

# Prevention and Treatment of Pressure Ulcers/Injuries: Methodology Protocol for the Clinical Practice Guideline (Third Edition)



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The Guideline Governance Group (GDG) responsible for oversight of the update of *Prevention and Treatment of Pressure Ulcer/Injuries: Clinical Practice Guideline* (i.e. third edition) first convened in September 2017. At that meeting the Guideline Governance Group reviewed the methodological documents used to guide the 2014 Guideline (second edition) development process. The methodology was revised with consideration to the methods used for previous Guideline editions, advances in the body of evidence on guideline methodology and current standards for guideline development. This revised protocol is made available to stakeholders on the guideline website throughout the guideline development period.

Suggested Methodology Protocol citation:

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## CHAPTER ONE: PURPOSE AND SCOPE

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### Purpose

The overall purpose of this international collaboration is to develop a third edition of *Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline* (first published 2009, second edition published 2014). The first and second editions of the Guideline contain evidence-based recommendations for the prevention and treatment of pressure injuries<sup>1</sup> that could be used to guide decision making by health professionals and individuals throughout the world. These recommendations will be updated to reflect the current state of the science.

A joint Guideline Governance Group (GGG) with representatives from the National Pressure Ulcer Advisory Panel (NPUAP), the European Pressure Ulcer Advisory Panel (EPUAP) and the Pan Pacific Pressure Injury Alliance (PPPIA) will plan the guideline development process and review all the documentation.

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

The **purpose of the recommendations on treatment of pressure injuries** is to guide evidence-based care of pressure injuries in individuals of all age groups, unless otherwise stated. The Guideline is intended for use by health professionals involved in the care of individuals who are at risk of developing pressure injuries, whether they are in a hospital, long-term care, community settings, or any other setting and regardless of their diagnosis or healthcare needs. It will also guide individuals and caregivers. Individuals with pressure injuries are usually at risk of additional pressure injuries; therefore, the recommendations for preventing pressure injuries should also be followed for these individuals.

### Scope

The **Guideline will make recommendations for best practice based on current evidence**, covering the following topics:

#### Background

- Pressure injury etiology
- Classification
- Scope of the problem

#### Prevention

- Risk factors and risk assessment
- Skin and soft tissue assessment
- Skin and soft tissue care and protection
- Medical device related pressure injuries

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<sup>1</sup> The term pressure injury is synonymous with the terms pressure ulcer and decubitous ulcer. Terminology varies in different geographic regions.

## Prevention and Treatment

- Nutrition
- Support surfaces
- Repositioning and mobilization
- Heel pressure injuries
- Patient consumer involvement

## Treatment

- Assessment of pressure injuries and methods to monitor healing
- Pain assessment and management
- Cleansing
- Debridement
- Topical agents for promoting pressure injury healing
- Assessment and treatment of infection and biofilms
- Wound dressings
- Biophysical agents
- Growth factors
- Biological dressings
- Surgery

## Specific Populations

Recommendations regarding several special populations will be addressed where evidence exists, and where the issue or intervention is unique to the specific population. These include:

- Individuals in the operating room
- Individuals receiving palliative care
- Individuals with spinal cord injury
- Children and neonates
- Individuals in critical care settings
- Individuals in community settings
- Bariatric individuals

## Facility Level Considerations in Implementing Best Practice

- Monitoring pressure injury incidence and prevalence
- Health professional education
- Facilitators and Barriers
- Monitoring the implementation of this clinical guideline

## Clinical Questions

The following broad clinical questions are proposed to guide the literature searches. More specific clinical questions, detailed in *Appendix One*, were used to synthesize the evidence and make recommendations.

### Prevention

- What is the state of the science in pressure injury prevention?  
How does this evidence answer the following key clinical questions:
  - What factors put individuals at risk for pressure injury development?
  - What are accurate and effective methods for pressure injury risk assessment?
  - What are accurate and effective methods for skin and tissue assessment?

- What are effective risk-based pressure injury prevention strategies?
  - What skin and soft tissue interventions are effective in preventing pressure injuries?
  - What nutritional interventions are effective in preventing pressure injuries?
  - What repositioning and mobilization interventions are effective in preventing pressure injuries?
  - What support surfaces are effective in preventing pressure injuries?
- What are the unique pressure injury prevention strategies for the following specific population groups:
  - Individuals with spinal cord injury
  - Individuals in the operating room
  - Bariatric individuals
  - Neonates and children
  - Individuals receiving palliative care
  - Individuals in critical care
  - Individuals in community settings
- What are effective strategies for engaging individuals in pressure injury prevention?

### **Treatment**

- What is the state of the science in pressure injury treatment?  
How does this evidence answer the following key clinical questions:
  - What are accurate and effective methods for pressure injury classification and assessment?
  - What are accurate and effective methods for evaluating/monitoring healing?
- What pressure injury treatment strategies are effective?
  - What local pressure injury treatments are effective for supporting healing (i.e. cleansing, debridement, topical agents, wound dressings, etc.)?
  - What nutritional interventions are effective in supporting pressure injury healing?
  - What strategies are effective in preventing, assessing and treating pressure injury pain?
  - What repositioning and mobilization methods are effective in supporting pressure injury healing?
  - What support surfaces are effective in supporting pressure injury healing?
  - What are effective biophysical agents for treating pressure injuries (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 injury healing?
  - What strategies are effective in selecting, preparing and managing an individual for surgical interventions?
- What are the unique pressure injury treatment strategies for the following specific population groups:
  - Individuals with spinal cord injury
  - Individuals in the operating room
  - Bariatric individuals
  - Neonates and children
  - Individuals receiving palliative care
  - Individuals in critical care
  - Individuals in community settings
- What are effective strategies for engaging individuals in pressure injury treatment?

## Implementation and Quality Improvement

The guideline developers recognize that best practice can be difficult to implement in increasingly complex healthcare organizations that are often challenged by cost restraints. The Guideline seeks to provide guidance on:

- monitoring the incidence and prevalence of pressure injuries
- successful implementation of the strategies included in this guideline
- promoting knowledge, skills and attitudes of health professionals related to pressure injury prevention and treatment
- facilitators and barriers to implementing this guideline
- potential resource implications for implementing this guideline
- quality indicators for auditing implementation of this guideline

## Research questions

- What valid and reliable assessment tools are available to evaluate health professional knowledge of pressure injury prevention and treatment?
- What interventions/programs are effective in attaining sustained improvements in health professional knowledge of pressure injury prevention and treatment?
- What interventions/programs are effective in attaining sustained improvements in health professional competency in pressure injury prevention and treatment?
- What workforce/staffing issues facilitate or are barriers to prevention and treatment of pressure injuries in the organisation?
- What organisation level interventions/quality improvement programs are effective in attaining sustained pressure injury prevention?
- What are the professional, structural and organisational components of organisation level interventions/quality improvement programs that are effective in attaining sustained pressure injury prevention?
- What organisation level issues facilitate or are barriers to implementing best practice in pressure injury prevention and treatment?
- What factors facilitate or are barriers to implementing an organisation level quality improvement program?

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## CHAPTER TWO: GUIDELINE METHODOLOGY

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### Introduction

The following methodology will be used for the third edition of the International Guideline. The methodology will be circulated to all participants in the guideline development process at commencement of the project and will be published on the guideline website ([www.internationalguideline.com](http://www.internationalguideline.com)).

The methodology for this edition of the guideline is revised from 2014 to ensure current international standards in guideline development are addressed and the rigorous guideline development is maintained. The guideline will continue to focus on primary evidence and include a consensus voting process (adapted-GRADE) 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 Guideline website was established to publish documents associated with the Guideline. The Guideline website will be used to disseminate the *Quick Reference Guideline*, acknowledge sponsors, and publish supportive documents. During the Guideline development, the website will be used to facilitate stakeholder consultation. The website platform will also be used to conduct the adapted-GRADE consensus voting process.

### Participants

All members of the development team will be screened for experience, expertise and potential conflicts of interest through an expression of interest and application process.

### Management of Conflicts of Interest

In the interest of transparency, all contributors to the guideline development will be required to identify potential conflicts of interest (COIs) and their approximate value. A COI arises in any situation in which a group member has a direct or indirect pecuniary or personal (e.g. academic advancement, community standing) 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 COI. Nevertheless, actual or potential conflicts of interest must be declared to enhance transparency and credibility of our guideline.

Potential COIs will be declared and managed based on an adapted version of the *Guidelines International Network Principles* (Schünemann, Al-Ansary et al., 2015). Conflict of interest declarations will be completed whenever a new conflict arises and on an annual basis. The final COI declarations for each member of the development team will be published in the Guideline. Every participant (see below) with a 'moderate' to 'very high' COI according to *Appendix Table 2* in Schünemann, Al-Ansary et al. (2015) will abstain from reviewing and/or critically appraising any papers in the area of the COI, and will be excluded from group discussions, statements and chapter preparations, and strength of evidence ratings.



## Guideline Development Team

### Member Organizations

This revision of the Guideline will be overseen by the core development Member Organizations: 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 Wounds Australia, the New Zealand Wound Care Society (NZWCS), the Hong Kong Enterostomal Therapist Society (HKETS) and the Wound Healing Society of Singapore (WHSS). Representatives from these Member Organizations form the Guideline Governance Group (GGG).

### Associate Organizations

Other international not-for-profit pressure injury organizations that share the mission, values and purposes of the GGG were invited to apply to join the Guideline development process through designation as Associate Organizations. The purpose of Associate Organization membership is to involve participation and international sharing of expertise from countries not currently represented by the EPUAP, PPPIA or NPUAP.

Associate Organizations were selected through an application process and acceptance by GGG vote. Associate Organizations do not have voting representatives on the GGG, but nominate Small Working Group (SWG) members (see below) to participate in the development process. For the 2019 Guideline edition, the following organizations contributed to the development as Associate Organizations:

- Chinese collaboration of: Chinese Nursing Association and Jiangsu Nursing Association
- Indonesian collaboration of: Indonesian Wound Ostomy and Continence Nursing Association and Indonesian Wound Care Clinician Association
- Canadian collaboration of: Canadian Association for Enterostomal Therapy and Wounds Canada
- Japanese Society for Pressure Ulcers
- Korean Association of Wound Ostomy Continence Nurses
- Malaysian Society of Wound Care Professionals
- Philippine Wound Care Society
- Saudi Chapter of Enterostomal Therapy
- Taiwan Wound Ostomy and Continence Nurse Association
- Thai Enterostomal Therapy Society
- World Council of Enterostomal Therapists
- Brazilian Association of Enterostomal Therapists: Wound, Ostomy and Continence Care

### Guideline Governance Group

The GGG will determine and monitor each step of the guideline development process, as well as manage the guideline dissemination strategy. Each of the three Member Organizations nominated four representatives each, to form the 12-member GGG. The four nominated representatives for each member organization appointed a Chair. The three Member Organizations each have four votes during joint deliberations, with the majority deciding. Examination of the evidence and consensus building will precede all voting. Minority opinions will be represented in meeting minutes. A full description of the GGG role is available in *Chapter Three*.

