 patients in group B only developed 11 pressure ulcers (stage of 6 of these could not be determined because of eschar) Grade 1: 1 Grade 2: 4	NR	NR	Poor	Partially funded by an educational grant from MicroPulse

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Berthe, 2007 ⁵⁶ Randomized trial	Modified Ek score: 1: 42 vs. 47, 2: 54 vs. 71, 3: 96 vs. 149, 4: 465 vs. 805. No significant differences between groups	Low risk	No	Incidence of pressure ulcers: 3.2% (21/657) vs. 1.9% (21/1072); RR = 1.63, 95% CI 0.90-2.96)	NR	NR	NR	Poor	NR
Brienza, 2010 ⁵⁷	Mean Braden score: 15.4 (SD ± 1.4) vs. 15.5 (SD ± 1.5)	At risk	No	Incidence (number ischial tuberosity pressure ulcers): 0.9% (1/113) vs. 6.7% (8/119), p=0.04, 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	NR	Fair	Eunice Kennedy Shriver National Institute on Child Health and Human Development Grant

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Cavicchioli, 2007 ⁵⁸	All had Braden score <17 Both treatment groups at greater risk than control (p<0.001)	High risk	Baseline ulcers: 8.7% (6/69) vs. 4.2% (3/71) vs. 18% (6/33)	Any pressure ulcer: 2.1% (3/140) vs. 36% (12/33); RR 17 (95% CI 5.1 to 57) Alternating low pressure vs. constant low pressure, in patients randomized to Duo2 Hill-Rom mattress Any pressure ulcer: 2.9% (2/69) vs. 1.4% (1/71); RR 2.1 (95% CI 0.19 to 22)	Stage 1 ulcer: 0.7% (1/140) vs. 36% (12/33); RR 0.02 (95% 0.003 to 0.15) Stage 2 or 3 ulcer: 1.4% (2/140) vs. 0% (0/33); RR 1.2 (95 CI 0.06 to 24)	NR	NR	Poor	Hill-Rom provided the intervention surfaces
Collier, 1996 ⁵⁹	Waterlow score range: 3 to 25	Various risk levels	Unclear, but appears prevention is the intention of the study	Incidence: No patients developed a pressure ulcer of any grade during the study	Not relevant	NR	NR	Poor	NR
Conine, 1990 ⁶⁰ Modified sequential randomized trial	Conine, 1990 ⁶⁰ Modified sequential randomized trial	At risk	No	Incidence: 133 ulcers in 54% (39/72) patients in group A vs. 148 ulcers in 59% (45/76) patients in group B, p=NS RR = 0.91, 95% CI 0.69-1.21	Severity: Grade 1: 64% (95/133) vs. 41% (91/148) Grade 2: 12% (15/133) vs. 13% (19/148) Grade 3: 24% (33/133) vs. 14% (36/148) Grade 4: 0 vs. 1% (2/148) (p=NS for all)	NR	NR	Poor	British Columbia Health Care Research Foundation

Author, Year Notes About Study Design, Publication Status	Baseline Ulcer Risk Score, p- value	Risk Level, Per General Cutoffs*	Baseline Pressure Ulcers, Defined as ≥10% of Population? (Y/N/unclear)	Results - Incidence and Characteristics (Number patients with Ulcers or Number Ulcers, varies)	Results – Severity (Number Patients with Ulcers or Number Ulcers, varies)	Results – Resource Utilization	Harms	Quality	Funding Source
Conine, 1993 ⁶¹	Mean Norton score at baseline: 11.5 vs. 12.1	At risk	No	Incidence: 175 sores in 84/123 patients vs. 184 sores in 85/125 patients, p=NS RR = 1.0, 95% CI 0.84-1.18	Severity: Grade 1: 57% (105/184) vs. 56% (98/175) Grade 2: 24% (45/184) vs. 27% (48/175) Grade 3: 17% (32/184) vs. 15% (27/175) Grade 4: 1% (2/184) vs. 1% (2/175) p=NS	NR	NR	Fair	Department of Health and Welfare Canada National Health Research and Development Program Grant
Conine, 1994 ⁶² Modified sequential randomized trial	Mean Norton score of patients at baseline: 12	At risk	No	Incidence (3 patients): 30/73 vs. 17/68, RR = 0.61, 95% CI 0.37- 1.00; p=0.049	Severity: Grade 1: 77% (20/26) vs. 57% (24/42) Grade 2: 11.5% (3/26) vs. 29% (12/42) Grade 3: 11.5% (3/26) vs. 14% (6/42) p=NS Grade 2 or 3: 8.8% (6/73) vs. 26% (18/68); RR 0.36, 95% CI 0.15 to 0.85	NR	Withdrawals due to discomfort: 8% (6/80) vs. 1% (1/83); RR 6.23, 95% CI 0.77 to 50.56	Fair	NR

Author, Year Notes About Study Design, Publication Status	Baseline Ulcer Risk Score, p- value	Risk Level, Per General Cutoffs*	Baseline Pressure Ulcers, Defined as ≥10% of Population? (Y/N/unclear)	Results - Incidence and Characteristics (Number patients with Ulcers or Number Ulcers, varies)	Results – Severity (Number Patients with Ulcers or Number Ulcers, varies)	Results – Resource Utilization	Harms	Quality	Funding Source
Cooper, 1998 ⁶³	Waterlow score on admission: 17 vs. 16	At risk	No	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	NR	Poor	Raymar research grant
Daechsel, 1985 ⁶⁴	Mean Norton score: 13.4 vs. 13.0	At risk	No	Incidence: 25% (4/16) of patients developed 5 ulcers vs. 25% (4/16) of patients developed 5 ulcers, p=NS RR = 1.0, 95% CI =0.30-3.32; p=NS	Severity: Mean Extton-Smith scores: 2.25 (0.82 SD) vs. 2.75 (0.74 SD), p=0.39	NR	NR	Poor	Gaymar Industries; Pearson Hospital
Demarre, 2012 ⁶⁵	Median Braden score: 14 vs. 14 Grade I ulcer at baseline: 15.4% (48/312) vs. 15.4% (46/298)	High	Grade I ulcer at baseline: 15.4% (48/312) vs. 15.4% (46/298)	Pressure ulcer grade II-IV: 5.8% (18/312) vs. 5.7% (17/298); RR 1.01 (95% CI 0.53-1.92); p=0.97 Pressure ulcer grade I: 12.2% (38/312) vs. 17.1% (51/298); RR 0.71 (95% CI 0.48-1.05); p=0.08	NR	NR	Discontinued intervention due to discomfort: 5.1% (16/312) vs. 3.7% (11/298)	Fair	Hill-Rom provided the intervention surfaces; Ghent University

Author, Year Notes About Study Design, Publication Status	Baseline Ulcer Risk Score, p- value	Risk Level, Per General Cutoffs*	Baseline Pressure Ulcers, Defined as ≥10% of Population? (Y/N/unclear)	Results - Incidence and Characteristics (Number patients with Ulcers or Number Ulcers, varies)	Results – Severity (Number Patients with Ulcers or Number Ulcers, varies)	Results – Resource Utilization	Harms	Quality	Funding Source
Donnelly, 2011 ⁶⁶	Mean Braden score: 14.8 vs. 15 Mean Barthel score: 16.4 vs. 17.4 (p=0.08)	At risk	No	Incidence (number patients): 7% (8/120) of patients vs. 26% (31/119) of patents, p<0.001 RR = 0.26, 95% CI 0.12-0.53; p<0.001 Incidence (number heel, foot, or ankle pressure ulcers): 0% (0/120) vs. 24.4% (29/119); p<0.001	Severity (number pressure ulcers): Grade 1: 0 vs. 18 Grade 2: 4 vs. 16; RR 0.25, 95% CI 0.09 to 0.72 Ungraded: 5 vs. 5 Note: Excluding Grade 1 ulcers did not change results	NR	Adverse events: 20* vs. 23*; p=0.69 (5 deaths, 21 life-threatening, 9 severe, 2 moderate, and 8 mild events - none deemed to be treatment-related) *Denominator unclear; text reported 45 adverse events but only accounted for 43	Good	Special Nursing Research Fellowship funded by the Research and Development Office for Health and Social Care in Northern Ireland
Feuchtinger, 2006 ⁶⁷	Norton score preoperatively, mean (SD; range): 22.2 (2.4;13-26) vs. 22.6 (1.9;17-25), p=0.43	Lower Risk	Preoperative incidence 2.3% (4 patients had grade 1 pressure ulcers)	Incidence (pressure ulcers): Total post-operative pressure ulcer incidence was 14.3% for both groups; 11.1% vs. 17.6%, p=0.22	Severity: Grade 1 ulcers postoperative days 0-5: 10% (9/90) vs. 15.3% (13/85) Grade 2 ulcers postoperative day 0-5: 1% (1/90) vs. 2.4% (2/85)	NR	NR	Fair	NR

Author, Year Notes About Study Design, Publication Status	Baseline Ulcer Risk Score, p- value	Risk Level, Per General Cutoffs*	Baseline Pressure Ulcers, Defined as ≥10% of Population? (Y/N/unclear)	Results - Incidence and Characteristics (Number patients with Ulcers or Number Ulcers, varies)	Results – Severity (Number Patients with Ulcers or Number Ulcers, varies)	Results – Resource Utilization	Harms	Quality	Funding Source
Gebhardt, 1996 ⁶⁸ Cluster trial	Norton score >8: n=5 vs. n=1 Norton score <8: n=18 vs. n=19	At risk	No	Incidence (number pressure ulcers): Grade 1: 1 vs. 3 Grade 2: 0 vs. 4 Grade 3: 0 vs. 2 RR = 0.08, 95% CI 0.01-0.56 Excluding Grade I ulcers: RR = 0.06, 95% CI 0.00-0.96	NR	NR	NR	Fair	North East Thames Regional Hospital Board research grant
Geyer, 2001 ⁶⁹ Pilot randomized trial	Initial Braden score, mean: 12.5 vs. 13.4	At risk	No	Incidence (patients): 40% (6/15) vs. 59% (10/17), p=NS RR = 0.68, 95% CI 0.33-1.42	NR	NR	NR	Fair	National Institute on Disability and Rehabilitation Research grant; authors received “assistance” for the study from ETAC USA, Crown Therapeutics, and Sunrise Medical

