Comparative Effectiveness Research Review Disposition of Comments Report

Research Review Title: *Pressure Ulcer Risk Assessment and Prevention: A Comparative Effectiveness Review*

Draft review available for public comment from June 11, 2012 to July 9, 2012.

Research Review Citation: Chou R, Dana T, Bougatsos C, Blazina I, Starmer A, Reitel K, Buckley D. Pressure Ulcer Risk Assessment and Prevention: Comparative Effectiveness. Comparative Effectiveness Review No. 87. (Prepared by Oregon Evidence-based Practice Center under Contract No. 290-2007-10057-I.) AHRQ Publication No. 12(13)-EHC148-EF. Rockville, MD: Agency for Healthcare Research and Quality. May 2013. www.effectivehealthcare.ahrq.gov/reports/final.cfm.

Comments to Research Review

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The tables below include the responses by the authors of the review to each comment that was submitted for this draft review. The responses to comments in this disposition report are those of the authors, who are responsible for its contents, and do not necessarily represent the views of the Agency for Healthcare Research and Quality.

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Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #1	General	General Comments: Highly meaningful; questions are well-defined and are appropriate	Thank you for the comment.
Peer Reviewer #1	General	Clarity and Usability: Yes	Thank you for the comment.
Peer Reviewer #1	Introduction	Introduction: Appropriate. I would be careful with statement that pressure ulcers affects 3 million adults in US. This number is taken from a reference which cites another 1989 source that is titled dermal ulcers (not pressure ulcers) among people who have died. I am not familiar with this reference but am skeptical as to the accuracy of this number and its support for statement.	We revised to give a broader range (1.3 to 3 million) as cited in an article by Lyder in JAMA. Unfortunately it is difficult to obtain an accurate estimates of pressure ulcer incidence in the U.S.
Peer Reviewer #1	Methods	Methods: Methods generally are appropriate; I have one concern regarding inclusion/exclusion criteria that apply to the entire document. There is no discussion of the spinal cord injury population. It does not appear that studies with spinal cord injury patients were excluded. That said, many people in the SCI community believe that tools such as Braden are inappropriate as everyone is at risk. I strongly recommend an explicit discussion of this population.	The reviewer is correct, patients with spinal cord injury were not excluded. However, few studies specifically addressed this population (either for assessments of risk assessment scales or preventive interventions). We revised the Discussion/Implications for Clinical and Policy Decisionmaking section to reflect the reviewer's comment: "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."
Peer Reviewer #1	Results	Results: Large number of studies are included. I was surprised that the extremely well done and large PRESSURE study published in 2006 in BMJ (Jane Nixon lead author) was not included in Table 11. Isn't this an example of dynamic compared to dynamic? Perhaps it was excluded as subjects not "at-risk" although I would argue that post-surgical patients are at-risk	This study was originally excluded because it enrolled more than 10% of patients with ulcers at baseline. However, several reviewers noted that this and similar studies were relevant for understanding the effectiveness of preventive interventions. We agreed that studies that enrolled some patients with pre-existing ulcers could be informative for understanding effectiveness for prevention if they reported incident ulcers. Therefore we revised the inclusion criteria to incorporate trials that enrolled <10% of patients with pressure ulcers at baseline and reported incident ulcers. This trial was added to the report.

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Peer Reviewer #1	Discussion	Discussion/ Conclusion: Given the lack of well-performed studies in many key areas, the future research section is relatively brief."	We fleshed out the Future Research section with the following: "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. More research is 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 heel ulcers compared with other types of pressure ulcers."
Peer Reviewer #1	Executive Summary	On page ES16 and in main text in discussing risk assessment instruments it states "No study that reported risk estimates attempted to control for confounding effects of differential use of interventions" This makes no sense. How could a risk assessment tool lead to better outcomes other than through the more appropriate use of interventions. One would expect that any benefit of risk assessment would disappear once one controlled for interventions.	The sentence in question is referring to studies of diagnostic accuracy, not studies of interventions. In studies of diagnostic accuracy, as this reviewer previously commented, differential use of interventions can affect predictive utility but can be adjusted for when analyzing HR's and RR's (i.e. the risk of an outcome in persons with a positive screen vs. the risk in persons with a negative screen, adjusted for use of interventions). We revised this sentence to be clearer that we are referring to studies of diagnostic accuracy.
Peer Reviewer #2	General	Clarity and Usability: The report is very well structured and organized, and the main points are clearly presented. It's not clear that the conclusions can be used to inform policy and practice but that is because of the weakness of the evidence base, not because of the limitations of the review itself.	Thank you for the comment.
Peer Reviewer #2	General	General Comments: The report is very clearly written and clinically meaningful. The target population and audience are explicitly defined. The key questions are appropriate and explicitly stated.	Thank you for the comment.
Peer Reviewer #2	Introduction	Introduction: The introduction is clearly written and appropriate. The authors may wish to consider the following comments:	Thank you for the comment. See responses to specific comments below.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #2	Executive Summary	On page ES-1 and elsewhere, the authors present estimates of pressure ulcer prevalence in different health care settings. The ranges for these estimates are extremely wide varying by several orders of magnitude in some cases (e.g., 0.4 to 38 percent in acute care hospitals). This wide range reflects the huge diversity in the prevalence studies with respect to the location, year, and methods used to detect pressure ulcers. For the review to present a meaningful introduction to the problem of pressure ulcers, it might be more useful to focus on a few recent studies that used reasonable detection methods. The results could be presented separately for the US and other countries if the estimates differ widely by geographic region.	Unfortunately there is no single "best" estimate of pressure ulcer incidence, and the estimates we reported are all relatively recent (since 2001) and from the U.S. However, we added this sentence regarding the variability in rates: The variation in estimates is due in part to differences in how ulcers are assessed and defined and differences in the populations evaluated.
Peer Reviewer #2	Executive Summary	On page ES-1 (and elsewhere), the authors state that higher body weight is a risk factor for increased pressure ulcer risk. However, there is at least one study that found that higher body weight was protective (Compher C et al. Journals of Gerontology: Medical Sciences 2007;62:1310-1312).	Thank you for pointing this out, it should have said "lower body weight". We corrected it.
Peer Reviewer #2	Executive Summary	On page ES-1 and elsewhere, the authors state that black skin is a risk factor for increased pressure ulcer risk. It might be more accurate to say that being black is the risk factor or that African Americans have a higher risk.	We changed to "black race"
Peer Reviewer #2	Executive Summary	On page ES-1, the authors state that the total annual cost of pressure ulcers in the US may be as high as $11 billion. The source for this statement is an AHRQ statistical brief that reported that “Adult hospital stays noting a diagnosis of pressure ulcers totaled $11.0 billion in 2006” (http://www.hcup-us.ahrq.gov/reports/statbriefs/sb64.pdf). Since it is not appropriate to attribute all health care costs among patients with a diagnosis of pressure ulcers to the pressure ulcers, it would be preferable to remove this statement from the review or to qualify it to avoid misinterpretation.	We deleted as suggested.
Peer Reviewer #2	Executive Summary	On page ES-1 (and elsewhere), review articles are cited as references. In general, it is preferable to cite the original article for a particular statement. This helps to avoid misinterpretation and to ensure that the reader is aware of the year in which the original finding was published.	We replaced references to review articles for estimates of cost. Some estimates come from guidelines, position statements, or key review articles and we believe are appropriate for Introductory/background material. Otherwise original sources are cited.
Peer Reviewer #2	Executive Summary	On page ES-5, it is not clear what is meant by “maintenance of comparable groups” as a quality criterion.	As described in the cited reference to USPSTF methods, this refers to studies not having differential rates of attrition, crossover, or use of co-interventions.
Peer Reviewer #2	Executive Summary	On page ES-6, the categorization of study quality is described. It is not clear whether blinding of the outcome assessment is a prerequisite for being classified as a good-quality study.	We revised to be clear that good-quality studies should have blinded measurement of outcomes (it said "appropriately measure outcomes" which was more vague)

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Peer Reviewer #2	Executive Summary	On page ES-16 (and elsewhere), the authors note that studies did not “control for potential confounding effects of differential use of interventions”. However, it would not be inappropriate to control for use of interventions as a confounder since use of interventions is a step in the causal pathway between risk assessment and pressure ulcer outcome. A more appropriate approach might be to use mediation analysis which would allow the investigator to estimate both the direct effect and the indirect effect (through differential use of interventions) of a given risk assessment result on pressure ulcer risk.	The sentence in question is referring to studies of diagnostic accuracy, not studies of interventions. In studies of diagnostic accuracy, as this reviewer previously commented, differential use of interventions can affect predictive utility but can be adjusted for when analyzing HR's and RR's (i.e. the risk of an outcome in persons with a positive screen vs. the risk in persons with a negative screen, adjusted for use of interventions). We revised this sentence to be clearer that we are referring to studies of diagnostic accuracy.
Peer Reviewer #2	Executive Summary	On page ES-17 (and elsewhere), the authors state that “If such interventions are truly effective, they would be expected to result in underestimates of pressure ulcers”. Using the word “underestimates” implies that there is bias, whereas the results of effective interventions would be a real reduction in pressure ulcer risk. Better wording might be “If such interventions are truly effective, they would be expected to result in lower pressure ulcer incidence”.	We revised to state: "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, and lower estimates of diagnostic accuracy."
Peer Reviewer #2	Executive Summary	On page ES-18 and elsewhere, the authors emphasize the fact that the studies of preventive interventions had usual care as the standard of comparison. It might be worth adding a discussion of the difficulties of conducting such studies, given that many clinicians would consider it unethical to withhold standard care practices from the comparison group participating in a clinical trial of a new preventive intervention. Also, the authors may wish to point out the ambiguity of the term “standard hospital mattress”.	We already note that "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" (ES-18 line 24-26), "It is critical that future studies of preventive interventions...clearly describe usual care and other comparison treatments" (ES-19 line 42-43) and have added a sentence to the Applicability section stating "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." (ES-17 line 40)
Peer Reviewer #2	Introduction	On page 1, fourth paragraph, the authors discuss pressure ulcer risk factors. The authors might consider a slight rewording the first sentence of that paragraph because it suggests that increased age is a comorbidity and that cognitive impairment affects tissue integrity.	Revised to state: "Risk factors for pressure ulcers include older age, cognitive impairment, and physical impairments that affect soft tissue integrity and healing (such as urinary incontinence, edema, impaired microcirculation, hypoalbuminemia, and malnutrition).

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Peer Reviewer #2	Methods	Methods: In general, the methods are appropriate and methodologic limitations of the review are clearly explained. The authors may choose to consider the following comments: On page ES-5, the authors state that one of the factors considered in rating the quality of the studies was “the similarity of compared groups at baseline”. Randomization should result in fairly balanced groups but can, by chance, result in groups that are not similar on all variables. It does not seem appropriate for a well-done study to receive a lower quality rating based on this outcome.	Baseline differences in a randomized trial can occur due to chance or because of manipulation of treatment allocation. In either case, baseline differences can result in biased estimates and are therefore appropriate markers for quality (and included in many quality rating instruments, including the Cochrane Back Review Group, the USPSTF, and others).
Peer Reviewer #2	Results	Results: The results section is comprehensive and very detailed. The key messages are explicit and applicable. Figures and tables are clear. The authors may choose to consider the following comments: Table 6: The date is missing for the Berthe et al. reference.	Thank you for the comment. We added the date for the Berthe reference
Peer Reviewer #2	Results	The authors often use the term “trend” to refer to situations where a result was not statistically significant at the conventional 5% level. It might be better to avoid this term unless a precise definition is provided. Better wording (as used, for example, on page 41) is “the results were just above the standard threshold for statistical significance” or (as used on page 52) “although results favored the warming intervention”.	We revised several places in the report to eliminate use of the term "trend" to refer to a result that did not reach standard statistical significance, and rather described the result more explicitly. For example: "Five fair-quality trials (n=83 to 543) found a more advanced static mattress or overlay associated with decreased risk of incident pressure ulcers (RR range 0.20 to 0.60) compared with a standard mattress, though the difference was not statistically significant in one trial.
Peer Reviewer #2	Results	Page 32, last paragraph: It would be preferable to drop the description of a study that did not meet inclusion criteria.	We deleted as suggested (this trial was only published as an abstract).

