Prevention and Treatment of Pressure Ulcers/Injuries: Methodology Protocol for the Clinical Practice Guideline (fourth edition)

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EUROPEAN PRESSURE ULCER ADVISORY PANEL

NPIAP℠ NATIONAL PRESSURE INJURY ADVISORY PANEL
Improving Patient Outcomes Through Education, Research and Public Policy

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In 2020, a Methodology Taskforce was established to review international guideline methodology and provide guidance on methods for the fourth edition of the Guideline. The methodology for the International Pressure Injury Guideline was revised with consideration to the methods used for previous editions, advances in the body of evidence on guideline methodology and current standards for guideline development with a focus on adherence to the GRADE methodology for guideline development. This revised protocol is made available to stakeholders on the guideline website throughout the guideline development period.

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CHAPTER ONE: PURPOSE, SCOPE AND AUDIENCE

Purpose

A joint Guideline Governance Group (GGG) with representatives from the National Pressure Injury Advisory Panel (NPIAP), the European Pressure Ulcer Advisory Panel (EPUAP) and the Pan Pacific Pressure Injury Alliance (PPPIA) will plan and deliver a clinical practice guideline through an international collaboration.

The international collaboration will include the three Member Organizations (the EPUAP, NPIAP and PPPIA) as well as representatives from other wound organizations from around the world that have an interest in pressure injury prevention and treatment, hereafter referred to as Associate Organizations.

The overall purpose of this international collaboration is to develop a fourth edition of *Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline* (first edition 2009, second edition 2014, third edition 2019; hereafter referred to as the International PI Guideline or the Guideline). Previous editions of the International PI Guideline contain evidence-based recommendations for the prevention and treatment of pressure injuries[1] (hereafter referred to as PIs) that could be used to guide decision making by health professionals and individuals throughout the world.

The purpose of this guideline is to make recommendations reflecting the current state of the science on the effectiveness of different interventions in preventing and treating PIs (Wieringa et al., 2018). The purpose of these recommendations is to guide the prevention and treatment of PIs through the application of evidence-based care to reduce variation and promote optimal outcomes for people with or at risk of PIs. Additionally, the Guideline will include recommendations on risk and skin assessment, assessment of PIs and the effectiveness of different implementation strategies used to promote evidence-based PI strategies.

Scope

The International PI Guideline will include background information on the etiology, risk factors for PIs, scope of the problem and geographic region-specific information on classification of PIs.

The International PI Guideline will include recommendations on:

- identifying individuals at risk of PIs,
- assessing the skin and tissues of individuals at risk of a PI,
- interventions to prevent PIs,[2]
- assessing PIs and the individual with a PI,
- interventions to treat PIs, and
- implementing evidence-based practice.

The processes included in this methodology document include those that will be used to develop and prioritize clinical questions that are relevant and highly desired by stakeholder groups. More specific details

[1] The term pressure injury is synonymous with the terms pressure ulcer and decubitus ulcer. Terminology varies in different geographic regions and is reflected in regional variations of the International Statistical Classifications of Diseases and Related Problems (ICD). World Health Organisation. (2019). *International Classification of Diseases (ICD) 11th Revision: The global standard for diagnostic information*. World Health Organisation,. https://icd.who.int/en). Whilst 'pressure ulcer' is the preferred term of the EPUAP and 'pressure injury' is the preferred term of the NPIAP and PPPIA; the three organizations have agreed to use the term pressure injury throughout the fourth edition of the International PI Guideline.

[2] Individuals with PIs are usually at risk of additional PIs; therefore, prevention of PIs focuses on both people who have never had a PI but are at risk, and on prevention of additional or recurring PIs for people who have experienced a PI.

of the areas/topics of interest and the specific clinical questions that will be addressed in the International PI Guideline will be determined by these processes.

The International PI Guideline will seek to include recommendations specific to special interest populations, where this is highly prioritized in the process of developing clinical questions and where appropriate research is available. Special interest populations that have been addressed in previous editions of the International PI Guideline include:

- individuals in the operating room,
- individuals receiving palliative care,
- individuals with spinal cord injury,
- elderly individuals,
- children and neonates,
- individuals in critical care settings,
- individuals in community settings, and
- individuals who are overweight or obese.