Author, Year Notes About Study Design, Publication Status	Baseline Ulcer Risk Score, p- value	Risk Level, Per General Cutoffs*	Baseline Pressure Ulcers, Defined as ≥10% of Population? (Y/N/unclear)	Results - Incidence and Characteristics (Number patients with Ulcers or Number Ulcers, varies)	Results – Severity (Number Patients with Ulcers or Number Ulcers, varies)	Results – Resource Utilization	Harms	Quality	Funding Source
Gilcreast, 2005 ⁷⁰	Braden score at baseline not reported for groups, but inclusion of only patients with Braden score <14	At risk	Not on foot but patients had pressure ulcers on other parts of body	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	NR	Poor	Tri Service Nursing Research Program grant
Goldstone, 1982 ⁷¹	Mean Norton score at admission: 13	At risk	Unclear, but states prevention is the intention of the study	Incidence (overall pressure ulcers): 15.6% (5 lesions in 5 patients) vs. 48.8% (35 lesions in 21 patients), p<0.005 RR = 0.32, 95% CI 0.14-0.76 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	NR	Poor	NR

Author, Year Notes About Study Design, Publication Status	Baseline Ulcer Risk Score, p- value	Risk Level, Per General Cutoffs*	Baseline Pressure Ulcers, Defined as ≥10% of Population? (Y/N/unclear)	Results - Incidence and Characteristics (Number patients with Ulcers or Number Ulcers, varies)	Results – Severity (Number Patients with Ulcers or Number Ulcers, varies)	Results – Resource Utilization	Harms	Quality	Funding Source
Gray, 1994 ⁷²	Waterlow score: 18.03 (3.23 SD) vs. 16.01 (2.58 SD), p=NS	At risk	Unclear, intact skin required, but this may include a grade 1 pressure ulcer	Grade 2 or greater ulcer incidence (number ulcers): 7% vs. 34%, p<0.001	NR	NR	NR	Fair	Research grant from Medical Support Systems
Gray, 2000 ⁷³	Waterlow score on admission: 13 vs. 14	At risk	No	Incidence of pressure ulcers: 4% (2/50) vs. 4% (2/50), p=NS	Grade 1: 1 vs. 1 Grade 2: 1 vs. 0 Grade 4: 0 vs. 1	NR	NR	Fair	NR
Gunningberg, 2000 ⁷⁴	Mean Modified Norton Scale (MNS) at ward admission: 19 vs. 19 % MNS <21: 69% (33/48) vs. 64% (34/53) Score of <21 considered at risk	At risk	No	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	NR	Poor	
Hampton, 1999 ⁷⁵	Mean Waterlow score: 14.6 vs. 12.8	Low risk (30%), at risk (20%), high risk (20%), and very high risk (22%)	Any ulcer at baseline: 2.4% (5/208) vs. 1.5% (3/199)	Any pressure ulcer: 2.9% (6/208) vs. 0%; RR 0.08 (95% CI 0.00- 1.46); p=0.09	NR	NR	NR	Poor	NR

Author, Year Notes About Study Design, Publication Status	Baseline Ulcer Risk Score, p- value	Risk Level, Per General Cutoffs*	Baseline Pressure Ulcers, Defined as ≥10% of Population? (Y/N/unclear)	Results - Incidence and Characteristics (Number patients with Ulcers or Number Ulcers, varies)	Results – Severity (Number Patients with Ulcers or Number Ulcers, varies)	Results – Resource Utilization	Harms	Quality	Funding Source
Hofman, 1994 ⁷⁶ Randomized trial, stopped early	Mean score (per 1985 Dutch consensus meeting criteria): 21 (10.3, 1.6 SD) vs. 23 (10.4, 1.4 SD) High risk	At risk	No	Incidence of at least grade 2 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)	Mean length of stay: 21 vs. 23 days	NR	Poor	NR

Author, Year Notes About Study Design, Publication Status	Baseline Ulcer Risk Score, p- value	Risk Level, Per General Cutoffs*	Baseline Pressure Ulcers, Defined as ≥10% of Population? (Y/N/unclear)	Results - Incidence and Characteristics (Number patients with Ulcers or Number Ulcers, varies)	Results – Severity (Number Patients with Ulcers or Number Ulcers, varies)	Results – Resource Utilization	Harms	Quality	Funding Source
Hoshowsky, 1994 ⁷⁷ Quasi- experimental study	Baseline NR Adapted Hemphill's Guidelines for Assessment of Pressure Sore Potential (Scale 0- 34, with 0-12 low, 13-25 moderate, 26-34 high)	Unclear risk (lower)	Unclear	Incidence per mattress: Stage I pressure ulcer, A. vs: B: OR 0.16 (95% CI 0.1 to 0.24; p<0.001) C: OR 0.49 (95% 0.34 to 0.72; p<0.001) Incidence per patient characteristics: Age 41-70 years: OR 2.13, CI 1.16 to 3.89, p<0.01 Age >70 years: OR 3.37, CI 1.46 to 7.81, p<0.0005 Vascular disease: OR 2.37, CI 1.10 to 4.89, p<0.02 Hemphill scale rating >4: 2.89, CI 1.25 to 6.69, p<0.01	NR	NR	NR	Poor	NR

Author, Year Notes About Study Design, Publication Status	Baseline Ulcer Risk Score, p- value	Risk Level, Per General Cutoffs*	Baseline Pressure Ulcers, Defined as ≥10% of Population? (Y/N/unclear)	Results - Incidence and Characteristics (Number patients with Ulcers or Number Ulcers, varies)	Results – Severity (Number Patients with Ulcers or Number Ulcers, varies)	Results – Resource Utilization	Harms	Quality	Funding Source
Inman, 1993 ⁷⁸	Unclear, but requirement to be critically ill for inclusion	At risk	Unclear, but prevention is the intention of the study	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 *Estimated from figure. All significant differences.	Incidence* 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 *Estimated from figure. All significant differences.	Mean length of stay: 18.8 vs. 15.4 days	NR	Fair	Kinetic Concepts Inc, San Antonio, Texas, maker of the KinAir air suspension bed

Author, Year Notes About Study Design, Publication Status	Baseline Ulcer Risk Score, p- value	Risk Level, Per General Cutoffs*	Baseline Pressure Ulcers, Defined as ≥10% of Population? (Y/N/unclear)	Results - Incidence and Characteristics (Number patients with Ulcers or Number Ulcers, varies)	Results – Severity (Number Patients with Ulcers or Number Ulcers, varies)	Results – Resource Utilization	Harms	Quality	Funding Source
Jesurum, 1996 ⁷⁹ Quasi- experimental pilot study	Braden score: 9.68 vs. 9.45	At risk	-	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 *Estimated from figure. All significant differences.	Incidence* 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 *Estimated from figure. All significant differences.	Mean length of stay: 18.8 vs. 15.4 days	NR	Fair	Kinetic Concepts Inc, San Antonio, Texas, maker of the KinAir air suspension bed

Author, Year Notes About Study Design, Publication Status	Baseline Ulcer Risk Score, p- value	Risk Level, Per General Cutoffs*	Baseline Pressure Ulcers, Defined as ≥10% of Population? (Y/N/unclear)	Results - Incidence and Characteristics (Number patients with Ulcers or Number Ulcers, varies)	Results – Severity (Number Patients with Ulcers or Number Ulcers, varies)	Results – Resource Utilization	Harms	Quality	Funding Source
Jolley, 2004 ⁸⁰ Open label randomized trial	Mean Braden score (range): 15.7 (13- 18) vs. 15.9 (13-18)	At risk	No	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 1 and 2; no grade 3 or 4 recorded) Number of incident grade 2 ulcers (% of all ulcers): 12 (44%) vs. 20 (34%)	Mean bed days: 7.9 vs. 7.0	Withdrawals due to heat- related discomfort: 5% (10/218) vs. 0% (0/223); RR 21, 95% CI, 1.3 to 364	Fair	National Health and Medical Research Council of Australia grant; CSIRO Textile and Fibre Technology, Leather Research Center
Kemp, 1993 ⁸¹	Mean Braden score on admission (SD): 14.00 (1.73) vs. 13.85 (1.1), p=NS	At risk	None	Incidence (number of patients): 46.7% (21/45) vs. 30.8% (12/39), p=0.18 RR = 0.50, 95% CI 0.28-0.87	Severity: Grade 1: 10 Grade 2: 47	NR	NR	Fair	AARP Andrus Foundation; Gamma Phi Chapter of Sigma Theta Tau International
Keogh, 2001 ⁸²	Waterlow score: NR Nutritional assessment score: 11.9 vs. 11.7 Mobility score: 3.4 vs. 3.7	High	Grade I ulcers at baseline: 28.5% (10/35) vs. 11.4% (4/35)	Any pressure ulcer: 0% vs. 0%	NR	NR	NR	Fair	NR

Author, Year Notes About Study Design, Publication Status	Baseline Ulcer Risk Score, p-value	Risk Level, Per General Cutoffs*	Baseline Pressure Ulcers, Defined as $\geq 10\%$ of Population? (Y/N/unclear)	Results - Incidence and Characteristics (Number patients with Ulcers or Number Ulcers, varies)	Results – Severity (Number Patients with Ulcers or Number Ulcers, varies)	Results – Resource Utilization	Harms	Quality	Funding Source
Lazzara, 1991 ⁸³	All had Norton score >15	High risk	Ulcers at baseline: 21% (7/33) vs. 6% (2/33)	Incidence of pressure ulcers in patients without ulcers at baseline: 31.7% (8/26) vs. 32.3% (10/31); RR 0.95 (95% CI 0.44-2.06)	Improvement in severity: 58% (7/12) vs. 60% (9/15) *No differences between groups	NR	NR	Poor	Gaymar Industries
Lim, 1988 ⁸⁴	Baseline Norton <14 for inclusion in study Mean Norton score (SD; range) of patients completing trial: 12.3 (1.4;10-16) vs. 12.3 (1.8;9-16)	At risk	No	Incidence of ulcers: By ulcer: 35 vs. 37, p>0.05 By 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	NR	Fair	Grant from the National Health Research and Development Program, Health and Welfare Canada
McGowan, 2000 ⁸⁵	Mean Braden score: 13.9 vs. 14.01	At risk	No	Incidence: 9% (14/155) patients developed 21 ulcers vs. 30.3% (43*/142) patients developed 67 ulcers, p<0.0001 Rate Ratio 0.28 (95% CI, 0.16 to 0.46) *40 with valid data	Severity Grade 1: All others Grade II: 4 Grade IV: 2 (both in same patient)	NR	Heat-related discomfort reported in unspecified number of group A patients; no incidence in group B (no data reported)	Poor	Sir Edward Dunlop Medical Research Foundation; Nurses Memorial Center Western Australia