### Small Working Groups

The guideline content will be divided into working topic areas and SWGs will be formed to review the evidence available for each topic. The SWG members will be selected by each participating organization based on experience and expertise. Representatives of industry will be excluded from SWGs. The SWGs will

be formed based on the principle of equal contribution from the Member Organizations and representation from at least one Associate Organization. A full description of the SWG role is available in *Chapter Four*.

Guideline development will be an iterative process, with GGG and SWG members maintaining communication via the methodologist. Evidence summaries and draft recommendations developed by the SWGs will be reviewed by the GGG 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.

### **Patient consumers and their informal caregivers**

Consumers (patients and caregivers) will be invited to engage in the development process. At commencement of the project, an international survey of consumers will be undertaken to establish consumer needs, consumer interest in outcome measures and inform development of the clinical questions.

A Consumer SWG will be established to review each chapter during the drafting phase. Member and Associate Organizations will recruit and nominate patient consumers from their geographic region, with a goal of 7 to 10 consumer representatives from each region. The Consumer SWG will be asked to consider:

- cultural aspects,
- sensitivity (language) of terms, and
- relevance to individuals with or at risk of pressure injuries.

Consistent with recommendations on engaging consumers in guideline development (Armstrong, Mullins et al., 2017; Patient-Centered Outcomes Research Institute (PCORI), 2015b; Qaseem, Forland et al., 2012), strategies will be implemented to promote non-tokenistic consumer engagement (see *Chapter Six: Consumer Engagement*).

### **Methodologist**

The guideline process will be overseen by an experienced guideline methodologist. The methodologist will assist the SWG members in implementing the documented methodology, appraising and summarizing the new literature, revising the 2014 guideline recommendations and developing new recommendations, and presenting the evidence. The methodologist will manage the confidential consensus voting process (adjusted-GRADE). The methodologist provided a link between the GGG and Associate Organizations, and between the GGG and the SWGs, and between the development team and patient consumers, managing communication and maintaining progress. The methodologist will attend GGG and SWG meetings, but will not participate in GGG voting.

### **Stakeholders**

The process of developing the guideline will be made available to stakeholders on the guideline website. A stakeholder is someone who has interest in pressure injuries and wishes to contribute to the International 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 may register as a stakeholder, either as an individual or as a representative for a society/organization.

In 2009 a total of 903 individuals and 146 societies/organizations registered as stakeholders. In 2014, 698 individuals registered as stakeholders to provide feedback as an individual or in representation of a society/organization. These stakeholders will all be invited to register as stakeholders for the 2019 guideline.

All members of the EPUAP, NPUAP and PPIIA will be invited to register as stakeholders and participate in this process. Additionally, patient consumer representative organizations will also be invited to participate in the stakeholder review process to provide a consumer perspective.

## Methods

The steps for the guideline development process are delineated below. For simplicity and clarity, the process is described as linear and sequential; however, the actual process will be iterative, with multiple drafts developed and progressively improved based on ongoing communication among GGG, methodologist, SWGs, patient consumers and other stakeholders.

### Step 1: Identifying the Evidence

#### Databases

The GGG 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 injury prevention and treatment, several electronic databases were consulted, including:

- AMED
- MEDLINE
- EMBASE
- Scopus
- The Cochrane Database of Systematic Reviews
- The Cochrane Central Register of Controlled Trials
- Health Technology Assessment

As the guideline builds on a previously published body of evidence, the search dates for this 2019 update will be 1<sup>st</sup> July 2013 through 31<sup>st</sup> August 2018. Some SWGs, particularly those that address evidence in topics newly introduced to the guideline, may extend the search to ensure previously published literature meeting the inclusion and exclusion criteria has been represented.

#### Search Strategy

A sensitive search strategy was developed for the development of the guideline and made available on the guideline website. The SWGs will be permitted to conduct additional focused searches to ensure the full depth and breadth of their topic area has been covered. Additional literature searches will be documented in full by the SWG members.

#### Inclusion and Exclusion Criteria

All references retrieved by the electronic literature search have been screened by the methodologist based on the following inclusion and exclusion criteria:

##### 1. General Eligibility Criteria

- The articles must be primarily focused on pressure injury prevention, risk assessment, or pressure injury treatment in human subjects.
- The articles must have been published in a peer reviewed journal.
- An abstract should be available.

Inclusion criteria for primary research:

- The studies should have used one of the following designs:

- randomized controlled trials (RCTs),
  - prospective controlled clinical trials (CCTs),
  - prospective cohort studies with a control group,
  - pre-test/post-test studies,
  - retrospective cohort studies,
  - observational studies,
  - cross-sectional studies,
  - survey studies,
  - case-control studies, and
  - case series.
- At least ten subjects must have been included in any case series.
  - Studies using established qualitative methodologies will only be considered as appropriate to the clinical question (e.g. the individual's experiences, such as pain).

Inclusion criteria for synthesized research:

- Systematic reviews and meta-analyses will be used only for comparative discussion, clearly delineated as supportive content in the guideline layout. These sources of evidence will not be included in the strength of evidence rating.
- Identified systematic reviews and meta-analyses will be screened for eligibility using the AMSTAR 2 tool. For inclusion, these evidence sources will be required to meet all of the critical domains listed in Table 1, adapted from those identified by Shea, Reeves et al. (2017).
- SWG members will review, analyze and use the original articles cited in systematic reviews and meta-analyses as the basis for guideline recommendations.
- Other forms of synthesized evidence (e.g. other clinical guidelines) will be considered only to support background discussion, good practice statements or implementation considerations, as required.

Inclusion criteria for evidence published in languages other than English:

- There will be no restriction based on the language.
- A pool of translators will be identified among SWG and GGG members.
- Publications in languages other than English will be screened for likelihood of providing unique evidence not available in the current body of evidence warranting translation.
- Screening will be conducted by evaluating the English abstract, and/or by requesting a translator to screen for relevance and study design.
- Articles meeting the inclusion criteria will be critically appraised and have data extraction performed by two translators.

**Table 1: Critical domains for systematic reviews to meet for inclusion (adapted from Shea, Reeves et al. (2017))**

<ul style="list-style-type: none"> <li>• Adequate literature search conducted as per criteria for YES on AMSTAR 2 tool (item 4)</li> <li>• Studies read in full but excluded are individually listed, with justification for excluding each individual study (Amstar 2, item 7)</li> <li>• Risk of bias in individual included studies is evaluated as per criteria on AMSTAR 2 tool. This includes assessment of risk of bias from specific items as per AMSTAR 2 tool. (item 9)</li> <li>• Appropriate meta-analytical methods are used as per criteria on AMSTAR 2 tool, with justification for combining in meta-analysis and use of an appropriate weighting technique and adjustment for heterogeneity when present (item 11)</li> <li>• Consideration is given to risk of bias in individuals studies when interpreting the review results by either including only RCTs at low risk of bias or if RCTs have a moderate or high risk of bias or non-randomized trials are included, the impact of this is discussed (Amstar 2 item 13)</li> <li>• An assessment is conducted of presence and likely impact of publication bias as per criteria on AMSTAR 2 tool i.e. for reviews with a quantitative synthesis, graphical or statistical tests for publication bias are performed and discussed the likelihood and magnitude of impact of publication bias (item 15)</li> </ul>
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## Exclusion criteria:

- Non-systematic literature reviews, narrative papers, opinion, commentary, other clinical guidelines and descriptive papers. Papers falling into this category will only used only to support background discussion, consensus-based recommendations or implementation considerations, 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, except to support background discussion, consensus-based recommendations or implementation considerations.
- Systematic reviews and meta-analyses that do not meet all the critical domains listed in Table 1.
- Papers without a substantial focus on pressure injury prevention or treatment or risk assessment.
- Foreign language studies for which the abstract does not indicate unique high-level evidence.

**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, with data covering at least 12 months.
- 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 injury 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 have not been considered for inclusion.

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

In the 2014 guideline, a systematic review by Coleman, Gorecki et al. (2013) was used as a basis for literature selection to identify patient characteristics that increase the probability of pressure injury development. In 2014, the Coleman review (Coleman, Gorecki et al., 2013) was supplemented by a search for literature up to July 1<sup>st</sup> 2013. This literature search will be extended to literature published up to 31<sup>st</sup> August 2018 for the 2019 edition. The inclusion and exclusion criteria applied by Coleman, Gorecki et al. (2013) are applied to all literature identified for the 2014 and 2019 editions:

Inclusion criteria utilised by Coleman, Gorecki et al. (2013):

- Primary research.
- Adult patients (aged  $\geq 18$  years)
- Outcome was the development of a new pressure injury.
- Prospective cohort, retrospective record review (where the risk factor preceded the pressure injury) 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 injury or equivalent.
- Multivariable analyses undertaken to identify factors affecting pressure injury outcome.
- The unit of analysis was the individual patient.

Exclusion criteria utilised by Coleman, Gorecki et al. (2013):

- 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 injury risk assessment tool scores of different raters using the same scale (interrater) or comparing pressure injury risk assessment tool scores of the same raters using the same scale at different times (intrarater).

The systematic review by Chou, Dana et al. (2013) 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 published review period and up to 31<sup>st</sup> August 2018.

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 injuries (analytical methods).
- Adult patients (aged  $\geq 18$  years)
- Follow-up data included for at least 75% of participants.
- Individuals were assessed systematically for the development of new pressure injuries (e.g., all participants have baseline skin assessment and at follow-up intervals suitable to identify new pressure injuries in the study population). Assessment only at baseline and discharge is not a suitable follow-up to detect all new pressure injuries.

- Risk assessment tools are completed at baseline.
- Outcome clearly defined as development of a Category/Stage I or greater pressure injury.
- 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.
- Retrospective study designs

### Direct Versus Indirect Evidence

Studies of pressure injuries in humans and individuals at risk of, or with existing pressure injuries are considered 'direct evidence' and will be required to support an A or B '*strength of evidence*' rating.

When studies of pressure injuries in humans at risk of, or with existing pressure injuries are not available, studies in normal human subjects, human subjects with other types of chronic wounds, laboratory studies using animals, or computational models might be used as indirect evidence to support recommendations with a C '*strength of evidence*' rating or to support GGG good practice statements.