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #2	Results	It might be misleading to use the term “diagnostic accuracy” when discussing studies of the pressure ulcer risk assessment tools. Diagnostic accuracy is generally determined in a cross-sectional study, where the investigators estimate the ability of the screening test or diagnostic test to detect disease that is present at the same time as the administration of the test. In such a situation, sensitivity is the proportion of those with the disease who are correctly identified by the test as having the disease, and specificity is the proportion of those without the disease who are correctly identified by the test as not having the disease. The studies reviewed in this document, however, were estimating the ability of a test to predict future pressure ulcers in situations where interventions that could potentially prevent pressure ulcers were almost certainly administered in the group identified as being at high risk. In such studies, sensitivity must be interpreted as the proportion, among those who developed a pressure ulcer some time after undergoing the risk assessment, whose earlier risk assessment score indicated high risk of pressure ulcers. Specificity is interpreted as the proportion, among those who did not develop a pressure ulcer some time after undergoing the risk assessment, whose earlier risk assessment score did not indicate high risk of pressure ulcers. As indicated by the authors, specificity is difficult to interpret in these studies given that it reflects some combination of the accuracy of the risk assessment tool, the frequency of use of preventive interventions among those categorized as being at high risk, and the effectiveness of those preventive interventions. Given this low level of interpretability, it might be appropriate for this review to suggest that further research of this type is not likely to be productive.	We do not think it is misleading to use the term diagnostic accuracy, as sensitivity, specificity, and the AUROC are measures of diagnostic accuracy. We agree with the reviewer's comments, and make many of the same points (see p 9 lines 13-19 and p 78 lines 11-13). In addition, in the Future Research section (p 78 lines 38-40) we recommend that studies report use of preventive interventions and consider reporting adjusted risk estimates.
Peer Reviewer #2		In light of the difficulty in interpreting the results of the studies of risk assessment tools, it may not be appropriate to conclude that “commonly used instruments can predict which patients are more likely to develop an ulcer”. The positive predictive value of most of these tools is very low, given their low specificity. For example, assuming an incidence of pressure ulcers of 20%, sensitivity of 90%, and specificity of 70%, only 43% of those classified as being at high risk would be predicted to develop a pressure ulcer. In fact, it might be more accurate to say that the risk assessment tools can predict which patients are LESS likely to develop an ulcer.	The predictive value of a risk prediction instrument depends both on the sensitivity and specificity at a specific cutoff, and is not solely dependent on the positive predictive value. In the example cited by the reviewer, the positive likelihood ratio is 3.0, meaning that the odds of an ulcer with a positive screen based on a risk prediction instrument is 3 times higher than prior to applying the risk prediction instrument. We believe that most clinicians would find this information clinically useful. In addition, risk prediction instruments are typically not designed to have high positive predictive values (e.g. "high-risk" patients based on cardiovascular risk prediction instruments have a 10-year risk of only >20%).

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Peer Reviewer #2	Discussion	Discussion/ Conclusion: The implications of the findings are clearly stated. The limitations of the studies and of the review are adequately described. The future studies section is clear and easily translated into new studies. The authors may choose to consider the following comments:	Thank you, for the comment.
Peer Reviewer #2	Discussion	One finding of the review is that there is little evidence regarding the effectiveness of advanced dynamic support surfaces. It might be worth mentioning that, in spite of this lack of evidence, advanced support surfaces (which are quite expensive) are in wide use in hospitals in many areas of the country.	We revised the Discussion/Implications for Clinical and Policy Decisionmaking section to state: "Despite limited evidence, advanced dynamic support surfaces are used in hospitals in many areas of the United States. Dynamic 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."
Peer Reviewer #2	Discussion	The search strategy included studies identified through MEDLINE as early as 1946 and through CINAHL as early as 1988. Some of the support surfaces evaluated many years ago (e.g., the Beaufort Bead Bed system) are no longer in use, limiting the applicability of those findings.	We revised the Discussion/Applicability section to state: "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."
Peer Reviewer #2	Discussion	It might be worth adding a discussion of the fact that many of the trials of support surfaces evaluated specific brand name products and that it may be difficult to generalize the results to other products in the same class. This problem is exacerbated by the constantly changing range of products sold and marketed by the major support surface manufacturers.	We added to the Discussion/Applicability section: "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."
Peer Reviewer #2	Tables	Page 2, table 1: The NPUAP classification refers to “staging” not “grading”. Also, here and elsewhere, there appears to be an error in the reference cited for the staging system.	Several reviewers commented on this. We revised Table 1 and the corresponding text to be consistent with the current (2009) NPUAP/EPUAP system
Peer Reviewer #2	Tables	Table 7: Given that the trials are arranged by quality ratings, it may not be necessary to repeat the quality rating in each row. The title “static compared with static” may be confusing to the reader. In the description of the Inman et al. trial, “95%” is missing from the “results” column. It is not clear what is meant by “open label” for the Jolley et al. trial.	We are re-organizing this table so it is organized alphabetically, as the reviewer notes the quality ratings are already included with each trial and we won't have a separate header for it. The complete title refers to "…static compared with static mattresses and overlays" which we believe should be clear to most readers. We added "95%" prior to the CI's for the Inman trial. "Open-label" means the trial was not blinded; we removed this since we didn't report it for every trial (the overall quality rating is provided).

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Peer Reviewer #2	Tables	Results tables: In the footnotes, “Pressure Ulcer Risk Assessment” should not have initial capitalizations. Also in the footnotes, it is not clear what is meant by “general” cutoffs for at-risk. Since the “patient characteristics” column refers to groups A and B, it might be better to have the “interventions” column precede the “patient characteristics” column.	We changed the footnote for the various results tables for KQ 3 to be clearer: "Higher 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". We reversed the orders for the interventions and patient characteristics columns for Tables 12 and 13.
Peer Reviewer #2	Tables	Table 16: The row for Key Question 2 is empty.	The results are provided below for the various risk instruments (Braden, Norton, etc.), see also KQ 1, 2a, 2b, 3, 3a, and 4
Peer Reviewer #2	General	Clarity and Usability: The report is very well structured and organized, and the main points are clearly presented. It’s not clear that the conclusions can be used to inform policy and practice but that is because of the weakness of the evidence base, not because of the limitations of the review itself.	Thank you for the comment.
Peer Reviewer #3	Abstract	"Abstract: Would benefit from stating all specific prevention strategies/interventions that were included in (Key Question 3)."	As stated in the Methods, we included all preventive interventions, so we did not want to be restrictive in describing which interventions were included.
Peer Reviewer #3	Executive Summary	Extended Executive Summary and Main Methods: These sections are quite difficult to navigate as a number of questions are addressed by this review. I suggest that Search Strategy and study selection; Data extraction and quality assessment; Data Synthesis, Implications and Future Research would benefit from sub-headings by key review questions to make it easy for users of the review to locate information.	The Methods are mostly applicable across key questions so we don't think it would be efficient to break up the Methods by key question. In addition, we feel that the Clinical Implications and Future Research sections are relatively brief (half a page or so) and do not warrant breaking down by Key Question.
Peer Reviewer #3	Methods	Data Synthesis and Rating the Strength of the Body of Evidence should be separated.	Because we did not perform meta-analysis, evidence synthesis and rating the body of evidence overlap substantially (e.g., both are based on the quality, precision, consistency, etc. of studies). Therefore we left these sections combined.

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Peer Reviewer #3	Methods	Data/Evidence synthesis should be structured with sub-headings based on the key questions. Analysis methods is partly determined by study designs acceptable and review question, so should be differentiated. There is insufficient information on methods used to synthesis the results for preventive intervention specifically, what data was extracted from eligible trials and how this was summarized. For eg., Is it what the study authors reported or did the review authors calculate relative risk for each trial based on the data presented so that there is some consistency in the presentation of the results? I am also not sure why meta-analysis was not attempted for some of the prevention devices (support surfaces) as there are sufficient studies to do so for some comparisons, eg., standard compared to static mattresses; sheepskins and for some other comparisons (see McInnes et al., 2011 – full citation below)."	The Data Extraction section (p 8) describes the type of data that was extracted from each trial. We revised to be clear that we calculated the RR from each trial to verify results: "For studies of interventions, we calculated relative risks 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." We did not perform meta-analysis because in our judgment there was substantial clinical heterogeneity even among the comparisons mentioned by the reviewer (e.g. the static support surfaces varied as well as the standard mattress control; the populations varied; and study quality varied--see response to similar comment by reviewer above [who was an author on the McInnes review]).
Peer Reviewer #3	Methods	There should also be some discussion of how cohort studies were considered relative to trials where both types of study design were available for an 'effectiveness' review question, as it is stated that cohort studies and trials were considered for questions 1,3,4 (ES-5). Was a sensitivity analysis done or were cohort studies discounted where there were adequate trials?	As stated in the Methods, we applied the methods outlined in the AHRQ Methods Guide for rating studies. RCT's are prioritized over cohort studies when present, assuming the RCT's were designed and conducted appropriately. For evaluation of preventive interventions this really had little bearing as almost all of the trials were RCT's (i.e. cohort studies had no real impact on how evidence was graded).
Peer Reviewer #3	Methods	Re. Search Strategy and Study Selection, ES-4, what was the basis of the decision to settle on excluding studies 'that enrolled >10 percent of the population with pressure ulcers at baseline? 'There just needs to be some explanation/rationale stated"	We originally used an a priori cutoff of >10% in order to focus on trials of prevention (rather than treatment). However, as described in responses to several comments by peer reviewers, we are now including trials that patients with pressure ulcers at baseline, as long as they reported incident ulcers and the prevalence of stage 2 or higher ulcers at baseline was <20%. We believe that the focus on incident ulcers still make such trials informative for understanding effect on prevention.
Peer Reviewer #3	Results	References McInnes E, Jammali-Blasi A, Bell-Syer S, Dumville J, Cullum, N. Support surfaces for pressure ulcer prevention. Cochrane Database of Systematic Reviews, Issue 4, 2011, doi:10.1002/14651858.CD001735.pub4"	We did not include systematic reviews, but reviewed the reference list of this review for potentially relevant studies, and discuss differences between the findings of this review and ours (p 76 lines 16-24).
Peer Reviewer #3	Figures	Fig 1 Diagram: Listing the preventive interventions in a box would be useful to ensure readers understand the scope of the review."	As stated in the Methods, we included all preventive interventions, so we did not want to be restrictive in describing which interventions were included.