Author, Year Notes About Study Design, Publication Status	Baseline Ulcer Risk Score, p- value	Risk Level, Per General Cutoffs*	Baseline Pressure Ulcers, Defined as ≥10% of Population? (Y/N/unclear)	Results - Incidence and Characteristics (Number patients with Ulcers or Number Ulcers, varies)	Results – Severity (Number Patients with Ulcers or Number Ulcers, varies)	Results – Resource Utilization	Harms	Quality	Funding Source
Mistiaen, 2010 ⁸⁶	Braden score ≤20: 70% vs. 71%, p=0.79 Braden score ≤18: 47% vs. 47%, p=0.84	At risk	No, free of pressure ulcers at the sacrum at admission	Incidence (number sacral pressure ulcers): 8.9% (24/271) vs. 14.7% (40/272), p=0.035 RR = 0.60, 95% CI 0.37-0.97 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 1 = 50 Grade 2 = 12 Grade 3 = 2 p=NS between groups	NR	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)	Fair	-
Nixon, 1998 ⁸⁷	Pre-operative Braden score 10-14: 0% (1/222) vs. 0% (0/224) 15-19: 8% (17/222) vs. 10% (23/224) 20-23: 91% (202/222) vs. 89% (200/224)	Lower risk	Unclear, excludes grade 2 or above (may include grade 1)	Incidence (number of patients that failed Torrance scale): 11% (22/205) vs. 20% (43/211), p=0.01, OR = 0.46 (95% CI 0.26- 0.82)	Severity: 56/65 ulcers conversions of grade 0 to grade 1 4/65 ulcers conversions of grade 0 to grade 2A 5/65 ulcers conversions of grade 0 to grade 2B	NR	NR	Fair	Northern and Yorkshire Regional Health Authority

Author, Year Notes About Study Design, Publication Status	Baseline Ulcer Risk Score, p- value	Risk Level, Per General Cutoffs*	Baseline Pressure Ulcers, Defined as ≥10% of Population? (Y/N/unclear)	Results - Incidence and Characteristics (Number patients with Ulcers or Number Ulcers, varies)	Results – Severity (Number Patients with Ulcers or Number Ulcers, varies)	Results – Resource Utilization	Harms	Quality	Funding Source
Nixon, 2006 ⁸⁸ RCT Same data as in Nixon, 2006 Health Technology Report	Mean Braden score: NR Bedfast: 81.3% vs. 76.8%	High risk	Grade 1b ulcers: 18.2% (180/989) vs. 14.8% (145/982) Wound (including ulcers and surgical wounds): 5.8% (57/989) vs. 6.1% (60/982)	Incidence of grade 2 or greater pressure ulcers: 10.7% (106/989) vs. 10.3% (101/982); Adjusted OR 0.94 (95% CI 0.68- 1.29)	Median ulcer area: 1.2 sq. cm vs. 1.1 sq. cm	NR	23.3% (230/990) vs. 18.9% (186/982) discontinued intervention for comfort or device-related reasons	Good	UK Department of Health
Russell, 2000 ⁸⁹	Mean Modified Knoll risk score 3.6+1 vs. 3.8 +1, p=NS The highest attainable score is 33; a score of >12 indicates a greater risk for altered skin integrity	Lower risk	No	Incidence (number of patients that developed ulcers): 2.2% (2/98) vs. 7% (7/100), p=NS Incidence (number of ulcers): 2 vs. 10, p=NR	Severity (number of ulcers), p=NR Grade 1: 0 vs. 2 Grade 2: 2 vs. 5 Grade 3: 0 vs. 3	NR	Adverse events: no difference between groups; no adverse events were treatment- related (no data reported)	Good	MicroPulse, Inc, Portage, Michigan
Russell, 2003 ⁹⁰	Mean Waterlow score: 17 vs. 17	High	Grade I ulcers at baseline: 12.4% (145/1168)	Any pressure ulcer (nonblanching erythema or worse), patients without prevalent erythema: 6.9% (34/494) vs. 9.3% (49/527); RR 0.74 (95% CI, 0.49 to 1.1) Any pressure ulcer, all patients: 15% (74/494) vs. 22% (115/527); RR 0.78 (95% CI 0.55 to 1.1)	NR	Mean bed days utilized per patient: 17.7 vs. 16.7 Number of dressings: 47.8 vs. 44.3	NR	Good	NR

Author, Year Notes About Study Design, Publication Status	Baseline Ulcer Risk Score, p- value	Risk Level, Per General Cutoffs*	Baseline Pressure Ulcers, Defined as ≥10% of Population? (Y/N/unclear)	Results - Incidence and Characteristics (Number patients with Ulcers or Number Ulcers, varies)	Results – Severity (Number Patients with Ulcers or Number Ulcers, varies)	Results – Resource Utilization	Harms	Quality	Funding Source
Sanada, 2003 ⁹¹	Mean Braden scale: 12.5 (1.7 SD) vs. 12.1 (1.4 SD) vs. 12.7 (1.7 SD), p=NS	At risk	No	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 1 (number ulcers): 0% (0/26) vs. 3% (1/29) vs. 15% (4/27), p=NR Grade 2 (number ulcers): 4% (1/26) vs. 14% (4/29) vs. 22% (6/27), p=NR	NR	NR	Poor	NR
Schultz, 1999 ⁹²	Admit Braden score: 22.15 (1.98 SD) vs. 22.41 (1.34 SD)	Lower Risk	No	Incidence: 26.7% (55/206) vs. 16.4% (34/207), p=0.0111	Severity, grade 2 or greater (number people): 2.9% (6/206) vs. 1.4% (3/207), p=NR	NR	NR	Good	Partially funded by Devon Industries, in conjunction with the AORN Foundation
Sideranko, 1992 ⁹³	Unclear	Unclear risk	No	Incidence (number of patients that developed ulcers): 25% (5/20) vs. 5% (1/20) vs. 12% (2/17), p=NS	NR	Mean length of stay: 10 vs. 9.4 vs. 8.9 days	NR	Poor	NR

Author, Year Notes About Study Design, Publication Status	Baseline Ulcer Risk Score, p- value	Risk Level, Per General Cutoffs*	Baseline Pressure Ulcers, Defined as ≥10% of Population? (Y/N/unclear)	Results - Incidence and Characteristics (Number patients with Ulcers or Number Ulcers, varies)	Results – Severity (Number Patients with Ulcers or Number Ulcers, varies)	Results – Resource Utilization	Harms	Quality	Funding Source
Stapleton, 1986 ⁹⁴	Mean Norton scores: 12 vs. 12.8 vs. 12.9	At risk	No	Incidence (number patients that developed ulcers): 34% (11/32) vs. 41% (14/34) vs. 35% (12/34), p=NR Incidence in patients >80 years: 63% (12/19) vs. 32% (7/22), p=0.055 RR = 1.99, 95% CI 0.98-4.00	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	NR	Poor	NR
Takala, 1996 ⁹⁵	All patients <8 on Norton Scale	High risk	No	Incidence: 0 vs. 37% (7/19 patients) developed 13 ulcers, p<0.005	Grade 1A: 9 Grade 1B: 4 (all in control group)	NR	NR	Poor	Ahlstrom Medical
Taylor, 1999 ⁹⁶	Waterlow score: 19 vs. 17	At risk	Unclear, intact skin but may have grade 1 ulceration	Incidence (number of patients that developed ulcers): 0% (0/22) vs. 9% (2/22), p=NR RR = 0.20, 95% CI 0.01-3.94	Both “superficial”	Mean length of stay: 10.5 vs. 11.6 days	NR	Fair	NR
Theaker, 2005 ⁹⁷	High risk, details NR	High risk	No	Incidence (number of patients that developed ulcers): 10% (3/30) vs. 19% (6/32), p=0.35 RR = 0.53, 95% CI 0.15-1.94	Grade II: 8 Grade III: 1	Mean duration on mattresses: no differences between groups	NR	Fair	NR
Tymec1997 ⁹⁸	Mean Braden score: 11.8	High risk	Unclear, intact skin on heel, but may have grade 1 ulceration	Incidence (ulcers): 6 vs. 2, p=NS	NR	NR	NR	Poor	EHOB Incorporated provided the Foot Waffles

Author, Year Notes About Study Design, Publication Status	Baseline Ulcer Risk Score, p-value	Risk Level, Per General Cutoffs*	Baseline Pressure Ulcers, Defined as $\geq 10\%$ of Population? (Y/N/unclear)	Results - Incidence and Characteristics (Number patients with Ulcers or Number Ulcers, varies)	Results – Severity (Number Patients with Ulcers or Number Ulcers, varies)	Results – Resource Utilization	Harms	Quality	Funding Source
van Leen, 2011 ⁹⁹	Norton score between 5-8 at baseline: 61.9% vs. 53.7% Norton score between 9-12 at baseline: 38.1% vs. 46.3%	At risk, high risk	No	Incidence (number patients with ulcers): 4.8% (2/42) vs. 17.1% (7/41), p=0.088 RR = 0.28, 95% CI 0.06-1.26; p=0.0978	Severity (number patients with ulcers): Grade 2: 1 vs. 2 Grade 3: 1 vs. 5	NR	NR	Fair	NR
Vanderwee, 2005 ¹⁰⁰	Mean Braden score: 14.6 vs. 14.2	High	Grade I ulcers at baseline: 33% (74/222) vs. 34% (76/225)	Pressure ulcer grade II-IV: 15% (34/222) vs. 16% (35/225); RR 0.98 (95% CI 0.64 to 1.5)	Stage 2 ulcer: 12% (26/222) vs. 15% (33/225); RR 0.80 (95% CI 0.49 to 1.3) Stage 3 or 4 ulcer: 3.6% (8/222) vs. 0.9% (2/225); RR 4.1 (95% CI 0.87 to 19)	NR	NR	Good	Ghent University and Huntleigh Healthcare
Vyhlidal, 1997 ¹⁰¹	Admission mean Braden scale: 14.7 vs. 14.5, p=0.75	At risk	No	Incidence (number patients with ulcers): 25% (5/20) vs. 60% (12/20), p=0.025 Incidence (number ulcers): 5 vs. 16 RR = 0.42, 95% CI 0.18-0.96	Severity (number patients): Stage 1: 2 vs. 4 Stage 2: 3 vs. 8	NR	NR	Fair	NR. BG Industries (manufacturer) and Baxter Corporation (distributor) provided the MAXIFLOAT mattresses for the study.

