

# Prevention and Treatment of Pressure Ulcers: Methodology Addendum



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## INTRODUCTION

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This document includes additional methodological documents used in the development of the second edition of the International Pressure Ulcer Guideline (see citation below). The Guideline Development Group (GDG) responsible for directing the 2014 guideline update (i.e. second edition) first convened in June 2012. At that meeting they reviewed the methodological documents used to guide the initial 2009 Guideline development process, revising these documents as appropriate. These revised documents were made publically available to potential stakeholders on the guideline website throughout the guideline development period.

An abridged version of this document (i.e. the methodology chapter of this document) was published in the printed version of the *Clinical Practice Guideline*. Guideline readers are encouraged to review the full methodology as presented in this document and made available on the guideline website until the next guideline update. The GDG respectfully requests that anyone evaluating the 2014 guideline also review this document for a comprehensive description of the guideline development methodology.

Printed copies of the English version of the *Clinical Practice Guideline* are available through links provided on the following websites:

NPUAP website:	<a href="http://www.npuap.org">www.npuap.org</a>
EPUAP website:	<a href="http://www.epuap.org">www.epuap.org</a>
Australian Wound Management Association (AWMA) website:	<a href="http://www.awma.com.au">www.awma.com.au</a>
Hong Kong Enterostomal Therapist Society website:	<a href="http://www.etnurse.com.hk">www.etnurse.com.hk</a>
New Zealand Wound Care Society (NZWCS) website:	<a href="http://www.nzwcs.org.nz">www.nzwcs.org.nz</a>
Wound Healing Society Singapore website:	<a href="http://www.woundhealingsociety.org.sg">www.woundhealingsociety.org.sg</a>
International Pressure Ulcer Guideline website:	<a href="http://www.internationalguideline.com">www.internationalguideline.com</a>

A *Quick Reference Guide* version that contains excerpts from the *Clinical Practice Guideline* is also available. The quick reference guide is intended for busy health professionals who require a quick reference in caring for individuals in the clinical setting. **Users should not rely on excerpts from the *Quick Reference Guide* alone.**

### Guideline Citation:

National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline. Emily Haesler (Ed.). Cambridge Media: Osborne Park, Western Australia; 2014.

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## PURPOSE AND SCOPE

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### Purpose

The overall purpose of this international collaboration is to develop a 2014 update of the international guidelines for the prevention and treatment of pressure ulcers, initially developed by the National Pressure Ulcer Advisory Panel (NPUAP) and European Pressure Ulcer Advisory Panel (EPUAP) and published in 2009.

The guidelines contain evidence-based recommendations for the prevention and treatment of pressure ulcers that could be used to guide decision making by health professionals and individuals throughout the world.

A joint Guideline Development Group (GDG) with representatives from the NPUAP, EPUAP and Pan Pacific Pressure Injury Alliance (PPPIA) will plan the guideline development process and review all the documentation.

The **purpose of the prevention recommendations** is to guide evidence-based care to prevent the development of pressure ulcers. The prevention recommendations will apply to all vulnerable individuals of all age groups. The guideline is intended for the use of health professionals who are involved in the care of individuals who are at risk of developing pressure ulcers, whether they are in a hospital, long-term care, community setting, or any other setting and regardless of their diagnosis or health care needs. It will also help to guide individuals and carers on the range of prevention strategies available.

The **purpose of the treatment recommendations** is to guide evidence-based care for individuals of all ages with existing pressure ulcers, regardless of care setting. The guideline is intended for use by health professionals who are involved in the care of individuals with existing pressure ulcers. It will also guide individuals and caregivers. Individuals with pressure ulcers are usually at risk of additional pressure ulcers; therefore, the prevention guideline should also be followed for these individuals.

### Scope

**This guideline will make recommendations for best practice based on current evidence.** The guideline will cover the following topics:

#### Background sections

- International trends in prevalence and incidence of pressure ulcers
- Pressure ulcer etiology
- International NPUAP/EPUAP Pressure Ulcer Classification System

#### Prevention

- Risk factors and risk assessment
- Skin and tissue assessment and management (i.e. preventive skin care)
- Emerging therapies for prevention (e.g. microclimate manipulation, dressings, electrical stimulation, ultrasound, topical agents and other emerging therapies as identified in the literature searches)

#### Prevention and Treatment

- Nutrition
- Support surfaces
- Repositioning and mobilization

## Treatment

- Assessment of pressure ulcers and methods to monitor healing
- Pain assessment and management
- Cleansing
- Debridement
- Dressings
- Topical agents
- Assessment and treatment of infection and biofilms
- Biophysical agents (e.g., light and energy therapies such as electrical stimulation, ultraviolet (UV) light, negative pressure wound therapy)
- Growth factors
- Biological dressings
- Surgery

## Special Populations

Recommendations regarding the unique needs of several special populations will be addressed where evidence exists. These include:

- individuals in the operating room,
- individuals requesting palliative care,
- spinal cord injured individuals,
- infants and children,
- individuals in critical care settings,
- bariatric individuals, and
- older adults.

## Clinical Questions

The following key clinical questions are proposed to guide literature searches, evidence synthesis and recommendation development. Above all, the key recommendations will address the questions related to health in the guideline.<sup>1</sup>

### Prevention

What is the state of the science in pressure ulcer prevention?

How does this evidence answer the following key clinical questions?

- What factors put individuals at risk for pressure ulcer development?
- What are the most accurate pressure ulcer risk assessment strategies?
- What skin care strategies are effective in preventing pressure ulcers?
- What nutritional interventions are effective in preventing pressure ulcers?
- What repositioning and mobilization strategies are effective in preventing pressure ulcers?
- What support surfaces are effective in preventing pressure ulcers?
- What other new emerging interventions are effective in preventing pressure?

### Treatment

What is the state of the science in pressure ulcer treatment?

How does this evidence answer the following key clinical questions?

- What are effective strategies for accurate and timely pressure ulcer classification and assessment?
- What are effective strategies for evaluating/monitoring healing?

- What are effective strategies for providing local pressure ulcer treatment that support healing (cleansing, debridement, topical agents, dressings etc.)?
- What nutritional interventions are effective in supporting pressure ulcer healing?
- What strategies are effective in preventing, assessing and treating pressure ulcer pain?
- What repositioning and mobilization strategies are effective in supporting pressure ulcer healing?
- What support surfaces are effective in supporting pressure ulcer healing?
- What biophysical agents are effective in treating pressure ulcers (e.g., electrical stimulation, ultrasound, negative pressure wound therapy)?
- What are effective strategies for preventing, diagnosing and treating infection and biofilms that interfere with pressure ulcer healing?
- What other new emerging interventions are effective in treating pressure ulcers?
- Do pressure ulcer prevention and treatment strategies vary according to unique population-specific needs (e.g., infants, children)?

### **Implementation and Quality Improvement**

The guideline developers recognize that best practice can be difficult to implement in increasingly complex health care organizations that are often challenged by cost restraints. Organizational implications of guideline and cost effectiveness analyses will be considered for this guideline, along with other organizational barriers, to facilitate optimal use of these best practices throughout the world.

Quality and safety research related to pressure ulcers will be evaluated to identify:

- successful guideline implementation strategies;
- facilitators and barriers to guideline implementation;
- resources required to apply guideline recommendations; and
- quality indicators and criteria for ongoing monitoring and auditing.

### **Consumer, Organization and Cost Implications**

Implications for consumers (i.e., individuals with pressure ulcers or at risk for developing pressure ulcers) will be explored in depth. Literature searches have identified new research on quality-of-life concerns and patient preferences. Consumers will be actively involved in the development of this guideline as valued stakeholders to ensure that recommendations are patient centered.

## **References**

1. Brouwers MC, Kho ME, Browman GP, Burgers JS, Cluzeau F, Feder G, et al. AGREE II: advancing guideline development, reporting and evaluation in health care. *CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne*. 2010;182(18):E839-42. Epub 2010/07/07.

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## GUIDELINE METHODOLOGY

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### Introduction

The following methodology was used for the 2014 revision of the guideline. The methodology was circulated to all participants in the guideline development process at commencement of the project and was published on the guideline website ([www.internationalguideline.com](http://www.internationalguideline.com)) where it was publically available throughout the guideline development period.

The methodology for this edition of the guideline was revised from 2009 with the intention of using a more rigorous process for guideline development. The inclusion criteria for research in the field were tightened in order to focus on primary evidence. A consensus voting process (GRADE) has also been added to the guideline development process in order to assign a '**strength of recommendation**' to each recommendation statement. This process is intended to provide an indication of the confidence a health professional can have that implementation of the recommendation will promote positive outcomes and can be used to prioritize interventions.

### Guideline Website

<http://www.internationalguideline.com>

The international guideline website was established to publish the methodology and guideline search strategy. The website was used to make guideline sections available to stakeholders, and to collect feedback. The website platform was also used to conduct the GRADE consensus voting process.

The guideline website will be used to distribute the *Quick Reference Guideline*, acknowledge sponsors, and publish supportive documents referred to throughout this *Guideline Methodology* and will remain accessible during the interim period until the next guideline revision.

### Participants

All members of the development team were screened for experience, expertise and potential conflicts of interest. In the interest of transparency, all guideline developers were asked to complete a form identifying potential conflicts of interest that covered the guideline review period. Declarations of potential conflict will be published on the guideline website.

### Guideline Development Group

This revision of the guideline was conducted by European Pressure Ulcer Advisory Panel (EPUAP), National Pressure Ulcer Advisory Panel (NPUAP) and the Pan Pacific Pressure Injury Alliance (PPPIA). The Pan Pacific Alliance consists of the Australian Wound Management Association Incorporated (AWMA), the New Zealand Wound Care Society (NZWCS), the Hong Kong Enterostomal Therapist Society and the Wound Healing Society of Singapore.

The Guideline Development Group (GDG) determined and monitored each step of the guideline development process, as well as managing guideline dissemination strategy. Each of the three partner organizations nominated four representatives each to form the 12 member GDG. From its nominated representatives, each partner organization appointed a Chair. The three partner organizations each had four votes during joint deliberations, with the majority deciding. Examination of the evidence and consensus building preceded all voting. Minority opinions were represented in meeting minutes. A full description of the GDG role is available in this document.

A nonvoting observer from the Japanese Society of Pressure Ulcers (JSPU) attended GDG meetings during the 2014 revision process, with the option to join the GDG for the next revision.