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Peer Reviewer #3	General	This is a very comprehensive document on an important topic which gives a welcome overview of the state of the evidence regarding pressure ulcer risk assessment and prevention. I appreciate that the work that has gone into this is immense. The summaries of evidence will be very useful for practitioners, policy-makers and researchers. The suggestions I have are mainly minor but may help to strengthen the overall document and improve the readability.	Thank you for the comment. See responses to specific comments below
Peer Reviewer #4	Introduction	Introduction: The definition of a pressure ulcer needs to be reviewed in line with the NPUAP 2009 guidelines	See responses to similar comments by other reviewers. We revised the description of pressure ulcers to "stages" using the 2009 NPUAP/EPUAP guidelines.
Peer Reviewer #4	Methods	Methods: The inclusion and exclusion criteria is justifiable The search strategies are explicitly stated and logical The definitions or diagnostic criteria for the outcome measures are appropriate The statistical methods used are appropriate	Thank you for the comment.
Peer Reviewer #4	Results	Results: The amount of detail presented in the results section is appropriate The characteristics of the studies are clearly described The key messages are explicit and applicable? Figures, tables and appendices are adequate and descriptive. Table 15 page 96 id missing Moore	Thank you for the comment. The Moore study on repositioning was not included in Table 15 because it did not report harms.
Peer Reviewer #4	Results	Did the investigators overlook any studies that ought to have been included For the dressings and topical agents interventions: Tora I Bou 2005 Journal of Wound Care 13(3):117-21 Han 2011 Chinese Nursing Research 25 (2A) 308-310	The Torra I Bou trial was reviewed and added to the report as it met inclusion criteria. The Han trial is Chinese language so does not meet inclusion criteria, but is listed in the Appendix showing non-English language trials that appeared to meet inclusion criteria.
Peer Reviewer #4	Results	Not clear why Vanderwee was excluded (repositioning study)	Vanderwee was originally excluded because it only included patients with pressure ulcers at baseline. It has been added to the report after revising the inclusion criteria to include patients with stage 1 ulcers at baseline if incident ulcers were reported
Peer Reviewer #4	Discussion	Discussion/ Conclusion: The implications of the major findings are clearly stated The limitations of the review/studies are described adequately Important literature is not omitted in the discussion Future research section is clear, however, through no fault of the authors this may not be easily translated	Thank you for the comment.
Peer Reviewer #4	General	Clarity and Usability: The report is well written, the conclusions may not be able to guide practice due to the overall poor quality of the research	Thank you for the comment.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #4	General	General Comments: The report is clinically meaningful. The target population and audience are explicitly defined. The key questions are appropriate and explicitly stated.	Thank you for the comment.
Peer Reviewer #5	Introduction	Introduction: Good, although It would be better not to expect the relation between the use of the scales and incidence/prevalence	See response to similar comment by this reviewer
Peer Reviewer #5	Methods	Methods: Excellent. Two remarks: in the abstract you forgot to mention the database CNAHL. Although by the results it is mentioned that there were dual reviews, I would like to see this in the method section, and the way you handled different scores between the reviewers. And when possible the interrator reliability between the reviewers.	We added CINAHL to the data sources in the abstract. P 6-7 of the Methods states that two investigators reviewed citations/full-text articles for inclusion and that discrepancies were resolved through discussion and consensus, with a third investigator as necessary. A similar process was used to assess quality and we added similar text to the Methods section there. We did not record interrater reliability; we are unaware of any data showing how such information affects the reliability or usefulness of systematic reviews.
Peer Reviewer #5	Discussion	Discussion/ Conclusion: See my remarks in the general comment section	See responses to other comments by this reviewer.
Peer Reviewer #5	General	Clarity and Usability: Clarity and usability is good.	Thank you for the comment.
Peer Reviewer #5	General	The assumption still will be that risk assessment scales adequately diagnose the risk of a patient. However until now there is no good risk assessment scale. They all are adequate to a certain degree, but we can't get them better. There is also a theoretical reason for. We test them in an environment where already preventive measures are used, which means that not very one who is at risk will develop a pressure ulcers (see attachment). So the instruments never will get an excellent sensitivity and specificity. But also when we would have an ideal environment it would not be possible, because there are so many factors involved, that it is impossible to measure them. Based on this I think the only recommendations can be the use one of the risk assessment scales and your clinical view. And regarding research, don't go one with developing or testing risk assessment scales (maybe when bio mechanic research will give more understanding of the development of pressure ulcers we can develop new instruments) but start testing preventive measures.	Thank you for the comment. We addressed the diagnostic accuracy of risk assessment instruments in one of the key questions, and discuss issues with interpreting diagnostic accuracy, particularly as related to differential use of interventions, in the Methods and in the Discussion. The purpose of this report is to summarize the evidence, not to make recommendations on clinical practice; though the American College of Physicians plans to use this report to inform clinical recommendations.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #5	General	The report is clinically meaningful. However my general remark is that it is a very technical report. What I mean is the following. All existing knowledge is put together in a very precise and adequate way. But I miss a more theoretical view. For instances with research question 1 it is investigated if the use of a risk assessment scale improves incidence and/or prevalence. However from a theoretical point of view there is no reason to expect that using a risk assessment scale improves incidence, although we would like this of course. Risk assessments scales only can improve the intention to use adequate preventive measures. If this intention can be done (preventive measures are available, nurses have the time to do it, have the knowledge which ones are the best etc) than it can have an effect on incidence or prevalence.	Thank you for the comment. We agree with the reviewer's statement that the effectiveness of using risk assessment scales in improving clinical outcomes will depend on the effectiveness of the interventions that follow. The goal, in fact, of any risk assessment instrument should be to improve clinical outcomes; otherwise why would they be used? Risk assessment instruments that are more accurate should lead to more informed and better use of interventions. This is true of any screening, diagnostic, or risk assessment instrument. Showing that use of risk assessment scales leads to improved clinical outcomes provides the most direct evidence about its clinical utility. Diagnostic accuracy (which we also evaluated), though it can provide some important information, is only an intermediate outcome.
Peer Reviewer #6	Introduction	Introduction: Page 33: the word grade has been dropped, use stage or category. Include Deep Tissue Injury. Unstageable ulcers are those in which the bottom of the ulcer cannot be seen, due to slough or eschar, not overlying purulent material (line 39) (not sure who uses "stage X") The S3I table has been updated, see npuap.org or 2009 guidelines Line 44, include microclimate page 35, line 47. The aspect being discussed is tailoring the interventions to the level and type of risk, rather than just the total score from the risk assessment tool. (Note this reviewer's comments refer to page numbers at the top rather than the report page numbers at the bottom, which is what we used).	See responses to similar comments by other reviewers. We revised the description of pressure ulcers to "stages" using the 2009 NPUAP/EPUAP guidelines.
Peer Reviewer #6	Methods	Methods: Nothing included on peds, need to acknowledge this (page 35) Include the palliative risk assessment tool by Chaplin (page 46, 52)	The Methods/Scope section states that the target population is adults (p 7 lines 14-15). The Chaplin study (Journal of Tissue Viability, 2000;10:27) was reviewed but does not meet inclusion criteria because it did follow patients for development of pressure ulcers or report measures of diagnostic accuracy.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #6	Results	Results: page 56, does the risk assessment tool aid in the prediction of heel ulcers? A recent analysis by NDNQI indicated that patients with pressure ulcers on the heels had Braden scores around 18. The problem is that heel ulcers develop in neuropathic and ischemic patients, risks for whom the scales do not directly address	Only one study (Tourtual et al, 1997) specifically evaluated the predictive utility of a risk assessment tool for heel ulcers. It compared the Braden scale to a number of alternative, derived scales, and found no difference in diagnostic accuracy. We added two sentences describing this study. "One poor-quality (n=291) study that focused on heel ulcers found a Braden 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." (section on the Braden scale). "One poor-quality study (n=291) found no difference in the AUROC for the Braden scale vs several alternative scales for prediction of heel ulcers." (Section on direct comparisons between scales). We also added a sentence to the Future Research section noting that more evidence is needed to understand if diagnostic accuracy for risk prediction instruments differs specifically for heel ulcers. We found one unpublished study that reported findings similar to those cited by the reviewer (Braden scores about 18 in persons with heel ulcers); the study did not report diagnostic accuracy.
Peer Reviewer #6	Results	page 57, line 20...the comparison group had no leg elevation!!	The reviewer is referring to the Donnelly et al 2011 trial which compared the Heelift suspension boot to usual care. The trial did not report leg elevation in the usual care. We revised the summary bullet point be clear this was the case: "One fair-quality trial (n=239) of fracture patients found the Heelift Suspension Boot associated with decreased risk...compared with usual care without leg elevation." and made a similar change in the text.
Peer Reviewer #6	Results	page 58, line 5, the incidence in both groups was high (18 and 21%), even though no stat sig difference, the outcome in both groups was very poor	Regarding the incidences of 18 and 21%, the place the reviewer is referring to describes a trial that reported incidences of 3% and 11%. In addition, incidences of 18% and 21% are well within the ranges reported in the trials included in this review.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #6	Results	Page 58, need to include data on dressings that reduce intraoperative and pressure/shear ulcers (Brindle, Cherry, Chaiken). Omitting these findings would be an error...the studies are not well designed but address a huge area of practice Need to include data on OR mattresses (Nixon)	We identified one trial by Brindle that will be included. We found no studies by Cherry that met inclusion criteria; most of the studies by this author addressed management of venous stasis ulcers (not prevention of pressure ulcers) and one article by this author on recommendations for preventing intraoperative ulcers did not cite any includable intervention studies. We also found no studies by Chaiken that met inclusion criteria; one intervention series addressed silicone border form in ICU patients but had no control group and didn't report harms. The Nixon trial has been addressed in responses to comments from other reviewers; it will be included.
Peer Reviewer #6	Results	Pages 62-64, table on support surfaces. The material used has changed greatly in the last 10 years. I don't believe it is a fair comparison. And of course, what is a standard mattress? It was springs in the 1990s, in the 2000s it was foam.	We revised the section describing the trials of support surfaces to point out this issue: "In addition, the "standard hospital mattress" comparator was not well described in a number of trials and probably differed across studies. Previously, typical hospital mattresses were spring mattresses but more recently, foam." We also added a sentence to the Results noting no clear difference in results depending on when the study was published: "There was no clear difference in results between trials conducted earlier and more recently, even though standard mattress control may have changed over time."
Peer Reviewer #6	Results	Page 71, see earlier comment. The control group had no heel elevation	See response to similar comment by this reviewer.
Peer Reviewer #6	Results	Page 73, Chair cushions need to be divided by patient risk, do not combine the spinal cord injured with the generally weak groups	All of the trials focused on older nursing home patients. We revised the text to make this more clear, and also added this sentence: "No trial focused on patients with spinal cord injury."
Peer Reviewer #6	Results	Page 76, please address somewhere how allocation to visible devices (boots, beds) can be concealed	Outcome assessors can still be blinded when assessing outcomes (e.g. the support surface could be covered and the boot removed just prior to assessment).
Peer Reviewer #6	Results	Page 83, dressings for prevention need to be included somewhere. There are dressings used on the heels to reduce friction injury and the sacrum to reduce shear, pressure and microclimate	Dressings and pads were addressed (page 51-52). Evidence was quite limited.
Peer Reviewer #6	Results	Page 83, the interaction of nonbreatheable incontinence pads on low air loss beds needs to be discussed	The trial on incontinence pads did not evaluate low air loss beds so we could not comment on it here.
Peer Reviewer #6	Results	Page 84, intraop warming is associated with reduce infection, etc. Doubt it will go away, despite what appears to be no effect on ulcers. Biggest problem is identifying true intraop pressure ulcers, which show up 48 hours after the case ends	Thank you for the comment. This report focused on effects of preventive interventions on ulcers.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #6	Results	Page 85, DMSO is an animal med in the US, not used in humans	Pennsaid (topical diclofenac plus DMSO) has been approved in the United States and DMSO is still sometimes used by itself. We revised the text to be clear that DMSO is not approved by the FDA: "DMSO, a commercial solvent with various purported medicinal properties that is not approved by the Food and Drug Administration for treatment of ulcers..."
Peer Reviewer #6	Results	Page 93, see Brindle data on dressings in OR...whoops may be a 2012 pub	The Brindle trial was published in March/April 2012 and we will be including it.
Peer Reviewer #6	Results	Page 93, if the ACS has asked for this review, please ask them to comment on alternating pressure mattresses in the OR!	The American College of Surgery did not nominate this review. However, trials of support surfaces in the intraoperative setting are covered on p 56 to 61 of the report.
Peer Reviewer #6	Results	Page 94, integrated beds are very high and increase the risk of falls and injury from falls. Overlays can also increase the height of the mattress, making the side rail ineffective	None of the trials of support surfaces/beds reported risk of falls/injuries.
Peer Reviewer #6	Results	Page 98, harm from aspiration of nutritional supplement would have eliminated the patient from the study. Confusion from "moving" surfaces could have been included	None of the trials of nutritional supplementation reported aspiration risk (and as noted by the reviewer such patients would have been excluded from oral supplementation). No study of support surfaces reported confusion.
Peer Reviewer #6	Results	The use of the word "risk" (page 26, line 37) needs to be clarified; the risk you are describing is the outcome of pressure ulcers, not the risk per the Braden.	The sentence in question states, "Some trials specifically evaluated lower risk patients undergoing surgery and were reviewed separately" and does in fact refer to risk as assessed by a risk prediction instrument.
Peer Reviewer #6	Results	Page 26, need to clarify repositioning vs turning	The repositioning intervention is described in detail: "…repositioning at a 30-degree tilt ever 3 hours…compared with usual care (90-degree lateral repositioning every 6 hours during the night."
Peer Reviewer #6	Results	Page 26, need to acknowledge that a study of no interventions for at risk patients to show prediction of Pressure ulcers would be unethical	We do not think such a statement belongs in the Results section. We do not recommend future research versus no treatment. In fact, the Discussion/Implications for Clinical and Policy Decisionmaking section states, "…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."
Peer Reviewer #6	Results	Page 101, please use caution in interpretation of the VandenWee study of repositioning, the high incidence in both groups is alarming	The Vanderwee trial was not included in the review, it was excluded because it only enrolled patients with stage 1ulcers at baseline. However, after revising inclusion criteria to include studies with patients with ulcers at baseline if they report incidence ulcers, it was added. The incidence of ulcers in the Vanderwee trial (16% and 21%) was within the range reported in other repositioning trials (3% to 63%).