## Step 2: Evaluating the Evidence

### Appraisal of Methodological Quality

The methodological quality of each study will be evaluated by two members from the development team. Where large discrepancy of opinion is noted (such that the paper's overall quality is rated differently by the two reviewers), a third reviewer will evaluate the paper.

The methodological quality of each study will be assessed by two reviewers using methodology checklists. Evaluation of study quality focuses on the internal and external validity of the studies. The following quality broad criteria will be 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 potential bias. Specific critical appraisal tools used are listed in Table 2.

**Table 2: Critical appraisal tools**

Study design	Tool	Access to tool	Version
Case series	Checklist based on a tool reported by Moga, Guo et al. (2012 )	<a href="https://www.ihe.ca/advanced-search/development-of-a-quality-appraisal-tool-for-case-series-studies-using-a-modified-delphi-technique">https://www.ihe.ca/advanced-search/development-of-a-quality-appraisal-tool-for-case-series-studies-using-a-modified-delphi-technique</a>	Version published 2012 (accessed November 2017)
Case control studies	Scottish Intercollegiate Guidelines Network (SIGN) checklist for case control studies	<a href="http://www.sign.ac.uk/checklists-and-notes.html">http://www.sign.ac.uk/checklists-and-notes.html</a>	Version accessed November 2017
Cohort studies	SIGN checklist for cohort studies	<a href="http://www.sign.ac.uk/checklists-and-notes.html">http://www.sign.ac.uk/checklists-and-notes.html</a>	Version accessed November 2017
Cross-sectional/survey studies	Checklist derived from the SIGN checklists		Developed 2012
Diagnostic studies	SIGN checklist for diagnostic Studies	<a href="http://www.sign.ac.uk/checklists-and-notes.html">http://www.sign.ac.uk/checklists-and-notes.html</a>	Version accessed November 2017
Implementation research	STaRI checklist (Pinnock, Barwick et al., 2017) <b>PLUS</b> an appropriate	<a href="http://www.bmj.com/content/356/bmj.i6795?panels_ajax_tab_tab=j">http://www.bmj.com/content/356/bmj.i6795?panels_ajax_tab_tab=j</a>	Version published 2017

	checklist to study design when applicable	<a href="#">nl_bmj_tab_related_art&amp;panels_ajax_tab_trigger=related#datasupp</a>	
Qualitative research	Critical Appraisal Skills Programme (CASP) Tool	<a href="http://docs.wixstatic.com/ugd/dde d87_25658615020e427da194a325e7773d42.pdf">http://docs.wixstatic.com/ugd/dde d87_25658615020e427da194a325e7773d42.pdf</a>	Version accessed November 2017
Quality improvement reports	Quality Improvement Reporting Excellence (SQUIRE 2.0) <b>PLUS</b> an appropriate checklist to study design when applicable	<a href="http://squire-statement.org/guidelines">http://squire-statement.org/guidelines</a>	Version published September 2015
Quasi-experiments	Checklist adapted from the SIGN checklist for RCTs, and consistent with methodology reported by Joanna Briggs Institute (Joanna Briggs Institute, 2014a, 2014b).	Components listed in quality appraisal tables presented on <a href="http://www.internationalguideline.com">http://www.internationalguideline.com</a>	Version developed 2012
Prognostic designs (excluding those related to risk)	QUIPS checklist (Hayden, van der Windt et al., 2013)	<a href="https://www.ncbi.nlm.nih.gov/pubmed/?term=23420236">https://www.ncbi.nlm.nih.gov/pubmed/?term=23420236</a>	Version published 2013
Randomized controlled trials	SIGN checklist for RCTs	<a href="http://www.sign.ac.uk/checklists-and-notes.html">http://www.sign.ac.uk/checklists-and-notes.html</a>	Version accessed November 2017
Risk factor studies with multivariable analyses	Methodology outlined by Coleman, Gorecki et al. (2013)		Version published 2013
Economic evaluations	SIGN checklist for economic evaluations, based on the requirements for submission to the British Medical Journal	<a href="http://www.sign.ac.uk/checklists-and-notes.html">http://www.sign.ac.uk/checklists-and-notes.html</a>	Version accessed November 2017
Systematic reviews	AMSTAR 2 checklist	<a href="http://www.bmj.com/content/bmj/suppl/2017/09/21/bmj.j4008.DC1/sheb036104.wf1.pdf">http://www.bmj.com/content/bmj/suppl/2017/09/21/bmj.j4008.DC1/sheb036104.wf1.pdf</a>	Version accessed November 2017

Unless otherwise stated in the specific tool design, each criterion on the critical appraisal checklist will be assessed as being met (Y), not met (N) not reported/unclear (U), or not applicable (NA). Unless alternate methods are stated on specific tools, studies will be described as high, moderate, or low quality using the following criteria:

- High quality studies: fully meeting at least 80% of applicable criteria
- Moderate quality studies: fully meet at least 70% of applicable criteria
- Low quality studies: did not fully meet 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, Gorecki et al. (2013) 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 will be appraised using the method described by Coleman, Gorecki et al. (2013) and the following factors were considered:

- The baseline study sample (i.e. individuals entering the study) is adequately described for key characteristics.
- A clear definition or description of the risk factor measured is provided (e.g. including dose, level, duration of exposure and clear specification of the method of measurement).
- Continuous variables used or appropriate (i.e. not data-dependent) cut-points for continuous data.
- Risk factor measurement valid and reliable.
- Adequate proportion of sample has complete data for risk factors.



- Range of potential risk factors are measured (i.e. Key variables in conceptual model; potential confounders accounted for in study design.)
- Range of potential risk factors are accounted for in the analysis (i.e. appropriate the adjustment; potential confounders accounted for in analysis.)
- Appropriate imputation.
- No selective reporting.

In addition, specific consideration was given to the following quality domain:

- 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 will be assessed as being met (yes/no/partial/unsure) using the quality criteria as outlined in Table 3. Address in the study report of the criteria will be used as the basis of a structured approach for classifying the overall study quality. Studies will be classified as high, moderate, low and very low quality using the following criteria:

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

**Table 3: Relationship between appraisal criteria and quality domains for risk factor studies (From Coleman thesis, used with permission)**

CRITERIA 1-8	QUALITY DOMAINS 1-4			
	1. Is there sufficient number of events (rule of thumb: more than 10 events per risk factor)?	2. Is there sufficient presentation of data to assess the adequacy of method and analysis?	3. Is the strategy for model building (i.e., inclusion of variables) appropriate and based upon a conceptual framework?	4. Is the selected model adequate for the design?
1.The baseline study sample is adequately described for key characteristics.		X		
2. A clear definition/ description of the risk factor measured is provided and a clear definition/ description of how the risk factor was measured is provided		X	X	X
3. Continuous variables used or appropriate (i.e. not data-dependent) cut-points for continuous data.		X	X	
4.An adequate proportion of sample has complete data for risk factors.		X	X	X
5.Range of potential risk factors are measured			X	X
6.Range of potential risk factors are accounted for in the analysis			X	X
7.Appropriate imputation			X	X
8.No selective reporting		X	X	X

## Level of Evidence

The '*level of evidence*' for individual intervention studies will be noted for each study containing direct evidence, using a classification system adapted from The Joanna Briggs Institute (Joanna Briggs Institute, 2014a, 2014b) (see Table 2).

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 4: Level of Evidence for Intervention Studies (Joanna Briggs Institute, 2014a, 2014b)**

<b>Level 1</b>	<b>Experimental Designs</b> <ul style="list-style-type: none"> <li>• Randomized trial</li> </ul>
<b>Level 2</b>	<b>Quasi-experimental design</b> <ul style="list-style-type: none"> <li>• Prospectively controlled study design</li> <li>• Pre-test post-test or historic/retrospective control group study</li> </ul>
<b>Level 3</b>	<b>Observational-analytical designs</b> <ul style="list-style-type: none"> <li>• Cohort study with or without control group</li> <li>• Case-controlled study</li> </ul>
<b>Level 4</b>	<b>Observational-descriptive studies (no control)</b> <ul style="list-style-type: none"> <li>• Observational study with no control group</li> <li>• Cross-sectional study</li> <li>• Case series (n=10+)</li> </ul>
<b>Level 5</b>	<b>Indirect evidence:</b> studies in normal human subjects, human subjects with other types of chronic wounds, laboratory studies using animals, or computational models

Studies on diagnostic and prognostic validity of pressure injury risk and pressure injury classification form an important body of knowledge in pressure injury 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 (Bossuyt, Reitsma et al., 2003). Therefore, cross-sectional designs are needed to establish the concurrent existence of both index test and reference standard results. Most studies in pressure injury risk research are not diagnostic accuracy studies according to this widely agreed upon definition, because the measured pressure injury risk is often compared with subsequent pressure injury occurrence. These designs resemble those of prognostic studies or diagnostic accuracy studies with imperfect reference standards (Rutjes, Reitsma et al., 2007).

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 (Sackett & Haynes, 2002). 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 injury risk assessment tool scores) are used to predict the probability of future events in individuals or groups (Altman, Vergouwe et al., 2009).

Test accuracy and validity estimates are only surrogate measures for clinical effectiveness (Ferrante di Ruffano, Hyde et al., 2012). The clinical effectiveness of diagnostic test procedures can only be adequately investigated by diagnostic RCTs (Merlin, Weston et al., 2009; Schunemann, Oxman et al., 2008). 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 (Merlin, Weston et al., 2009; OCEBM Levels of Evidence Working Group, 2011) and have been adopted by the GGG since the 2014 guideline edition.

**Table 5: Adapted levels of evidence for diagnostic studies (Merlin, Weston et al., 2009; OCEBM Levels of Evidence Working Group, 2011)**

<b>Level 1</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 2</b>	Non-consecutive studies or studies without consistently applied reference standards.
<b>Level 3</b>	Case-control studies or poor or non-independent reference standard.
<b>Level 4</b>	Mechanism-based reasoning, study of diagnostic yield (no reference standard). Low and moderate quality cross sectional studies.

**Table 6: Adapted levels of evidence for prognostic studies (Merlin, Weston et al., 2009; OCEBM Levels of Evidence Working Group, 2011)**

<b>Level 1</b>	A prospective cohort study.
<b>Level 2</b>	Analysis of prognostic factors amongst persons in a single arm of a randomized controlled trial.
<b>Level 3</b>	Case-series or case-control studies, or low quality prognostic cohort study, or retrospective cohort study.

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

### Data Extraction

The full papers of included references will be obtained and made available to the relevant SWGs on a web-based platform.

A data extraction template will be 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. Data extraction tables have been prepared during the interim development period (i.e., period between the publication of the 2014 guideline and the commencement of the 2019 guideline development period). The members of the SWGs will be provided with the preliminary data extraction tables for checking, and expanding on details if required.