## Small Working Groups

The guideline content was divided into working topic areas and Small Working Groups (SWGs) were formed to review the evidence available for each topic. The SWG members were selected by each participating organization based on an experience and expertise. Representatives of industry were excluded from SWGs. The SWGs were formed based on the principle of equal contribution from all participating organizations. A full description of the SWG role is available in this document. A total of 104 SWG members contributed to the guideline development process, with many members contributing to more than one SWG.

Guideline development was an iterative process, with GDG and SWG members maintaining communication via the methodologist. Evidence summaries and draft recommendations developed by the SWGs were reviewed by the GDG for:

- comprehensiveness and accuracy of literature reviews,
- methodological rigor in evidence analysis and application to clinical practice, and
- clarity and appropriateness of recommendations for an international audience.

## Methodologist

The guideline process was overseen by an experienced guideline methodologist. The methodologist assisted the SWG members in implementing the documented methodology, appraising and summarizing the new literature, revising the 2009 guideline recommendation and developing new recommendations, and presenting the evidence. The methodologist also managed the confidential consensus voting process (GRADE). The methodologist provided a link between the GDG and the SWG, managing communication and maintaining progress. The methodologist attended GDG and SWG meetings, but did not participate in GDG voting.

## Stakeholders

The entire process of developing the guideline was made available to stakeholders on the guideline website. A stakeholder is someone who has interest in pressure ulcers and wishes to contribute to the guideline by reading the methodology, search strategies, references under consideration, and draft recommendations, ensuring that all relevant evidence had been included and commenting on the draft guideline within the timeframes allowed. Anyone was invited to register as a stakeholder, either as an individual or as a representative for a society/organization. All members of the EPUAP, NPUAP and PPIA were invited to register as stakeholders and participate in this process.

In 2009 a total of 903 individuals and 146 societies/organizations registered as stakeholders. These stakeholders were all invited to register as stakeholders for the 2014 guideline. Additionally, patient representative organizations were also invited to participate in the stakeholder review process to provide a consumer perspective. A total of 988 individuals were formally invited to register as stakeholders, and many more received information about the process through colleagues and organizations. A total of 698 individuals registered as stakeholders to provide feedback as an individual or in representation of a society/organization.

When new sections of the guideline were made available on the guideline website, registered stakeholders were notified by electronic mail. The GDG reviewed all stakeholder comments and any additional evidence recommended by stakeholders before approving final recommendations.

## Methods

The steps of the guideline development process are delineated below. For simplicity and clarity, the process is described as linear and sequential; however, the actual process was iterative, with multiple drafts developed and progressively improved based on ongoing communication among GDG members, methodologist, SWG members, and stakeholders.

## Step 1: Identifying the Evidence

### Databases

The GDG identified clinical questions to guide literature searches. The *Purpose and Scope*, available at the guideline website, outlines these questions in detail. To identify the scientific literature on pressure ulcer prevention and treatment, several electronic databases were consulted, including:

- PubMed
- CINAHL
- MEDLINE
- EMBASE
- Scopus
- Biomedical Reference Collection
- Health Business Elite
- The Cochrane Database of Systematic Reviews
- The Cochrane Central Register of Controlled Trials, Health Technology Assessment and AMED databases.

As the guideline builds on a previously published body of evidence, the search dates for this update were 1<sup>st</sup> January 2008 through 1<sup>st</sup> July 2013. Some SWGs, particularly those that were addressing evidence in topics newly introduced in this version of the guideline, used different inclusion dates, as per the inclusion and exclusion criteria detailed below.

### Search Strategy

A sensitive search strategy was developed for the development of the guideline and made available on the guideline website. The SWGs were permitted to conduct additional focused searches to ensure the full depth and breadth of their topic area has been covered.

### Inclusion and Exclusion Criteria

All references retrieved by the electronic literature search were screened by the interim methodologist (during the interim period between guideline development periods from 2009 to 2012) and by the methodologist based on the following inclusion criteria:

#### 1. General Eligibility Criteria

Inclusion criteria:

- The articles must be primarily focused on pressure ulcer prevention, risk assessment, or pressure ulcer treatment in human subjects.
- The articles must have been published in a peer reviewed journal.
- An abstract must be available.
- The studies should have used one of the following designs:
  - randomized controlled trials (RCTs),
  - controlled clinical trials (CCTs),
  - quasi-experimental studies,
  - cohort studies,
  - cross-sectional studies,
  - survey studies,
  - prevalence or incidence studies,
  - case-control studies, and
  - case series.
- At least ten subjects must have been included in any case series.
- Systematic reviews or meta-analyses were eligible if they used the Cochrane methodology or met at

least 9 out of 11 quality criteria of the critical appraisal tool Assessment of Multiple Systematic Reviews (AMSTAR).

- SWG members reviewed, analyzed and use the original articles cited in systematic reviews and meta-analyses as the basis for guideline recommendations and systematic reviews were cited as additional supporting evidence. In order to rate the level of evidence (see step 2), the quality of the systematic review was assessed, using the AMSTAR checklist. Meta-analyses should not be equated with systematic reviews.
- Studies using established qualitative methodologies were considered, as appropriate to the research question.
- There was no restriction on the basis of the language of a study. However, studies published in languages other than English were required to indicate a high level of quality and unique data in the abstract report to warrant translation.

Exclusion criteria:

- Non-systematic literature reviews, narrative papers, opinion, commentary and descriptive papers. Papers falling into this category were used only to support expert opinion as required.
- Case series with less than 10 participants.
- Conference abstracts or other short papers with insufficient detail to enable an appraisal of the study methodology.
- Duplicate reports of research.
- Computational modeling and other research conducted in non-human subjects.
- Systematic reviews and meta-analyses that do not meet at least 9 of 11 criteria on the AMSTAR checklist.
- Papers without a substantial focus on pressure ulcer prevention or treatment or risk assessment.
- Foreign language studies for which the abstract does not indicate a high level study (i.e. at least Level 2) with unique data.

## *2. Eligibility Criteria for Research Reporting on Quality Improvement and Education*

In addition to the criteria outlined above, additional inclusion criteria were:

- Articles with a time series design with at least three outcome measurement time points.
- Project should be institution-wide (i.e., not individual units). Projects in individual units could be covered in special population sections as appropriate (e.g., pediatrics, critical care).
- Outcomes should be incidence or facility-acquired pressure ulcer rates.
- Quality improvement projects should be described in sufficient detail to enable replication (i.e., specific methods used, barriers and facilitators).

Exclusion criteria for research reporting on Quality Improvement and Education:

- Publications before January 2008 and after December 2012 were not appraised for these guideline sections.

## *3. Eligibility Criteria for Research Reporting on Risk Factor for Pressure Ulcers*

The systematic review by Coleman et al. (2013)<sup>1</sup> was used as a basis for literature selection to identify patient characteristics that increase the probability of pressure ulcer development. This was supplemented by a search for literature published from 31<sup>st</sup> March 2010 to July 1<sup>st</sup> 2013.

Inclusion criteria utilised by Coleman et al. (2013)<sup>1</sup> were:

- Primary research.
- Outcome was the development of a new pressure ulcer(s).
- Prospective cohort, retrospective record review where the risk factor preceded the pressure ulcer or CCTs.
- Length of follow-up at least three days, with the exception of operating room studies for which no minimal time period was set.
- Outcome clearly defined as Category/Stage I or greater pressure ulcer or equivalent.

- Multivariable analyses were undertaken to identify factors affecting pressure ulcer outcome.
- The unit of analysis was the individual patient.

Exclusion criteria utilised by Coleman et al. (2013)<sup>1</sup> were:

- Cross-sectional, case-study, patient recall, patient self-report or analysis of general practitioner records.
- Duplicate publication of a patient dataset.
- Cohort studies (prospective and record reviews) in which more than 20% of the study sample were excluded from analysis for reasons including withdrawal, death, loss to follow-up and missing records.
- Controlled trials in which the following minimum criteria did not apply: randomised allocation to treatment and intention to treat analyses.

#### *4. Eligibility Criteria for Research Reporting on Risk Assessment Tools*

Additional inclusion criteria for papers addressing the reliability of risk assessment tools were:

- Risk assessment tools are completed by qualified health professionals.
- The research involved comparing pressure ulcer risk assessment tool scores of different raters using the same scale (interrater) or comparing pressure ulcer risk assessment tool scores of the same raters using the same scale at different times (intrarater).

The systematic review by Chou et al. (2013)<sup>2</sup> was used as a basis for literature selection related to identifying the validity of risk assessment tools. This was supplemented by literature published after the end of the review period (i.e., from 31<sup>st</sup> July 2012 to 1<sup>st</sup> July 2013).

Additional inclusion criteria for papers addressing the validity of risk assessment tools were:

- Prospective study design (i.e., RCTs, CCT, prospective cohort study).
- Reporting the evaluation of one or more risk assessment tool in the prevention of pressure ulcers (analytical methods).
- Follow-up data included on at least 75% of participants.
- Participants were aged over 18 years.
- Individuals were assessed systematically for the development of new pressure ulcers (e.g., all participants have baseline skin assessment and at follow-up intervals suitable to identify new pressure ulcers in the study population). Assessment only at baseline and discharge is not a suitable follow-up to detect all new pressure ulcers.
- Risk assessment tools are completed at baseline.
- Outcome clearly defined as development of a Category/Stage I or greater pressure ulcer.
- Analysis methods: sensitivity, specificity, positive predictive value (PPV), negative predictive value and area under the receiver operating characteristic (AUROC) curve.

Exclusion criteria:

- Data used to generate the risk assessment tool are the same data used for the calculation of validity measures.

#### *5. Eligibility Criteria for Research Reporting Prevalence and Incidence*

Due to the vast volume of evidence relating to this new background chapter of the guideline for which literature had not previously been reviewed, a recent comprehensive publication<sup>3</sup> was used to provide an overview of the trends in pressure ulcer prevalence and incidence. Pieper et al. (2012)<sup>3</sup> included international pressure ulcer prevalence and incidence studies published from January 2000 to November 2011. This was supplemented by literature published after the end of the review period (i.e., from 1<sup>st</sup> November 2011 to 31<sup>st</sup> December 2012).

Studies not initially identified by bibliographic searches yet meeting these criteria were included when listed in reference lists of identified articles or recommended by SWG members or stakeholders.

## Direct Versus Indirect Evidence

Studies of pressure ulcers in humans and individuals at risk of, or with existing pressure ulcers were considered 'direct evidence' and were required to support an A or B '*strength of evidence*' rating. When studies of pressure ulcers in humans at risk of, or with existing pressure ulcers were not available, studies in normal human subjects, human subjects with other types of chronic wounds, laboratory studies using animals, or computational models were used as indirect evidence to support recommendations with a C '*strength of evidence*' rating.