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #6	Results	Page 108, please reintroduce the need for accuracy when completing any risk scale. There is much inaccuracy in risk scores, with "reliance on previous documentation" to predicting risk on what might happen...eg., patient has orders to get up today, and not recognizing the risk assessment is contemporaneous to the risk now, akin to vital signs. NDNQI data shows that high risk patients, Braden 12 and below, do not have pressure ulcers at the same rate as patients at mid-range of risk. One conclusion is that the risk assessments are inaccurate or when midrange, no interventions seem to be needed.	Thank you for commenting on this important issue. However, addressing quality control recommendations in pressure ulcer assessment and prevention is outside the scope of this report.
Peer Reviewer #6	Discussion	Discussion/ Conclusion: The incorrect assessment of risk leading to no preventive interventions and then ulceration needs to be considered. This is a fairly common occurrence, and it is very unlikely anyone would write about it due to legal exposure. (page 25)	Thank you for commenting on this important issue. However, addressing quality control recommendations in pressure ulcer assessment and prevention is outside the scope of this report.
Peer Reviewer #6	General	General Comments: I am concerned about the meaningfulness of the report. It does not address common clinical issues, I have highlighted them in my comments.	See responses to other specific comments by this reviewer.
Peer Reviewer #6	General	Clarity and Usability: One of the major issues in hospitals is getting financial approval for support surfaces in high risk patients. We often have to admit that we don't turn the patient as often as we could or should to get the bed. Once a patient is placed on a surface, the nurses assume they no longer have to turn the patient because the bed is doing all the work...this fallacy must be stopped and should be addressed in this document.	Thank you for commenting on this important issue. However, addressing quality control recommendations in pressure ulcer assessment and prevention is outside the scope of this report.
Peer Reviewer #7	Results	The term stepped care is used and should be defined the first time it appears, it is not a term used commonly that I am aware of	We revised to define as: "...initial use of less advanced and expensive interventions followed by more advanced and expensive interventions if ulcers began to develop, based on a pre-defined algorithm…"
Peer Reviewer #7	Discussion	Implications are reasonable based on the limitations of the literature.	Thank you for the comment.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #7	Discussion	For future results, there were several key questions that could not be addressed due to lack of studies--this should be a point made in the section on future research. Authors also suggest that risk assessment tools should be compared in future research, however the tools are very continent based, Waterlow in the UK/Europe, Braden in US. I suggest that research needs to focus on aspects/subscales within these tools to refine risk assessment, and to include other factors known to influence risk and pressure ulcer development such as perfusion issues. Risk also needs to be studied within specific patient populations==acute, icu, long term care, home care--as these cannot be considered equivalent populations.	The lack of studies in many areas is discussed in the section "Limitations of the Evidence Base." The fact that there are geographic differences in which risk assessments are typically used does not preclude the need for research comparing different risk assessment instruments. We added to the Future Research section: "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. More research is 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 heel ulcers compared with other types of pressure ulcers."
Peer Reviewer #7	Figures	My main comments on it were that I thought Figure 1 was incomplete--why the numbers and are these meant to represent relationships?	The numbers refer to the key questions, we added a note so that is clearer
Peer Reviewer #7	General	General Comments: This is a well written report that will be useful to clinicians and to researchers.	Thank you for the comment.
Peer Reviewer #7	General	I found the report to be well written and comprehensive. Questions, methods results etc are well detailed and explained.	Thank you for the comment.
Peer Reviewer #8	Abstract	Abstract: Page v, line 7-8 Include the latest search dates for each database	We added the search dates for the MEDLINE and Cochrane searches
Peer Reviewer #8	Executive Summary	Executive Summary Page ES-3 Is Analytic Framework really the correct title for Figure A? Surely (if any kind of framework) it's a conceptual or organizational framework or model but there is nothing analytical about it	See response to similar comment by this reviewer.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #8	Executive Summary	ES-5, lines 42-48 Your quality criteria conflate efficacy and effectiveness issues and this is unhelpful; also they are not sufficiently well defined (here at least). So does “blinding” refer to patients, caregivers, outcome assessors, etc? They are of differing importance in this regard (the only really important blinding in a pragmatic trial is blinding of outcome assessment). This is a review for comparative effectiveness purposes and therefore some of these criteria are irrelevant e.g., blinding of care givers and patients, maintenance of comparable groups (essential for continuing to avoid selection bias but less important regarding “performance bias”). To be maximally informative for practice this needs to be an effectiveness review which does not downplay pragmatic trials (since their results will be more akin to real life).	See response to similar comment by reviewer regarding quality criteria. As described in Appendix F and the Evidence Tables, blinding is assessed separately for patients, care providers, and outcome assessors. We disagree that the only important blinding in pragmatic trials is of outcome assessors; no blinding still results in increased risk of bias regardless of whether a trial is pragmatic or not. Same with maintenance of comparable groups.
Peer Reviewer #8	Executive Summary	ES-5; lines 35 – 47 I would have liked to see further consideration of risk assessment tool issues. It seems odd to me to consider them as diagnostic – the condition they are identifying (through screening) is a predisposition to a future event so I do not think this is the same as diagnosis (the risk is being compared to whether the condition develops at a later time). They are always used as part of a screen and treat policy (at least purportedly though implementation is probably poor). Consequently if use of diagnostic methods is correct I would like to have seen more of a methodological justification of it. Also there is no gold standard diagnostic test so all you can really look at is agreement between tools or comparison with whether an ulcer develops at a later time. Alternatively you can conceptualize this as a risk prediction and evaluate as clinical prediction rules.	See response to similar comment by reviewer regarding the risk prediction instruments. Studies on the predictive value of risk prediction instruments are studies of diagnostic accuracy, since they use the same methods/measures as studies of diagnostic tests (sensitivity, specificity, etc.). The main difference is that there is a longitudinal time element, whereas many studies of diagnostic tests are cross-sectional. We revised the Methods to be clear that we are referring to studies of risk prediction instruments: e rated the quality of each study evaluating the diagnostic accuracy or predictive value of risk prediction instruments..."
Peer Reviewer #8	Introduction	Introduction: Well written and comprehensive. The NPUAP has now adopted the term "Stage" rather than "Grade". This probably warrants amendment (Table 1, p.2). See http://www.npuap.org/pr2.htm	Several other reviewers made a similar comment and we will change the term "Stage" to "Grade"
Peer Reviewer #8	Introduction	Page 2, lines 34 - 48. It is worth stating here or in the Discussion that the development of risk assessment tools has not used epidemiological principles - they have not been developed from data generated about prognostic factors from inception cohort studies. They do not have the heritage that medical clinical prediction rules often have.	The methods used to develop and test the risk assessment scales varied in rigor. We believe it is inaccurate to characterize all of the risk assessment scales as not having been developed like other prediction rules. Also, one of the key questions in the review focuses on determining the diagnostic accuracy/predictive utility of the risk assessment tools, which is more important from a clinical standpoint than how the tools were developed.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #8	Methods	Methods: 1) Suggest place eligibility criteria before search strategy for reasons of logic.	We followed the AHRQ Content Guide for Comparative effectiveness reviews, which places the literature search strategy first.
Peer Reviewer #8	Methods	2) Provide operational definitions of CONTROLLED CLINICAL TRIALS, COHORT STUDIES, DIAGNOSTIC ACCURACY STUDIES.	We believe these common terms are generally well understood and do not require operational definitions.
Peer Reviewer #8	Methods	3) Somewhere need a discussion of why risk assessment tools are regarded as diagnostic; need a justification of the methods used (may be in Introduction, Methods or Discussion).	Studies on the predictive value of risk prediction instruments are studies of diagnostic accuracy, since they use the same methods/measures as studies of diagnostic tests (sensitivity, specificity, etc.). The main difference is that there is a longitudinal time element, whereas many studies of diagnostic tests are cross-sectional. We revised the Methods to be clear that we are referring to studies of risk prediction instruments: "We rated the quality of each study evaluating the diagnostic accuracy or predictive value of risk prediction instruments."
Peer Reviewer #8	Methods	4) Avoid conflation of quality of conduct and quality of reporting.	We applied standardized quality criterion, which necessarily are dependent on what was reported in the study methods. When there was inadequate information to judge whether a study met a criterion it was graded as "unclear"
Peer Reviewer #8	Methods	5) Avoid conflation of quality criteria that relate to efficacy studies and those that relate to comparative effectiveness studies.	In general quality criteria do not differ for studies regardless of whether they are efficacy or effectiveness studies. For example, lack of blinding of patients and caregivers increases the risk of bias regardless of whether a study is an efficacy or effectiveness study. Similarly, inadequate blinding, high attrition, or failure to perform intention-to-treat analyses are quality issues regardless of whether a study is an efficacy or effectiveness study.
Peer Reviewer #8	Methods	6) I think some pooling of similar studies could have been undertaken cf. similar reviews. I do not understand why there is no meta analysis.	We determined that pooling was not appropriate due to substantial differences/heterogeneity across trials in patient populations, outcomes, interventions, and comparators, as described in the Results.
Peer Reviewer #8	Methods	7) I do not understand why some studies have been excluded e.g., our Nixon et al trial of nearly 2000 participants randomized between alternative pressure overlays and alternating pressure mattresses. That is an awful lot of data excluded - reason give - "Wrong intervention" (????).	See response to similar comment by this review regarding the Nixon trial. It should have said that the trial was excluded because of the "wrong population " (it enrolled >10% of patients with ulcers at baseline) but we revised the inclusion criteria and it will be included.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #8	Methods	8) The differences in places between studies included/excluded here and the McInnes Cochrane review needs more careful consideration and explication. Theoretically this review should contain more studies than the Cochrane review because that only included RCTs, but there are unexplained discrepancies in the other direction.	The main reason for the difference in which studies were included/excluded in our review and the review by McInnes et al is that the McInnes review included more trials that included patients with pre-existing ulcers. As described in responses to other comments, we have revised our inclusion criteria to include trials of patients with baseline ulcers if they reported incident ulcers, so there is less of a discrepancy in terms of included studies between the McInnes review and our revised report. Only RCT's were included for evaluating efficacy of preventive interventions, so cohort studies were not relevant.
Peer Reviewer #8	Methods	9) The rest of the world (including the WHO) uses GRADE to assess and summaries evidence quality - why not AHRQ? It would make things much easier to follow.	We used methods for grading bodies of evidence as outlined in the AHRQ Methods Manual, which are modified from GRADE methods. For further details about modification to GRADE and rationale please see the EPC Methods Guide at http://www.effectivehealthcare.ahrq.gov/search-for-guides-reviews-and-reports/?pageaction=displayProduct&productID=1163. We have updated our chapter on Strength of Evidence grading.
Peer Reviewer #8	Methods	Pages 6 and 7 Literature Search Strategy and Study Selection It makes more sense to me to present eligibility criteria BEFORE search strategy i.e., this is what we were looking for and this is how we looked for it (rather than this is how we looked and this is what we looked for).	We followed the order of presenting information in the AHRQ Content Guide for Comparative Effectiveness Reviews, which describes the search strategy before eligibility criteria.
Peer Reviewer #8	Methods	8; lines 5-6 Please define what you mean by controlled clinical trials; did the control have to be contemporaneous if not randomized? There are many diverse interpretations of this phrase (more so than for RCT).	Controlled clinical trials are trials in which allocations to interventions are under the control of the investigator, and there are more than one group. It is a broad term and we applied it broadly (i.e. it did not necessarily have to be contemporaneous controls). We don't think this requires further elucidation since it only involved one study included in the review (KQ 1)