The International PI Guideline will include recommendations and guidance on implementation of the guideline in clinical settings, where this is highly prioritized in the process of developing clinical questions and where appropriate research is available. Implementation strategies covered in previous editions of the International PI Guideline include:

- monitoring PI incidence and prevalence,
- health professional and consumer education,
- facilitators and barriers to implementing the recommendations, and
- monitoring the implementation of this clinical guideline.

Target Audience

The International PI Guideline is intended for use by an international audience that includes:

- individuals with or at risk of PIs and their informal carers,
- health professionals involved in the care of individuals with or at risk of developing PIs regardless of their diagnosis or healthcare needs,
- academic educators and researchers with an interest in PIs,
- health policy makers, administrators and associated personnel at the government, organization and/or facility level,
- other stakeholders with an interest in evidence-based PI prevention and treatment.

The International PI Guideline is intended to be relevant to the above groups whether their interests relate to PI prevention and treatment care in acute/tertiary care settings, rehabilitation settings, long-term/residential care settings, primary care settings or community settings.

Within this document, these intended audience groups are often referred to as **stakeholders** because they have specific interest in the content and implementation of the final Guideline.

CHAPTER TWO: GUIDELINE METHODOLOGY

Introduction

With each new edition of the International PI Guideline, the methodology used for previous editions is critically reviewed by a Methodology Taskforce consisting of at least one representative from each of the Member Organizations and a methodologist to ensure the reliability, validity and integrity of the guideline development process. 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 of the guideline process and products and will require agreement by the Methodology Taskforce and approval of the EPUAP, NPIAP and PPPIA governing bodies.

The following chapter outlines the project processes and methodology that will be used for the fourth edition of the International PI Guideline. The methodology will be circulated to all participants in the guideline development process and will be published on the guideline website.

The methodology for this edition of the Guideline is revised from 2019 to ensure current international standards in guideline development are addressed and the rigorous guideline development is maintained.

This edition of the International PI Guideline will be developed using methodology that closely adheres to the current standards of guideline methodology (Brouwers et al., 2020; Jue et al., 2019; Schünemann et al., 2013; Schünemann et al., 2014). The GRADE methodology will be used for developing clinical questions; identifying, appraising and synthesizing relevant evidence; summarizing and evaluating the body of evidence; and for translating the body of evidence into recommendations. This process will be undertaken by an international Guideline Development Team, under the oversight of a Guideline Governance Group (GGG) representing the Member Organizations with ownership of the International PI Guideline.

Guideline Development Team

The guideline development will be undertaken by an international Guideline Development Team, with input from interested stakeholders (see *Figure 2.1*).

The Guideline Development Team is composed of:

- Guideline Governance Group (GGG) (oversight of the process),
- Methodologist,
- Core Review Group (review and appraisal of research literature),
- Panel Groups for various topical areas (formerly known as Small Working Groups [SWGs],
- Consumer Panel Group (panel group reviewing recommendations from a consumer perspective), and
- Associate Organizations.

All members of the Guideline Development Team will be screened for experience, expertise and potential conflicts of interest (COI) through an expression of interest and application process. In the interest of transparency, all members of the Guideline Development Team will be required to identify potential COI and their approximate value. A COI arises in any situation in which a Guideline Development Team member has a direct or indirect pecuniary or personal (e.g., academic advancement, community standing) interest in the content of the International PI Guideline; how evidence is appraised, synthesized and evaluated; or how recommendations and/or statements are framed.

Potential COI will be declared and managed based on an adapted version of the *Guidelines International Network Principles* (Schünemann et al., 2015). The processes for declaration and management of COI are presented in detail in *Chapter 6: Conflict of Interest Management*.