Appendix Table H12. Key Questions 3 and 4: quality assessment of support surfaces trials

Author, Year	Randomization adequate?	Allocation concealment adequate?	Groups similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Care provider masked?	Patient masked?	Reporting of attrition	Loss to followup: differential/high	Intention-to-treat analysis	Quality rating
Andersen, 1982 ⁵⁴	Unclear	Unclear	Yes	Yes	No	No	No	Yes	No/Yes	No	Poor
Aronovitch, 1999 ⁵⁵	No; by week	Unclear	Yes; group differences on diagnosis, and type of surgeries but otherwise comparable	Yes	Unclear	No	Unclear	Yes	No/No	No	Poor
Berthe, 2007 ⁵⁶	Unclear	No	Unclear	Yes	No	No	No	Yes	No	Yes	Poor
Brienza, 2010 ⁵⁷	Unclear	Yes	Yes for gender, age, race and Braden score. Lower rates of ambulation in patients in the intervention group, p= 0.03	Yes	Yes	No	No	Yes	Unclear/Yes 21%- 24%	Yes	Fair
Cavicchioli, 2007 ⁵⁸	Unclear	Yes	Yes	Yes	Unclear; control group visibly different, treatments supposedly blinded but seems easy to tell which mattresses are alternating and which aren't	No	No	Yes	Yes (20% of treatment group)	No	Poor
Collier, 1996 ⁵⁹	Unclear	Unclear	Unclear	No	No	Unclear	Unclear	Yes	No	No	Poor
Conine, 1990 ⁶⁰	Unclear	No	Yes	Yes	Yes	No	No	Yes	No/No	No	Fair
Conine, 1993 ⁶¹	Unclear	No	Yes	Yes	Yes	Unclear	Unclear, cushion covered with identical polyester covers but not stated that patients were masked	Yes	No/No	No	Fair

Author, Year	Randomization adequate?	Allocation concealment adequate?	Groups similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Care provider masked?	Patient masked?	Reporting of attrition	Loss to followup: differential/high	Intention-to-treat analysis	Quality rating
Conine, 1994 ⁶²	Unclear	Yes	Yes	Yes	Yes	Unclear	Yes	Yes	Yes (more people, 6 vs. 1, dropped out from the intervention group due to discomfort, p=0.05)/No	No	Fair
Cooper, 1998 ⁶³	Unclear	Yes	Yes	Yes	No	No	No	Yes	No	No	Poor
Daechsel, 1985 ⁶⁴	Unclear	Unclear	No; not age or sex	Yes	Unclear	No	No	Yes	No	Yes	Poor
Demarre, 2012 ⁶⁵	Yes	Unclear	Yes	Yes	No	No	No	Yes	Differential: No High: Yes	Yes	Fair
Donnelly, 2011 ⁶⁶	Yes	Yes	Yes	Yes	No	No	No	Yes	No	Yes	Fair
Feuchtinger, 2006 ⁶⁷	Unclear	Unclear	Yes; significant difference in presence of renal insufficiency between groups but otherwise comparable	Yes	Yes	Yes	Yes	No	No	Yes	Fair
Gebhardt, 1996 ⁶⁸	Yes	Unclear	Yes; Differences between groups on cancer diagnosis, breathlessness, and medications but otherwise comparable	Yes	Unclear	No	No	Yes	No	No	Fair
Geyer, 2001 ⁶⁹	Yes	Yes	Yes	Yes	Yes	No	No	Yes	No	Yes	Fair
Gilcreast, 2005 ⁷⁰	Yes; shuffled unmarked cards	Yes; identical sealed envelopes used	No; significant difference in distribution of sexes between groups	Yes	No	No	No	Yes	Unclear/Yes	No	Poor

Author, Year	Randomization adequate?	Allocation concealment adequate?	Groups similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Care provider masked?	Patient masked?	Reporting of attrition	Loss to followup: differential/high	Intention-to-treat analysis	Quality rating
Goldstone, 1982 ⁷¹	No	No	Yes	Yes	No	No	No	No	Unclear	No	Poor
Gray, 1994 ⁷²	Unclear	Yes	Yes	Yes	Unclear	No	No	Yes	No	Yes	Fair
Gray, 2000 ⁷³	Unclear	Yes	Yes	Yes	Yes	No	No	Yes	No	No	Fair
Gunningberg, 2000 ⁷⁴	Unclear	Unclear	No	Yes	No	No	No	Yes	No	Yes	Poor
Hampton, 1999 ⁷⁵	Unclear	Unclear	Yes	Yes	No	No	No	Yes	No	Yes	Poor
Hofman, 1994 ⁷⁶	No	Unclear	Yes	Yes	No	No	No	Yes	No/Yes (~20% from each group)	No	Poor
Hoshowsky, 1994 ⁷⁷	Unclear, and convenience sample	Unclear	Yes; patients served as their own controls	Yes	No	No	Unclear	Yes	No	Yes	Poor
Inman, 1993 ⁷⁸	Yes	Unclear	Yes	Yes	Unclear	Unclear	Unclear	Yes	No/No	No	Fair
Jesurum, 1996 ⁷⁹	Unclear	Unclear	No; intervention group more females	Yes	Unclear	No	No	Yes	No	No	Poor
Jolley, 2004 ⁸⁰	Yes; shuffled cards in envelopes	Yes	Yes; more emergency admissions in intervention but otherwise comparable	Yes	No	No	No	Yes	No/No	No	Fair
Kemp, 1993 ⁸¹	Yes	Unclear	Yes	Yes	Unclear	No	No	Yes	No	Yes	Fair
Keogh, 2001 ⁸²	Yes	Yes	No; not sex	Yes	No	No	No	Yes	No	Yes	Fair
Lazzara, 1991 ⁸³	Yes; random numbers table	Unclear	Yes	Yes	Unclear	No	No	Yes	Unclear	No	Poor
Lim, 1988 ⁸⁴	Unclear	Unclear	Yes	Yes	Yes	No	No	Yes	No	No	Fair

Author, Year	Randomization adequate?	Allocation concealment adequate?	Groups similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Care provider masked?	Patient masked?	Reporting of attrition	Loss to followup: differential/high	Intention-to-treat analysis	Quality rating
McGowan, 2000 ⁸⁵	Unclear	Yes	No; more males and knee replacement patients in intervention group	Yes	No	No	No	Yes	No	No	Poor
Mistiaen, 2010 ⁸⁶	Yes, randomization scheme was created in SPSS	Yes	Yes	Yes	No	No	No	No	No	Yes	Fair
Nixon, 1998 ⁸⁷	Yes	Yes	Unclear	Yes	Yes	No	No	Yes	No	Unclear	Fair
Nixon, 2006 ⁸⁸	Yes	Yes	Yes	Yes	No	No	No	Yes	No	Yes	Good
Russell, 2000 ⁸⁹	Yes	Yes	Yes	Yes	No	No	No	Yes	No	Yes	Good
Russell, 2003 ⁹⁰	Yes	Yes	Yes	Yes	No	No	No	Yes	No	Yes	Good
Sanada, 2003 ⁹¹	Unclear	Yes	Yes; Systolic blood pressure higher in one-cell mattress group	Yes	No	No	No	Yes	Yes; 24.1% attrition	No	Poor
Schultz, 1999 ⁹²	Yes	Yes	Yes	Yes	Yes	Yes	Yes, mattress covered with a sheet	Yes	No	Yes	Good
Sideranko, 1992 ⁹³	Unclear	Unclear	Yes	Yes	Unclear	No	No	No	Unclear	Unclear	Poor
Stapleton, 1986 ⁹⁴	No	No	Yes	Yes	Unclear	No	No	Yes	No	No	Poor
Takala, 1996 ⁹⁵	Unclear	Unclear	Yes	Yes	Unclear	No	No	Yes	Yes/Yes 35-45%	Yes	Poor
Taylor, 1999 ⁹⁶	Unclear	Yes	Yes	Yes	Unclear	No	No	Yes	No	Yes	Fair
Theaker, 2005 ⁹⁷	Unclear	Yes	Yes	Yes	No	No	No	Yes	No	Yes	Fair
Tymec, 1997 ⁹⁸	Yes	Unclear	Unclear	Yes	Unclear	No	No	No	Unclear	Unclear	Poor
van Leen, 2011 ⁹⁹	Unclear	Yes	No; Intervention group higher risk	Yes	Unclear	No	No	Yes	No	Yes	Fair
Vanderwee, 2005 ¹⁰⁰	Yes	Yes	Yes	Yes	Unclear	No	No	Yes	No	Yes	Good

Author, Year	Randomization adequate?	Allocation concealment adequate?	Groups similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Care provider masked?	Patient masked?	Reporting of attrition	Loss to followup: differential/high	Intention-to-treat analysis	Quality rating
Vyhlidal, 1997 ¹⁰¹	Yes	Yes	No	Yes	Unclear	No	No	Yes	No	Yes	Fair