## Step 2: Evaluating the Evidence

### Appraisal of Methodological Quality

The methodological quality of each study was evaluated by two members of the SWGs. Where large discrepancy of opinion was noted (such that the paper's overall quality was rated differently by the two reviewers), a third reviewer evaluated the paper. The methodologist completed a quality check on a random sample of 80% of the critical appraisals for papers selected for potential appraisal, including those papers that the SWG assessed as not meeting inclusion criteria.

The methodological quality of each study was assessed by two reviewers using methodology checklists that were based on tools developed by the Scottish Intercollegiate Guidelines Network.<sup>4</sup> Evaluation of study quality focused on the internal and external validity of the studies. The following quality criteria was considered: internal validity of the study; clear and appropriate research question(s); selection of subjects; allocation; baseline comparability; outcomes; blinding; confounding factors; statistical analysis; overall assessment of the study; and bias.

A range of critical appraisal tools were used based on different types of study design:

- Cross-sectional/survey/prevalence studies.
- Case-control studies.
- Cohort studies.
- RCTs.
- Quasi-experimental studies.
- Diagnostic studies.
- SQUIRE guideline checklist for quality improvement papers.
- Critical Appraisal Skills Program (CASP) Qualitative Research Checklist.
- AMSTAR criteria for systematic reviews.

Each criteria on the critical appraisal forms was assessed as being fully met (++), partially met (+), not met/not reported/unclear (—), or not applicable (NA). Studies were generally described as high, moderate, or low quality using the following criteria:

- High quality studies: fully met at least 80% of applicable criteria
- Moderate quality studies: partially or fully met at least 70% of applicable criteria
- Low quality studies: did not partially or fully met at least 70% of applicable criteria

### *Appraisal of Methodological Quality for Risk Factor Papers*

In the absence of guidelines for the quality assessment of risk factor studies, Coleman et al. (2013)<sup>1</sup> used an assessment framework based upon guidelines for assessing quality and risk of bias in prognostic studies and methodological considerations in the analysis, meta-analysis and publication of observational studies. Each study was appraised using the method described by Coleman et al. (2013)<sup>1</sup> and the following factors were considered:

- Baseline characteristics are adequately described.
- Study attrition: clear definition of risk factors.
- Continuous variables used or appropriate cut-points for continuous data.

- Risk factor measurement valid and reliable.
- Method/sampling of measurement used for all individual patients.
- Appropriate imputation methods.
- Appropriate classification for outcome.
- Potential confounders accounted for in study design.
- Potential confounders accounted for in analysis.
- No selective reporting.

In addition, specific consideration was given to the following criteria:

- Is there sufficient number of events (rule of thumb: more than 10 events per risk factor)?
- Is there sufficient presentation of data to assess the adequacy of method and analysis?
- Is the strategy for model building (i.e., inclusion of variables) appropriate and based upon a conceptual framework?
- Is the selected model adequate for the design?

Each of the above four criteria was assessed as being met (yes/no/partial/unsure) and these criteria were used as the basis of a structured approach for the classification of overall study quality. Studies were classified as high, moderate, low and very low quality using the following criteria:

- High quality studies: yes for all criteria
- Moderate quality studies: yes for criteria 1 and at least two other criteria
- Low quality studies: no for criteria 1 and no or partial for two other criteria
- Very low quality studies: no for criteria 1 and no or partial for all three remaining criteria

## Level of Evidence

The '*level of evidence*' for individual intervention studies was noted for each study containing direct evidence, using a classification system adapted from Sackett (1989)<sup>5</sup>. A more sophisticated and complex classification systems has been developed;<sup>6</sup> however, the elegant simplicity of their early work provided greater consistency when used with a large international group of reviewers.

Levels of evidence are typically applied to intervention studies (e.g., RCTs, CCTs or case series studies) because these types of studies are regarded as most important knowledge sources for clinical decision making. However, there are many more study designs (e.g., epidemiological or descriptive studies) that provide valuable evidence to guide practice, yet cannot be classified with an intervention-based level of evidence system.

**Table 1: Level of Evidence for Intervention Studies**

<b>Level 1</b>	Randomized trial(s) with clear-cut results and low risk of error OR systematic literature review or meta-analysis according to the Cochrane methodology or meeting at least 9 out of 11 quality criteria according to AMSTAR appraisal tool.
<b>Level 2</b>	Randomized trial(s) with uncertain results and moderate to high risk of error.
<b>Level 3</b>	Non randomized trial(s) with concurrent or contemporaneous controls.
<b>Level 4</b>	Non randomized trial(s) with historical controls.
<b>Level 5</b>	Case series with no controls. Specify number of subjects.

Studies on diagnostic and prognostic validity of pressure ulcer risk and pressure ulcer classification form an important body of knowledge in pressure ulcer management that should be appraised independently from intervention studies. Diagnostic accuracy studies are studies in which results of index tests are compared with results from reference standards at the same point in time.<sup>7</sup> Therefore, cross-sectional designs are

needed to establish the concurrent existence of both index test and reference standard results. Most studies in pressure ulcer risk research are not diagnostic accuracy studies according to this widely agreed upon definition, because the measured pressure ulcer risk is often compared with subsequent pressure ulcer occurrence. These designs resemble those of prognostic studies or diagnostic accuracy studies with imperfect reference standards.<sup>8</sup>

Comparable to different phases of intervention research phases of diagnostic and prognostic research can also be distinguished. In diagnostic research, Phase I and II studies focus on differentiation between individuals with the target from those without. Phase III studies are typical diagnostic accuracy studies whereas phase IV research investigates the clinical impact of diagnostic procedures.<sup>9</sup> Prognostic studies are comparable with diagnostic accuracy studies with the difference that based on factors or diagnostic cues future events are predicted. These types of studies are typically used to develop prognostic models. Prognostic models (e.g. pressure ulcer risk assessment tool scores), are used to predict the probability of future events in individuals or groups.<sup>10</sup>

Test accuracy and validity estimates are only surrogate measures for clinical effectiveness.<sup>11</sup> The clinical effectiveness of diagnostic test procedures can only be adequately investigated by diagnostic RCTs.<sup>12, 13</sup> In case of diagnostic or prognostic RCTs the described level of evidence hierarchy of intervention studies is used.

Corresponding '**level of evidence**' hierarchies for diagnostic and prognostic accuracy and many other studies have been proposed<sup>12, 14</sup> and have been adopted by the GDG in the guideline update.

The technical documents summarizing critical appraisals of included studies are made available at the guideline website. Permission to use the technical documents for purposes other than education can be requested at the website.

**Table 2: Levels of evidence for diagnostic studies in the EPUAP-NPUAP-PPPIA guideline update<sup>12, 14</sup>**

<b>Level 1</b>	Systematic review of high quality (cross sectional) studies according to the quality assessment tools with consistently applied reference standard and blinding.
<b>Level 2</b>	Individual high quality (cross sectional) studies according to the quality assessment tools with consistently applied reference standard and blinding among consecutive persons.
<b>Level 3</b>	Non-consecutive studies, <sup>7</sup> or studies without consistently applied reference standards.
<b>Level 4</b>	Case-control studies, <sup>7</sup> or poor or non-independent reference standard.
<b>Level 5</b>	Mechanism-based reasoning, study of diagnostic yield (no reference standard).

**Table 3: Levels of evidence for prognostic studies in the EPUAP-NPUAP-PPPIA guideline update<sup>12, 14</sup>**

<b>Level 1</b>	Systematic review of high quality (longitudinal) prospective cohort studies according to the quality assessment tools.
<b>Level 2</b>	A prospective cohort study.
<b>Level 3</b>	Analysis of prognostic factors amongst persons in a single arm of a randomized controlled trial.
<b>Level 4</b>	Case-series or case-control studies, or poor quality prognostic cohort study, retrospective cohort study.
<b>Level 5</b>	Not applicable.

## Data Extraction

The full papers of selected references were obtained and made available to the relevant SWGs on a web-based (Google Docs) platform.

A data extraction template was used to extract relevant data from individual papers, including study design; description of participants; study groups and interventions; outcome measures; length of follow up; study results; and comments and limitations. Preliminary data extraction tables were prepared in the interim development period (i.e., period between the publication of the 2009 guideline and the commencement of the 2014 guideline development period).

The members of the SWGs were provided with the preliminary data extraction tables for checking, expanding on details and adding studies that had not yet undergone data extraction. The methodologist completed a quality check of a random sample of 80% of the completed evidence tables and the GDG completed a quality check of a random sample of 10% of the completed evidence tables.

The technical documents summarizing data extraction of included studies are made available at the guideline website. Permission to use the technical documents for purposes other than education can be requested at the website.

### **Step 3: Drafting/Revising Recommendations**

Based on the identified, appraised and summarized empirical evidence recommendations were formed. Each SWG formulated conclusions about the body of available evidence based on the evidence tables and critical appraisals and levels of evidence. Evidence tables from previous guidelines were also made available to SWGs to ensure the full body of scientific literature was reviewed. A first draft of recommendations was developed by the respective SWGs. The GDG reviewed the draft recommendations, making revisions as necessary.

To ensure uniformity and internal consistency in the final guideline, the GDG provided the following guidance:

- Each recommendation should start with an action verb and be a simple, short, direct, declarative statement, free of jargon.
- Multiple complex recommendations should be broken down into a series of smaller, discrete recommendations.
- The SWGs were advised to start with broad, directive statements, followed by subsequent statements with more detail (how, when, how often).
- Recommendations should be specific and unambiguous.
- When available, information on health benefits, side effects and risks should be provided.
- Spelling will be based on the conventions of American English.

The GDG reviewed all recommendations to ensure the wording of the recommendations accurately translated available research into best practice while being sensitive to the many different individual cultures and professional standards represented among the international audience for these guidelines.

The term 'individual' was selected to describe the patient, client, resident, or person with a pressure ulcer or at risk for a pressure ulcer. The terms 'health professional' and 'interprofessional team' were selected for use when referring to health professionals providing professional health care services to the individual. The disciplines of professionals performing a given service may vary from country to country based on the laws and regulations governing health care providers. Products available in one country may not be available in another. Generic names were used when referring to drugs and other products.

### **Step 4: Assigning Strength of Evidence Ratings**

'*Strength of evidence*' ratings were assigned to recommendations. This rating identifies the strength of cumulative body of evidence supporting each recommendation.