The technical documents summarizing data extraction of included studies will be made available at the guideline website after the guideline has been published. 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 will be formed. Each SWG will formulate conclusions about the body of available evidence-based on the evidence tables and critical appraisals and levels of evidence. Evidence tables from previous guideline editions will also be made available to SWGs to ensure the full body of scientific literature is reviewed.

A first draft of recommendations was developed by the respective SWGs. The GGG will review the draft recommendations, making revisions as necessary.

To ensure uniformity and internal consistency in the final guideline, the GGG provides the following guidance:

- Each recommendation should start with a direct action verb and be a simple, short, direct, declarative

statement, free of jargon.

- Recommendation statements should be broad recommendations on clinical practice (e.g. broad, directive statements). Additional subsequent statements with more detail (e.g. how, when or how often) that support recommendations can be included as implementation considerations.
- 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 GGG will review all recommendations to ensure the wording of the recommendations accurately translates 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. This will additionally be reviewed by the Consumer SWG.

### Terminology

The term '*individual*' was selected to describe the patient, client, resident, or person with a pressure injury or at risk for a pressure injury.

The terms '*health professional*' and '*interprofessional team*' were selected for use when referring to health professionals and non-professional healthcare workers providing formal healthcare services to the individual. The disciplines of professionals/healthcare workers performing a given service may vary from country to country based on the laws and regulations governing healthcare providers.

The term '*informal caregiver*' was selected to describe people providing care to the individual outside the context of formal healthcare services. This generally refers to family members and friends.

Products available in one country may not be available in another. Generic names were used when referring to drugs and other products.

### Product names

The Guideline will not endorse or be seen to endorse the use of any specific products, manufacturers, services or companies. Consistent with best practice in developing clinical guidelines, brand/product names will not be used in recommendation statements or the Guideline text (Cochrane Style Manual Working Group, 2016; National Institute for Health and Care Excellence (NICE), 2017). Where available, generic names or product classifications will be used to describe medications and products. The Guideline will include descriptions of the features of products that may relate to their effectiveness (or otherwise) when reporting study results. Descriptions of **products** used in the appraised research will be used in reporting as they are presented in publications, and more information may be sought from the manufacturer's product information if required. In evidence tables, product names will be used to describe intervention and control products used in a specific trial on the first time the product/s are referenced. Thereafter, generic terms (e.g. "the intervention wound dressing") will be used.

### Step 4: Assigning Strength of Evidence Ratings

'**Strength of evidence**' ratings will be assigned to recommendations. This rating identifies the strength of cumulative body of evidence supporting each recommendation. Table 5 outlines the strength of evidence rating system to be used for the 2019 guideline edition (adapted from NHMRC methodology) (NHMRC GAR consultants, 2009).

**Table 7: Strength of evidence rating for each recommendation (adapted from NHMRC) (NHMRC GAR consultants, 2009)**

<b>A</b>	<ul style="list-style-type: none"> <li>• More than one high quality Level I study providing direct evidence</li> <li>• Consistent body of evidence</li> </ul>
<b>B1</b>	<ul style="list-style-type: none"> <li>• Level 1 studies of moderate or low quality providing direct evidence</li> <li>• Level 2 studies of high or moderate quality providing direct evidence</li> <li>• Most studies have consistent outcomes and inconsistencies can be explained</li> </ul>
<b>B2</b>	<ul style="list-style-type: none"> <li>• Level 2 studies of low quality providing direct evidence</li> <li>• Level 3 or 4 studies (regardless of quality) providing direct evidence</li> <li>• Most studies have consistent outcomes and inconsistencies can be explained</li> </ul>
<b>C</b>	<ul style="list-style-type: none"> <li>• Level 5 studies (indirect evidence) e.g., studies in normal human subjects, humans with other types of chronic wounds, animal models</li> <li>• A body of evidence with inconsistencies that cannot be explained, reflecting genuine uncertainty surrounding the topic</li> </ul>
<b>Good practice statement</b>	<ul style="list-style-type: none"> <li>• Statements by the GGG that are not supported by a body of evidence as listed above but considered significant for clinical practice.</li> </ul>

The '**strength of evidence**' supporting the recommendation is not the same as the '**strength of the recommendation**'. For example, there may be no RCTs in individuals with pressure injuries evaluating commonly implemented practices. Therefore, a recommendation may 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.

GGG good practice statements will be only made when they are perceived to be necessary. They should help clinicians to take appropriate actions in areas of uncertainty (G. H. Guyatt, Schunemann et al., 2015). GGG good practice statements will not be given a strength of recommendation, consistent with current best practice in guideline development (G. H. Guyatt, Schunemann et al., 2015).

In this guideline, evidence gaps will be explicitly identified. Systematic searches will be 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. Indirect evidence may be identified to support C '**strength of evidence**' ratings or GGG good practice statements. In the absence of indirect evidence, a GGG good practice statement may be made.

## Step 5: Summarizing Supporting Evidence

The SWGs will summarize the evidence supporting each recommendation. An explicit link between the recommendation and supporting evidence is expected. The strengths and limitations of this body of evidence will be clearly described. All recommendations with a '**strength of evidence**' rating of A or B (1 or 2) will require an explicit summary of one or more studies conducted with human subjects with pressure injuries or at risk for pressure injury development. The '**level of evidence**' for each study and its quality rating will also be identified in the summary.

The summary statements for recommendations with '**strength of evidence**' (SoE) of C and Good practice statements will clarify whether the recommendation was supported by:

- SOE C: indirect evidence from studies of normal subjects.

- SOE C: studies with intermediate or surrogate outcomes.
- SOE C: studies of humans with other types of chronic wounds, and animal studies or other basic bench research.
- Good practice statement: expert opinion supported by other evidence-based clinical guidelines OR expert opinion of the SWG and GGG members as reviewed by international stakeholders.

Evidence gaps identified in these summary statements will serve as an agenda for future research efforts and will be reported by the GGG in the document *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. The following points should be considered: (Alonso-Coello, Oxman et al., 2016; Alonso-Coello, Schünemann et al., 2016; Atkins, Best et al., 2004; G. Guyatt, Oxman et al., 2008; Jaeschke, Guyatt et al., 2008)

- 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 financial 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? (Ferrante di Ruffano, Hyde et al., 2012; Sackett & Haynes, 2002; Schunemann, Oxman et al., 2008)

The '**strength of recommendation**' grades will be achieved via a formal consensus process using an adapted-GRADE grid (See *Table 8*). In this consensus process, all SWG and the GGG members are invited to take part, each voting on every recommendation in the guideline. The consensus voting process will be conducted on the website, with each team member provided with a unique identification. The participants will be required to confirm their understanding of the procedure before commencing.

**Table 8: Five types of recommendations (Alonso-Coello, Oxman et al., 2016; Alonso-Coello, Schünemann et al., 2016; Atkins, Best et al., 2004; G. Guyatt, Oxman et al., 2008; Jaeschke, Guyatt et al., 2008)**

Recommendation	Symbol	Description	Implications
<b>Do it:</b> Strong recommendation for an intervention (We recommend offering this option)	↑↑	Indicates a judgment that most well informed people would make.	<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 an intervention (We recommend against offering this option)	↓↓		<i>For quality monitors</i> —Adherence to this recommendation could be used as a quality criterion or performance indicator.
<b>Probably do it:</b> Conditional recommendation for using an intervention (We suggest offering this option)	↑	Indicates a judgment that a majority of well informed people would make, but a substantial minority would not.	<i>For patient consumers</i> —Most people would want the suggested course of action, but many would not. <i>For health professionals</i> —Examine, and be prepared to discuss, the evidence with patients, as well as their values and preferences.
<b>Probably don't do it:</b> Conditional recommendation against using an intervention (We suggest not offering this option)	↓		<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> Conditional recommendation for either the intervention or the comparison (We make no suggestion on offering this option)	↔	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 'strength of recommendation'.

The process will be facilitated using an evidence to decision framework (Alonso-Coello, Oxman et al., 2016; Alonso-Coello, Schünemann et al., 2016) that will be finalized by the GGG. An evidence to decision framework presents relative pros and cons for interventions and ensures individuals voting on recommendations do so with a more complete understanding of the evidence and implications of recommendations (see *Appendix 2*). For each recommendation to be evaluated using the adapted-GRADE process, voters will be presented with a tabulated summary of the evidence relevant to the following questions that are presented by Alonso-Coello, Oxman et al. (2016):

*Derived from the reviewed evidence:*

- How substantial are the desirable anticipated effects?
- How substantial are the undesirable anticipated effects?
- What is the overall certainty of the evidence of effects?
- Does the balance between desirable and undesirable effects favor the intervention or the comparison?
- How substantial are the resource requirements (costs)?

*Derived from the reviewed evidence, input from SWG responsible for relevant chapter and stakeholder review:*

- Is the intervention feasible to implement?

*Derived from the reviewed evidence, input from the Consumer SWG and stakeholder review:*

- Is there important uncertainty about or variability in how much patient consumers and their informal caregivers value the main outcomes?

- Is the intervention acceptable to patient consumers and their informal caregivers?
- Is the intervention feasible for patient consumers and their informal caregivers?

After reviewing the evidence to decision table, voters will be asked to select a '**strength of recommendation**' grade from the options presented in *Table 7* and an additional option to abstain from voting (with reason provided). Votes will be recorded and calculated using a software program designed for the purpose. Participants will be able to nominate a '**strength of recommendation**' for as few or as many recommendations as they prefer, but will be strongly encouraged to vote on all recommendations.

Rules were determined based on previous applications of the GRADE process, and a desire to obtain significant consensus. Determination of the final '**strength of recommendation**' will be 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'.

## Implementation Considerations

An implementation consideration is a suggestion on how to implement the core recommendations in the guideline that aim to provide guidance on clinical questions. Implementation considerations may describe how, when, where, who or how often to implement a recommended practice, or may identify core principles to consider when implementing the recommendation. Implementation considerations will cover supplemental information considered pertinent to practice and may be supported by level 1 to 5 evidence or consensus of the SWG and/or GGG.

## Final Review and Recommendations

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

The GGG 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 Quick Reference Guide was translated into 17 different languages, the 2014 full guideline was translated into two different languages and the Quick Reference Guide was translated into 11 different languages.

Additionally, quality indicators that could be used to monitor the implementation of this guideline will be developed. 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 will be designed to monitor the specific recommendations for practice that are included in this guideline. They will be selected based on expert opinion on their intrinsic value as an indicator of quality care for prevention and treatment of pressure injuries, 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.