Appendix Table H13. Key Questions 3 and 4: data extraction of nutrition trials

Author, Year	Study Design	Setting Country	Eligibility Criteria and Exclusions	Study Duration of Followup	Number Screened/ Enrolled/ Analyzed	Withdrawals	Loss to Followup
Bourdel-Marchasson, 2000 ¹⁰²	Randomized trial (cluster)	Multicenter, hospitals France	>age 65 in acute phase of critical illness, unable to move themselves, unable to eat independently at admission and without pressure ulcers Ward inclusion: >40% of inpatients on ward were older than 65 years; included wards had to demonstrate involvement / participate in pressure ulcer prevention training program (changing positions, special mattresses, cleaning care)	15 days or until death or discharge	35 wards selected that met age inclusion criteria; 19 wards then participated in pressure ulcer prevention program and were therefore selected to participate; 672 patients included (295 intervention, 377 control); unclear how many excluded	Not reported	Not reported
Ek, 1991 ¹⁰³	Randomized trial	Hospital Sweden	Patients newly admitted to a long-term medical ward, with expected stay >3 weeks	26 weeks	501 enrolled/ 495 analyzed	9 patients withdrawn due to development of clinical indications for nutritional support	19 patients missing data; 39 refused nutritional supplementation; only about 1/3 of patients completed full 26 weeks of study
Hartgrink, 1998 ¹⁰⁴	Randomized trial	Hospital The Netherlands	Patients with hip fractures and a pressure-sore risk score of ≥ 8 (according to scores of 0-3 on 10 risk indices) Exclude: Patients with grade II or greater pressure sores on admission	2 weeks	140 randomized/129 enrolled (11 post-randomization exclusions due to failure to meet inclusion criteria)	Of the 62 patients assigned to intervention, only 25 accepted tube for 1 week and 16 for two weeks	39 patients lost by 2 weeks

Author, Year	Study Design	Setting Country	Eligibility Criteria and Exclusions	Study Duration of Followup	Number Screened/ Enrolled/ Analyzed	Withdrawals	Loss to Followup
Houwing, 2003 ¹⁰⁵	Randomized trial	Hospitals The Netherlands	Post-operative patients (n=103) s/p hip fracture with CBO PU risk score >8 Exclusion: terminal care, metastatic hip fracture, insulin-dependent diabetes, renal disease, hepatic disease, morbid obesity, pregnancy or lactation	28 days or until discharge	NR/103/103	None	None
Delmi, 1990 ¹⁰⁶	Randomized trial	Orthopaedic unit of the University hospital of Geneva and "second (recovery)" hospital	Elderly patients > 60 years old, mean age 82) with femoral neck fractures after accidental fall; exclusion: fractures from violent external trauma, pathological fractures (tumors, non-osteoporotic osteopathies), patients with overt dementia or hepatic, renal or endocrine disease, gastrectomy or malabsorption, or treatment with phenytoin, steroids, barbiturates, fluoride, or calcitonin	Supplement given throughout hospital stay (mean 32 days); measurements at admission, day 14,21,28, at discharge from convalescent hospital, and at 6 months	NR/59/59	Unclear whether withdrawal or loss to follow up; analyzed 59 at admission, 24 at recovery hospital, and 53 at 6 months	Unclear whether withdrawal or loss to follow up; analyzed 59 at admission, 24 at recovery hospital, and 53 at 6 months
Theilla, 2007 ¹⁰⁷	Randomized trial	Hospital Israel	Patients aged ≥ 18 years, suffering from acute lung injury ($\text{PaO}_2/\text{FIO}_2$ ratio below 250) Exclude: Patients with head trauma, cerebral bleeding, coagulation disorders, receiving steroids in a dose >0.25 mg/kg/day methylprednisolone or nonsteroidal anti-inflammatory agents, pregnant, or having loose stool more than 3 times	1 week	100 enrolled/95 analyzed	5 excluded due to diarrhea or food intolerance	0

Author, Year	Intervention	Baseline Demographics (Age, Sex, Race)	Ulcer Risk	Results	Harms	Quality	Funding Source
Bourdel-Marchasson, 2000 ¹⁰²	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/day). nutritional intervention implemented up to 15 consecutive days or until discharge or death	Mean age: 84 vs. 83.0 years Sex: 68% vs. 63% female Race: NR 672 patients older than 65 in acute phase of critical illness; intervention group included more patients with stroke, heart failure, and dyspnea and fewer with antecedent falls, delirium, lower limb fractures and digestive disease.	Norton Score (%): 5-10: 28.5% vs.35.5% 11-14: 40.3% vs.46.9% >14: 31.2% vs. 18.6% Nutritional intervention group had lower baseline Norton score, were less dependent (Kuntzman score), and had a lower serum albumin	Any pressure ulcer (90% stage 1):40% (118/295) vs.48% (181/377) RR: 0.83 (95% CI 0.70 to 0.99); adjusted RR 0.64 (95% CI 0.42 to 0.97) Proportion of erythema 90% for both groups, no significant (p value NR) differences in development of erythema between two groups	NR	Poor	Projet hospitalier de recherche clinique, ministere de la sante et de l'action humanitaire, deraction generale de la sante and direction dex hopitaux
Ek, 1991 ¹⁰³	A: Nutritional supplement (200 ml; 838 kJ; 8 g protein; 8 g fat; 23.6 g carbohydrates; minerals and vitamins) twice daily in addition to hospital diet B: Standard hospital diet (2200 kcal)	Mean age: 80.1 years Sex: 62% female Race: NR Demographics not reported by group	28.5% malnourished at baseline 14.1% had prevalent pressure ulcers	Incidence of pressure ulcers among patients without prevalent ulcers: 9.9% vs. 12%; p=NS Second or third pressure ulcer development: 11.1% vs. 24.6%; p=NS Incidence of pressure sores after 9 th week: 3.6% vs. 7.6%; p=NS	NR	Poor	Swedish Medical Research Council; Research Fund of the County of Ostergotland; Regional Hospital at Linkping and the University of Linkoping
Hartgrink, 1998 ¹⁰⁴	A: Nasogastric tube feeding (1 liter Nutrison Steriflo Energy-plus; 1500 kcal; 60 g protein) in addition to standard hospital diet B: Standard hospital diet	Mean age: 84 vs. 83 years Sex: 84% vs. 91% female Race: NR	Pressure-sore risk score: 9.0 vs. 9.2	Incidence of pressure sores (grade II or greater) at 1 week: 37% (20/54) vs. 48% (30/62);RR 0.77 (95% CI 0.50-1.18); p=0.26 Incidence of pressure sores (grade II or greater) at 2 weeks: 52% (25/48) vs. 57% (30/53); RR 0.92 (95% CI 0.64-1.32); p=0.69	Death: 7 vs. 0 Most patients did not accept tube feeding	Poor	Nutricia Corp.
Houwing, 2003 ¹⁰⁵	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) by mouth daily B: Non caloric, water-based placebo (n=52) by mouth daily	Mean age 82 vs. 80 years(p=0.528) Sex: 78% vs. 84% female (p = 0.456) Race: NR	CBO risk assessment score: 11.1 +/- 0.3 vs.11.2 +/- 0.2 (p=0.629)	Any pressure ulcer: 55% (27/49) vs. 59% (30/51); RR 0.94 (95% CI 0.67 to 1.3)Stage 1 ulcers: 37% (18/49) vs. 31% (16/51); RR 1.2 (95% CI 0.68 to 2.0) Stage 2: 18% (9/49) vs. 28% (14/51); RR 0.67 (95% CI 0.32 to 1.4)	NR	Poor	Numico Research BV, Wageningen, the Netherlands

Author, Year	Intervention	Baseline Demographics (Age, Sex, Race)	Ulcer Risk	Results	Harms	Quality	Funding Source
Delmi, 1990 ¹⁰⁶	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)	Mean age 80 vs. 83 years Sex: 89% vs. 91% female Race: NR Other categories similar except 25-hydroxyvitamin D plasma level slightly lower in non-supplemented patients; of note, all patients nutritionally at risk with below normal values for baseline retinol binding protein, vitamin A, carotene, triceps skinfold, upper arm circumference	Not measured; most patients had nutritional deficiencies on admission	Any pressure ulcer at discharge: 7.4% (2/27) vs. 9.4% (3/32); RR 0.79 (95% CI 0.14 to 4.4) Any pressure ulcer at 6 months: 0% (0/25) vs. 7.4% (2/27); RR 0.22 (95% CI 0.01 to 4.3)	NR	Poor	NR
Theilla, 2007 ¹⁰⁷	A: High fat, low carbohydrate enteral formula with eicosapentanoic acid, gamma-linolenic acid, and vitamins A, C, and E (n=46) B: High fat, low carbohydrate enteral formula (n=49)	Mean age: 57 vs. 62 years Sex: 37% vs. 43% female Race: NR	Pressure ulcer on admission: 15.2% (7/46) vs. 28.6% (14/49) * Risk not measured	Any pressure ulcer: 33% (15/46) vs. 49% (24/49); RR 0.67 (95% CI 0.40-1.10)	NR	Fair	Abbott Laboratories

Note: CBO=Dutch Institute for Health Care Improvement, CI=confidence interval, IU=international units, NR=not reported, PU=pressure ulcer, RR=relative risk.