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #8	Methods	p.8; lines 50 – 55 See comments above. You must define what you mean for each quality criterion (AND provide an operational definition somewhere e.g., appendix). If this is already in an Appendix it needs linking to here. Do not conflate efficacy and effectiveness criteria – this is a comparative effectiveness review so some issues e.g., of blinding of participants or care givers are not relevant (specifically notrelevant issues are: blinding as above, maintenance of comparable groups in terms of performance bias e.g., co-interventions, cross over, adherence and contamination). Of course these issues should be reported but they are not quality issues for pragmatic trials as the aim is to represent outcomes as they would happen in real life when all these issues operate. The main quality criteria for pragmatic RCTs are randomization sequence, allocation concealment, blinding of outcome assessment, avoidance of attrition bias, continued maintenance of randomized groups by intention to treat analysis and complete data ascertainment. Also by same token avoid conflating reporting quality with conduct quality ("adequate reporting of dropouts" is a reporting quality issue). NB other undefined quality issues slip in later in Tables e.g., powered, nonpowered	The quality criteria are shown in Appendix F, we were missing the call-out for this Appendix in the text and added it to the text. We disagree that quality criteria differ for effectiveness/pragmatic and efficacy trials; the same factors that increase risk of bias in efficacy trials increase risk of bias in effectiveness/pragmatic trials. Not reporting dropouts is a validated criterion that has been empirically associated with biased estimates of effects by Jadad and others, and is included in many quality assessment instruments.
Peer Reviewer #8	Methods	9; lines 7 – 19 See earlier comment re. risk screening versus diagnosis.	See response to previous comment by this reviewer
Peer Reviewer #8	Results	Results: My main issue with the results is that the Tables are rather inconsistent in presentation. I became confused my which tables were in the text and which in appendices and which contained quality assessment data and where/how this was presented. even the quality criteria seemed to change e.g., powered / non-powered cropped up later.	As is standard in AHRQ Comparative Effectiveness Reviews, the in-text tables are referred to as "Tables" and appendix tables as "Appendix Tables". "Powered/nonpowered" in Table 6 is a description of the type of support surface (i.e. a powered or nonpowered support surface), not quality. We changed the column header to "Power source required?"

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #8	Results	I do not understand why: Nixon J, Cranny G, Iglesias C, Nelson EA, Hawkins K, Phillips A, et al. Randomised, controlled trial of alternating pressure mattresses compared with alternating pressure overlays for the prevention of pressure ulcers: PRESSURE (pressure relieving support surfaces) trial.[Erratum appears in BMJ.2006 Jul 1;333(7557):30]. Bmj. 2006 Jun17;332(7555):1413. PMID: 16740530 Also published as Nixon J, Nelson EA, Cranny G, Iglesias CP, Hawkins K, Cullum NA, et al. Pressure relieving support surfaces: a randomised evaluation. Health Technology Assessment. 2006;10(22):1-180. PMID:16750060 was excluded. This is two versions of the same study. The first (BMJ) is listed in Appendix D as excluded because ""Wrong Population"". The second publication (report to the funder - Health Technology Assessment) is excluded in Appendix D for ""wrong intervention"". This was a randomized comparison of nearly 2000 at risk patients between alternating pressure overlays and alternating pressure mattresses. I fail to see how it is either the wrong intervention (fits into category dynamic vs. dynamic) or wrong population.	See response to similar comment by this review regarding the Nixon trial. It should have said that the trial was excluded because of the "wrong population " (it enrolled >10% of patients with ulcers at baseline) but we revised the inclusion criteria and it has been added.
Peer Reviewer #8	Results	I personally would not have included non-randomized studies in the effectiveness review.	As outlined in the AHRQ Methods Manual, observational studies can provide important information, especially when RCT's are not feasible, not available, or insufficient to address important questions. For preventive interventions, we only included observational studies for assessments of harms (KQ 4), as recommended in the AHRQ Methods Manual, and revised the Methods to be clearer about this.
Peer Reviewer #8	Results	Effectiveness section generally I am unclear why some pooling of studies has not been undertaken where it would have been scientifically defensible to do so (e.g., high spec foam vs. standard foam; sheepskin vs. usual care).	See responses to similar previous comments by this reviewer. Briefly: We assessed each set of trials and determined that there was too much clinical heterogeneity to perform meta-analyses, as well as poor study quality and differences in populations and interventions assessed. For example, of the three medical sheepskin trials, one was poor-quality, one was limited to sheepskin over the sacral area and two were in the hospital and one in long-term care.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #8	Results	I am also unclear why some trials have been excluded (Nixon J, Nelson EA, Cranny G, Iglesias CP, Hawkins K, Cullum NA, et al. Pressure relieving support surfaces: a randomised evaluation. Health Technology Assessment. 2006;10(22):1-180. PMID: 16750060) – reason given "wrong intervention" (this was a nearly 2000 patient randomised comparison between two alternating pressure products – an overlay and a mattress replacement – why is this not eligible??).	See responses to similar previous comments by this reviewer. Briefly, the Nixon trial was excluded because more than 10% of patients had ulcers at baseline, in accordance with our pre-defined criteria. It should have said excluded for "wrong population". However, we are revising our criteria to include trials that enrolled more patients with ulcers at baseline as long as they reported incident ulcers.
Peer Reviewer #8	Results	Whilst (for whatever reason) the authors have chosen to list our Cochrane review and say that it was "not used" I really do think it is incumbents on them to cross check studies included and explain discrepancies.	The studies included in the Cochrane review were each reviewed to determine whether they met inclusion or exclusion and the disposition of each study was provided in an Appendix.
Peer Reviewer #8	Discussion	Discussion/ Conclusion: The Discussion is clearly written and the major findings are clearly stated. I do however think that the Future Research section should consider the difficulties of evaluating devices that change rapidly and also the need for fundamental epidemiology to understand prognostic factors. See attached file.	See response to more detailed version of this comment below.
Peer Reviewer #8	Discussion	Future Research page 78 Risk assessment tools should be developed that are based on data from prospective cohort studies of which factors are prognostic for future ulceration – none of the current tools have been developed in this way. Blinding of patients and care givers is not only not feasible but not advisable in comparative effectiveness research; we want to know how interventions work in the real world, used as they would be in real life – not how they perform in a tightly controlled experiment. This section could usefully discuss the challenges/wisdom of undertaking large, rigorous expensive evaluations of devices that the manufacturers then change the design of shortly afterwards. We need a more considered approach to evaluation in this field – preferably of types of device that adhere to particular performance and design standards rather than specific products. This would avoid the results of a study becoming obsolete shortly after publication.	We already state that studies should evaluate the use of validated risk assessment instruments. The rigor with which risk assessment tools was developed varies, and we do not believe that currently validated tools with reasonable predictive utility should be abandoned because of how they were developed. Failure to blind patients and caregivers increases risk of bias regardless of whether a trial is an efficacy or effectiveness study. We do not feel that we can advise funders to not develop/study specific products.
Peer Reviewer #8	Tables	The change in the presentation of study quality data between the first questions about risk assessment and the subsequent questions about pressure ulcer prevention interventions is disconcerting for the reader; ideally study quality assessment would be a column in the tables (not a row heading).	The reviewer seems to be referring to Table 6 in referring to a column "powered/nonpowered"; this was not a quality criteria but simply a description of whether the support surface required a power source (as described in the Introduction). We changed the column header to state "Power source required?"