## **Guideline Updates**

The GGG will continue to monitor the pressure injury literature after the 2019 guideline has been published. Another revision is planned for 2024 (or sooner, if ongoing literature reviews reveals major advances in pressure injury prevention and treatment prior to 2024).

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## CHAPTER THREE: GUIDELINE GOVERNANCE GROUP

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### Goal of Guideline Governance Group

The goal of the Guideline Governance Group (GGG) is to develop evidence-based recommendations for the prevention and treatment of pressure injuries that can be used to guide professional and patient consumer decisions internationally. 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 GGG.

### Guideline Governance Group Membership

The GGG will consist of four voting members from each of the Member Organizations: National Pressure Ulcer Advisory Panel (NPUAP), European Pressure Ulcer Advisory Panel (EPUAP) and the Pan Pacific Pressure Injury Alliance (PPPIA). The (nonvoting) guideline methodologist will attend and report to meetings. GGG members are selected by their respective organizations and should meet the following qualifications:

1. Possess expertise in pressure injury 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. GGG members and others involved in the actual development of the guideline are screened for potential conflicts of interest by the Member Organization that has appointed them. In the interest of transparency, GGG 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 2019 Guideline. GGG members will be asked to disclose all conflicts of interest at the beginning of each meeting and recuse themselves as appropriate.
3. NOT have their primary employment in industry. Representatives of industry are excluded from developmental groups but are invited to participate as stakeholders.
4. The GGG should include representatives from the disciplines necessary to make informed decisions regarding the evidence and its appropriate application to practice.

### Role and Responsibilities

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

1. Developing the guideline scope and purpose.
2. Analyzing and approving proposed guideline methodology changes 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 GGG. Representatives are not required to vote as a block with their parent organization.
8. Serving as an advisory group in financial and business matters with respect to the Guideline.
9. Declaring competing (or conflicting) interests with recusal from GGG discussion and voting as appropriate.

## **Term of Appointment**

Appointment of GGG members is at the discretion of the Member Organizations. At least one previous GGG member should be included from each Member Organization to ensure a core of experienced members and continuity in the guideline process. Each GGG member will serve a three-year term. Current GGG members have committed to remaining on the GGG until completion of the 2019 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. Additionally, the Member Organizations should encourage at least one GGG member remains engaged during the interim phase between Guideline editions to oversee issues arising (e.g. methodological reviews, requests for use of Guideline material, interim publications etc.).

## **Attendance at GGG Meetings**

- A minimum of one face-to-face GGG meeting will be scheduled per year in Europe, the US, or in the Pan Pacific region during active Guideline revisions. Additional phone and video conferences will be convened as necessary.
- GGG members are highly encouraged to attend all meetings and phone/video conferences.
- The quorum for all GGG meetings will be seven, with at least two GGG members from each Member Organization. The methodologist is not counted for quorum purposes.

- If a GGG member is absent for an official GGG meeting or phone/video conference, voting will still occur at the meeting so that the work of the GGG can progress. If the votes of missing member(s) could have altered the GGG decision (i.e. close votes), then the methodologist will organize voting be repeated by email ballot, giving all individuals the opportunity to vote in close decisions.
- The GGG may schedule GGG-SWG meetings at various conferences for the convenience of members. These ad-hoc meetings do not constitute official meetings of the GGG and are convened to enhance communication among GGG and SWG members.
- The GGG may schedule “sub-group meetings/working parties” of GGG members to discuss specific issues, but all decisions will be taken back to the full GGG for discussion and voting.
- At the commencement of GGG meetings, the Chair will call for a volunteer from the GGG to take the minutes. The minute-taker will circulate the minutes as soon as possible following the meeting to enable other attendees to check for accuracy and commence addressing actions arising.

## Lead Members

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

## Key GGG Processes

1. **Collaboration:** By mutual agreement, the GGG members will collaboratively review the research literature meeting inclusion criteria and revise the comprehensive 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 GGG 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 GGG with revisions made as appropriate.
5. **Patient Consumer Involvement:** Peer consumer representatives will be invited to participate as outlined in *Chapter Two*. Health professionals involved in the development of the guideline are encouraged to invite colleagues and patient consumers to register as stakeholders at Guideline website.

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## CHAPTER FOUR: SMALL WORKING GROUPS

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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 individuals with or at risk of pressure injuries throughout the world.

The Guideline Governance Group (GGG) will decide on the final composition of each SWG and each group will nominate a leader. The SWGs will consist of at least one person (preferably at least two) from each of the three GGG Member Organizations, plus additional representatives from Associate Organizations.

### Role of the Small Working Groups

The SWGs are responsible for reviewing the research relevant to the clinical questions within a given topic/section and making recommendations to the GGG for guideline revision based on their review of relevant evidence. Ideally, SWGs should be composed of members various scientific and clinical disciplines as well as from various geographic locations. This broad representation of expertise enhances the quality of SWG discussions and the quality of the guideline as a whole. 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.

The SWGs will meet electronically (e-mail, Skype, phone or video conference). Each SWG will share information using a web-based platform.

### Member Qualifications

1. Possess expertise in the SWG content area and a working knowledge of research methods sufficient for conducting critical appraisal of research studies. SWG members will be asked to submit a two-page resume relevant to SWG topic area(s) and their research skills.
2. Be free of major competing (or conflicting) interests. Disclose the nature of any 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 required to complete a form identifying potential conflicts of interest on an annual basis.
3. Be a member of one of the Member or Associate 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. Have sufficient computer literacy to use word processing software, a web-based interface for document sharing, and web-based conferencing applications. SWG members will require regular access to a computer with internet access, ability to access Word and PDF documents and an email address that is **accessed on a regular basis**. Some technical support will be provided by the methodologist and a web administrator; however, it is the responsibility of SWG members to ensure they have appropriate equipment and onsite support as required.
6. **Be responsive to communication** from other members of their SWG, the GGG and the methodologist. It is reasonable to respond to email within five days when working on a collaborative project.

## Small Working Group Process

The SWG will nominate a leader. In the absence of a leader, the methodologist will take this role.

The SWG should review the methodology at the first meeting and monitor adherence to the methodology. The guideline methodologist will advise the SWGs, provide assistance in the evidence identification and critical appraisal process and work within each SWG to ensure that the guideline process progresses in adherence to the a-priori methodology. The SWG will work with the methodologist to undertake the steps presented below (n.b. this is a summary of the process, presented in *Chapter Two* of the Methodology).

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

1. Review the clinical questions specific to the topic/section.
2. Review the literature identified in searches conducted since 2013.
3. Determine if additional literature searches are needed. Any additional searches should have a specific goal and consider the search limits (e.g. date). Additional literature searches will be done by the methodologist and the search should be documented.
4. Review citations identified in the preliminary review as potentially meeting inclusion criteria. Determine/confirm if the inclusion criteria are met, including relevance to the specific SWG topic.
5. For all studies meeting inclusion criteria and providing direct evidence, complete the critical appraisal form appropriate to the study design. The methodologist will assign appraisal responsibilities according to the project need within your SWG.
6. For all studies meeting inclusion criteria, validate information on the preliminary evidence (data extraction) table or revise the content, or create a new evidence table summary as needed.
7. Note the limitations of the studies included on the evidence table.
8. Confirm the level of evidence and quality for the studies included on the evidence table.

If there is insufficient direct evidence from primary studies of patients with, or at-risk for, pressure injuries, the SWG members may 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 individuals with mixed chronic wounds, laboratory research), you will need to do a comprehensive search of the indirect evidence. For example, if an intervention has not been adequately studied in pressure injuries, you could include evidence from trials in other types of chronic wounds. To avoid bias, you would need to fully explore the literature on the intervention in chronic wounds rather than selecting only a few key articles. Recommendations solely supported by indirect evidence will be **Strength of Evidence C**.
2. **Systematic reviews and meta-analyses:** Guideline recommendations should be based on individual studies as published in peer-reviewed journals (i.e. primary research). Systematic reviews may be cited as additional supporting information or to broadly summarize the state of the science, but only where they meet the inclusion criteria. When using systematic reviews to support discussion, this will be clearly identified in the guideline and all primary studies in the systematic review should be appraised and presented.
3. **Other evidence-based clinical guidelines:** When evidence from primary research and systematic reviews is insufficient, synthesized research from other clinical guidelines might be presented. This form of evidence will not be used to support recommendation statements, but might provide a reference for implementation considerations or discussion.
4. **Expert opinion (good practice statements):** 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 if the recommendation is followed? What are the potential benefits? Consider if the statement

is a good practice statement or would better be presented as a practice point to support an evidence-based recommendation.

### Step 3: Drafting Recommendations and implementation considerations

Recommendations should be drafted after a thorough review of available evidence. The intent of the Guideline is to provide systematically developed, evidence-based statements to assist health professional and patient consumer decisions about appropriate healthcare for specific clinical circumstances. Recommendations should be sufficiently broad to apply to individuals throughout the world, yet specific enough to guide health professional and patient consumer decisions.

Recommendations should have a supporting Evidence to Decision Framework (see *Appendix 2*). The methodologist will assist in development of the supporting framework.

The GGG anticipate that recommendations would be adapted for local use. To that end, the Guideline is translated into several languages. Local organizations develop policies, procedures, and protocols that adapt International Guideline recommendations for use in the context of specific countries, healthcare systems, settings and patient populations.

To promote uniformity and consistency in the Guideline, a recommended format for guideline statements is provided:

- Start with simple, direct, broad statement.  
e.g. “Reposition all at-risk individuals.”
- Subsequent implementation considerations provide more detail (how, when, how often)  
e.g. “Reposition every two hours.”; “Avoid placing patient directly on trochanter.”
- Start each recommendation with a direct action verb.
- Recommendations should be simple, short, declarative statements, free of jargon.
- Recommendations should be specific and unambiguous.
- Recommendations are not mandates or standards and should be written in a tone that provides guidance to professional colleagues and patient consumers.
- Break up multiple thoughts into multiple recommendations or implementation considerations.
- Use ‘individual’ to refer to the patient, client, resident etc. Where the context of the word ‘individual’ would be unclear use, ‘person’ or ‘patient consumer’.
- Use ‘health professional’ or ‘interprofessional team’ to describe the formal care provider(s). Scope of practice for various disciplines varies widely. Avoid suggesting that a recommendation applies specifically to one healthcare 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.
- 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.
  - 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 individuals or specific situation, mention this – note that there are specific SWGs responsible to subsets of individuals.
  - If a recommendation carries a risk of harm (or is clearly contraindicated) in a specific subset of Individuals or specific situation, be sure to include this information.
- Discuss cost and resource implications when appropriate. Cost analyses vary widely among healthcare systems; however, required resources should be discussed as appropriate to the professional-patient consumer decision making process.
- Consider feasibility of implementing recommendations. This may vary widely between healthcare systems.