Appendix Table H14. Key Questions 3 and 4: quality assessment of nutrition trials

Author, Year	Randomization adequate?	Allocation concealment adequate?	Groups similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Care provider masked?	Patient masked?	Reporting of attrition	Loss to followup: differential/high	Intention-to-treat analysis	Quality
Bourdel-Marchasson, 2000 ¹⁰²	Unclear	Unclear	No; Nutritional intervention group had lower baseline Norton score, were less dependent (Kuntzman score), and had a lower serum albumin; intervention group included more patients with stroke, heart failure, and dyspnea and fewer with antecedent falls, delirium, lower limb fractures and digestive disease.	Unclear	Unclear	Unclear	No	Unclear	Unclear	Unclear	Poor
Ek, 1991 ¹⁰³	Unclear	Unclear	Yes	Yes	Unclear	No	No	Yes	No	No	Poor
Hartgrink, 1998 ¹⁰⁴	Unclear	Unclear	Yes	Yes	No	No	No	Yes	Yes	No	Poor
Houwing, 2003 ¹⁰⁵	Unclear	Unclear	Yes	Yes	Unclear	Unclear	Unclear; different taste of supplements	Yes	No	Unclear	Poor

Author, Year	Randomization adequate?	Allocation concealment adequate?	Groups similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Care provider masked?	Patient masked?	Reporting of attrition	Loss to followup: differential/high	Intention-to-treat analysis	Quality
Delmi, 1990 ¹⁰⁶	Unclear	Unclear	Yes	Yes	Unclear	No	No	Yes	Yes; varied between 12-60% (at 6 months and during second hospital stay)	Unclear	Poor
Theilla, 2007 ¹⁰⁷	Unclear	Unclear	Yes	Yes	No	No	No	Yes	No	Yes	Fair

Appendix Table H15. Key Questions 3 and 4: data extraction of repositioning trials

Author, Year	Study Design	Setting Country	Eligibility Criteria and Exclusions	Study Duration of Followup	Number Screened/ Enrolled/ Analyzed	Withdrawals	Loss to Followup	Intervention
Brown, 1985 ¹⁰⁸	Randomized trial	4 nursing homes United States	Newly admitted or readmitted patients without pressure ulcers and a score of <14 on a 20-point risk assessment (where lower scores indicate higher risk)	2 weeks	15 enrolled	0	1 patient in control group (unexplained)	A: Small shifts of body weight in addition to repositioning every 2 hours B: Respositioning every 2 hours
Defloor, 2005 ¹⁰⁹	Randomized trial	11 elder-care nursing homes Belgium	Braden score <17 or Norton score <12, informed consent	8 weeks (4 weeks of one intervention, followed by re-randomization and another 4 week intervention)	1,952 screened/838 eligible/262 enrolled in intervention groups and 576 to control	0	0	A: Usual care B: 2-hour turning C: 3-hour turning D: 4-hour turning E: 6-hour turning
Moore, 2011 ¹¹⁰	Randomized trial (cluster)	12 long-term care facilities Ireland	Patients aged >65 years, at risk of pressure ulcer development according to Braden score, no prevalent pressure ulcers, and no medical condition that would preclude repositioning	28 days	270 screened/213 enrolled	6 (3 patients in each group died)	0	A: Repositioning at 30 degree tilt every 3 hours during the night B: Repositioning at 90 degree lateral every 6 hours during the night
Smith, 1990 ¹¹¹	Randomized trial (pretest-posttest)	A single long-term care facility United States	Patients aged ≥65 years, with a Norton score ≤14	2 weeks	56 eligible/26 enrolled/19 analyzed	0	0	A: Repositioning every 2 hours, and small shifts in body position using a rolled hand towel during unscheduled interactions (n=9) B: Repositioning every 2 hours (n=10)

Author, Year	Study Design	Setting Country	Eligibility Criteria and Exclusions	Study Duration of Followup	Number Screened/ Enrolled/ Analyzed	Withdrawals	Loss to Followup	Intervention
Vanderwee, 2007 ¹¹²	Randomized trial	16 nursing homes Belgium	Patients with no grade II or greater ulcers, could be repositioned, expected to stay >3 days, and developed non-blanchable erythema	5 weeks	2663 screened/379 eligible/235 enrolled	0	0	A: Repositioning with unequal time intervals (4 hours in semi-Fowler 30 degree, 2 hours in right-side later position 30 degree, 4 hours in semi-Fowler 30 degree, 2 hours in left-side lateral 30 degree (n=122) B: Same positions but for equal 4-hour intervals (n=113)
Young, 2004 ¹¹³	Randomized trial	Hospital (acute ward) United Kingdom	Elderly Caucasian patients at risk of pressure ulcer development, without existing ulcers, able to lie in 30 degree tilt position	1 night	46 enrolled	7 (5 in experimental group unable to tolerate intervention, 2 in control group died overnight)	0	A: 30 degree tilt repositioning B: Standard repositioning

Author, year	Baseline Demographics (Age, Sex, Race)	Ulcer Risk	Results	Harms	Quality	Funding Source	Comments
Brown, 1985 ¹⁰⁸	Mean age: 81 vs. 78 years Sex: 75% vs. 67% female Race: NR	High risk: 12.5% (1/8) vs. 50% (3/6) Very high risk: 87.5% (7/8) vs. 50% (3/6)	Any pressure ulcer: 0% vs. 17% (1/6); RR 0.26 (95% CI 0.01-5.44); p=0.38	NR	Poor	NR	
Defloor, 2005 ¹⁰⁹	Mean age: 84 vs. 85 vs. 85 vs. 85 vs. 85 Sex: 78.3% vs. 88.9% vs. 87.9% vs. 81.8% vs. 77.8% female Race: NR	Mean Braden score: 13.2 vs. 13.3 vs. 13.2 vs. vs. 13.1 vs.13.0 Mean Norton score: 10.1 vs. 10.4 vs. 9.6 vs. 9.8 vs. 9.5	Any pressure ulcer: 63% (324/511) vs. 62% (39/63) vs. 69% (40/58) vs. 45% (30/66) vs. 62% (39/63); RR 0.98 (95% CI 0.80 to 1.2) for B vs. A, RR 1.1 (95% CI 0.90 to 1.3) for C vs. A, RR 0.72 (95% CI 0.55 to 0.94) for D vs. A, RR 0.98 (95% CI 0.80 to 1.2) for E vs. A Stage 1 pressure ulcer: 43% (220/511) vs. 48% (30/63) vs. 45% (26/58) vs. 42% (28/66) vs. 46% (29/63); RR 1.1 (95% CI 0.84 to 1.5) for B vs. A, RR 1.0 (95% CI 0.77 to 1.4) for C vs. A, RR 0.99 (95% CI 0.73 to 1.3) for D vs. A, RR 1.1 (95% CI 0.79 to 1.4) for E vs. A Stage 2 or greater pressure ulcer: 20% (102/511) vs. 14% (9/63) vs. 24% (14/58) vs. 3% (2/66) vs. 16% (10/63); RR 0.72 (95% CI 0.38 to 1.3) for B vs. A, RR 1.2 (95% CI 0.74 to 2.0) for C vs. A, RR 0.15 (95% CI 0.04 to 0.60) for D vs. A, RR 0.80 (95% CI 0.44 to 1.4) for E vs. A Stage 3 or 4 pressure ulcer: 5.7% (29/511) vs. 3.2% (2/63) vs. 3.4% (2/58) vs. 0% (0/66) vs. 3.2% (2/63); RR 0.56 (95% CI 0.14 to 2.3) for B vs. A, RR 0.61 (95% CI 0.15 to 2.5) for C vs. A, RR 0.12 (95% CI 0.008 to 2.1) for D vs. A, RR 0.56 (95% CI 0.14 to 2.3) for E vs. A	NR	Good	NR	

Author, year	Baseline Demographics (Age, Sex, Race)	Ulcer Risk	Results	Harms	Quality	Funding Source	Comments
Moore, 2011 ¹¹⁰	Age: 53% between 81 and 90 years, 13% between 91 and 100 years Sex: 79% female	NR	Any pressure ulcer: 3.0% (3/99) vs. 11.4% (13/114); RR 0.27 (95% CI 0.08 to 0.91)	NR	Fair	Health Research Board of Ireland Clinical Nursing & Midwifery Research Fellowship	
Smith, 1990 ¹¹¹	Mean age: 79 vs. 82 years Sex: NR Race: NR	Mean Norton score: 10.3 vs. 12	Any pressure ulcer: 11% (1/9) vs. 10% (1/10); RR 1.1 (95% CI 0.08 to 15)	NR	Poor	NR	
Vanderwee, 2007 ¹¹²	Median age: 87 vs. 87 years Sex: 83 vs. 84% female Race: NR	Mean Braden score: 15.1 vs. 15.0	Pressure ulcer incidence: 16.4% (20/122) vs. 21.2% (24/113); p=0.4; RR 0.66 (95% CI 0.37-1.20)	NR	Fair	NR	
Young, 2004 ¹¹³	Mean age: 70 vs. 70 years Sex: 50% vs.50% female Race: 100% White	Mean Waterlow score: 20 vs.20	Non-blanching erythema: 13% (3/23) vs. 9% (2/23); RR = 1.5 (95% CI 0.28-8.2)	21.7% (5/23) could not tolerate intervention	Fair	NR	38% vs. 18% nursed on low-air-loss mattresses 15% drop-out rate, more than half of patients spontaneously repositioned themselves between turnings

Note: CI=confidence interval, IRR=incidence rate ratio, NR=not reported, OR=odds ratio, RR=relative risk.

Appendix Table H16. Key Questions 3 and 4: quality assessment of repositioning trials

Author, Year	Randomization adequate?	Allocation concealment adequate?	Groups similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Care provider masked?	Patient masked?	Reporting of attrition	Loss to followup: differential/high	Intention-to-treat analysis	Quality rating
Brown, 1985 ¹⁰⁸	Unclear	Unclear	Yes	Yes	No	No	No	No	No	No	Poor
Defloor, 2005 ¹⁰⁹	Yes; computerized randomization tables	Yes; sealed envelope	Yes	Yes	Yes	No	No	Yes	No	Unclear	Good
Moore, 2011 ¹¹⁰	Yes; computerized	Yes; distance randomization	Yes	Yes	Unclear	No	No	Yes	No	Yes	Fair
Smith, 1990 ¹¹¹	Yes	Unclear	Yes	Yes	No	No	No	No	No	No	Poor
Vanderwee, 2007 ¹¹²	Yes; Using SPSS random number list, but randomized at ward level	Unclear	Yes	Yes	Unclear	No	No	Yes	No	Yes	Fair
Young, 2004 ¹¹³	Yes	Yes	Yes	Yes	Yes	No	No	Yes	No	No	Fair

Appendix Table H17. Key Questions 3 and 4: data extraction of dressing trials

Author, Year	Study Design	Setting Country	Eligibility Criteria and Exclusions	Study Duration of Followup	Number Screened/ Enrolled/ Analyzed	Withdrawals	Loss to Followup
Brindle, 2012 ¹¹⁴	Cohort	Hospital (cardiac surgery ICU) United States	Patients presenting with cardiac arrest; a surgical procedure expected to last more than 6 hours; vasopressors >48 hours; in septic shock, systemic inflammatory response syndrome, or multiple organ dysfunction syndrome; or has five of the following: weeping edema, traction, morbid obesity, age >65 years, diabetes, bed rest, liver failure, malnutrition, sedation/paralytics >48 hours, mechanical ventilation >48 hours, quadriplegia or spinal cord injury, nitric oxide ventilation, restraints, drive lines, or a past history of pressure ulcers Exclude: Prevalent ulcers >stage I, under age 18, pregnant, or prisoner.	NR	100 enrolled/85 analyzed	11% overall (11% vs. 10%)	5% (5/100)
Fader, 2003 ¹¹⁵	Randomized trial (cross-over)	Nursing and residential homes for older people with physical and mental disabilities United Kingdom	Females, aged >65, residing in nursing home, using incontinence pads for heavy incontinence every night Exclusion: Incontinent of feces 3 or more times per week; unable to comply with measurement; affected by skin condition of the groins, upper thighs, or buttocks; or with a grade 2 pressure ulcer; non-Caucasian or with pigmented skin in measurement area; in the terminal phase of an illness; or acutely ill	2-week baseline period followed by two 4-week interventions	81 enrolled	0	0