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #8	Tables	"Similarly the distinction between efficacy and effectiveness trials seems to come from nowhere into Table 7; what is the purpose of this and where is the operational definition? What is the reader to make of this distinction in their interpretation? Is it meaningful? These distinctions (quality; efficacy vs. effectiveness) then seem to disappear altogether from subsequent tables – very confusing – or presented in another different way see Table 13)."	For Table 7, we agree that the terms "efficacy" and "comparative effectiveness" were confusing. In fact we did not mean to use the terms "efficacy" and "effectiveness" to distinguish trials that were more selected and restrictive vs. those that are more "real-world", we were organizing the trials according to whether they compared a support surface vs. usual care (we should have used the term "effectiveness") or whether they compared a support surface vs. another support surface ("comparative effectiveness"), not whether they were efficacy or effectiveness trials. We deleted these headers and reorganized the Table so that the studies are simply listed alphabetically. Table 13 is simply labeled "effectiveness of lotions and cleansers for pressure ulcer prevention."
Peer Reviewer #8	Tables	Page 27, table 6 What does “powered or non-powered” mean? If this refers to whether a sample size calculation is reported then this is not terribly helpful to users as it says nothing about whether study was adequately powered. I presume you have not undertaken post hoc power calculations so ??????	This table is describing the characteristics of the support surface intervention, and refers to whether the support surface requires a power source, as described in the Introduction (p 3 lines 36-37). It is not referring to statistical power. We revised the column header to be clearer about this.
Peer Reviewer #8	Figures	I think it is rather over-stating it to describe Figure ! as an "analytic framework"; it is an organizing structure, conceptual framework or similar (see my attached file). There is nothing analytical about it.	Thank you for the comment. We used the term "Analytic Framework" as coined and developed by the U.S. Preventive Services Task Force and adopted by the AHRQ Effective Health Care Program and others to describe the graphical representation of the populations, interventions, outcomes; clinical understanding of the issues; and key questions. Our Analytic Framework follows the typical format/structure as these tools are currently utilized and understood.
Peer Reviewer #8	Appendices	H-93 Quality assessment of support surfaces trials. Again this conflates reporting, conduct issues. Not obviously linked to operational definitions of criteria. How is “Groups similar at baseline?” judged? And surely its not the similarity that is important (since after all this cannot/should not be tested for in RCTs) it is what was done about imbalances i.e., adjusted analyses.	All quality criteria are dependent on what is reported in the trials. Trials that do not report attrition cannot be judged with respect to attrition, and therefore are downgraded. Jadad and others have shown an empirical association between failure to report attrition and biased estimates of effect. Similarity of groups at baseline is judged by looking at baseline characteristics such as age, sex, pressure ulcer risk scores, etc. We do not agree with the reviewer that baseline imbalances are unimportant; baseline imbalances may indicate problems with randomization or allocation and result in biased estimates of effect. Adjustment alone does not resolve these issues.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #8	General	Clarity and Usability: I have integrated these comments in the above e.g., re. presentation of Tables. On the whole OK but could be improved by increasing consistency of presentation.	See response to comment regarding the tables above.
Peer Reviewer #8	General	On the whole the report is relevant to practice; target population defined. Key questions clearly defined and appropriate. This is a complex area and the authors are to be congratulated on the relative clarity they bring to this review.	Thank you for the comment.
Peer Reviewer #8	General	I was surprised that the extremely well done and large PRESSURE study published in 2006 in BMJ (Jane Nixon lead author) was not included in Table 11. Isn't this an example of dynamic compared to dynamic? Perhaps it was excluded as subjects not "at-risk" although I would argue that post-surgical patients are at-risk.	This study was originally excluded because it enrolled more than 10% of patients with ulcers at baseline. However, several reviewers noted that this and similar studies were relevant for understanding the effectiveness of preventive interventions. We agreed that studies that enrolled some patients with pre-existing ulcers could be informative for understanding effectiveness for prevention if they reported incident ulcers. Therefore we revised the inclusion criteria to incorporate trials that enrolled up to 20% of patients with pressure ulcers at baseline if they reported incident ulcers. This trial was added to the report.
Peer Reviewer #9	Introduction	Introduction: Please update the definition of a pressure ulcer has been changed by the NPUAP and EPUAP. Friction has been eliminated from the definition as it causes superficial skin changes. Here is the new definition from their joint 2009 Clinical guideline. A pressure ulcer is 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. A number of contributing or confounding factors are also associated with pressure ulcers; the significance of such factors has yet to be elucidated.P.16 of the NPUAP-EPUAP Prevention and treatment of pressure ulcers: Clinical Practice guideline. 2009"	We revised the definition of ulcers to remove the reference to friction, as per the NPUAP/EPUAP 2009 guideline.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #9	Introduction	A major concern is the definitions of pressure ulcers and table 1 on page 33-34. Once again, please consider the NPUAP-EPUAP definitions which are used in the USA. Pressure ulcers are classified using categories or stages, not grades. There are only 4 numerical stages (stage I, II, III, IV) and 2 others, unstageable and deep tissue injury, It is very confusing that you have identified a stage X, this is not used clinically nor in the literature. Also there is no grade V. You have not included at all in your description, deep tissue injury (DTI), yet this has been reported in the literature since 1996 and the research by Van Gilder and colleagues (2010) Advances in Skin and Wound Care, report that DTI rates have increased and account for the heel being the most frequent location.	We were using the 2007 criteria and updated the text and tables with the 2009 NPUAP/EPUAP criteria
Peer Reviewer #9	Methods	It is not clear that the report includes or excludes palliative care/hospice patients. There are specific risk assessment tools for this patient population (Chaplin J. Pressure sore risk assessment in palliative care. Journal of Tissue Viability. 2000 10(1) 27-31)as well as consensus statements about skin care at life's end (Sibbald et al, advances in skin and wound care) that are not included).	As described in the Methods (p 7 and p 8), we included all adults in all settings, which include palliative care and hospice patients. Only one trial (Bale) specifically evaluated patients in a hospice setting; we added a sentence to highlight it's results: "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."
Peer Reviewer #9	Methods	Methods: Have you considered that one of the problems with pressure ulcer risk assessment is that after identification, risk assessment interventions are not implemented in a timely way? For example, consider the research of Shayna E, Rich, Shardell, M, Margolis, D, Baumgarten, M (2009) Pressure ulcer prevention device use among elderly patients early in the hospital stay. Nursing Research March/April 2009 58(2) 95-104. They evaluated 792 patients aged 65 years and older. Only 15% had any preventive device at day 3 of admission 51% of at risk patients had a preventive device 68% of patients with pressure ulcer had documented PU in record.	This study does not meet inclusion criteria because it does not evaluate the clinical utility or predictive value of risk prediction instruments, or the benefits/harms of a preventive intervention. However, we added it to the Introduction as background regarding suboptimal use of preventive interventions: "However, research indicates that many patients at high risk of pressure ulcers do not receive preventive interventions."
Peer Reviewer #9	Results	Also consider this article on the incidence of pressure ulcers in persons at the end of life Brennan, M.R., Trombley, K. Kennedy Terminal Ulcers – a palliative care unit's experience over a 12-month period of time. WCET 2010, 30(3):20-22	This is a study on prevalence/incidence that does not address any of the key questions.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #9	Results	The notion of timely intervention once pressure ulcer risk assessment is identified using tools as well as communication of risk status among health care professionals caring for a patient is not addressed in your report.	Studies of risk prediction instruments and of preventive interventions typically evaluated patients on admission and implemented preventive interventions immediately. The reviewer may be referring to how well research findings translate to clinical practice. We revised the Applicability section of the Discussion to discuss this issue: "In addition, the applicability of trial findings to clinical practice could be limited by delays in use of preventive interventions."
Peer Reviewer #9	Results	Results: More detail is needed in describing the studies.	The characteristics of the studies are briefly summarized in the in-text tables, with more depth in the Evidence Tables, and Results section. As always there is a balance between providing adequate detail and too much unnecessary detail. We believe we have provided sufficient detail for readers to understand the key characteristics of the studies.
Peer Reviewer #9	Discussion	Discussion/ Conclusion: You have not addressed persons at end of life, this needs to be included. Future research section not clear.	Persons at the end of life were included. Few trials focused on this population. We added this sentence to the Applicability section in the Discussion: "No trial of preventive interventions specifically evaluated patients at end of life."
Peer Reviewer #9	General	Clarity and Usability: The evidence tables are helpful. Because you have used different pressure ulcer definitions from the NPUAP clinical practice guidelines for pressure ulcers (2009) as well as those that conflict with CMS regulations for LTC, home Care, LTCH etc, this is problematic in terms of policy as well as practice decisions. Recommend that you use the NPUAP definitions and not use stage X, Stage V and include deep tissue injury."	See response to similar comment from this reviewer regarding staging of ulcers.
Peer Reviewer #10	Introduction	Introduction: Concise and well-defined intro. NPUAP , cost, scores defined well	Thank you for the comment
Peer Reviewer #10	Methods	Methods: -Inclusion and exclusion criteria well-defined and justifiable appropriate to the prevention of pressure ulcers -Diagnostic criteria for outcome measures are appropriate -Statistical methods are relevant and appropriate	Thank you for the comment
Peer Reviewer #10	Results	Results: -No studies have been overlooked and no studies should have been excluded -Figures and tables are appropriate and relevant to description /discussion	Thank you for the comment
Peer Reviewer #10	Discussion	Discussion/ Conclusion: -Implications and negative/positive associations are clearly stated -Future Research section well-defined -No significant omissions of literature noted	Thank you for the comment
Peer Reviewer #10	General	Clarity and Usability: Excellent review with significant relevance to policy and practice in acute and long-term settings	Thank you for the comment

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #10	General	General Comments: - Report is clinically meaningful and relevant -Target population and audience are very well-defined Key questions are explicit, appropriate and relevant	Thank you for the comment
Abbott	Results	Two studies, Ek et al[1] and Hartgrink et al[2] were excluded from the final AHRQ report analysis, with the reason given as "wrong population." This was likely due to the fact that greater than 10% of the patient population in each of these studies had pressure ulcers at baseline. AHRQ provides the following justification for the 10% threshold as an exclusion criterion: "As treatment of existing pressure ulcers is addressed in a separate report, we excluded studies that enrolled >10 percent of the population with pressure ulcers at baseline." However, neither of these two nutritional supplementation studies was actually included in the AHRQ report on pressure ulcer treatment and both of the studies were specifically designed to measure pressure ulcer prevention and monitor an adult patient population at high risk for pressure ulcer development. Thus, the exclusion criteria of the AHRQ report on pressure ulcer prevention eliminated a significant portion (two of five studies) of the data on pressure ulcer prevention related to nutritional supplementation. We recommend that the exclusion criteria for the AHRQ report be reconsidered, as including the Ek et al and Hartgrink et al studies would likely change the strength of evidence and ultimately impact the report's conclusions. 1. Ek AC, Unosson M, Larsson J, Von Schenck H, Bjurulf P: The development and healing of pressure sores related to the nutritional state. Clin Nutr 1991, 10(5):245-250. 2. Hartgrink HH, Wille J, Konig P, Hermans J, Breslau PJ: Pressure sores and tube feeding in patients with a fracture of the hip: a randomized clinical trial. Clin Nutr 1998, 17(6):287-292.	Both trials were originally excluded because they enrolled >10% of patients with ulcers at baseline. However, after reviewing peer review and public comments we revised the inclusion criteria to include trials that enrolled up to 20% of patients with ulcers at baseline if incident ulcers were reported. Both of these trials have been added to KQ 3. They were both rated poor-quality and did not change conclusions of the review.

Commentator & Affiliation	Section	Comment	Response
Abbott	Results	Results: Nutritional Supplementation (Page 81) It is stated that “None of the trials reported length of stay or measures of resource utilization.” However, these values were reported in the Delmi study [3]. In fact, nutritional supplementation resulted in better clinical outcome (Positive course in 56% vs. 13%), lower mortality (44% vs. 87%), lower complications and deaths after 6 months (40% vs. 74%), and lower median duration of hospital stay (24% vs. 40 days). Abbott recommends the sentence “None of the trials reported length of stay or measures of resource utilization” be changed to reflect the fact that one of the studies provided data on hospital length of stay. Delmi et al. found a median reduction in hospital length of stay from 40 to 24 days in the supplemented group.	When reporting Results of the Delmi trial, we revised to state: "Nutritional supplementation was associated with shorter median duration of hospitalization (24 vs. 40 days, p<0.04)."
Abbott	Results	As mentioned previously, the exclusion criteria of the AHRQ report eliminated a significant portion (two of five studies) of the data on pressure ulcer prevention related to nutritional supplementation. We believe that, if the true body of scientific evidence on nutritional supplementation and pressure ulcer prevention is considered (all five studies), the studies on nutritional supplementation would meet the standard set forth in the AHRQ report for moderate, i.e. “moderate confidence that the evidence reflects the true effect.” Thus, in addition to a reconsideration of the exclusion criteria to allow for these two studies, Abbott recommends that the strength of evidence for nutritional supplementation be considered “moderate.”	See response to similar comment by Abbott above.

Commentator & Affiliation	Section	Comment	Response
Abbott	Results	Nutrition is important in both the prevention and treatment of many chronic diseases, medical conditions, complications, and comorbidities such as pressure ulcers. The inability to maintain adequate nutrition, leading to malnutrition, is associated with increased morbidity and mortality. Notable among these increases in morbidity are higher hospital costs, longer lengths of stay, increased infection rates [5, 6] and delayed wound healing [7]. Nutritional supplementation has been an effective strategy to minimize these complications and for patients with pressure ulcers it has worked synergistically with other treatment modalities towards the ultimate goal of pressure ulcer healing. Nutritional supplementation has also been an effective strategy for pressure ulcer prevention as malnourished patients have an elevated risk of developing pressure ulcers [8, 9]. Recognition of this fact has led to the inclusion of nutritional status as a key component in each of the three most common tools for pressure ulcer risk assessment: the Braden Scale, the Norton Scale, and the Waterlow Scale. Nutritional supplementation has been a standard treatment strategy to help improve nutrition status [10], and ultimately to help prevent the development of pressure ulcers [4]. Unequivocally demonstrating these benefits at the very high strength of evidence level defined by the AHRQ report is difficult because of the complex nature of nutrition research and pressure ulcer development. First, adequate nutrition is essential for life and thus it has a fundamental role in the effective prevention and recovery from a disease or medical condition. Second, prospective, randomized clinically controlled trials of nutritional supplementation are often difficult or impossible to complete because it is unethical to withhold feeding. Third, in the scientific literature nutritional supplementation is often used as a broad term that includes a wide range of nutritional interventions and specific nutrients; this contributes to considerable variability among findings. Finally, to prospectively analyze the incidence of pressure ulcer development in a randomized and controlled trial, researchers need a very large sample size of patients at risk of developing pressure ulcers. Samples of adequate size are often difficult to obtain and follow for prolonged periods.	Thank you for the comment. We systematically assessed the available evidence on nutritional supplementation. Unfortunately, most of the trials were poor-quality, and we rated the strength of evidence on nutritional supplements as low-quality, as described above.

Commentator & Affiliation	Section	Comment	Response
Abbott	Results	A recent review article on nutritional supplementation for the prevention and treatment of pressure ulcers [11] stated that "medical nutrition therapy is imperative for the prevention and treatment of pressure ulcers." In the largest study in the AHRQ report, nutritional supplementation resulted in a reduction in pressure ulcer incidence from 47.2 to 40.6% [12]. This corresponded to a relative risk of developing a pressure ulcer of 1.57 in the control group compared to the group receiving nutritional supplementation. Two other studies in the AHRQ report also showed a quantitative reduction in pressure ulcer incidence, but were likely not adequately powered to find statistical significance. In the study by Houwing et al.,[13], researchers found trends towards both a later onset and decreased severity of pressure ulcers with nutritional supplementation. However, the sample in their study was only 1/7 the size they estimated would be necessary to find statistical significance prior to the start of the study. In the study by Delmi et al. [3] there were also numerically fewer pressure ulcers, but again the statistical power was not sufficient. Two additional studies not included in the AHRQ report also looked at the effect of nutritional supplementation on pressure ulcer development in adults [1, 2]. Like many of the previous studies, these had numerical reductions in incidence, but were not adequately powered to find statistical significance. However, a meta-analysis was conducted combining these two studies with the three studies previously mentioned in the AHRQ report. Authors of the meta-analysis found an odds ratio of pressure ulcer development of 0.75 (95% CI 0.62 to 0.88) comparing nutritional supplementation to standard care. This equated to the prevention of one pressure ulcer for every 19.25 patients given nutritional supplementation. The AHRQ report also emphasized that any effective prevention or treatment strategy for pressure ulcers should minimize the risk of complications [14]. Nutritional supplementation is a low-risk, non-prescription therapy for pressure ulcers. Nutritional supplementation is also low-cost, with a net-cost savings in overall care with nutritional supplementation [15].	Thank you for the comment. As stated in responses to similar comments by Abbott, the trials on nutritional supplementation were generally poor-quality. We do not think meta-analysis is appropriate given the heterogeneity in nutritional interventions evaluated, and the poor quality of the underlying trials. The reported RR for nutritional supplementation versus no supplementation cited for the first study in the comment is incorrect, it's 1.2, not 1.6. We added the other two trials mentioned in the comment after revising inclusion criteria to permit trials that enrolled up to 20% of patients with ulcers at baseline as long as they reported incident ulcers. Including these trials did not change the conclusions, as both were poor-quality and one of the trials found no effect.