#### Step 4: Assigning Strength of Evidence (SoE) Ratings

Examine the cumulative body of evidence supporting each recommendation. Assign a rating according to the **Strength of Evidence** table described in *Chapter Two*.

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 the designs and quality of studies supporting the recommendation. **Strength of Evidence** are assigned by the SWG and methodologist and reviewed/confirmed by the GGG.

The **Strength of the Recommendation** evaluates how strongly 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. The **Strength of Recommendation** is assigned through a review of the tabulated evidence and a consensus voting process.

#### 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 a **Strength of evidence A or B (1 or 2)** should have an explicit summary that describes the findings of one or more studies of human subjects with prar risk for pressure injuries. For **Strength of evidence C**, specify what type indirect evidence on which the recommendation is based. For **good practice statements**, provide supporting references for opinion.

#### Step 6: Participating in the Strength of Recommendation consensus process

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

#### Work process and content review

The content of the guideline will be edited and peer-reviewed. The process is iterative, with the methodologist facilitating communications between peer-reviewers, GGG and SWG members. Each section will usually undergo numerous drafts before being finalized.

As each SWG progresses through the above process at a different rate, there are times when delays can occur. The goal of the team is to meet the timelines as much as possible. The methodologist will assist in communications and progress.






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## CHAPTER FIVE: CONFLICT OF INTEREST

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### Introduction

All individuals engaged in the guideline development are required to complete a Conflict of Interest (COI) Disclosure form in order to be involved and to receive acknowledgement as a member of the team. The GGG and SWG members are required to be free of major competing (or conflicting) interests and are requested to disclose the nature of any minor competing interest and recuse themselves from related decisions.

### Conflict of Interest Form Background

In order to participate in the guideline development and update process group members **must declare** whether they have any **potential COI**. A COI arises in any situation in which a group member has a direct or indirect pecuniary or personal (e.g. academic advancement, community standing) 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 COIs 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.

Potential conflicts of interests (COI) will be declared and managed based on an adapted version of the Guidelines International Network Principles (Schünemann et al. 2015). Every COI will be given a weight (based on how much money is associated with the conflict) and a rating based on relevance. The weight of potential COIs will be evaluated in conjunction with "relevance to topic" (Schünemann, Al-Ansary et al., 2015)

Every GGG and SWG member must declare any potential COI according to the Disclosure Form. Conflicts of interests regarding the development and update of the 2019 International Pressure Ulcer/Injury Guideline 2019 that may arise from the following payments or services from industry within the **past 3 years** before commencing work on the guideline will be declared.

The COI statements are kept with the Chairpersons of the NPUAP, EPUAP and PPIA and the methodologist, and are valid for one year. Emergent conflicts of interest during the year must be declared immediately within the working process or meetings and on an updated COI form.

The Conflict of Interest (COI) Disclosure form will be completed:

- As a part of application to participate in the guideline development (declaring all conflicts for the preceding three years before involvement).
- New COI will be declared as they arise.
- Within the 12 months prior to guideline completion.



## Conflict of Interest Form for Completion

Name: \_\_\_\_\_ Organization: \_\_\_\_\_

Type of Interest	Nil/no interest	Interest to declare (see below)				Topics List guideline topics to which this COI relates
		Money paid to you	Money paid to your institution	Name of entity	Weight (1, 2, or 3)	
Grants						
Consulting fees or honoraria						
Board memberships						
Payments/honoraria for lectures or publications						
Payments/honoraria for development of educational presentations						
Patents						
Support for travel to meetings for the guideline development/update						
Payment for writing or reviewing the guideline or parts of it						
Provision of other assistance for guideline development /update						
Other (e.g. academic)						

Please tick the relevant box(es) for the total value of declarations for three years preceding guideline commencement and annually thereafter: Include monetary values (e.g. payment, a product etc.) and non-monetary values (e.g. paid travel, tickets etc.):

Up to \$1,000: **weight = 1**

\$1,000 to 5,000: **weight = 2**

\$5000 and more: **weight = 3**

*In the final guideline methodology documents prepared after completion of the guideline project (i.e. guideline publication), the weighted range, sources of conflict and relevance level will be made available and published on the guideline website. No precise amount will be published. Prior to publication information will be available to Chairs of the GGG and guideline organizers.*

Adapted from: Schünemann, H. J., Al-Ansary, L. A., Forland, F., Kersten, S., Komulainen, J., Kopp, I. B., Macbeth, F., Phillips, S. M., Robbins, C., van der Wees, P., Qaseem, A., Board of Trustees of the Guideline International Network. (2015). Guidelines International Network: Principles for disclosure of interests and Management of conflicts in guidelines. *Ann Intern Med*, 163(7), 548-553.

**Appendix 1: Conflict Weight (Schünemann, Al-Ansary et al., 2015)****Appendix Table 1. "Weight" of potential conflict of interest based on "value."\*\***User instructions

Step 1. In Table A1, select a monetary and/or nonmonetary "value" on the scale labeled adding up all declared values for the 3 years prior to submission of the project or application per company or commercial sponsor (see examples in the legend to the table).

Step 2. Determine the "weight" using the column labeled "weight."

**TABLE A1. "WEIGHT" OF POTENTIAL CONFLICT OF INTEREST (COI) BASED ON "VALUE"**

Value Category (Monetary and/or Nonmonetary)*	Weight†
1. Up to \$1,000‡	1
2. \$1,001-5,000§	2
3. \$5,001-10,000¶	3
\$10,001-5,000	
\$50,001-100,000	
\$100,001 or more	

\* Select a value category for the potential COI that reflects both monetary and non-monetary value combined (see ‡, §, ¶ below to determine any non-monetary value). Include direct or indirect financial interests such as research grants or similar (based on categories and ranges specified by the ATS Committee on Ethics and Conflict of Interest) in US\$; amounts will not be published or reported within ATS conferences or projects or otherwise reported by ATS to the public, with the exception of ATS official documents, where the dollar amount range of each participant's relationship per company or commercial sponsor (for the 3 years prior to submission of the draft document to the ATS Board of Directors) should be included in the disclosure statement that is published with the document. This information will be available ONLY to chairs and organizers of official ATS activities who will evaluate the COI disclosures and to the ATS Board of Directors and the Committee on Ethics and Conflict of Interest, if necessary.

† Used with relevance rate (see Table A2) to calculate significance.

‡ Example of nonmonetary value in category 1: a pen, pencil, cell phone.

§ Example of nonmonetary value in category 2: paid tickets to the Super Bowl or World Cup final for the family.

¶ Example of nonmonetary value in category 3: free first class ticket to Australia from North America for spouse or family.

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**Appendix 2: Conflict Relevance and its Management**

	Relevance of COI to the working group topic							
	None 0	Very low 1	Low 2	Moderate 3	Moderate to high 4	High 5	Very high 6	Too high 7
<b>Relevance description</b>	The declared conflict/s of interest is unrelated to the guideline			The working group topic is somewhat related to the declared conflict/s of interest			The working group topic is highly related to the declared conflict/s of interest	Employed in industry.
<b>Example</b>	Team member has consulted for companies that are not engaged in the field of pressure injuries.	Team member has presented on methodology or background PI material for an event sponsored by a company that produces products that are likely to be discussed in the guideline.	Team member received personal honorarium for presenting on products produced by a company. That company produces other products likely to be included in guideline.	Team member has received personal honorarium for presenting products likely to be recommended in the section of the guideline to which the team member is assigned.	Team member's career is focused on research about topics likely to have guide recommendations suggesting additional resources by funding bodies in the field.	Team member has received personal honorarium or grant from for-profit company to explore products likely to be recommended in the guideline.	Team member is a patent holder or shareholder in company that produces products likely to be recommended in the guideline.	
<b>Conflict management</b>	None	No specific management. Chairs alert to potential COI.	No specific management. Chairs alert to potential COI.	Team member will not appraise papers about the product; will refrain from finalizing relevant recommendations; and excluded from Strength of Recommendation voting on related recommendations.	Team member will not appraise papers about the product; will refrain from finalizing relevant recommendations; and excluded from Strength of Recommendation voting on related recommendations.	Team member will not appraise papers about the product; will refrain from finalizing relevant recommendations; and excluded from Strength of Recommendation voting on related recommendations.	Team member will not be assigned to work on that topic. Team member excluded from Strength of Recommendation voting on related recommendations.	Excluded from participating in the guideline.

Adapted from: Schünemann, H. J., Al-Ansary, L. A., Forland, F., Kersten, S., Komulainen, J., Kopp, I. B., Macbeth, F., Phillips, S. M., Robbins, C., van der Wees, P., Qaseem, A., Board of Trustees of the Guideline International Network. (2015). Guidelines International Network: Principles for disclosure of interests and Management of conflicts in guidelines. *Ann Intern Med*, 163(7), 548-55

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## CHAPTER SIX: CONSUMER ENGAGEMENT

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### Goal of Consumer Engagement

Consumer engagement is recognized as a requirement for high quality, international clinical guidelines (Armstrong, Mullins et al., 2017; National Health and Medical Research Council (NHMRC), 2016; Patient-Centered Outcomes Research Institute (PCORI), 2015b; Qaseem, Forland et al., 2012). In the context of this Guideline, consumer engagement refers to involvement in guideline development from the following groups:

- patient consumers (i.e. individuals with or at risk of a pressure injury),
- informal caregivers (i.e. individuals who provide care in an informal capacity such as family members, friends or community); and
- consumer stakeholders (i.e. professional consumer representatives).

Recognising international standards, the goals of consumer engagement in this guideline development process are to (Légaré, Boivin et al., 2011):

- promote the relevance of recommendations and guideline content to patient consumers
- promote patient consumer values and preferences in development of recommendations and guideline content
- acknowledge and respond to the needs of specific populations groups
- respond to consumer education/information needs
- promote consumer awareness of the International Guideline

The primary audience of the International Guideline is health professionals, academics and organizations/facilities, and the content and terminology are appropriate to this audience. Input from patient consumers is hoped to provide guidance on the development of companion resources for the Guideline, including topics for region-specific patient consumer education.

### Process to Engage Consumers in Guideline Development

The Guideline Governance Group (GGG) recognizes the diverse range of barriers guideline development teams face in promoting consumer engagement. The literature identifies a wide range of barriers to consumer engagement (Armstrong, Mullins et al., 2017; Légaré, Boivin et al., 2011; National Health and Medical Research Council (NHMRC), 2016), including discrepancies between health professional experts and consumer perspectives regarding topics of interest; difficulty integrating consumer opinion into recommendation development; consumer recruitment and retention issues; limitations in consumer understanding of technical terminology; time and financial constraints; resistance to change; feelings of being undervalued; and cultural (e.g. language), health (e.g. sensory impairment) and physical (e.g. lack of internet) barriers.