Figure 2.1 Structure of Guideline Development Team and Stakeholders

Member Organizations

This revision of the Guideline will be overseen by the Member Organizations: European Pressure Ulcer Advisory Panel (EPUAP), National Pressure Injury Advisory Panel (NPIAP) and the Pan Pacific Pressure Injury Alliance (PPPIA), which consists of the Hong Kong Enterostomal Therapist Society (HKETS), the New Zealand Wound Care Society (NZWCS), Wounds Australia and the Wound Healing Society of Singapore (WHSS). These organizations have chosen to be Member Organizations and receive membership benefits and rights to participate in the guideline development process through processes established in their Letter of Agreement.

Associate Organizations

Other international PI/wound organizations that share the mission, values and purposes of the GGG will be invited to apply to join the Guideline Development Team through designation as Associate Organizations. The purpose of Associate Organizations is to promote participation and international sharing of expertise from countries not currently represented within the Member Organizations.

Associate Organizations will be selected through an application process and acceptance by GGG vote. Associate Organizations do not have voting representatives on the GGG but participate through nomination of Panel Group Members (see below) to participate in the development process.

Further information about the roles, responsibilities and agreements with Associate Organizations is outline in *Appendix 1: Associate Organization Agreement*.

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 member of the GGG will have voting rights for decisions associated with the guideline development process. The GGG will consist of:

- four representatives appointed by the EPUAP, one of which will be selected as the EPUAP Chair,
- four representatives appointed by the NPIAP, one of which will be selected as the NPIAP Chair,
- four representatives appointed by the PPPIA, one of which will be selected as the PPPIA Chair, and
- one consumer representative, appointed by the above GGG members.

The above three Chairs have nominated one member to undertake the role of GGG Chair.

Guideline development will be an iterative process overseen by the GGG, with the GGG maintaining communication with the rest of the Guideline Development Team via the methodologist. A full description of the GGG role is available in *Chapter 3: Guideline Governance Group*.

Methodologist

The guideline process will be overseen by an experienced guideline methodologist. The methodologist will assist the Guideline Development Team in implementing the documented methodology, appraising and summarizing the new literature, compiling evidence, evaluating the body of evidence and reaching recommendations. The methodologist provides a link between all the groups that make up the Guideline Development Team, undertakes the database searches; identifies relevant literature; participates in critical appraisal, data extraction and analysis; undertakes editorial and medical writing; co-ordinates the Review Team and Panel Groups and acts as a project manager to ensure the guideline work remains on-track and consistent with the documented processes.

Core Review Group

The Guideline Development Team will include a Core Review Group (CRG) that will be responsible for the core work of appraising and analyzing the evidence. The CRG members will include the methodologist, nominated members of the GGG and other appropriately qualified individuals appointed by the GGG. The CRG will:

- critically appraise the identified research for each clinical question,
- compile the Summary of Findings (SoF) tables (see *Appendix 2*),
- compile the Evidence to Decision (EtD) frameworks (see *Appendix 3*),
- develop draft recommendations and good practice statements, and
- suggest implementation considerations arising from the evidence.

The methodologist will coordinate the CRG work by delegating appraisals to CRG members, monitoring inter-rater reliability and organizing CRG meetings as required. The CRG work will be undertaken using:

- project specific software to coordinate critical appraisal and data extraction,
- Revman software to undertake meta-analysis as required,
- GRADEPro software to compile SoF tables and EtD frameworks, and
- GRADEPro software to coordinate consensus voting, decision-making and drafting recommendations.

A full description of the CRG is available in *Chapter 4: Core Review Group and Panel Groups*.

Panel Groups

The Guideline Development Team will include Panel Groups consisting of Panel Group Members (PGMs) who will represent Member and Associate Organizations. The PGMs will be selected based on experience and expertise. Representatives of industry will be ineligible.

Panel Groups will be formed based on the principle of equal contribution from the Member Organizations, representation from at least one Associate Organization, and where possible will include PGMs from a range of different clinical disciplines and settings, as well as representatives from the academic and education sectors.

The Panel Groups will be based around the clinical questions/guideline topics. The PGMs will primarily be responsible for ensuring that the recommendations, implementation considerations and guideline content are appropriate and sufficiently comprehensive for international health professionals to implement in clinical practice. The PGMs will:

- review EtD frameworks (see *Appendix 3)* for comprehensiveness, clarity and appropriate ratings,
- review draft recommendations, good practice statements and implementation considerations for clarity, appropriateness and relevance to clinical practice,
- identify any gaps in the area of practice covered by recommendations that might be addressed through

good practice statements that have not emerged from the evidence review, and
- draft additional good practice statements and implementation considerations based on evidence from study designs not considered in the GRADE process and from clinical expertise.