Author, Year	Study Design	Setting Country	Eligibility Criteria and Exclusions	Study Duration of Followup	Number Screened/ Enrolled/ Analyzed	Withdrawals	Loss to Followup
Nakagami 2007 ¹⁶	Experimental bilateral comparison study (intervention randomized to right or left trochanter)	Long-term care facility Japan	Inclusion: aged ≥ 65, Braden score < 15 Exclusion: impaired judgment, lack of consciousness, presence or pressure ulcer/skin disorder in study area, poor general medical conditions, inability to position body in either a left or a lateral position	4 weeks	NR/37/37	A vs. B: NR Total = Death: 5.4% (2/37) Pruritus: 2.7%	A vs. B: NR

Author, Year	Intervention	Baseline Demographics (Age, Sex, Race)	Ulcer Risk	Results	Harms	Quality	Funding Source
Brindle, 2012 ¹¹⁴	A: Placement on low-air-loss bed, use of silicone border foam dressing, and Mepilex Border Sacrum dressing (n=56) B: Placement on low-air-loss bed and use of silicone border foam dressing (n=39)	Mean age: 61 vs. 63 years Sex: 38% vs. 29% female Race: NR	Mean Braden score: 11.1 vs. 11.3	Any pressure ulcer: 2.0% (1/50) vs. 12% (4/35); RR 0.18 (95% CI 0.02 to 1.5); unadjusted HR 0.23 (95% CI 0.03 to 2.0), adjusted HR 0.28 (95% CI 0.02 to 3.1)	NR	Fair	NR
Fader, 2003 ¹¹⁵	A: Incontinence pad changing at 10pm, 2am, and 6am B: Incontinence pad changing at 10pm and 6am	Mean age: 85 years 100% female Race: NR	Mean Norton score: 11 Mean Braden score: 13	Any pressure ulcer: 0 vs. 5 (crossover trial; OR not reported, but 95% CI 0-1.09)	NR	Fair	NHS Research and Development grant
Nakagami 2007 ¹¹⁶	A: REMOIS PAD (dressing with a skin adhesive layer (hydrocolloid), a support layer (urethane film), outer layer of multifilament nylon fibers, .45 mm thick, oval 10 cm x 7 cm) B: No dressing	Mean age (whole sample): 86 years 76% female Race: NR	Mean Braden Score: 10.4	Persistent erythema: 5.4% (2/37) vs. 30% (11/37); RR 0.18 (95% CI: 0.04 to 0.76)	Safety of direct application of PPD tested, 1 pt. developed pruritus around the dressing, no severe product-related complications observed.	Poor	Dressing provided by ALCARE Corp., funded by a Ministry of Education, Culture, Sports, Science and Technology, Japan

Note: CI=confidence interval, NHS=National Health Service, NR=not reported, OR=odds ratio, PPD=pressure ulcer preventive dressing, RR=relative risk.

Appendix Table H18. Key Questions 3 and 4: quality assessment of dressing trials

Author, Year	Randomization adequate?	Allocation concealment adequate?	Groups similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Care provider masked?	Patient masked?	Reporting of attrition	Loss to followup: differential/high	Intention-to-treat analysis	Quality rating
Brindle, 2012 ¹¹⁴	No	Unclear	Yes	Yes	No	No	No	Yes	No	No	Fair
Fader, 2003 ¹¹⁵	Yes; coin toss	Unclear	Yes	Yes	Yes	No	No	Yes	No	Yes	Fair
Nakagami, 2007 ¹¹⁶	No	No	NA	Yes	No	No	No	No	No	Yes	Poor

Appendix Table H19. Key Questions 3 and 4: data extraction of other intervention trials

Author, Year	Study Design	Setting Country	Eligibility Criteria and Exclusions	Study Duration of Followup	Number Screened/ Enrolled/ Analyzed	Withdrawals	Loss to Followup	Intervention
Barton, 1976 ¹¹⁷	Randomized trial	Hospital England	NR 65+, no evidence of pressure sores at the time of operation	NR	NR/NR/85	NR	NR	A: 80 IU of corticotropin in a gelatin solvent, administered intramuscularly B: 80 IU gelatin solvent, administered intramuscularly
Scott, 2001 ¹¹⁸	Randomized trial	A single acute-care National Health Service trust United Kingdom	Patients aged ≥ 40 years, scheduled to undergo major surgery with an expected hospital stay of five days, with no existing sacral pressure ulcers Exclude: Patients whose procedure uses intraoperative warming as standard practice, or requires patients to use a lateral or prone position	NR (conducted over 21 months, each patient hospitalized at least 5 days)	338 enrolled/324 analyzed	14 (5 changed surgical procedure, 6 cancelled surgery, 3 due to communication breakdown)	0	A: Forced-air warming therapy and warming of all IV fluids B: Usual care included regulation of ambient temperature, minimal exposure, and availability of warming blankets immediately post-operative
Verbelen, 2007 ¹¹⁹	Randomized trial	Hospital Belgium	Patients with an expected ICU stay of ≥ 7 days, without prevalent heel or sacral ulcers	24 days	241 screened/23 enrolled	0	0	A: Treatment with polarized light for 10 minutes per day, and standard preventive care (viscoelastic or low-air-loss mattress, repositioning, and/or a viscoelastic pillow) (n=10) B: Standard preventive care (viscoelastic or low-air-loss mattress, repositioning, and/or viscoelastic pillow) (n=13)

Author, Year	Baseline Demographics (Age, Sex, Race)	Ulcer Risk	Results	Harms	Quality	Funding Source
Barton, 1976 ¹¹⁷	NR	NR	Any pressure ulcer: 12% (5/42) vs. 28% (12/43), RR = 0.43 (95% CI 0.16-1.11) By operation type Hip replacement: 0% (0/16) vs. 31% (5/16), RR 0.09 (95% CI 0.005 to 1.5) Fractured femur: 19% (5/26) vs. 26% (7/27), RR 0.74 (95% CI 0.27 to 2.0)	No complications observed	Poor	Armour Pharmaceutical Co. Limited
Scott, 2001 ¹¹⁸	Mean age: 68.4 vs. 68.2 years Sex: 54% vs. 54% female Race: NR	Mean BMI: 26.7 vs. 26.7 Diabetes: 11% vs. 7.4% Heart disease: 25% vs. 17% (p=0.09)	Any pressure ulcer: 5.6% (9/161) vs. 10.4% (17/163); RR 0.54 (95% CI 0.25 to 1.2)	NR	Fair	Augustine Medical; NHS Executive
Verbelen, 2007 ¹¹⁹	Mean age: 62 vs. 66 years Sex: 38% vs. 40% female Race: NR	NR	Any pressure ulcer: 69% (9/13) vs. 30% (3/10); RR 0.43 (95% CI 0.16-1.19); p=0.11 Pressure ulcers grade II or greater: 54% (7/13) vs. 0% (0/10); RR 0.08 (95% CI 0.01-1.33); p=0.08	NR	Poor	Equipment lent by Haromed Wound and Skin Care Solutions and Smith & Nephew

Note: BMI=body mass index, CI=confidence interval, IU=international unit, IV=intravenous, NHS=National Health Service, NNT=number needed to treat, NR=not reported, RR=relative risk.

Appendix Table H20. Key Questions 3 and 4: quality assessment of other intervention trials

Author, Year	Randomization adequate?	Allocation concealment adequate?	Groups similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Care provider masked?	Patient masked?	Reporting of attrition	Loss to followup: differential/high	Intention-to-treat analysis	Quality rating	Comment
Barton, 1976 ¹¹⁷	Unclear	Unclear	Unclear	No	Unclear	Unclear	Yes	No	Unclear	Unclear	Poor	Preliminary communication, many details missing
Scott, 2001 ¹¹⁸	Unclear; "block randomization system" undescribed	Yes; opaque envelopes	Yes	Yes	Yes	No	No	Yes	No	Yes; less than 5% unanalyzed	Fair	
Verbelen, 2007 ¹¹⁹	Unclear	Yes	Yes	Yes	Unclear	No	No	Yes	Yes (28% loss to follow-up)	No	Poor	

Appendix Table H21. Key Questions 3 and 4: data extraction of lotion trials

Author, year	Study design	Setting Country	Eligibility criteria & exclusions	Study Duration of Followup	Number Screened/ Enrolled/ Analyzed	Withdrawals	Loss to Followup	Intervention
Cooper, 2001 ¹²⁰	Randomized trial	5 long-term care facilities United Kingdom	Urinary and/or fecal incontinence	14 days	93/93/87 (66 no pressure ulcer at baseline)	6% (6/93)	None; withdrawn patients excluded from analysis	A. Clinisan cleanser (includes silicone, triclosan, benzylicum and emolients) B. Standard hospital soap
Declair, 1997 ¹²¹	Randomized trial	Intensive care unit Brazil	NR	Mean of 21 days	NR/NR/86	NR	NR	A: 1.6gm EFA with linoleic acid extracted from sunflower oil, 112 IU Vitamin A, and 5 IU Vitamin E B: 1.6 gm mineral oil, 112 IU Vitamin A, and 5 IU Vitamin E
Duimel-Peeters, 2007 ¹²²	Randomized trial (cross-over)	8 nursing homes Holland	Patients with light skin color, residing in nursing home for more than 2 months, resting on an anti-pressure-ulcer mattress, and at a high risk of pressure ulcers using a Braden cutoff of 20 Exclude: Patients already treated with massage for another purpose, undergoing surgery in near future or in prior 2 weeks, prevalent pressure ulcers at coccyx, heels, or ankles, expected short length of stay, or life expectancy less than 10 months	Two treatment periods of 4 weeks, separated by a 2-week washout period	79 eligible/79 enrolled	0	0	A: 2-3 minute massage with an indifferent cream, and repositioning every 6 hours B: 2-3 minute massage with a 5% dimethyl sulfoxide cream, and repositioning every 6 hours C: Repositioning every 6 hours
Houwing, 2008 ¹²³	Randomized trial	8 nursing homes Holland	Patients resting on an anti-pressure-ulcer mattress, at high risk of developing pressure ulcers according to Braden score <20 Exclude: Patients treated with other ointments or creams, who had were scheduled to have surgery or had undergone surgery in previous 2 weeks, with existing pressure ulcers, or with dark skin	4 weeks	79 enrolled	0	0	A: 30 degree tilt repositioning every 6 hours B: 30 degree tilt repositioning every 6 hours, plus 3-minute massage of the buttock, heel, and ankle with an indifferent cream every 6 hours C: 30 degree tilt repositioning with massage using 5% dimethyl sulfoxide cream