**Table 4: Strength of evidence rating for each recommendation**

<b>A</b>	The recommendation is supported by direct scientific evidence from properly designed and implemented controlled trials on pressure ulcers in humans (or individuals at-risk for pressure ulcers), providing statistical results that consistently support the guideline statement. (Level 1 studies required)
<b>B</b>	The recommendation is supported by direct scientific evidence from properly designed and implemented clinical series on pressure ulcers in humans (or individuals at-risk for pressure ulcers), providing statistical results that consistently support the recommendation. (Level 2, 3, 4, 5 studies)
<b>C</b>	The recommendation is supported by indirect evidence (e.g., studies in normal human subjects, humans with other types of chronic wounds, animal models) and/or expert opinion.

A '**strength of evidence**' rating of A required Level 1 studies conducted in individuals with pressure ulcers or at risk for pressure ulcers. This rating is consistent with recommendations derived using the Cochrane methodology. '**Strength of evidence**' ratings of B required Level 2, 3, 4, and/or 5 studies in these populations. Recommendations supported by A and B '**strength of evidence**' ratings were developed first. This strategy provided recommendations with very direct evidentiary support. Where the guideline was considered to lack the breadth and depth of guidance necessary to provide care, additional recommendations based on expert opinion and/or indirect evidence and given a '**strength of evidence**' rating of C were developed to fill the evidence gap.

The '**strength of evidence**' supporting the recommendation is not the same as the '**strength of the recommendation**'. For example, there are no RCTs in individuals with pressure ulcers that evaluate debridement compared to no debridement. Therefore, this recommendation would have a relatively low '**strength of evidence**' supporting the recommendation, yet the recommendation may be strongly recommended in many clinical situations based on evidence from studies of other types of chronic wounds, proof of principle from basic science research, and/or expert opinion. See step 6 for assigning strength of recommendations.

In this guideline, evidence gaps have been explicitly identified. Systematic literature reviews were conducted to identify indirect evidence from studies of normal subjects, studies with intermediate or surrogate outcomes, studies of humans with other types of chronic wounds, and animal studies. For many recommendations, indirect evidence may be identified to support C '**strength of evidence**' ratings. In the absence of indirect evidence, consensus from previous guidelines or expert opinion may support C '**strength of evidence**' ratings, providing a broader base of expert opinion than that available in the SWGs and GDG. The SWG members were encouraged to evaluate previous guidelines for quality using the AGREE II Tool.<sup>15</sup> All recommendations, including those supported solely by expert opinion were reviewed by stakeholders.

## Step 5: Summarizing Supporting Evidence

The SWGs summarized the evidence supporting each recommendation. An explicit link between the recommendation and supporting evidence was expected. The strengths and limitations of this body of evidence were clearly described. All recommendations with a '**strength of evidence**' rating of A or B required an explicit summary of one or more studies conducted with human subjects with pressure ulcers or at risk for pressure ulcer development. The '**level of evidence**' for each study was also identified in the summary.

The summary statements for recommendations with '**strength of evidence**' of C clarify whether the recommendation was supported by:

- indirect evidence from studies of normal subjects.

- studies with intermediate or surrogate outcomes.
- studies of humans with other types of chronic wounds, and animal studies or other basic bench research.
- expert opinion supported by previous evidence-based guidelines.
- the expert opinion of the SWG and GDG members as reviewed by international stakeholders.

Evidence gaps identified in these summary statements serve as an agenda for future research efforts, as reported by the GDG in the guideline section *Further Research Needs*.

## Step 6: Assigning Strength of Recommendation Grades

As previously discussed, '**strength of evidence**' ratings identify the strength of cumulative evidence supporting the recommendation. In contrast, '**strength of recommendation**' grades require a different analysis. The recommendations are rated based on their importance and their potential to improve individual patient outcomes. The '**strength of recommendation**' is the extent to which a health professional can be confident that adherence to the recommendation will do more good than harm. The grading of importance is not necessarily related to the strength of internal or external evidence. The overall aim is to help health professionals to prioritize interventions. According to Atkins et al. (2004)<sup>16</sup> and Guyatt et al. (2008)<sup>17</sup> the following points should be considered to grade the strength of recommendations:

- The balance between benefits and harms. The larger the difference between both, the higher the likelihood for giving a strong recommendation.
- The overall quality of evidence across all studies upon the recommendation is based. The higher the quality, the higher the likelihood that a strong recommendation is warranted.
- Translation of the evidence into practice in specific clinical settings or uncertainty of baseline risk in the populations of interest.
- The higher the costs of an intervention, the greater the resources consumed, the lower the likelihood that a strong recommendation is warranted unless cost effectiveness can be demonstrated.

Besides overall methodological study quality and the balance between risks, harms and resources in diagnostic accuracy and prognostic studies the following additional question need to be considered for recommendation development:

- How strong is the confidence, that estimated probabilities improve clinical decision making, treatment decisions and subsequent patient outcomes?<sup>9, 11, 13</sup>

The '**strength of recommendation**' grades were achieved via a formal consensus process using the GRADE grid (See *Table 5*). In this consensus process all SWG and the GDG members were invited to take part, each voting on every recommendation in the guideline. The consensus voting process (GRADE) was conducted on the website. Each guideline development team member was provided with a unique identification. Before commencing in the GRADE process, the methodology was outlined, including the considerations to be made in casting a vote. The participant was required to nominate their understanding of the procedure before commencing, or to request further information.

For each section of the guideline, the recommendation statements were presented. The participant was required to actively select to read the evidence supporting each recommendation statement, and then make a selection for a '**strength of recommendation**' grade from the options presented in *Table 5* and an additional option to abstain from voting (a reason was required). Votes were recorded and calculated using a software program designed for the purpose. Participants could nominate a '**strength of recommendation**' for as few or as many recommendations as they preferred, but were strongly encouraged to grade on all recommendations.

**Table 5: The GRADE grid<sup>18</sup> is used for establishing consensus for every recommendation**

Balance btw desirable & undesirable consequences	Desirable clearly outweigh undesirable	Desirable probably outweigh undesirable	Trade-offs equally balanced or uncertain	Undesirable probably outweigh desirable	Undesirable clearly outweigh desirable
<b>Recommendation example</b>	<b>Strong: definitely do it</b>	<b>Weak: probably do it</b>	<b>No specific recommendation</b>	<b>Weak: probably don't do it</b>	<b>Strong: definitely don't do it</b>
'Use structured approach to risk assessment'	" "	" "	" "	" "	" "
'Limit head-of-bed elevation to 30°'	" "	" "	" "	" "	" "

Rules were determined based on previous applications of the GRADE process,<sup>16-18</sup> and a desire to obtain significant consensus. Determination of the final '**strength of recommendation**' was made according to the following rules:

- To achieve a strong positive (do it) or strong negative (don't do it) recommendation, 100% of votes must be cast in the same direction (positive or negative), with at least 70% voting for a strong recommendation, and 0% voting in the opposite direction.
- To achieve a weak positive (probably do it) or weak negative (probably don't do it) recommendation, at least 70% of votes must cast in the same direction (positive or negative), and less than 20% voting in the opposite direction.
- Any other combination of voting results in 'no specific recommendation'.

This resulted in five potential '**strengths of recommendation**' (see table 6).

**Table 6: Five types of recommendations<sup>16-18</sup> are used in this guideline**

Recommendation	Symbol	Description	Implications
<b>Do it</b> (Strong recommendation for using an intervention)			<i>For patient consumers</i> —Most people would want the recommended course of action and only a small proportion would not. <i>For health professionals</i> —Most people should receive the intervention. If health professionals choose not to follow the recommendation, they should document their rationale.
<b>Don't do it</b> (Strong recommendation against using an intervention)		Indicates a judgment that most well informed people would make.	<i>For quality monitors</i> —Adherence to this recommendation could be used as a quality criterion or performance indicator.
<b>Probably do it</b> (Weak recommendation for using an intervention)			<i>For patient consumers</i> —Most people would want the suggested course of action, but many would not.
<b>Probably don't do it</b> (Weak recommendation against using an intervention)		Indicates a judgment that a majority of well informed people would make, but a substantial minority would not.	<i>For health professionals</i> —Examine, and be prepared to discuss, the evidence with patients, as well as their values and preferences. <i>For quality monitors</i> —Clinicians' discussion and consideration of pros and cons of the intervention, and documentation of discussion, could be used as a quality indicator.
<b>No specific recommendation</b>		Trade-offs between risk and benefit unclear or lack of agreement between voting participants.	The advantages and disadvantages are equivalent; and/or the target population has not been identified; and/or there is insufficient evidence on which to formulate a ' <u>      </u> '-strength of recommendation'.

## Final Review and Recommendations

The GDG was integrally involved in each of these steps. Following review and approval of individual recommendations, the methodologist and the GDG reviewed all guideline documents for internal consistency, logical coherence and adherence to the guideline methodology. Based on this final review, the GDG will provide a global assessment of the strengths and limitations of the body of evidence supporting the guideline and recommendation for future research.

The GDG will continue to monitor guideline implementation after the guideline is published, encouraging translation of the guideline into non-English languages for maximum dissemination. The 2009 guideline was translated into 17 different languages.

To facilitate application of the guideline, a SWG was established to review existing quality and safety literature addressing common facilitators and barriers to guideline implementation and to make recommendations to support implementation. These recommendations are outlined in the guideline section, *Implementing the Guideline: Facilitators, Barriers and Implementation Strategy*. Health professionals are encouraged to use the ADAPTE Tool<sup>19</sup> in adapting this guideline for specific populations and settings.

Additionally, a SWG was established to review the recommendations in the guideline and identify quality indicators that could be used to monitor the implementation of this guideline. A wide range of clinical indicators are currently used around the world as part of ongoing health service accreditation programs, international benchmarking projects and at local levels for monitoring ongoing quality improvement. The quality indicators identified in the guideline section *Implementing the Guideline: Quality Indicators* are designed to monitor the specific recommendations for practice that are included in this guideline. They were selected based on expert opinion on their intrinsic value as an indicator of quality care for prevention and treatment of pressure ulcers and their '**strength of recommendation**', with consideration to practicalities of ongoing auditing. The indicators are proposed for use in health facilities/services in addition to other quality indicators as a measure of effectiveness in implementing the guideline locally.

The GDG will continue to monitor the pressure ulcer literature after the 2014 guideline has been published. Another revision is planned for 2019 (or sooner, if ongoing literature reviews reveals major advances in pressure ulcer prevention and treatment prior to 2019).

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## GUIDELINE DEVELOPMENT GROUP DESCRIPTION AND ROLE

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### Goal of Guideline Development Group

The goal of the Guideline Development Group (GDG) is to develop evidence-based recommendations for the prevention and treatment of pressure ulcers that can be used to guide professional and patient decisions on an international basis. This goal is accomplished by critically examining the evidence, exploring varying opinions, negotiating to achieve consensus, and voting on all recommendations, with dissenting opinion recorded as necessary.