Commentator & Affiliation	Section	Comment	Response
Abbott	Discussion	Implications for Clinical and Policy Decisionmaking (Page 27 and 109) Abbott supports the statement, “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.” This is an important acknowledgement, as proper nutrition plays a key role in both the prevention and treatment of many chronic diseases, medical conditions, complications, and comorbidities such as pressure ulcers and this is why it remains important as a standard of quality patient care.	Thank you for the comment
Abbott	Discussion	Discussion, Table 16. Summary of evidence (Page 105) Although only three studies were included in the report, AHRQ considered a total of five studies on the use of nutritional supplementation in pressure ulcer prevention. The AHRQ report’s guide for grading the strength of a body of evidence when comparing medical interventions has four criteria for developing a grade. The first AHRQ criterion is risk of bias. All five studies were randomized controlled trials, which limits their risk of bias. In addition four of these five studies demonstrated a high level of consistency which was the second criterion used for grading. In a separately conducted meta-analysis by Stratton and colleagues[4], the four studies’ odds ratios (or best estimates of the true effect) were in the direction of a benefit for nutritional supplementation within a very narrow range of 0.72 to 0.83. The fifth study showed a much greater reduction in pressure ulcers with nutritional supplementation, although it was less adequately powered. The third AHRQ criterion is directness. All five of the studies considered were direct comparisons between nutritional supplementation and standard care. The final criterion is precision, or the certainty surrounding an effect estimate. The guide for grading evidence suggests that this should be assessed using “the boundaries of the pooled confidence interval.” A meta-analysis has been conducted on these five studies and the 95% confidence interval for the odds ratio was calculated to be 0.62 to 0.88, which is a narrow range [4].	The quality of RCT's depends on how well they were designed and conducted. Five of the six trials that were included on nutritional supplementation were rated poor. In addition, results were inconsistent, in that one of the trials found no difference in risk (RR 0.92), and the other trials were small, with imprecise estimates, with only one showing a statistically significant reduction in risk of ulcers. Therefore, this body of evidence warrants a "low" strength of evidence for no clear benefit. We do not believe that meta-analysis is appropriate due to the heterogeneity in nutritional interventions and comparisons, and the poor quality of the trials.

Commentator & Affiliation	Section	Comment	Response
Abbott	Discussion	Limitations of the Comparative Effectiveness Review Process (Page 109) If no change in the exclusion criteria is made to accommodate existing, quality data that has not been included in either the AHRQ prevention or treatment reports, we recommend that AHRQ add the following statement to the prevention report in the Limitations of the Comparative Effectiveness Review Process section (page 109): "Studies that had greater than 10% of patients with pressure ulcers at baseline were not evaluated in this report and may also not have been evaluated in the AHRQ pressure ulcer treatment report, and thus there may be clinical evidence of effect that was not considered in either of these reviews."	In response to peer reviewer and public comments, we revised the inclusion criteria to include trials that enrolled patients with up to 20% pressure ulcers at baseline, as long as they reported incident ulcers. See response to a similar comment by Abbott above
Abbott	Discussion	In summary, nutritional supplementation helps provide basic nutrition that is necessary for life, helps prevent additional complications including development of pressure ulcers, and represents a low-risk and low-cost prevention strategy. All of these contributions make it a valuable strategy for the prevention of pressure ulcers. In the current AHRQ report, there is strong evidence that nutritional supplementation reduces the risk of developing a pressure ulcer, with a separate meta-analysis of five studies on pressure ulcer prevention showing an odds ratio of developing pressure ulcers of 0.75 (95% CI 0.62 to 0.88) in patients receiving nutritional supplementation. This equated to the prevention of one pressure ulcer for every 19.25 patients who received nutritional supplementation.	Please see response to similar comments from Abbott above.
Altarum Institute	Results	Regarding Subquestion 1b - Does the comparative effectiveness of risk-assessment tools differ according to patient characteristics, such as age, race or skin tone, physical impairment, body weight, specific medical comorbidities (e.g., diabetes, peripheral vascular disease), and other known risk factors for pressure ulcers, such as nutritional status or incontinence? I suggest including patient functional status (i.e., ability to perform a specific number or proportion of independent activities of daily living); presence or, lack thereof, wound or systemic infection; and not only anthropomorphic measures of nutritional status such as BMI or recent weight loss but also laboratory-based nutritional assessment. Brown KL and Phillips TJ. Nutrition and wound healing. Clinics in Dermatology (2010) 28, 432–439.	All of the risk factors cited by the reviewer were included within the patient characteristics described (e.g. functional status falls under physical impairment; nutritional status already listed). The cited article is a review article without original data that does not meet inclusion criteria.

Commentator & Affiliation	Section	Comment	Response
Altarum Institute	Results	Furthermore, for key co-morbidities such as diabetes, severity of illness along with presence of co-morbidities may be key factors (e.g., degree of diabetes management).	Studies that evaluated how comparative effectiveness varies depending on the presence or severity of diabetes or other co-morbidities would have been included.
Altarum Institute	Results	Lastly, along with the scales listed for risk assessment please consider AHRQ's On-time Pressure Ulcer Prevention and Treatment Program risk assessment (http://www.innovations.ahrq.gov/content.aspx?id=2153)	This article did not meet inclusion criteria; it was an observational study that did not report harms.
Hill-Rom	Results	The wording in some of the most important parts of the Prevention document may not be entirely clear to the typical consumer of this information. One of the principal conclusions concerns the effectiveness of LAL surfaces which appears in the conclusions only in the quotation below from page 32 (includes our underlining and italics). Eleven trials compared a more advanced static support surface to a standard mattress control. All five fair-quality trials (n=83 to 543) found the more advanced static mattress or overlay associated with decreased risk of any (primarily grade I) incident pressure ulcers (RR range 0.20 to 0.60) or a trend towards decreased risk (RR 0.28, 95% CI 0.06 to 1.3) (Table 7). Duration of follow-up ranged from 7 days to 6 months. The static support surfaces evaluated in the trials were the Soft form mattress a sheepskin overlay, an air suspension bed, and an air overlay. One trial also found a more advanced static support surface (an air suspension bed) associated with decreased risk of grade II or higher pressure ulcers compared with a standard intensive care unit bed (4.1 vs. 29 percent, RR 0.21, 95% CI 0.11 to 0.39), but there were too few events in these trials to reliably evaluated effects on risk of more severe (grade II or higher) incident pressure ulcers. Four poor-quality trials also found a more advanced static support surface (bead overlay, cubed foam mattress, medical sheepskin, or low air pressure mattress) associated with decreased incidence of pressure ulcers compared with a standard mattress. Two other poor-quality trials evaluating a visco-elastic foam mattress or a low-air-loss mattress found no benefit compared with a standard mattress.	Categorization of low-air-loss beds as dynamic or static is somewhat unclear and inconsistent. We reorganized KQ 3 on support surfaces to discuss trials of low-air-loss beds separately, and results are presented now in separate bullet points as well. Unfortunately the evidence on low-air loss mattresses or overlays vs. standard hospital beds or other types of mattresses or overlays is limited (3 trials) and not strong enough to draw reliable conclusions about effectiveness.

Commentator & Affiliation	Section	Comment	Response
Hill-Rom	Results	In fact, LAL surfaces are included in the "static support surface category" (which is different terminology than appears in the Treatment document) and their effectiveness is supported with moderate strength over a number of reviewed studies. The term static is often used in the industry as synonymous with passive or unpowered and many would not intuitively include low air-loss or microclimate management surfaces in this category when the conclusions are lifted out of context. That is, the first half of this paragraph supports the efficacy of LAL surface but the only use of the familiar term "LAL" is associated with lack of effectiveness. This is an important point in that the current body of literature allows for only a small number of relatively definitive conclusions regarding surface effectiveness and a re-wording to specifically call-out micro-climate management or LAL surfaces in this category would be a service to the typical clinician, who is likely to be a skimming the document for conclusions. Adding to this confusion – to re-emphasize - is the fact that the only use of the actual term low air-loss appears in association with a study that showed no benefit.	See response above.
Hill-Rom	General	We would like to request a meeting with an AHRQ team representative to discuss our concerns.	This comment is for AHRQ.
Kenneth Olshansky,M.D.	Methods	Given the loss of so many preventive studies, the exec. summary fails to reflect the potential benefit of many simple, effective preventative interventions.	We expanded the inclusion criteria to include trials that enrolled up to 20% of patients with ulcers at baseline, if they reported incident ulcers.
Mary Arnold Long	General	The title should be changed to "Pressure Ulcer Risk Assessment and Prevention in the Adult: A Comparative Effectiveness Review" since this is referencing only the adult population. The summary doesn't include Brem's study cited in American Journal of Surgery from 2010 identifying that a HAPU stg IV pu costs over $129,000. This is significantly higher cost than the cost of treatment identified in your background statement. On page ES-4 "(SIPS) were requested from identified drug and device manufacturers of pressure ulcer treatments..." I'm wondering who those manufacturers were since none of the data re: soft silicone dressings as a prophylactic pressure ulcer dressing showed up in this document. Surely, Molnlycke would have shared their findings with you.	We added "Adults" to the Title. The Brem article focuses on costs of stage IV ulcers based on 19 patients and we do not believe this data is robust enough to replace estimates based on HCUPS data. SIPS were requested from 70 manufacturers and a public notice requesting SIPS was also posted. A SIP was requested from MoInLycke, but the company did not respond after 6 weeks.

Commentator & Affiliation	Section	Comment	Response
Mary Arnold Long	Results	I know of several studies re: soft silicone foam as a prophylaxis for pressure ulcers. These may be considered more "practice-based" studies, but yet, they are studies that have been published in a peer-reviewed journal. 1 - Use of a Sacral Silicone Border Foam Dressing as One Component of a Pressure Ulcer Prevention Program in an Intensive Care Unit Setting Walsh, Nancy S.; Blanck, Alyson W.; Smith, Lisa; Cross, Maribeth; Andersson, Liane; Polito, Carol Journal of Wound, Ostomy & Continence Nursing: March/April 2012 - Volume 39 - Issue 2 - p 146–149 2-Prophylactic Dressing Application to Reduce Pressure Ulcer Formation in Cardiac Surgery Patients Brindle, C. Tod; Wegelin, Jacob A Journal of Wound, Ostomy & Continence Nursing: March/April 2012 - Volume 39 - Issue 2 - p 133–142 3-Reduction of Sacral Pressure Ulcers in the Intensive Care Unit Using a Silicone Border Foam Dressing Chaiken, Nancy Journal of Wound, Ostomy & Continence Nursing: March/April 2012 - Volume 39 - Issue 2 - p 143–145	We reviewed the cited references. The Walsh and Chaiken studies are uncontrolled studies that do not meet inclusion criteria. The Brindle trial was recently published and has been added to the report.
Mary Arnold Long	Results	Brem H et al American Journal of Surgery (2010) 200, 473-477 1 - Use of a Sacral Silicone Border Foam Dressing as One Component of a Pressure Ulcer Prevention Program in an Intensive Care Unit Setting Walsh, Nancy S.; Blanck, Alyson W.; Smith, Lisa; Cross, Maribeth; Andersson, Liane; Polito, Carol Journal of Wound, Ostomy & Continence Nursing: March/April 2012 - Volume 39 - Issue 2 - p 146–149 2-Prophylactic Dressing Application to Reduce Pressure Ulcer Formation in Cardiac Surgery Patients Brindle, C. Tod; Wegelin, Jacob A Journal of Wound, Ostomy & Continence Nursing: March/April 2012 - Volume 39 - Issue 2 - p 133–142 3-Reduction of Sacral Pressure Ulcers in the Intensive Care Unit Using a Silicone Border Foam Dressing Chaiken, Nancy Journal of Wound, Ostomy & Continence Nursing: March/April 2012 - Volume 39 - Issue 2 - p 143–145	We reviewed the cited references. The Brem, Walsh and Chaiken studies are uncontrolled studies that do not meet inclusion criteria. The Brindle trial was recently published and has been added to the report.
Maureen Dailey	General	The American Nurses Association (ANA) supports the comments submitted by the Wound, Ostomy and Continence Nurses Society™ (WOCN®).	Thank you for the comment.