A full description of the Panel Groups is available in *Chapter 4: Core Review Group and Panel Groups*.

Patient Consumers and Informal Carers

International standards for guideline development recommend involvement of consumer representatives in key structures and components of the guideline development process (Schünemann et al., 2014). Consistent with recommendations on promoting consumer participation in guideline development (Armstrong et al., 2017; Patient-Centered Outcomes Research Institute (PCORI), 2015b; Qaseem et al., 2012), strategies will be implemented to collect stakeholder opinions and promote active patient and informal carer involvement.

Consumers (patients and informal carers) will be engaged in the development of the fourth edition of the International PI Guideline in three ways:
- an international, open-invitation Stakeholder Survey (see *Appendix 4*) to collect data to assist in clinical question development and evaluation of evidence,
- a consumer representative role established on the GGG, and
- formation of a Consumer Panel Group.

At commencement of the project, an international Stakeholder Survey that includes patient consumers and their informal carers will be undertaken. The Stakeholder Survey will be used to collect data on priorities for topics to be included in the International PI Guideline. Additionally, the survey will canvas the opinion of stakeholders on the importance of different clinical outcomes. This data will be used by the GGG to develop the clinical questions. The data will also be used in the development of EtD frameworks and for evaluating the body of evidence. The Stakeholder Survey methods are reported in *Appendix 4*, and the use of the data is reported in more detail throughout this protocol.

A consumer representative will be appointed to the GGG and involved in reviewing decisions about the guideline content at the highest level. A description of the work to be undertaken by the GGG consumer representative is available in *Chapter 5: Consumer Participation*.

A consumer Panel Group will be established to contribute to the evaluation of the body of evidence during the drafting phase. Member Organizations will recruit and nominate patient consumers and informal carers from their geographic region. A full description of the work to be undertaken the consumer Panel Group is available in *Chapter 5: Consumer Participation.*

Stakeholders

A stakeholder is someone who has interest in PIs and wishes to provide input into the International PI Guideline by participating in opportunities to provide opinion and feedback. Anyone may register as a stakeholder, either as an individual or as a representative for a society/organization and anyone who is eligible can participate in stakeholder surveys undertaken in conjunction with the development and implementation of the International PI Guideline. The primary processes for formal involvement of stakeholders are participation in:
- an international, open-invitation survey for all stakeholders (i.e., patients, informal carers, health professionals, academics, researchers, policy makers, industry representatives, etc.) undertaken in the guideline planning phases (see *Appendix 4*), and
- the stakeholder feedback process undertaken after the draft guideline is prepared.

Methods

The fourth edition of the International PI Guideline will be undertaken using GRADE methodology, as outlined in detail in the GRADE Handbook (Schünemann et al., 2013). The GRADE approach to guideline development is the gold standard for international guidelines because it addresses and includes (Granholm et al., 2019; Schünemann et al., 2013):
- clear delineation of confidence in the estimates and the final strength of recommendation,

- explicit and transparent ways in which evidence is downgraded or upgraded,
- a transparent pathway from evidence to recommendations,
- factors of importance to stakeholders, including values and preferences, and
- clear interpretation of strong versus weak recommendations.

The steps for the guideline development process are broadly 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 across and between groups within the Guideline Development Team and from stakeholders. The GRADE Handbook should be referred to for more detailed descriptions and guidance about the processes and evaluations that are performed throughout guideline development (Schünemann et al., 2013).

Aspects of the guideline development will be conducted using the GRADEPro software, and the GRADEPro GDT Handbook contains guidance on the following aspects of the process that can be performed in GRADEPro.

Developing the Clinical Questions

Consistent with the GRADE methodology (Schünemann et al., 2013), the GGG will develop clinical questions using the PICOT format (see Table 2.1).