The GGG considered the above factors in developing a consumer engagement strategy. Strategies to promote consumer engagement were developed based on recommendations on the literature on promoting consumer engagement (Armstrong, Mullins et al., 2017; Légaré, Boivin et al., 2011; National Health and Medical Research Council (NHMRC), 2016; Patient-Centered Outcomes Research Institute (PCORI), 2015a). Consumer engagement strategies were developed for each of the guideline steps: Recruitment, Preparation, Logistics and Reassessment (Armstrong, Mullins et al., 2017) (see Table 1).

**Table 1: Guideline development team strategies to promote patient consumer engagement (Armstrong, Mullins et al., 2017; Légaré, Boivin et al., 2011; National Health and Medical Research Council (NHMRC), 2016; Patient-Centered Outcomes Research Institute (PCORI), 2015a)**

Guideline step	Processes to promote patient engagement
Recruitment	<ul style="list-style-type: none"> <li>Information about the guideline development process will be publicly available.</li> <li>Both patient consumers and consumer stakeholders will be eligible and invited to participate.</li> <li>Diverse patient consumers will be encouraged by recruiting in all countries involved in the guideline development, with consideration to population groups with specific needs (defined elsewhere in the methodology).</li> <li>Diverse health professionals will be recruited to promote consideration of the needs of diverse patient consumers.</li> <li>A methodologist with qualitative research skills will provide moderation support for a Consumer SWG.</li> </ul>
Preparation	<ul style="list-style-type: none"> <li>Patient consumers will have the methodologist as a point of contact and will have contact details of the GGG Chair in their geographic region.</li> <li>Patient consumers will receive background information about the guideline and goals of consumer participation.</li> </ul>
Logistics	<ul style="list-style-type: none"> <li>Methods for providing opportunity for patient consumer contribution are pre-identified in this protocol.</li> <li>The guideline methodologist will co-ordinate consumer engagement (e.g. ethics application, web platforms, translations, data analysis etc.)</li> <li>Accessible language will be used for consumer survey materials.</li> <li>Contribution from patient consumers will be sought in an online survey, with consideration to simplicity in language, questions, methods of response and time to complete the survey.</li> <li>Consumer survey results will be published to feedback to consumer participants.</li> <li>Consumers will be invited to register as stakeholders to review the guideline.</li> <li>A consumer will be invited to help launch the guideline by involving the patient perspective.</li> <li>Updates on the guideline development process are published on the International Guideline website.</li> </ul>
Reassessment	Evaluation of consumer engagement at the completion of the guideline development as a part of methodology review.

### Inviting Consumer Engagement

Consumers (patients, informal caregivers and representatives) will be invited to engage in the development process. Consumers will be recruited to complete a consumer survey, participate in a Consumer SWG and/or register as a stakeholder. Consumer engagement will be invited through:

- Website invitations.
- Invitation via GGG and SWG members.
- Invitations to consumer stakeholder groups, Indigenous groups and patient support network groups (e.g. SCI patient groups) known to GGG members in all geographic regions.
- Social media.

## Consumer survey

At commencement of the project, an international survey of consumers (patients and their informal caregivers) will be undertaken to establish, information needs, consumer interest in outcome measures (goal priorities) and to inform development of the clinical questions. Broad consumer input will be sought, with a goal of collecting information from consumers in all geographic regions participating in the guideline. The online survey to explore:

- Topics of patient priority.
- Relevance of clinical questions to patient needs.
- Additional clinical questions to answer.
- Interest in registering as stakeholder.

Information collected via the survey will be used to review and revise the list of clinical questions, to contribute to the evidence to decision framework and to develop priorities for consumer education material.

Data from the consumer survey will contribute to the the evidence to decision framework for evaluating:

- Relevance to the goals of individuals with or at risk of pressure injuries.
- Acceptability of interventions (e.g. preferences, cultural considerations).
- Importance of information to consumers and their informal caregivers

Information collected during the consumer survey will contribute to final development of recommendations and implementation considerations and the Strength of Recommendation grading, as well as for developing priorities for consumer education material.

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## APPENDIX 1: SPECIFIC CLINICAL QUESTIONS

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**Black bullet points = major clinical questions outlined in *Chapter One***

**White bullet points = specific clinical questions**

### 1. Classification of pressure ulcers/injuries

- What are accurate and effective methods for pressure injury classification and assessment?
  - What are the most commonly recognized and used pressure injury classifications scales and how do they relate to one another?
  - What are the recognized characteristics of a pressure injury Category/Scale 1 to 4, unstageable pressure injury and deep tissue injury?
  - Are some pressure injuries unavoidable? If so, what are the characteristics of unavoidable pressure injuries?

### 2. Risk factors and risk assessment

- What factors put individuals at risk for pressure injury development?
- What are accurate and effective methods for pressure injury risk assessment?

### 3. Skin and Soft Tissue Assessment

- What are accurate and effective methods for skin and tissue assessment?
  - Are scale/ tools effective methods to assess the skin and soft tissue?
  - What are effective methods of assessing erythema?
  - Is ultrasound an effective method for assessing the skin and soft tissue?
  - Is evaluation of skin and tissue moisture an effective method of assessing the skin and soft tissue?
  - Is evaluation of skin and tissue temperature an effective method of assessing the skin and soft tissue?
  - Are there additional technologies that are accurate and effective methods of assessing skin and soft tissue?
  - What methods are effective for assessing skin and soft tissue in individuals with darkly pigmented skin?

### 4. Skin and Soft Tissue Care and Protection

- What skin and soft tissue interventions are effective in preventing pressure injuries?
  - Is massage effective in promoting healing of pressure injuries?
  - Are topical products (e.g. moisturizers, emollients, hyperoxygenated fatty acids) effective in preventing pressure injuries?
  - Is a prophylactic dressing effective for preventing pressure injuries?
  - Are continence management strategies effective in preventing and treating pressure injuries?
  - Are low friction or microclimate control fabrics effective for preventing pressure injuries?

### 5. Preventing Medical Device Related Pressure Ulcers/Injuries (MDRPI)

- What factors should be considered when selecting a medical device?
- What local management strategies are effective in preventing MDRPIs?
  - Is a prophylactic dressing effective for preventing MDRPIs?
  - If so, what factors should be considered when selecting a prophylactic dressing?

### 6. Nutrition for Prevention and Treatment of Pressure Ulcers/Injuries

- What are accurate and effective methods for assessing nutritional status of individuals with or at risk of pressure injuries?
- What nutritional interventions are effective in preventing pressure injuries?
  - Is there an ideal nutritional regimen to reduce the risk of pressure injuries, and if so, what should it include?

- Are any nutritional supplements (e.g. formulas, specific vitamins/minerals) effective in reducing risk of pressure injury development?
- What nutritional interventions are effective in supporting pressure injury healing?
  - Is there an ideal nutritional regimen to promote healing of pressure injuries, and if so, what should it include?
  - Are any nutritional supplements (e.g. formulas, specific vitamins/minerals) effective in promoting healing of pressure injuries?

### **7. Support surfaces for Prevention and Treatment of Pressure Ulcers/Injuries**

- What support surfaces are effective in preventing pressure injuries?
  - What reactive support surfaces are effective in preventing pressure injuries?
  - What active support surfaces are effective in preventing pressure injuries?
  - When should an active support surface be used to prevent pressure injuries?
  - What is the most effective seating support surface for preventing pressure injuries?
- What support surfaces are effective in supporting pressure injury healing?
  - What reactive support surfaces are effective in supporting pressure injury healing?
  - What active support surfaces are effective in supporting pressure injury healing?
  - When should an active support surface be used to supporting pressure injury healing?
  - What is the most effective seating support surface for preventing pressure injuries?

### **8. Repositioning and Mobilization for Prevention and Treatment of Pressure Ulcers/Injuries**

- What repositioning and early mobilization interventions are effective in preventing pressure injuries?
  - How often should repositioning be performed to reduce the risk of pressure injuries?
  - What criteria should be used to determine and monitor frequency of turning?
  - What positioning techniques are most effective in redistributing pressure and preventing shear?
  - Do programs of early mobilization affect pressure injury rates?
- What repositioning and mobilization methods are effective in supporting pressure injury healing?

### **9. Heel Pressure Ulcers/Injuries**

- What factors put individuals at risk for heel pressure injury development?
- What are accurate and effective methods for assessing heel skin and tissue?
- What are effective local management strategies (e.g. skin care, prophylactic dressings) in preventing heel pressure injuries?
- What heel repositioning interventions are effective in preventing heel pressure injuries?
- What support surfaces and devices are effective in preventing heel pressure injuries?
- What are effective local management strategies for treating heel pressure injuries?
- What factors affect healing of heel pressure injuries?

### **10. Involvement of Patient Consumers and Their Caregivers**

- What are effective strategies for engaging individuals in pressure injury prevention?
- What are effective strategies for engaging individuals in pressure injury treatment?
- What are effective strategies for promoting quality of life for individuals with or at risk of pressure injuries?

### **11. Assessment of Pressure Ulcers/Injuries and Monitoring of Healing**

- What are accurate and effective strategies for evaluating/monitoring healing?
  - What are accurate and effective strategies for evaluating/assessing pressure injuries?
  - What are accurate and effective strategies for monitoring healing over time?
  - What are the most commonly recognized and used pressure injury assessment/monitoring tools/scales and how do they relate to one another?
  - Which pressure injury monitoring tools are most responsive to change over time and most accurately describe the healing trajectory of the wound (i.e., healing, deteriorating, and stalled)?

**12. Assessment and Treatment of Pain**

- What strategies are effective in preventing, assessing and treating pressure injury pain?
  - What are accurate and effective methods to assess pressure injury pain?
  - What are effective pharmacological interventions for reducing pressure injury pain?
  - What are effective non-pharmacological interventions for reducing pressure injury pain?

**13. Wound Care: Cleansing, Debridement and Topical Agents for Healing**

- What local pressure injury treatments are effective for supporting healing (i.e. cleansing, debridement, topical agents, wound dressings, etc.)?

**14. Wound Dressings**

- What local pressure injury treatments are effective for supporting healing (i.e. cleansing, debridement, topical agents, wound dressings, etc.)?
  - What wound dressings are effective for supporting healing of partial thickness pressure injuries?
  - What wound dressings are effective for supporting healing of full thickness pressure injuries?
  - What wound dressings are effective for pressure injuries with higher levels of exudate?