### Guideline Methodology

The methodology adopted for the development of the 2009 guideline will be used for all revisions of the guideline to ensure the reliability, validity and integrity of the guideline process and products. The methodology may be modified to conform to advances in the science of guideline development. Any significant modifications to the methodology must be examined for threats to reliability, validity and integrity and will require a 2/3 majority vote of the GDG.

### Guideline Development Group Membership

The GDG will consist of four voting members from each of the participating organizations: National Pressure Ulcer Advisory Panel (NPUAP), European Pressure Ulcer Advisory Panel (EPUAP) and the Pan Pacific Pressure Injury Alliance (PPPIA). A nonvoting observer from the Japanese Society of Pressure Ulcers (JSPU) will attend GDG meetings during the 2014 revision process with the option to join the GDG for the next guideline revision. The (nonvoting) guideline methodologist will attend and report to meetings. GDG members are selected by their respective organizations and should meet the following qualifications:

1. Possess expertise in pressure ulcer prevention and treatment as well as a working knowledge of research methods for quality reviews.
2. Be free of major competing (or conflicting) interests. Disclose the nature of any minor competing interest and recuse themselves from related decisions. GDG members and others involved in the actual development of the guideline are screened for potential conflicts of interest. In the interest of transparency, GDG members will be asked to complete a form identifying potential conflicts of interest on a yearly basis. Declarations of potential conflict will be published with the guideline.
3. NOT have their primary employment in industry. Representatives of industry are excluded from developmental groups but are invited to participate as stakeholders.

### Role and Responsibilities

The GDG members serve as representatives of their respective organizations and are responsible for communicating guideline revisions and other relevant GDG decisions to their sponsoring organizations for review, critique and approval as needed. In their representative capacity, GDG members are responsible for:

1. Developing the guideline scope and purpose.
2. Analyzing and approving proposed guideline methodology changes which meet criteria to ensure the reliability, validity and integrity of the guideline.
3. Overseeing the guideline development and revision process to ensure the reliability, validity and integrity of the guideline.

4. Educating, mentoring and guiding Small Working Group (SWG) members to ensure the reliability, validity and integrity of the guideline development and revision process.
5. Reviewing evidence summaries and draft recommendations developed by the SWGs for:
  - (a) comprehensiveness and accuracy of literature reviews,
  - (b) methodological rigor in evidence analysis and application to clinical practice, and
  - (c) clarity and appropriateness of recommendations for an international audience.
6. Reviewing stakeholder comments with guideline revisions as appropriate.
7. Approving guideline revisions as a voting representative on the GDG. Representatives are not required to vote as a block with their parent organization.
8. Serving as an advisory group in financial and business matters.
9. Declaring competing (or conflicting) interests with recusal from GDG discussion and voting as appropriate.

## Term of Appointment

Appointment of GDG members is at the discretion of the parent organization. At least one previous GDG member should be included from each organization to ensure a core of experienced members and continuity in the guideline process. Each GDG member will serve a three year term. Current GDG members have committed to remaining on the GDG until completion of the 2014 guideline revision, barring unforeseen circumstances. There is no restriction on the number of terms; however, a balance of new and experienced members should be maintained.

## Attendance at GDG Meetings

- A minimum of two face-to-face GDG meetings will be scheduled per year in Europe or the US during active guideline revisions. Additional phone and video conferences will be convened as necessary.
- GDG members are highly encouraged to attend all meetings and phone/video conferences.
- If a GDG member is absent for an official GDG meeting or phone/video conference, voting will still occur at the meeting so that the work of the GDG can progress. If the votes of missing member(s) could have altered the GDG decision (i.e. close votes), then voting will be repeated by e-mail ballot, giving all individuals the opportunity to vote in close decisions.
- The GDG may schedule GDG-SWG meetings at various conferences for the convenience of members. These ad-hoc meetings do not constitute official meetings of the GDG and are convened to enhance communication among GDG and SWG members.

## Lead Members

Each participating organization (i.e. EPUAP, NPUAP, and PPPIA) will appoint a 'Chair' with authority to represent their respective organization in negotiations regarding financial and business issues. The Executive Director/President of the each organization may also be included in these negotiations, but not in determining or influencing the content of the guideline.

## Key GDG Processes

1. **Collaboration:** By mutual agreement, the GDG members will collaboratively review the research literature meeting inclusion criteria and revise the comprehensive prevention/treatment

guideline based on that review.

2. **Conflicts** will be resolved through re-examination of available evidence, discussion, and revision of documents to develop an acceptable compromise.
3. **Revision, Addition or Deletion of Guideline Recommendations** require a majority vote of the GDG with any dissenting opinions recorded.
4. **Peer Review:** Draft recommendations will be made available on a website for review by international stakeholders. All stakeholder comments will be reviewed by the GDG with revisions made as appropriate.
5. **Patient Consumer Involvement:** Peer consumer representatives will be invited to participate as stakeholders. Health professionals involved in the development of the guideline are encouraged to invite colleagues and patient consumers to register as stakeholders at the international guideline website.

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## SMALL WORKING GROUPS DESCRIPTION AND ROLE

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Small Working Groups (SWGs) are essential to the guideline development process. The SWG members work collaboratively to critically analyze the available evidence and draft the evidence-based recommendations that will guide the future care of patients throughout the world.

The GDG will decide on the final composition of each SWG and nominate a provisional SWG leader. The SWG's will consist of three to six members, with at least one person from each of the three GDG parent organizations wherever possible.

### Role of the Small Working Groups

The SWGs are responsible for reviewing the research within a given topic/section and making recommendations to the Guideline Development Group (GDG) for guideline revision based on their review of relevant evidence. Ideally, SWGs should be composed of members from various countries as well as various scientific and clinical disciplines. This broad representation of expertise enhances the quality of SWG discussions and the quality of the guideline as a whole. The SWGs will meet electronically (e-mail, Skype, phone or video conference). Each SWG will share information using the 'Google Docs' platform.

### Member Qualifications

1. Possess expertise in the SWG content area and a working knowledge of research methods sufficient for quality reviews. SWG members will be asked to submit a 2 page resume relevant to SWG topic area(s).
2. Be free of major competing (or conflicting) interests. Disclose the nature of any minor competing interest and recuse themselves from related decisions. The SWG members and others involved in the actual development of the guideline are screened for potential conflicts of interest. In the interest of transparency, SWG members will be asked to complete a form identifying potential conflicts of interest. Declarations of potential conflict will be published on the guideline website.
3. Be a member of one of the participating organizations (e.g., member, trustee, board member, former trustee or board member [alumni]), be invited to participate by one of the participating organizations or self nominate.
4. NOT have their primary employment in industry.
5. The SWG should include broad international representation from the various disciplines necessary to make informed decisions regarding the evidence and its appropriate application to practice.

### Small Working Group Process

The GDG will appoint a temporary leader for the first meeting for each SWG. The SWG will then nominate a leader. In the absence of a leader, the Guideline Methodologist will take this role.

The SWG should review the methodology at the first meeting and is responsible for monitoring adherence to the methodology. The guideline methodologist will advise the SWGs, provide assistance in the evidence appraisal process and work within each SWG to ensure that the guideline process progresses. The SWG will work with the methodologist to undertake the following steps:

#### **Steps 1 and 2: Identifying and Evaluating Evidence**

1. Review the clinical/health questions specific to the topic/section.
2. Review the relevant citations and abstracts from the pressure ulcer literature searches conducted since January 2008.
3. Review and revise relevant preliminary evidence table(s) (as available).

4. Determine if additional literature searches are needed for adequate investigation of the topic.
5. Review all articles identified in the preliminary review as potentially meeting inclusion criteria. Determine if the inclusion criteria are met, including relevance to the specific SWG topic.
6. For all studies meeting inclusion criteria, complete the critical appraisal form appropriate to the type of study for all direct evidence.
7. For all studies meeting inclusion criteria, validate information on preliminary evidence tables (or create new evidence table summaries as needed). Revise existing content as needed.
8. Note the limitations of the studies included on the evidence table.
9. Add a Level of Evidence for the studies included on the evidence table.
10. Keep track of search strategies, numbers of articles reviewed, number of articles included.

If there is insufficient direct evidence from primary studies of patients with pressure ulcers or at-risk for pressure ulcers, the SWG members may wish to use other types of evidence. In order to control for bias and maintain the validity, reliability and quality of the guideline the following will be considered:

1. **Indirect Evidence:** If you decide to incorporate indirect evidence (e.g., studies of patients with mixed chronic wounds, in vitro studies), you will need to do a comprehensive search of the indirect evidence. For example, if growth factors have not been adequately studied in pressure ulcers, you could include evidence on growth factor trials in other types of chronic wounds. To avoid bias, you would need to fully explore the literature on growth factors in chronic wounds rather than selecting only a few key articles. The strength of evidence for any recommendations solely supported by indirect evidence will be “C” with an explanation of the indirect evidence.
2. **Systematic Reviews and Meta-analyses:** Guideline recommendations should be based on individual studies as published in peer-reviewed journals (i.e. primary sources). Systematic reviews may be cited as additional supporting information or to broadly summarize the state of the science. In the 2009 Guideline, the GDG included systematic reviews that followed the Cochrane methodology. Some guideline authors included reviews that followed other criteria (or that, in their judgment were valid). In this update, non-Cochrane reviews will be appraised using the AMSTAR criteria and meet a score of at least 9/11. In addition, all included studies should be appraised.
3. **Guidelines:** When evidence from primary studies was insufficient, 2009 authors reviewed other guidelines. If this strategy is used for the 2014 revision, SWGs should evaluate the quality of the guideline using the AGREE II tool.
4. **Expert Opinion:** Recommendations based on expert opinion should be written with caution. Is there any evidence to support the opinion? Is bias involved? What are the risks of harm to the patient if the recommendation is followed? What are the potential benefits? Provide supporting references.

### **Step 3: Drafting Recommendations**

Recommendations should be drafted after a thorough review of available evidence. The intent of the 2009 Guideline was to provide systematically developed statements to assist health professional and patient consumer decisions about appropriate health care for specific clinical circumstances. Recommendations were broad enough to apply to patients throughout the world, yet specific enough to guide health professional and patient consumer decisions. The GDG anticipated that these recommendations would be adapted for local use. To that end, guidelines were translated into several languages. Local organizations developed policies, procedures, and protocols that adapted the 2009 International Guideline recommendations for use in the context of specific countries, health care systems, settings and patient populations.