Table 2.1: PICOT format for clinical questions (Fineout-Overholt, 2006; Gallagher Ford, 2019; Ryan et al., 2019; Schünemann et al., 2013)

Component		General description	Application to International PI Guideline
P	Patient population/ disease	The patient population or disease of interest, for example: • Demographics: Age/gender/ethnicity • With specific co-morbidities/clinical conditions • Cared for in specific clinical settings	**Prevention** • Populations at risk of PIs • Specific population sub-groups based on age, clinical characteristics and/or clinical setting, where this is likely to be of significance to the estimates of effect **Treatment** • Populations with an existing PI • Specific population sub-groups based on age, clinical characteristics and/or clinical setting, where this is likely to be of significance to the estimates of effect
I	Intervention or issue of interest	The intervention or range of interventions of interest, for example: • Intervention: Intervention/therapy • Diagnosis and prognosis: Prognostic factor, clinical condition or risk factor • Etiology: Clinical condition	**Prevention** Interventions considered to be of priority that are designed to prevent a PI **Treatment** Interventions considered to be of priority that are designed to treat a PI
C	Comparison intervention or issue of interest	What you want to compare the intervention or issue against, for example: • Intervention: Alternative intervention/therapy, placebo, or no intervention/therapy • Diagnosis and prognosis: Prognostic factor, absence of clinical condition or risk factor • Etiology: Absence of clinical condition	**Prevention and treatment** • Gold standard treatment (where one is exists) • Placebo, standard care, no intervention or comparator interventions, as defined a-priori
O	Outcome	Outcome of interest, for example: • Intervention: Outcome expected from therapy/ intervention • Risk of disease • Accuracy of diagnosis • Rate of occurrence of adverse outcome	**Prevention** • Development of any PI • Other clinical outcomes as defined a-priori and identified in the core outcome set produced by the OUTPUTs study (Lechner et al., 2022) (see *Appendix 5*)

Component		General description	Application to International PI Guideline
			Treatment • Complete healing of a PI • Other clinical outcomes, as defined a-priori and informed by a-priori stakeholder survey.
T	Time	The time involved to demonstrate an outcome, for example: • Intervention: The time taken for the intervention to achieve outcome • Etiology and prognosis: The time over which populations are observed for outcome to occur	**Prevention and treatment** • Determined as relevant to the outcome of interest

To inform the development of the clinical questions, the GGG Chairs and methodologist will undertake a Stakeholder Survey (see *Appendix 4*). The purpose of this survey will be to ascertain the relative priority of specific interventions to stakeholders in order to both inform the development of the clinical questions and to provide data to assist in the priority evaluation included on EtD frameworks (see *Appendix 3*) (Ryan et al., 2019; Schünemann et al., 2013). As noted in *Appendix 4,* stakeholders will also be asked to rank the level of importance they place on various clinical outcomes associated with PI treatments when making decisions related to use or otherwise of interventions. This data will be used in conjunction with previous work undertaken to produce a core outcome set of clinical outcomes (the OUTPUTs study) associated with prevention of PIs (Lechner et al., 2022; Lechner et al., 2019; Lechner et al., 2021) (see *Appendix 5*).

After reviewing the findings from the stakeholder survey, the GGG members will themselves rank the clinical questions and clinical outcomes using the scale identified in *Appendix 4.* In their ranking of the priority of clinical questions, the GGG members will pragmatically consider:

- perspectives of the stakeholder groups who provided feedback in the stakeholder survey,
- the scope of the International PI Guideline,
- clinical priority of areas covered by the International PI Guideline,
- the evidence base available to respond to clinical questions, and
- feasibility of the project.

Consistent with GRADE methodology (Schünemann et al., 2013), the above data will be used by the GGG to produce a preliminary list of clinical questions and a hierarchy of clinical outcomes per clinical question, with specific consideration given to clinical outcomes ranked as critical and/or important by the GGG and stakeholders (Schünemann et al., 2013). This information will be used to undertake the PICOT-based searches of the PI literature database (see below).