Commentator & Affiliation	Section	Comment	Response
Tom Denberg	General	Mention is made that "black skin" is a risk factor for pressure ulcers. Given that pressure ulcers develop because of skin breakdown, it's a minor editorial point, but my interpretation is that it's not black skin, per se (e.g. melanin) that's a direct risk factor for pressure ulcers, but it's black RACE that's associated with a greater likelihood of developing pressure ulcers (most likely as a confounder). It would be worth making this clearer in the text.	We changed to refer to "black race"
Anonymous	General	The purpose is defined (page 1) as..... [risk assessment] .....'and to evaluate the benefits and harms of preventive interventions for pressure ulcers, in different settings and patient populations. However, the methodological design (discussed below) restricts the ability of this review to do as simply stated in the introduction. It seems to only focus on comparison specifically where the population, risk or setting is different. This misses the most valuable opportunity to report simple outcomes in each of those groups e.g. what works in surgical patients, what works in paediatrics etc. and the rejected literature compilation shows just how significant these omissions are. I think this is a clinically relevant weakness in what would otherwise be a worthwhile report.	We did not restrict inclusion only to studies in which the population, risk, or setting was different. KQ 1, 2, 3, and 4 included studies that evaluated risk assessment instruments and preventive interventions in any patient population, risk group, or setting; the sub-questions addressed whether estimates might vary depending on setting or patient characteristics.
Anonymous	General	Question 3 simply states: 'In patients at increased risk of developing pressure ulcers what is the effectiveness and comparative effectiveness of preventative interventions in reducing the incidence or severity of pressure ulcers'? This would have been fine left as is, but completely fails to capture some very relevant clinical evidence when the question is further broken down into parts: 3a: ....differ by risk level 3b.....differ by setting 3c.....differ by patient characteristics I believe Question 3 to limit the value of this review. The phrasing of the main question is restricted by the sub-clause focus, which seems to negate the value of 'effectiveness' in favour of 'comparative effectiveness'. The focus on the three sub-groups contradicts, complicates and confounds the main question and so has lead to the exclusion of a great many preventive studies.	Key Question 3 was evaluated separately from the sub-questions (i.e. it was not restricted by having to compare effectiveness in different settings, patient groups, etc).
David Brienza	Results	Pg. 41, Section on results from Wheelchair cushion studies The study by Brienza et. al. J Am Geriatr Soc 58:2308–2314, 2010 is misrepresented. The study was not simply a comparison of wheelchair seat cushions' effectiveness in preventing pressure ulcers. The study evaluated the cushion's effect on pressure ulcer incidence WHEN USED WITH A	We revised the text to be clear that the wheelchair cushions were used in conjunction with a fitted wheelchair. We calculated a standard relative risk with 95% CI based on the incidence rates reported in the trial (9.9% vs. 6.7%); the 95% CI was 0.02 to 1.0 and the p value 0.054 (the trial did not report a relative risk). The loss to follow-up exceeded the

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		FITTED WHEELCHAIR. The conclusion as stated, was “Skin protection cushions used with fitted wheelchairs lower pressure ulcer incidence for elderly nursing home residents and should be used to help prevent pressure ulcers.” The statistical significance of the primary outcome, incidence of ischial tuberosity pressure ulcers between treatment and control groups is p=0.04 and not p=0.054 as stated in the draft document. A Fisher’s Exact test was used for this analysis. The study is judged to be of "poor" quality "due to unclear allocation concealment, unclear blinding of outcome assessors, and high loss to follow up." None of these assertions are correct. Allocation concealment is described in the publication by the following statement "A research team member independent of those with participant contact prepared a 1:1 allocation randomization scheme stratifying according to clinical facility. Randomized blocks of varying length (containing random permutations of the two treatment combinations) were used for randomization. This approach allowed relative balance of treatment allocations overall and within each clinical center while effectively keeping clinical center staff masked as to the treatment the next participant was to receive." Blinding of the assessors is also described in the paper: "The research team’s skin assessor (a research nurse trained in detecting and staging pressure ulcers; MK) who was masked to the treatment assignment performed weekly skin and risk assessments (Braden score). ... Although the intervention was not completely masked because of the readily identifiable differences in configuration and weight between the SPC and the SFC cushions, the research staff members who performed outcome measures were masked to treatment group assignment. Removing all identifying labels from the cushions and using the same color and style of incontinence covers for all cushions accomplished this objective. The research team’s skin assessor monitored pressure ulcer status while the subject was in bed." Finally, the percentage of participants lost to follow up was 18.1% (42/232, 21 in each group) Intention-to-treat analysis reported. According to the CONSORT 2010 Statement “There should be concern when the frequency or the causes of dropping out differ between the intervention groups.” This was not the case for this RCT.	20% threshold based on the number of patients randomized to each group and the number who did not have follow-up data (25/119 and 27/113); high attrition can result in attrition bias even when it's similar between groups. We re-rated randomization method as unclear because the method used to generate the randomization sequence was not reported (e.g., computer generated, random numbers table). Block allocation does not tell how the randomization sequence was generated. We re-rated the allocation concealment as adequate; it is preferable to use standardized method such as centralized randomization where it is clear there is no knowledge of patients by the person allocating interventions or sealed opaque envelopes but we judged this method to be acceptable on re-review. We originally rated blinding of outcome assessors as unclear but on re-review rated as adequate, even though the authors acknowledge it may not have been complete. We re-rated the study overall as fair.

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Anonymous	General	Too restricted due to KQ3 phrasing and so has a considerable risk of reporting bias.	We do not see how 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?) is too restrictive or why it would result in reporting bias for the defined outcomes.
Anonymous	General	This is a hugely valuable piece of work which, unfortunately, due to the phrasing of Q3, limits the ability to inform clinical practice in a useful way. It could be so much stronger if Q3 was reinstated as a question in its own right, in addition to the sub-groups 3a-c.	We are not sure what this comment is referring to. Key Question 3 is analyzed and reported separately from Key Questions 3a and 3c.
Anonymous	General	The Braden and Norton scales have been validated in the literature. I am not familiar with the Waterloo tool.. ? The use of risk assessment tools for pressure ulcers is supported by many clinical guidelines. ? It is standard of care to conduct a risk assessment for pressure ulcers.	Thank you for the comment. The purpose of KQ 1 and 2 was to determine the clinical utility and predictive validity of risk assessment tools.
Anonymous	General	The CER, however, examined: 1) only RCT's 2) only studies comparing one tool to another 3) only the outcome of care without the processes Randomized clinical trials are, of course, considered a gold standard of evidence and necessary to establish efficacy. The experimental protocols, however, often call for more rigidity than one would desire in a complex clinical situations that call for multiple layers of intervention and complex clinical decision making. Effectiveness studies are required to demonstrate that the intervention can work in a real world setting. "If designed and conducted rigorously, they can produce strong evidence of the effectiveness of the studied practice. If conducted under less rigorous conditions, they can still show some evidence of effectiveness, but are less likely to be proof that the practice can be replicated in other setting1,pg 38." Such evaluations often compare outcomes before and after introduction of a given practice and while they most often do not have control groups for comparison, they are more likely to provide information about what happens in routine rather than experimentally controlled situations.	This report did not include only RCT's, as described in the Methods; non-randomized studies were included for assessments of risk assessment instruments and harms. RCT's are not necessarily efficacy studies, they can also be designed as effectiveness studies and include evaluations of processes. We did not include only studies comparing one tool to another; and in fact many studies included for KQ 2 evaluated a single risk assessment tool. The ability to draw reliable inferences about effectiveness from uncontrolled studies of preventive interventions is limited and therefore these were excluded from the review.

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Anonymous	General	Safer2, in discussing evaluation of screening tools, distinguishes between screening for disease detection such as breast cancer and screening for risk factors to identify persons with potentially reducible risks. He contends that screening for treatable and currently present disease is based on a biomedical model while screening for risk factors of a disease that is not currently present and may be preventable through risk reduction is based on a general susceptibility model. Because of this inherent difference, he believes that screening for risk factors should be evaluated differently.	Thank you for this interesting comment. See response below.
Anonymous	General	In discussing methods for evaluation of screening for risk factors, Safer2 uses a health education model and discusses efficacy and effectiveness of a screening program combined with health education. He suggests that efficacy and effectiveness be measured in terms of the person at risk learning new information about risk factors and risk reduction, using this information to engage in risk-reducing behaviors, engaging in behavior that meaningfully reduces risk and those behaviors actually reduce morbidity and mortality. This model can be applied to prospective cohort studies where nursing staff are educated in risk assessment and risk reduction and processes of care are monitored with measurement of outcomes related to incidence and severity of pressure ulcers such as the study by Lynn, et al3.	Thank you for this interesting comment. However, we believe that in order to assess the utility of risk prediction instruments it is necessary to understand how their use impacts clinical outcomes (KQ 1) and how well they predict the develop of ulcers (KQ 2). The study by Lynn et al is an uncontrolled study that essentially evaluates a quality/process improvement initiative that does not meet inclusion criteria.
Anonymous	Results	1. Hyde P, Falls K, Morris JA, Schoenwald SK. Turning Knowledge into Practice: A Manual for Human Services Administrators and Practitioners about Understanding and Implementing Evidence-Based Practices. Boston, MA: The Technical Assistance Collaborative; 2010. Morris J. A., Day S. and Schoenwald S. K., eds. 2. Safer MA. A comparison of screening for disease detection and screening for risk factors. Health Education Research. 1986;1(2):131-138. 3. Lynn J, West J, Hausmann S, et al. Collaborative clinical quality improvement for pressure ulcers in nursing homes. J Am Geriatr Soc. 2007;55(10):1663-1669.	We reviewed these studies; none of them meet inclusion criteria.
Virginia Pressure Ulcer Resource Team	General	1) Your study made it very clear that there is a paucity of good basic research studies as it relates to preventing pressure ulcers. The difficulty of course is how one ethically designs human research studies.	Thank you for the comment.

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Virginia Pressure Ulcer Resource Team	General	2) The document did an excellent job in discussing prevention but put almost all of its emphasis on Risk Assessment Scales. There was almost no mention what role the quality of the caregivers play in prevention. Too much emphasis is placed on the patients' risk factors rather than the quality of care given or not given which in fact may be the most critical factor whether a patient develops a pressure ulcer.	We added a sentence to the Discussion (Applicability): "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."
Virginia Pressure Ulcer Resource Team	General	3) There is the suggestion that Risk Assessment Scales have the ability to predict who will develop a pressure ulcer. This is not the case. The Risk Assessment Scales can only "assess" risk. The main determining factor whether the patient will develop a pressure ulcer will be if the staff uses the information from the Risk Assessment Scales and implements the necessary preventive interventions.	Thank you for the comment. This was the purpose of Key Question 1, to determine whether use of risk assessment instruments results in better clinical outcomes (presumably through use of effective preventive interventions).