To ensure uniformity and consistency in the 2009 International Guideline, a recommended format for guideline statements was provided:

- Start with simple, direct, broad statement.  
e.g. “Reposition all at-risk individuals.”
- Subsequent statements (or sub-recommendations) provide more detail (how, when, how often)  
e.g. “Reposition every two hours.”; “Avoid placing patient directly on trochanter.”
- Break up multiple thoughts into multiple individual statements.

- Start each recommendation with an action verb.
- Recommendations should be simple, short, declarative statements, free of jargon.
- Recommendations should be specific and unambiguous.
- Use 'individual' to refer to the patient, client, resident etc. Where the context of the word 'individual' would be unclear use 'patient consumer'.
- Use 'health professional' or interprofessional team to describe the professional care provider(s). Scope of practice for various disciplines varies widely. We did not want to suggest that the recommendation applied specifically to one discipline. Each professional is responsible for observing the relevant scope of practice laws.
- Use generic names for drugs and other products. Avoid using brand names if at all possible.
- Spelling should follow the style of American English.
- Guideline recommendations are not mandates or standards and should be written in a tone that provides guidance to professional colleagues and patient consumers.

Based on a review of the AGREE II Tool, we would encourage SWGs to:

- Provide sufficient information about health benefits, side effects and risks for the health professional and patient consumer to make informed choices in the context of their individual situation.
  - If there are known risks and side effects, identify them.
  - The review of literature should provide some indication of the nature and magnitude of health benefits expected.
  - If a recommendation 'only works' or 'works best' on a specific subset of patients or specific situation, mention this.
  - If a recommendation carries a risk of harm (or is clearly contraindicated) in a specific subset of patients or specific situation, be sure to include this information.
- Discuss cost and resource implications when appropriate. Cost analyses vary widely among health care systems; however, required resources should be discussed as appropriate to the professional-patient decision making process.
- Qualitative studies should be evaluated for guidance on patient consumer preferences.

#### **Step 4: Assigning Strength of Evidence Ratings**

Examine the cumulative body of evidence supporting each recommendation. Assign an A, B, or C rating according to the ***Strength of Evidence*** rating described in the methodology section. Note that ***Strength of Evidence*** and ***Strength of Recommendation*** are not the same. ***Strength of Evidence*** ratings are an evaluation of the strength of the cumulative scientific evidence supporting the recommendation based on type of study (e.g., RCT vs. uncontrolled case series) and quality of the study. The ***Strength of the Recommendation*** evaluates how strongly you believe the recommendation should be used in clinical practice. This question should be answered in the context of the patient consumer's situation. Our role is to provide the data to inform those patient care decisions.

#### **Step 5: Summarizing Supporting Evidence**

Briefly summarize the evidence supporting each recommendation. This should give professionals and patient consumers an understanding of the evidence you used in making this recommendation. All recommendations with an A or B strength of evidence rating should have an explicit summary that describes the findings of one or more studies of human subjects with pressure ulcers or at risk for pressure ulcer development. For C ratings, specify whether the recommendation is based on expert opinion, indirect evidence, studies of normal volunteers, or previously published guidelines.

#### **Step 6: Participating in a consensus process to determine Strength of Recommendation ratings**

The SWG members will be provided with information on how to participate in grading the strength or recommendations when it is required.

## Supporting Material and Services

### Google Drive

A folder will be set up in Google Docs for each SWG. Members of the SWG will have read and write access to all documents within their folder. SWGs can use Google Docs to communicate with each other and make revisions to various drafts of the new guideline recommendations. Each folder will include the following documents as related to the SWG topic:

- Reference list of relevant articles
- Evidence table (if developed)
- PDF versions of all articles meeting guideline inclusion criteria
- Guideline recommendations and evidence summary from the 2009 guideline to use in making revisions.
- An Endnote file of relevant articles for those who have Endnote bibliographic management software.

Additional background information will be available in read only folders. These files include a description of the guideline methodology, forms for quality appraisals and new evidence tables, Technical Reports from the 2009 International Guideline and other documents that may be helpful to SWGs.

### Mailing List

Each SWG will have its own email list for communication purposes, registered at the domain internationalguideline.com. It is expected that SWG members will be responsive to email in a timely manner.

### Web Conferencing

An appropriate web conferencing service will be established for groups to undertake video conferencing at no cost to individual members.

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## SEARCH STRATEGY

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### Search Strategies for Treatment

pressure ulcer OR pressure ulcers OR pressure injury OR bed sore OR bed sores OR bedsore OR bedsores OR pressure sore OR pressure sores OR decubitus ulcer OR decubitus ulcers OR decubital ulcer OR decubital ulcers OR pressure ulcer[mesh]

AND

(((((("Randomized Controlled Trials as Topic"[Mesh] OR "Randomized Controlled Trial "[Publication Type])) OR ("Controlled Clinical Trials as Topic"[Mesh] OR "Controlled Clinical Trial "[Publication Type])) OR "Double-Blind Method"[Mesh]) ) OR "Cohort Studies"[Mesh]) OR ("Meta-Analysis "[Publication Type] OR "Meta-Analysis as Topic"[Mesh])) OR "Cross-Sectional Studies"[Mesh]) OR ("Practice Guidelines as Topic"[Mesh] OR "Practice Guideline "[Publication Type] OR "Guidelines as Topic"[Mesh])) OR "Guideline "[Publication Type]) OR ("Consensus Development Conferences as Topic"[Mesh] OR "Consensus Development Conferences, NIH as Topic"[Mesh] OR "Consensus Development Conference, NIH "[Publication Type] OR "Consensus Development Conference "[Publication Type])) OR ("Multicenter Studies as Topic"[Mesh] OR "Multicenter Study "[Publication Type])) OR ("Evaluation Studies "[Publication Type] OR "Evaluation Studies as Topic"[Mesh])) OR "Follow-Up Studies"[Mesh]

OR

rct OR randomized controlled trial OR randomized controlled trials OR randomised controlled trial OR randomised controlled trials OR double blind OR double-blind OR random allocation OR cohort study OR cohort studies OR systematic review OR systematic reviews OR meta-analysis OR meta-analyses OR meta analysis OR meta analyses OR practice guideline OR practice guidelines OR guideline OR guidelines OR multicenter study OR multicenter studies OR multi-center study OR multi-center studies OR multi center study OR multi center studies OR evaluation study OR evaluation studies OR follow-up study OR follow-up studies OR follow up study OR follow up studies OR cochrane OR consensus development conference OR consensus development conferences OR case series OR controlled clinical trial OR controlled clinical trials OR systematic[sb]

NOT

(((((("Editorial "[Publication Type] OR "Addresses "[Publication Type]) OR ("Bibliography "[Publication Type] OR "Bibliography as Topic"[Mesh])) OR "Biography "[Publication Type]) OR "Dictionary "[Publication Type]) OR ("Interviews as Topic"[Mesh] OR "Interview "[Publication Type])) OR "In Vitro "[Publication Type]) OR "Lectures "[Publication Type]) OR "Legal Cases "[Publication Type]) OR ("Legislation "[Publication Type] OR "Legislation as Topic"[Mesh])) OR "News "[Publication Type]) OR "Newspaper Article "[Publication Type]) OR "Patient Education Handout "[Publication Type]

Limits: human only

## Search Strategies for Prevention

("pressure ulcer"[MeSH Terms] OR pressure ulcer[Text Word] OR Pressure Ulcers[Text Word] OR "Ulcer Pressure"[Text Word] OR "Ulcers Pressure"[Text Word] OR Bed Sores[Text Word] OR Bed Sore[Text Word] OR "Sore Bed"[Text Word] OR "Sores Bed"[Text Word] OR Bedsore[Text Word] OR Bedsores[Text Word] OR Decubitus Ulcer[Text Word] OR Decubitus Ulcers[Text Word] OR "Ulcer Decubitus"[Text Word] OR "Ulcers Decubitus"[Text Word] OR Pressure Sore[Text Word] OR Pressure Sores[Text Word] OR "Sore Pressure"[Text Word] OR "Sores Pressure"[Text Word] OR decubitus[Text Word]) AND (("risk"[MeSH Terms] OR risk[Text Word]) AND score[All Fields] OR ("skin"[MeSH Terms] OR skin[Text Word]) AND assessment[All Fields] AND ("weights and measures"[All Fields] OR "weights and measures"[MeSH Terms] OR scale[Text Word]) OR ("risk"[MeSH Terms] OR risk[Text Word]) AND calculator[All Fields]) OR "Risk Assessment"[MeSH] OR Risk assessment[Text Word] OR "Risk Assessments"[Text Word] OR Risk Assessments[Text Word] OR "Risk Assessment"[Text Word] OR Benefit-Risk Assessment[Text Word] OR "Benefit-Risk Assessment"[Text Word] OR "Benefit-Risk Assessments"[Text Word] OR Benefit Risk Assessment[Text Word] OR Benefit-Risk Assessments[Text Word] OR Risk-Benefit Assessment[Text Word] OR "Risk-Benefit Assessment"[Text Word] OR "Risk-Benefit Assessments"[Text Word] OR Risk Benefit Assessment[Text Word] OR Risk-Benefit Assessments [Text Word] OR Risks and Benefits[Text Word] OR Benefits and Risks[Text Word] OR ("risk"[MeSH Terms] OR risk[Text Word]) AND prediction[All Fields]) OR "Risk Factors"[MeSH] OR "Risk Factor" [Text Word] OR "Risk Factors" [Text Word] OR Risk Factor[Text Word] OR (clinical[All Fields] AND assessment[All Fields]) OR "Risk Management"[MeSH] OR "Risk Management"[Text Word] OR Management Risk[Text Word] OR Management Risks[Text Word] OR "Management Risk"[Text Word] OR "Management Risks"[Text Word] OR "Hospital Risk Reportings"[Text Word] OR Hospital Risk Reporting[Text Word] OR Hospital Risk Reportings [Text Word] OR "Hospital Risk Reporting"[Text Word] OR "Risks Management"[Text Word] OR "risks Managements"[Text Word] OR Risks Management[Text Word] OR Risks Managements[Text Word] OR "Hospital Incident Reporting"[Text Word] OR "Hospital Incident Reportings"[Text Word] OR Hospital Incident Reporting[Text Word] OR Hospital Incident Reportings[Text Word] OR "Nursing Assessment"[MeSH] OR "Nursing Assessment"[Text Word] OR "Risk Assessments"[Text Word] OR Nursing Assessments[Text Word] OR "Nursing Protocols" [Text Word] OR Nursing Protocol[Text Word] OR "Nursing Protocol"[Text Word] OR Nursing Protocols[Text Word] OR "Beds"[MeSH] OR beds[Text Word] OR Bed[Text Word] OR Mattresses[Text Word] OR Mattress[Text Word] OR "Bedding and Linens"[MeSH] OR Linens and Bedding[Text Word] OR Bedding[Text Word] OR Beddings[Text Word] OR Linens[Text Word] OR Linen[Text Word] OR cushion[All Fields] OR cushions[All Fields] OR "Wheelchairs"[MeSH] OR Wheelchairs[Text Word] OR Wheelchair[Text Word] OR Wheel Chairs[Text Word] OR "Wheel Chair"[Text Word] OR "Wheel Chairs"[Text Word] OR Wheel Chair[Text Word] OR "Wheel Chair"[Text Word] OR "Wheel Chairs"[Text Word] OR ("pressure"[MeSH Terms] OR pressure[Text Word]) AND relief[All Fields]) OR ("pressure"[MeSH Terms] OR pressure[Text Word]) AND relieving[All Fields]) OR alternating[All Fields] OR "Protective Devices"[MeSH] OR protective devices[Text Word] OR "Protective Device"[Text Word] OR "Protective Devices"[Text Word] OR Protective Device[Text Word] OR Safety Devices[Text Word] OR "Safety device"[Text Word] OR "Safety devices"[Text Word] OR Safety Device[Text Word] OR "Equipment and Supplies, Hospital"[MeSH] OR Hospital Equipment and Supplies[Text Word] OR Hospital Equipment[Text Word] OR "Hospital Equipment"[Text Word] OR Hospital Supplies[Text Word] OR Hospital Supply[Text Word] OR "Hospital Supplies"[Text Word] OR Hospital Supply[Text Word] OR "Equipment and Supplies"[MeSH] OR Equipment and Supplies[Text Word] OR Supplies and Equipment[Text Word] OR Apparatus and Instruments[Text Word] OR Instruments and Apparatus[Text Word] OR Devices[Text Word] OR Device[Text Word] OR Equipment[Text Word] OR Inventories[Text Word] OR Inventory[Text Word] OR Medical Devices[Text Word] OR "Medical Devices"[Text Word] OR "Medical Device"[Text Word] OR Medical Device[Text Word] OR Supplies[Text Word] OR Repositioning[All Fields] OR Reposition [All Fields] OR turning[All Fields] OR turn[All Fields] OR position[All Fields] OR positioning[All Fields] OR mobilization[Text Word] OR mobilisation[Text Word] OR "Posture"[MeSH] OR Posture[Text Word] OR Postures[Text Word] OR "Supine Position"[MeSH] OR "Supine Position"[Text Word] OR "Supine positions"[Text Word] OR Supine Positions[Text Word] OR Dorsal Position[Text Word] OR Dorsal Positions[Text Word] OR "Dorsal position"[Text Word] OR "Dorsal positions"[Text Word] OR "Prone Position"[MeSH] OR prone position[Text Word] OR "Prone position" [Text Word] OR "Prone Positions" [Text Word] OR Prone Positions[Text Word] OR "Classification"[MeSH] OR