Author, year	Study design	Setting Country	Eligibility criteria & exclusions	Study Duration of Followup	Number Screened/ Enrolled/ Analyzed	Withdrawals	Loss to Followup	Intervention
Smith, 1986 ¹²⁴	Randomized trial	6 Long-term care facilities United Kingdom	Exclusion: existing PU	24 weeks (6 months)	NR/258/258	Redness: 2.3% (3/129) vs.0.8% (1/129) Rash: 0% (0/129) vs.0.8% (1/129) Shingles: 0.8% (1/129) vs.0% (0/129) Non compliance: 0% (0/129) vs.0.8% (1/129) Death: 16.3% (21/129) vs. 19.4% (25/129)	Transfer: 0% (0/129) vs.1.6% (2/129)	A: Conotrane (20% dimethicone 350 and .05% hydrargaphen) B: Unguentum (description NR)
Torra I Bou, 2005 ¹²⁵	Randomized trial	13 centers (hospitals and long-term care) Spain	Patients at medium, high, or very high risk of PU development; able to participate for 30 days Exclude: Patients who were terminally ill or receiving chemotherapy; had more than 3 PUs; were allergic to hyperoxygenated fatty acid or topical fatty products; or had peripheral vascular disease	30 days	380 enrolled/331 completed study	49 withdrawals: death (2), transferred or discharged (7), deterioration of condition (2), did not complete questionnaire (38)	0	A: Mepentol (hyperoxygenated fatty acids compound of oleic, stearic, palmitic, palmitoleic, linoleic, gamma linoleic, arachidonic, and eicosenoic acids and extracts of Equisetum arvense and Hypericum perforatum) (n=164) B: Inert lotion (trioistearin and perfume) (n=167)
van der Cammen, 1987 ¹²⁶	Randomized trial	Hospital (geriatric wards) United Kingdom	Chair bound patients with Norton scores between 5 and 14, without prevalent ulcers, no severe or terminal illness, and an expected stay of 3 or more weeks	3 weeks	NR/120/104	16 (6 in Prevasore group and 10 in Dermalex group; 8 deaths, 6 discharges, 1 transfer, 1 wet sore)	0	A: Prevasore cream B: Dermalex cream

Author, year	Baseline Demographics (Age, Sex, Race)	Ulcer Risk	Results	Harms	Quality	Funding Source
Cooper, 2001 ¹²⁰	Mean age 85 vs. 79 years 80% vs. 55% female Race: NR Duration of hospitalization 1.72 vs. 0.38 years	All patients had incontinence Results reported separately for patients with no pressure ulcers at baseline	Any pressure ulcer: 18% (6/33) vs. 42% (14/33); RR 0.43 (95% CI 0.19 to 0.98) Stage 2 ulcer: 3.0% (1/33) vs. 12% (4/33); RR 0.25 (95% CI 0.03 to 2.1)	One case of blistering in a Group B patient; determined not to be study related	Fair	Venture Healthcare
Declair, 1997 ¹²¹	Mean age: 60 (range 26- 78) % women: NR % nonwhite: NR	Mean Norton score: 9 (whole sample) Pressure ulcers at baseline: Not reported	Any pressure ulcer: 4.7% (2/43) vs. 28% (12/43); RR 0.17 (95% CI 0.04 to 0.70) PU incidence according to severity: Stage 1 ulcer: 4.6% (2/43) vs. 0% (0/43); RR 5.0 (95% CI 0.25 to 101) Stage 2: 0% (0/43) vs. 28% (12/43); RR 0.04 (95% CI 0.002 to 0.66)	NR	Poor	NR
Duimel- Peeters, 2007 ¹²²	Mean age: 81 years Sex: 70% (55/79) female Race: NR	Mean BMI: 21.7	Treatment period 1 Incident ulcers: 41.9% (13/31) vs. 62.1% (18/29) vs. 38.9% (7/18); p=0.189 AOR: 1.14 (p=0.834) vs. 2.57 (p=0.126) vs. 0.64 (p=0.35) Treatment period 2 Incident ulcers: 13.6% (3/22) vs. 12.0% (3/25) vs. 5.9% (1/17); p = 0.726 AOR: 2.53 (p=0.441) vs. 2.18 (p=0.516) vs. 0.06 (p=0.007)	NR	Poor	NR
Houwing, 2008 ¹²³	Median age: 83 vs. 85 vs. 81 years Sex: 82% vs. 75% vs. 72% female Race: NR	Incontinence (sometimes/ always): 100% vs. 94% vs. 83% Pressure ulcers at baseline: Excluded	Any pressure ulcer: 62% (18/29) vs. 31% (10/32) vs. 39% (7/18); RR 2.0 (95% CI 1.1 to 3.6) for A vs. B, RR 1.6 (0.84 to 3.0) for A vs. C, and RR 0.80 (95% CI 0.37 to 1.7) for B vs. C Buttock ulcer: 38% (11/29) vs. 22% (7/32) vs. 33% (6/18); RR 1.7 (95% CI 0.78 to 3.9) for A vs. B, RR 1.1 (95% CI 0.51 to 2.5) for A vs. C, RR 0.66 (95% CI 0.26 to 1.7) for B vs. C Heel/ankle ulcers: 55% (16/29) vs. 16% (5/32) vs. 17% (3/18); RR 3.5 (95% CI 1.5 to 8.4) for A vs. B, RR 3.3 (95% CI 1.1 to 9.8) for A vs. C, RR 0.94 (95% CI 0.25 to 3.5) for B vs. C	Higher incidence of pressure ulcers in intervention group than control	Poor	NR

Author, year	Baseline Demographics (Age, Sex, Race)	Ulcer Risk	Results	Harms	Quality	Funding Source
Smith, 1986 ¹²⁴	Mean age: 82 years (63-98) vs.83 years (69-102) % women: 81% vs.82% nonwhite: NR	Baseline ulcer risk not reported Pressure ulcers at baseline: Excluded	One or more ulcers: 27% (35/129) vs. 36% (47/129); RR 0.74 (95% CI 0.52 to 1.1) Grade 3 or 4 (Barbarell et al system): 3.9% (5/129) vs. 3.9% (5/129); RR 1.0 (95% CI 0.30 to 3.4)	11 patients developed redness of skin and/or rash, only 5 withdrew.	Poor	W.B. Pharmaceuticals
Torra I Bou, 2005 ¹²⁵	Mean age: 84 vs. 84 years Sex: 75% vs. 72% female Race: NR	Mean Braden score: 12.4 vs. 12.4 Pressure ulcer at admission: 24.4% vs. 21.6%	Incidence of pressure ulcer development: 7.3% (12/164) vs. 17.4% (29/167); p<0.006; RR 0.42 (95% CI 0.22-0.80)	Not reported	Fair	Laboratorios Bama-Geve SA
van der Cammen, 1987 ¹²⁶	Mean age: 82 vs. 83 years Sex: 74% vs. 74% female Race: NR	Mean Norton score at entry: 11.4 vs. 11.5 Pressure ulcers at baseline: Excluded	Deterioration in skin condition: 13% (7/54) vs. 22% (11/50); RR 0.59 (95% CI 0.25 to 1.4)	Wet sore developed in one group, possibly related to treatment (does not report which group)	Poor	NR

*Grading according to Barbenel, 1977¹²⁷: Grade I - skin intact; Grade II - superficial sore; Grade III - skin destruction without cavity; Grade IV - Skin destruction with cavity.

Note: AOR=adjusted odds ratio, BMI=body mass index, CI=confidence interval, EFA=essential fatty acids, IU=international unit, NR=not reported, OR=odds ratio, PU=pressure ulcer, RR=relative risk.

Appendix Table H22. Key Questions 3 and 4: quality assessment of lotion trials

Author, Year	Randomization adequate?	Allocation concealment adequate?	Groups similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Care provider masked?	Patient masked?	Reporting of attrition	Loss to followup: differential/high	Intention-to-treat analysis	Quality rating	Comment
Cooper, 2001 ¹²⁰	Unclear	Yes	No (gender; length of stay)	Yes	Yes	No	No	Yes	No	Yes	Fair	
Declair, 1997 ¹²¹	Unclear	Unclear	Unclear	No	Yes	Yes	Yes	No	Unclear	Unclear	Poor	
Duimel-Peeters, 2007 ¹²² (Same study population as Houwing, 2008 ¹²³)	Yes; dice throw (cluster randomization)	No	Yes	Yes	No	No	No	Yes	No	No	Poor	No assessment of cluster correlation
Houwing, 2008 ¹²³ (Same study population as Duimel-Peeters, 2007 ¹²²)	Yes; dice throw (cluster randomization)	No	Yes	Yes	No	No	No	Yes	No	Yes	Poor	No assessment of cluster correlation
Smith, 1986 ¹²⁴	Unclear	Unclear	Unclear	No	Unclear	Yes	Yes	No	Yes	Yes	Poor	
Torra I Bou, 2005 ¹²⁵	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Fair	
van der Cammen, 1987 ¹²⁶	Unclear	Unclear	Yes	Yes	Unclear	No	No	Yes	No	No	Poor	

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