<u>Clinical questions for diagnostic/prognostic tests and tools</u>

The PICOT format discussed above will be used for clinical questions related to diagnostic tests (e.g., PI assessment). Consistent with GRADE methods, the purpose of the test will be established (e.g., establishing a diagnosis, predicting prognosis or monitoring treatment response). In general, the comparator should be "gold standard" or the "reference standard" (current best practice) (Schünemann et al., 2013).

<u>Relative importance of clinical outcomes</u>

Relative importance of clinical outcomes will be re-evaluated throughout the project. As this guideline development is an iterative process, additional clinical outcomes may be addressed if critical information becomes available during the review of the evidence (e.g., adverse effects that were not considered a-priori to the evidence review) (Schünemann et al., 2013; Schünemann et al., 2014).

The information attained from the Stakeholder Survey (PI treatment outcomes) and the OUTPUTs study (PI prevention outcomes) will inform the evaluations made when completing the EtD frameworks. In this process, the relative importance of clinical outcomes will be reassessed by the CRG, after reviewing the evidence to ensure that important outcomes identified in the evidence review have been identified for

consideration. The Panel Groups will be responsible for evaluating the importance of the clinical outcomes presented in the SoF tables, and for informing the methodologist if the importance of a clinical outcome requires re-evaluation in the context of the intervention and in the context of balancing desirable versus undesirable outcomes (Schünemann et al., 2013).

Consistent with GRADE methods, only outcomes considered critical (rated 7-9) will be used to determine the overall quality of evidence supporting a recommendation, because these are the primary factors influencing a recommendation (Schünemann et al., 2013). For prevention interventions, only outcomes identified in the core outcome set produced by the OUTPUTS study will be considered (Lechner et al., 2022).

Identifying the Evidence

To identify the scientific literature on PI prevention and treatment, the following electronic databases will be searched by the methodologist:

- 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 new search dates for the fourth edition update will be 01 September 2018 through 31 August 2023. New papers may be considered through 1 January 2024 if they provide new information relevant to the Guideline. Only evidence published in English will be eligible for inclusion.

Identification of literature relevant to pressure injuries

A sensitive search strategy has been used for previous editions of the International PI guideline to identify literature relevant to the assessment, prevention and treatment of PIs, and factors influencing the implementation of PI initiatives.

In the first instance, this search will be conducted to maintain a database of PI literature that is potentially relevant to the clinical questions, implication considerations, any narrative discussion and education resources. The identified literature will be screened against the inclusion and exclusion criteria below.

Inclusion criteria:

- Articles must be primarily focused on PI prevention, risk assessment, PI assessment, PI treatment, or implementation considerations for PI initiatives,
- Studies conducted in participants with different types of wounds must either report clinical outcomes for PIs independently, or at least 80% of the population (Institute for Quality and Efficiency in Health Care (IQWiG), 2022) must have a PI.
- Articles must have been published in a peer-reviewed journal in English.
- Other clinical guidelines and consensus documents from reputable sources (e.g., wound organizations).
- Qualitative research.

Exclusion criteria:

- Articles without a substantial focus on PI prevention or treatment.
- Case series with less than ten participants.
- Conference abstracts or other short papers with insufficient detail to enable an appraisal of the study methodology.
- Case studies.
- Editorials and letters.
- Duplicate reports of research.
- Computational modeling and other research conducted in non-human subjects.
- Non-systematic literature reviews and systematic reviews/meta-analyses that do not include a critical

appraisal of the included studies.
- Narrative/discussion papers.

These PI-relevant sources of evidence will be combined with the PI-relevant sources of evidence identified in the searches for previous editions of the International PI Guideline to create a comprehensive PI source library. Sensitive search strategies will identify most relevant studies. Researchers may also submit their studies for consideration with the understanding that the inclusion-exclusion criteria listed above apply and the submitted study will be appraised using the same criteria as all other studies considered by the Guideline Development Team.

Identification of literature relevant to clinical questions (PICOT-specific searches)

The above database will be searched using terms relevant to each PICOT question. Search terms used for identifying literature relevant to specific interventions from the previous editions of the International PI Guideline will be considered. Identified literature will be hand-screened for relevance to comparator interventions, clinical outcomes and follow-up periods.