"classification"[Subheading] OR Classification[Text Word] OR Classifications[Text Word] OR Systematics[Text Word] OR Taxonomy[Text Word] OR Taxonomies[Text Word] OR hierarchies[Text Word] OR hierarchy[Text Word] OR (("pressure"[MeSH Terms] OR pressure[Text Word]) AND ("physiology"[Subheading] OR "physiology"[MeSH Terms] OR physiology[Text Word])) OR "Nutritional Sciences"[MeSH] OR "Nutritional Science"[Text Word] OR "Nutritional Sciences"[Text Word] OR Nutrition Science[Text Word] OR "Nutrition Science"[Text Word] OR "Nutrition Sciences"[Text Word] OR Nutrition Sciences[Text Word] OR Nutritional Science[Text Word] OR "Nutrition Disorders"[MeSH] OR Nutrition Disorder[Text Word] OR Nutritional Disorders[Text Word] OR Nutritional Disorder[Text Word] OR "Nutritional Requirements"[MeSH] OR Nutritional Requirement[Text Word] OR "Nutritional Requirement"[Text Word] OR "Nutritional Requirements"[Text Word] OR Nutrition Requirements[Text Word] OR Nutrition Requirement[Text Word] OR "Nutrition Requirement"[Text Word] OR "Nutrition Requirements"[Text Word] OR Dietary Requirements[Text Word] OR Dietary Requirement[Text Word] OR "Dietary Requirement"[Text Word] OR "Dietary Requirements"[Text Word] OR "Nutritional Status"[MeSH] OR "Nutritional Status"[Text Word] OR "Nutrition Status"[Text Word] OR "Nutrition Status"[Text Word] OR "Nutrition Assessment"[MeSH] OR "Nutrition Assessments"[Text Word] OR "Nutrition Assessment"[MeSH] OR "Nutrition Assessments"[Text Word] OR "Nutrition Assessment"[Text Word] OR Nutritional Assessment[Text Word] OR "Nutritional Assessment"[Text Word] OR "Nutritional Assessments"[Text Word] OR Nutritional Assessments[Text Word] OR Nutrition Assessments[Text Word] OR Nutrition Indexes[Text Word] OR "Nutrition Indexes"[Text Word] OR Nutrition Index[Text Word] OR "Nutrition Index"[Text Word] OR "Nutrition Indices"[Text Word] OR Nutrition Indices[Text Word] OR Nutritional Index[Text Word] OR "Nutritional Index"[Text Word] OR "Nutritional Indices"[Text Word] OR Nutritional Indices[Text Word] OR Prognostic Nutritional Index[Text Word] OR "Prognostic Nutritional Index" [Text Word] OR "Prognostic Nutritional Indices"[Text Word] OR Prognostic Nutritional Indices[Text Word] OR (nutritional[All Fields] AND ("diagnosis"[Subheading] OR "mass screening"[MeSH Terms] OR screening[Text Word])) OR (nutritional[All Fields] AND intervention[All Fields]) OR "nutrition physiology"[MeSH Terms] OR nutrition[Text Word] OR "Nutrition Physiology" [Text Word] OR Nutritional Physiology [Text Word] OR "Nutritional Physiology" [Text Word] OR "prevention and control"[Subheading] OR "Primary Prevention"[MeSH] OR primary prevention[Text Word] OR "Accident Prevention"[MeSH] OR preventive measures[Text Word] OR preventive therapy[Text Word] OR prophylaxis[Text Word] OR control[Text Word] OR prevention[Text Word] OR "prevention primary"[Text Word] OR "Prevention Accident"[Text Word] OR Accident Preventions[Text Word] OR "Preventions Accident"[Text Word] OR "etiology"[Subheading] OR "Causality"[MeSH] OR etiology[Text Word] OR causes[Text Word] OR causality[Text Word] OR pathogenesis[Text Word] OR Causalities[Text Word] OR Enabling Factors[Text Word] OR Enabling Factor[Text Word] OR "Factor Enabling"[Text Word] OR "Factors Enabling"[Text Word] OR Multifactorial Causality[Text Word] OR "Causalities Multifactorial"[Text Word] OR "Causality Multifactorial"[Text Word] OR Multifactorial Causalities [Text Word] OR Multiple Causation [Text Word] OR "Causation Multiple"[Text Word] OR "Causations Multiple"[Text Word] OR Multiple Causations[Text Word] OR Predisposing Factors[Text Word] OR "Factor Predisposing"[Text Word] OR "Factors Predisposing"[Text Word] OR Predisposing Factor[Text Word] OR Reinforcing Factors[Text Word] OR "Factor Reinforcing"[Text Word] OR "Factors Reinforcing"[Text Word] OR Reinforcing Factor[Text Word] OR Causation[Text Word] OR Causations[Text Word] OR "Skin Care"[MeSH] OR Skin care[Text Word] OR "Care Skin"[Text Word]) AND ((case[All Fields] AND series[All Fields]) OR "Multicenter Study"[Publication Type] OR "Evaluation Studies"[Publication Type] OR "Comparative Study"[Publication Type] OR "Validation Studies"[Publication Type] OR "randomized controlled trial"[Publication Type] OR "randomized controlled trials"[MeSH Terms] OR "randomized controlled trials"[Text Word] OR "randomised controlled trials"[Text Word] OR "review"[Publication Type] OR "review literature"[MeSH Terms] OR "systematic review"[Text Word] OR "controlled clinical trial"[Publication Type] OR "controlled clinical trials"[MeSH Terms] OR "controlled clinical trials"[Text Word] OR "meta-analysis"[Publication Type] OR "meta-analysis"[MeSH Terms] OR "meta-analysis"[Text Word] OR Meta Analysis[Text Word] OR Meta-Analyses[Text Word] OR "Clinical Trial Overviews"[Text Word] OR Clinical Trial Overview[Text Word] OR "Clinical Trial Overview"[Text Word] OR Clinical Trial Overviews[Text Word] OR Data Pooling[Text Word] OR Data Poolings[Text Word] OR "cohort studies"[MeSH Terms] OR Cohort Studies[Text Word] OR Cohort Study[Text Word] OR "Cohort Studies"[Text Word] OR "Cohort study"[Text Word] OR "Concurrent studies"[Text Word] OR Concurrent Study[Text Word] OR "Concurrent study"[Text Word] OR Concurrent Studies[Text Word] OR Closed Cohort