**15. Assessment and treatment of Infection and Biofilm**

- What are effective strategies for preventing, diagnosing and treating infection and biofilms that interfere with pressure injury healing?
  - What are accurate and effective methods to assess the presence of infection in a pressure injury?
  - What are the accurate and effective methods to assess the presence of biofilm in a pressure injury?
  - What is the role of topical agents in preventing and treating infection and/or biofilm?
  - What wound dressings are effective in reducing infection and/or biofilm?
  - How should biofilm be treated?
  - Are there any emerging treatments for preventing infection and/or biofilm?

**16. Biophysical Agents for Treatment of Pressure Ulcers/Injuries**

- What are effective biophysical agents for treating pressure injuries (e.g., electrical stimulation, ultrasound and negative pressure wound therapy etc.)?
  - Is electrical stimulation an effective intervention for treating pressure injuries?
  - Is electromagnetic field therapy an effective intervention for treating pressure injuries?
  - Is pulsed radio frequency energy an effective intervention for treating pressure injuries?
  - Is phototherapy an effective intervention for treating pressure injuries?
  - Is ultrasound therapy (low frequency, high frequency, non-touch) an effective intervention for treating pressure injuries?
  - Is sub-atmospheric therapy (e.g negative pressure wound therapy, suction, tension) an effective intervention for treating pressure injuries?
  - Is kinetic therapy (e.g. whirlpool, pulsatile lavage, vibration) an effective intervention for treating pressure injuries?
  - Is atmospheric therapy (e.g hyperbaric oxygen therapy, topical oxygen therapy) an effective intervention treating pressure injuries?
  - Are there other biophysical agents that are effective for treating pressure injuries?
  - Are any biophysical agents effective for preventing pressure injuries?
  - For biophysical agents that are effective for treating pressure injuries, what is the most effective regimen for use?

**17. Biological Dressings for Treatment of Pressure Ulcers/Injuries**

- What local pressure injury treatments are effective for supporting healing (i.e. cleansing, debridement, topical agents, wound dressings, etc.)?
  - What biological dressings are effective for supporting healing of pressure injuries?

**18. Growth Factors for Treatment of Pressure Ulcers/Injuries**

- What local pressure injury treatments are effective for supporting healing (i.e. cleansing, debridement, topical agents, wound dressings, etc.)?
  - What growth factors are effective for supporting healing of pressure injuries?

**19. Surgery for Treatment of Pressure Ulcers/Injuries**

- What strategies are effective in selecting, preparing and managing an individual for surgical interventions?
  - What indicators are appropriate for considering eligibility for surgical intervention for a pressure injury?
  - What preoperative interventions are effective for supporting the individual undergoing surgical intervention for a pressure injury?
  - What intraoperative interventions are effective for supporting the individual undergoing surgical intervention for a pressure injury?
  - What postoperative interventions are effective for supporting the individual undergoing surgical intervention for a pressure injury?
  - What interventions are effective for reducing recurrence of a pressure injury following surgical intervention?

**20. Individuals with Spinal Cord Injury**

- What are the unique pressure injury risk factors to consider for individuals with spinal cord injury?
- What are the unique pressure injury prevention strategies for individuals with spinal cord injury?
- What are the unique pressure injury treatment strategies for individuals with spinal cord injury?

**21. Individuals in the Operating Room**

- What are the unique pressure injury risk factors to consider for individuals in the operating room?
- What are the unique pressure injury prevention strategies for individuals in the operating room?
- What are the unique pressure injury treatment strategies for individuals in the operating room?

**22. Bariatric individuals**

- What are the unique pressure injury risk factors to consider for bariatric individuals?
- What are the unique pressure injury prevention strategies for bariatric individuals?
- What are the unique pressure injury treatment strategies for bariatric individuals?

**23. Neonates and children**

- What are the unique pressure injury risk factors to consider for neonates and children?
- What is a reliable and valid method of conducting a structured risk assessment for neonates and children?
- What are the unique pressure injury prevention strategies for neonates and children?
- What are the unique pressure injury treatment strategies for neonates and children?

**24. Individuals Receiving Palliative Care**

- What are the unique pressure injury risk factors to consider for individuals receiving palliative care?
- What are the unique pressure injury prevention strategies for individuals receiving palliative care?
- What are the unique pressure injury treatment strategies for individuals receiving palliative care?

**25. Individuals in Critical Care**

- What are the unique pressure injury risk factors to consider for individuals in critical care?
- What are the unique pressure injury prevention strategies for individuals in critical care?
- What are the unique pressure injury treatment strategies for individuals in critical care?

**25. Individuals in Community Settings**

- What are the unique pressure injury risk factors to consider for individuals in community settings?
- What are the unique pressure injury prevention strategies for individuals in community settings?
- What are the unique pressure injury treatment strategies for individuals in community settings?

**36. Implementation**

- What valid and reliable assessment methods are available to evaluate health professional knowledge of pressure injury prevention and treatment?
- What interventions/programs are effective in attaining sustained improvements in health professional knowledge of pressure injury prevention and treatment?
- What interventions/programs are effective in attaining sustained improvements in health professional competency in pressure injury prevention and treatment?

## APPENDIX 2: EVIDENCE TO DECISION FRAMEWORK

Evidence to Decision Frameworks are recommended by the GRADE team to facilitate reaching recommendation and determining their strength for intervention studies. The framework is used to summarize the benefits and risks, costs, feasibility and acceptability of an intervention to help the guideline development team reach decisions on recommendations. Table one provides an overview.

**Table one: Evidence to decision framework adapted from GRADE (Schünemann, Brozek et al., 2013)**

Criteria	Evaluation	Questions	Explanations
<b>Is there important uncertainty about how much people value the main outcomes?</b>	<ul style="list-style-type: none"> <li>○ Important uncertainty or variability</li> <li>○ Possibly important uncertainty or variability</li> <li>○ Probably no important uncertainty of variability</li> <li>○ No important uncertainty of variability</li> <li>○ No known undesirable</li> </ul>	<ul style="list-style-type: none"> <li>• <i>How much do those affected by the option value each of the outcomes in relation to the other outcomes (i.e. what is the relative importance of the outcomes)?</i></li> <li>• <i>Is there evidence to support those value judgements, or is there evidence of variability in those values that is large enough to lead to different decisions?</i></li> </ul>	The more likely it is that differences in values would lead to different decisions, the less likely it is that there will be a consensus that an option is a priority (or the more important it is likely to be to obtain evidence of the values of those affected by the option). Values in this context refer to the relative importance of the outcomes of interest (how much people value each of those outcomes). These values are sometimes called 'utility values'.
<b>What is the overall certainty of the evidence of effectiveness? (the likelihood that the effect will be substantially different from what the research found)</b>	<ul style="list-style-type: none"> <li>○ Very low</li> <li>○ Low</li> <li>○ Moderate</li> <li>○ High</li> </ul>	<i>What is the overall certainty of this evidence of effects, across all of the outcomes that are critical to making a decision?</i>	The less certain the evidence is for critical outcomes (those that are driving a recommendation), the less likely that an option should be recommended (or the more important it is likely to be to conduct a pilot study or impact evaluation, if it is recommended).
<b>How substantial are the desirable anticipated effects?</b>	<ul style="list-style-type: none"> <li>○ Substantial</li> <li>○ Probably substantial</li> <li>○ Probably not substantial</li> <li>○ Not substantial</li> <li>○ Unclear</li> </ul>	<i>How substantial (large) are the desirable anticipated effects (including health and other benefits) of the option (taking into account the severity or importance of the desirable consequences and the number of people affected)?</i>	The larger the benefit, the more likely it is that an option should be recommended.
<b>How substantial are the undesirable anticipated effects?</b>	<ul style="list-style-type: none"> <li>○ Substantial</li> <li>○ Probably substantial</li> <li>○ Probably not substantial</li> <li>○ Not substantial</li> <li>○ Unclear</li> </ul>	<i>How substantial (large) are the undesirable anticipated effects (including harms to health and other harms) of the option (taking into account the severity or</i>	The greater the harm, the less likely it is that an option should be recommended.

		<i>importance of the adverse effects and the number of people affected)?</i>	
<b>Do the desirable effects outweigh the undesirable effects?</b>	<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Uncertain <input type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies	<i>Are the desirable effects large relative to the undesirable effects?</i>	The larger the desirable effects in relation to the undesirable effects, taking into account the values of those affected (i.e. the relative value they attach to the desirable and undesirable outcomes) the more likely it is that an option should be recommended.
<b>How large are the resource requirements?</b>	<input type="radio"/> Substantial <input type="radio"/> Probably substantial <input type="radio"/> Probably not substantial <input type="radio"/> Not substantial <input type="radio"/> Unclear	<i>How large an investment of resources would the option require or save?</i>	The greater the cost, the less likely it is that an option should be a priority. Conversely, the greater the savings, the more likely it is that an option should be a priority.
<b>Is the option acceptable to key stakeholders?</b>	<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Uncertain <input type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies	<i>Are key stakeholders likely to find the option acceptable (given the relative importance they attach to the desirable and undesirable consequences of the option; the timing of the benefits, harms and costs; and their moral values)?</i>	<ul style="list-style-type: none"> <li>• The less acceptable an option is to key stakeholders, the less likely it is that it should be recommended, or if it is recommended, the more likely it is that the recommendation should include an implementation strategy to address concerns about acceptability.</li> <li>• Acceptability might reflect who benefits (or is harmed) and who pays (or saves); and when the benefits, adverse effects, and costs occur (and the discount rates of key stakeholders; e.g. politicians may have a high discount rate for anything that occurs beyond the next election). Unacceptability may be due to some stakeholders: <ul style="list-style-type: none"> <li>○ Not accepting the distribution of benefits, harms and costs</li> <li>○ Not accepting costs or undesirable effects in the short term for desirable effects (benefits) in the future</li> <li>○ Attaching more value (relative importance) to the undesirable consequences than to the desirable consequences or costs of an option (because of how they might be affected personally or because of their perceptions of the relative importance of consequences for others)</li> <li>○ Morally disapproving (i.e. in relationship to ethical principles such as autonomy,</li> </ul> </li> </ul>



			nonmaleficence, beneficence or justice)
<b>Is the option feasible to implement?</b>	<ul style="list-style-type: none"> <li><input type="radio"/> No</li> <li><input type="radio"/> Probably no</li> <li><input type="radio"/> Uncertain</li> <li><input type="radio"/> Probably yes</li> <li><input type="radio"/> Yes</li> <li><input type="radio"/> Varies</li> </ul>	<i>Can the option be accomplished or brought about?</i>	The less feasible (capable of being accomplished or brought about) an option is, the less likely it is that it should be recommended (i.e. the more barriers there are that would be difficult to overcome).