These sources of evidence will be categorized based on the study design, to establish the body of evidence potentially relevant each the clinical question.

Selecting the Evidence

Consistent with GRADE methodology, evidence-based recommendations will be made on the best available evidence that provides effects estimates (Foroutan et al., 2020; Schünemann et al., 2013). GRADE methodology specifies that:

> A guideline panel can use already existing high quality systematic reviews or conduct its own systematic review depending on the specific circumstances such as availability of high quality systematic reviews and resources, but **GRADE recommends that systematic reviews should form the basis for making health care recommendations** (Schünemann et al., 2013).

Although published systematic reviews are preferred, modifications have been made in the Methodology to complete additional systematic reviews and meta-analyses using available primary studies and consider primary studies for priority clinical questions not answered by systematic reviews. Based on the underpinning principle of the GRADE methods (Schünemann et al., 2013), evidence for each clinical question will be selected using the hierarchy outlined in Table 2.2 Where evidence meeting the criteria at a higher tier has been identified for inclusion, evidence at lower tiers will not be considered for inclusion (excepting the situations specified in Table 2.2). GRADE methods, including selection of study designs, are applicable to intervention studies, but are also recommended for addressing diagnostic and prognostic clinical questions (Foroutan et al., 2020; Schünemann et al., 2013; Schünemann et al., 2020).

Studies on diagnostic validity of PI classification and various assessments associated with PIs form an important body of knowledge in PI management that should be appraised independently from intervention studies. The clinical effectiveness of diagnostic test procedures can only be adequately investigated by diagnostic RCTs (Merlin et al., 2009; Schünemann et al., 2008), meta-analyses of which form best available evidence on which to make recommendations (Schünemann et al., 2013).

Table 2.2: Evidence tiers

Tier	Evidence type (Intervention studies)	Comments (including Management of >1 evidence source from the Tier)
Note: Where evidence meeting the criteria at a higher tier has been identified for inclusion, evidence at lower tiers will not be considered for inclusion as a basis for recommendations but may be considered to support implementation considerations (excluding exceptions as noted in the comments).		
1	Systematic review with a meta-analysis that: • Meets all PICOT elements of the clinical question of interest • Meets all the following critical domains of the AMSTAR	Where more than one systematic review addressing a clinical question meets the criteria for inclusion, the following steps will be taken: • Evaluate whether there is overlap of primary

Tier	Evidence type (Intervention studies)	Comments (including Management of >1 evidence source from the Tier)
	2 tool (Shea et al., 2017): ○ Adequate literature search has been conducted (as defined in the supplementary notes of the AMSTAR 2 tool) ○ Includes a risk of bias assessment of the individual studies included in the review (using a recognized tool that includes primary components of the Cochrane RoB tools) ○ Consideration of the risk of bias is made when interpreting the review results ○ Assessment of presence and likely impact of publication bias, or comment on why this was not undertaken • Provides effect estimates based on appropriate meta-analytical methods or sufficient endpoint data (event rates and effect measures) from included primary studies that allow incorporation into quantitative synthesis of effect estimates.	studies included between the reviews • If there is no overlap, conduct an overview of reviews using Cochrane methods (Pollock et al., 2022) • If there is overlap of primary studies between the reviews, the CRG should select one meta-analysis to use based on (Pollock et al., 2022): ○ Prioritizing Cochrane reviews ○ Prioritizing the most recent review ○ Prioritizing the "most relevant" review ○ Prioritizing the "most comprehensive" review • Alternatively, where the CRG determine that none of the identified reviews adequately reflects the best available evidence from primary studies, the CRG may choose to select tier 2 evidence.
2	Systematic review without meta-analyses that: • Meets all PICOT elements of the clinical question of interest • Meets the critical domains of the AMSTAR 2 tool (Shea et al., 2017) as listed above. • Reports critical appraisal results for the included studies	• A meta-analysis should be conducted of the studies identified in systematic reviews that include the same/comparable clinical outcomes using Cochrane methods, with consideration to over-lap as discussed above. • In addition to studies reported in systematic reviews, additional primary research (see Tier 3) that meets inclusion criteria and has been published after the systematic review search date will also be considered for inclusion in the meta-analysis. • Statistical heterogeneity or clinical or methodological diversity will not be considered a barrier to conducting a meta-analysis because the GRADE determinants of certainty of the evidence (e.g., inconsistency) allow for a qualitative consideration of heterogeneity. • Where there is incompletely reported outcome or effect estimates, or the studies report different effect measures, the CRG will follow methods outlined by the Cochrane Group to calculate or transform effect estimates.(McKenzie & Brennan, 2022) • Where the provided data in systematic reviews is inadequate to undertake the meta-analysis, the primary research should be accessed (while utilizing the critical appraisal published in the existing systematic reviews).
3	Primary research that: • Meets all PICOT elements of the clinical question of interest • Uses one of the following designs (Cochrane Effective Practice and Organisation of Care (EPOC), 2017): ○ **3A** Randomized controlled trials (RCTs) ○ **3B** Prospective controlled clinical trials (CCTs)	Multiple identified primary research studies should be combined in meta-analysis using Cochrane methods when possible (see comments under Tier 2). When criteria in Tiers 1 through 3 have not been met and the PICOT question has not been