Studies[Text Word] OR "Closed Cohort Studies"[Text Word] OR Closed Cohort Study[Text Word] OR "Closed Cohort Study"[Text Word] OR Historical Cohort Studies[Text Word] OR "Historical Cohort Studies"[Text Word] OR "Historical Cohort Study"[Text Word] OR Historical Cohort Study[Text Word] OR Incidence Studies[Text Word] OR Incidence Study[Text Word] OR "Incidence studies"[Text Word] OR "Incidence study"[Text Word] OR "Cohort Analysis"[Text Word] OR "Cohort Analyses"[Text Word] OR Cohort Analyses[Text Word] OR Cohort Analysis[Text Word] OR "case-control studies"[MeSH Terms] OR case-control studies[Text Word] OR Case-Control Study[Text Word] OR "Case-Control Study"[Text Word] OR Case-Base Studies[Text Word] OR Case Base Studies[Text Word] OR Case-Base Study[Text Word] OR "Case-Base Studies"[Text Word] OR "Case-Base Study"[Text Word] OR Case-Comparison Studies[Text Word] OR Case Comparison Studies[Text Word] OR Case-Comparison Study[Text Word] OR "Case-Comparison Studies"[Text Word] OR "Case-Comparison Study"[Text Word] OR Case-Referent Studies[Text Word] OR Case Referent Studies[Text Word] OR Case-Referent Study[Text Word] OR Case-Referent Studies[Text Word] OR Case-Referent Study[Text Word] OR Case-Referent Studies[Text Word] OR Case-Referent Study[Text Word] OR Case-Referent Studies[Text Word] OR Case-Referent Study[Text Word] OR "Case-Referent Studies"[Text Word] OR "Case-Referent study"[Text Word] OR Case-Compeer Studies[Text Word] OR Case Compeer Studies[Text Word] OR Case-Compeer Study[Text Word] OR "Case-Compeer Studies"[Text Word] OR "Case-Compeer Study"[Text Word] OR Case Control Studies[Text Word] OR Case Control Study[Text Word] OR "Case Control Studies"[Text Word] OR "Case Control Study"[Text Word] OR Matched Case-Control Studies[Text Word] OR "Matched Case-Control Studies"[Text Word] OR "Matched Case-Control Study"[Text Word] OR Matched Case Control Studies[Text Word] OR Matched Case-Control Study [Text Word] OR "Matched Case-Control Studies" [Text Word] OR "Matched Case-Control Study"[Text Word] OR Nested Case-Control Studies[Text Word] OR "Nested Case-Control Studies"[Text Word] OR "Nested Case-Control Study"[Text Word] OR Nested Case Control Studies[Text Word] OR Nested Case-Control Study[Text Word] OR "Nested Case-Control Studies"[Text Word] OR "Nested Case-Control Study"[Text Word]) AND "humans"[MeSH Terms] AND ("1998/01/01"[PDAT]: "2007/12/31"[PDAT])

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## APPRAISAL TOOLS

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### Critical Appraisal of Case control Studies

We used the Scottish Intercollegiate Guidelines Network (SIGN) checklist for Case Control studies. We did not seek permission to reproduce the SIGN checklists in this methodology document.

Checklist available from SIGN: <http://www.sign.ac.uk/methodology/checklists.html>

### Critical Appraisal of Cohort Studies

We used the SIGN checklist for Cohort Studies.

Checklist available from SIGN: <http://www.sign.ac.uk/methodology/checklists.html>

### Critical Appraisal of Cross-sectional/Survey/Prevalence Studies

We used a checklist derived from the SIGN checklists.

Checklist available from SIGN: <http://www.sign.ac.uk/methodology/checklists.html>

### Critical Appraisal of Diagnostic Studies

We used the SIGN checklist for Diagnostic Studies.

Checklist from SIGN: <http://www.sign.ac.uk/methodology/checklists.html>

### Critical Appraisal of Randomized Controlled Trials

We used the SIGN checklist for Randomized Controlled Trials.

Checklist from SIGN: <http://www.sign.ac.uk/methodology/checklists.html>

### Critical Appraisal of Case Series

We used a checklist based on: Moga C, Guo B, Schopflocher D, Harstall C. *Development of a Quality Appraisal Tool for Case Series Studies Using a Modified Delphi Technique*. Edmonton AB: Institute of Health Economics. 2012.

Available from: <http://www.ihe.ca>

### Critical Appraisal of Quasi-Experiments

We used a checklist adapted from the SIGN checklist for Randomized Controlled Trials.

Checklist from SIGN <http://www.sign.ac.uk/methodology/checklists.html>

### Critical Appraisal of Systematic Reviews

We used the SIGN checklist for Systematic Reviews.

Checklist from SIGN: <http://www.sign.ac.uk/methodology/checklists.html>

We also used the AMSTAR (assessment of multiple systematic reviews) checklist. We did not seek permission to the AMSTAR checklist in this methodology document.

Checklist from: [http://amstar.ca/Amstar\\_Checklist.php](http://amstar.ca/Amstar_Checklist.php)

### **Critical Appraisal of Quality Improvement Reports**

We used the Standards for Quality Improvement Reporting Excellence (SQIRE) Guidelines Checklist. We did not seek permission to reproduce the SQIRE checklist in this methodology document.

Checklist available from: <http://squire-statement.org/guidelines>

### **Critical Appraisal of Qualitative Research**

We used the Critical Appraisal Skills Programme (CASP) Tool. We did not seek permission to reproduce the CASP tool in this methodology document.

Checklist available from: <http://www.casp-uk.net/>

### **Critical Appraisal of Multivariable Analyses (risk factors)**

We used a methodology outlined in: Coleman S, Gorecki C, Nelson A, Closs SJ, Defloor T, Halfens R, Farrin A, Brown J, Schoonhoven L, Nixon J. Patient risk factors for pressure ulcer development: Systematic review. International Journal of Nursing Studies. 2013;e-pub

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## CONFLICT OF INTEREST

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### Introduction

All guideline developers were required to complete a Conflict of Interest Disclosure form in order to be involved in the guideline development process and to receive acknowledgement as a member of the guideline development team within the guideline. The GDG and SWG members were required to be free of major competing (or conflicting) interests and were requested to disclose the nature of any minor competing interest and recuse themselves from related decisions. Additionally, the SWG members were instructed that appraisal of a study in which he or she was an author or significantly involved in the study undergoing appraisal presents a potential conflict of interest, and other SWG members undertook the appraisal.

### Disclosure Form of Potential Conflicts of Interest

In order to participate in the guideline development and update process group members must declare whether they have any competing interests. A conflict of interest arises in any situation in which a group member has a direct or indirect pecuniary interest in the way the guideline is developed, how decisions are made or how statements and/or recommendations are framed. Not all financial relationships with industry or other funding bodies represent true conflict of interests but nevertheless actual or potential conflicts of interest must be declared to enhance transparency and credibility of our guideline. The declarations will be published with the guideline.

The conflict of interest statements are kept with the guideline methodologist and are valid for the guideline development period. Emergent conflicts of interest during the year must be declared immediately within the working process or meetings.

Please complete the following information:

First name: \_\_\_\_\_

Last name: \_\_\_\_\_

I am a member of:

*(Please mark)*

- the guideline development group.
- a small working group.

Please list all (potential) conflicts of interests regarding the development and update of the International Pressure Ulcer Guideline 2014 that may arise from the following payments or services from industry for you or your institution:

Type of Interest	Nil interest	Interest to declare		
		Money paid to you	Money paid to your institution	Name of entity
Grants				
Consulting fees or honoraria				
Board memberships				
Payments for lectures				
Payments for developments of educational presentations				
Employments				
Patents				
Support for travel to meetings for the guideline development/update				
Payment for writing or reviewing the guideline or parts of it				
Provision of assistance for guideline development /update				
Other				

\_\_\_\_\_  
Name of signatory

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature (*electronic is acceptable*)

## Declarations

The following declarations of potential conflict of interest were registered. All other guideline developers declared they had no potential conflict of interest.

Maarit Ahtiala	Received grants from Mölnlycke and 3M to participate in two conferences. Received payment from industry and municipal organizations to participate in educational lectures.
Yufitriana Amir	Government education grant paid to institution.
Katrin Balzer	Received grant from B-Braun Stiftung Foundation for research associated with pressure ulcer risk assessment.
Dimitri Beeckman	Grants paid to institution from Hill-Rom and Sage Products. Received consulting fees from 3M Europe related to work associated with incontinence associated dermatitis (IAD). Reimbursement as a member of the 3M IAD Board.
Joyce Black	Received consulting fees and payment for educational lectures from Arjo-Huntleigh, Coloplast, Celleration, Hill-Rom, KCI, Mölnlycke Healthcare and Sage Products. Received payments for developing education material from Celleration and Sage Products. Member of the ROHO Board.
Barbara Braden	Received payment from Arjo-Huntleigh for educational lectures.
David Brienza	Grants paid to institution from Hil-Rom and ROHO.
Jill Campbell	Received grant from Royal Brisbane Women's Hospital Received payment from Smith and Nephew for educational lectures.
Virgina Capasso	Received reimbursement as an expert witness for US Attorney, Boston.
Michael Clark	Received grants, consulting fees, payments for development of education material and payment for board memberships to self and industry from 15 to 20 wound care industry partners.
Kerrie Coleman	Received consulting fees from World Union of Wound Healing Societies.
Teresa Conner-Kerr	Grants paid to institution from NIGMS.
Jill Cox	Grants paid to institution from Medline Industries. Reimbursement as a member of the Hill Rom Advisory Board.
Sandra Dean	Received payments for developing education material from Pegasus and Aidacare.
Lisebet Demarré	Grants paid to institution from Hill-Rom.
Jeannie Donnelly	Received payment from Queens University Belfast for educational lectures.
Nancy Estocado	Received reimbursement related to patent of an assessment tool. Received reimbursement for software development from Healthline Information System. Received support from Medline Industries to attend meetings.
Amit Gefen	Received grants from Mölnlycke Healthcare and ROHO. Reimbursement as a member of the ROHO Scientific Advisory Board. Has a portfolio of patents associated with pressure ulcer prevention.
Margaret Goldberg	Reimbursement to self and institution as a member of the NPUAP Board.
Ruud Halfens	Grants to institution from ZONmw and Ministry of Health.
David Huber	Board membership and patents associated with Viater Medical
Holly Kirkland Walsh	Grants to institution from Children's Miracle Network, UCDCM, Sacramento, CA, Cardinal Health Grant
Jan Kottner	Received consulting fees and reimbursement for educational lectures from 3M Skin Integrity Board. Reimbursement as a member of the 3M Skin Integrity Board.

Diane Langemo	Received consulting fees and reimbursement for travel from Wound Vision.
Jane Nixon	Received grant paid to institution from Mölnlycke Healthcare and consulting fees paid to institution from Smith and Nephew.
Tracy Nowicki	Received payment for educational lectures from Ausmed.
Cees Oomens	Received payment for educational lectures.
Jos Schols	Received grants from Danone, received a consulting fee from CUBE study, received reimbursement for travel.
Lisette Schoonhoven	Reimbursement as a member of the 3M Skin Integrity Board. Received reimbursement for educational lectures from 3M.
Lorna Semple	Received reimbursement for educational lecture from Smith and Nephew
Aamir Siddiqui	Received grants from Wellsense Inc. and Smith and Nephew
Sue Templeton	Consulting fees and reimbursement for educational lectures paid to institution from Royal Adelaide Hospital and various government-owned aged care facilities.
Aletha Tippet	Received reimbursement for educational lectures from ProCare Hospice Care.
Tracey Yap	Grants paid to institution from National Hartford Centers of Gerontological Excellence
Cathy Young	Received payments for developing education material from Pegasus and Aidacare.