Tier	Evidence type (Intervention studies)	Comments (including Management of >1 evidence source from the Tier)
	○ **3C** Controlled before-after study ○ **3C** Interrupted-time series study with at least three data points each before and after the intervention ○ **3C** Repeated measures study with at least three data points each before and after the intervention ○ **3C** Other study designs that include groups defined by interventions that provide an effect estimate (e.g., prospective cohort study, retrospective cohort study, and non-concurrent cohort study) • Provides effect estimates in sufficient detail to include (or to calculate for inclusion) in a meta-analysis. • Be published after the publication period covered by eligible systematic reviews (Tier 2) and meets the eligible systematic review inclusion criteria.	adequately addressed, primary research studies that address the PICOT question will be summarized to inform stakeholders of the current state of the science and encourage future research to support the efficacy of potentially promising innovations. In the absence of quality systematic reviews, primary studies may be considered to support recommendations based on the level and quality of primary study evidence. Search strategies are designed to produce a comprehensive PI library that will include Tier 3 studies. To ensure transparency, reasons for the exclusion of any study (including Tier 3) will be documented.

Tier	Evidence type (diagnostic studies)
Note: Where evidence meeting the criteria at a higher tier has been identified for inclusion, evidence at lower tiers will not be considered for inclusion as a basis for recommendations but may be considered to support implementation considerations.	
1	Systematic review with a meta-analysis that: • Meets all elements of the clinical question of interest • Provides estimates based on appropriate meta-analytical methods from included primary studies
2	Systematic review without meta-analyses that: • Meets all elements of the clinical question of interest • Report meeting all elements of a systematic review
3	Primary research that: • Meets all elements of the clinical question of interest • Uses one of the following designs: ○ **3A** Direct, blinded comparative study (cross sectional or cohort) comparing index and reference tests ○ **3B** Comparative study (cross sectional or cohort) comparing index and reference tests • Provides estimates of sensitivity and specificity in sufficient detail to pool results. • Be published after the publication period covered by eligible systematic reviews (Tier 2) and meets the eligible systematic review inclusion criteria.

Tier	Evidence type (prognostic studies)
Note: Where evidence meeting the criteria at a higher tier has been identified for inclusion, evidence at lower tiers will not be considered for inclusion as a basis for recommendations but may be considered to support implementation considerations.	
1	Systematic review with a meta-analysis that: • Meets all elements of the clinical question of interest • Provides estimates based on appropriate meta-analytical methods from included primary studies
2	Systematic review without meta-analyses that: • Meets all elements of the clinical question of interest • Reports critical appraisal results for the included studies
3	Primary research that: • Meets all elements of the clinical question of interest • Uses one of the following designs: ○ **3A** Longitudinal, prospective cohort study ○ **3B** Prognostic factor analysis in untreated arm in an RCT (or the entire RCT cohort with adjustment for intervention) ○ **3C** Retrospective cohort study • Provides estimates in sufficient detail to include in a meta-analysis. • Be published after the publication period covered by eligible systematic reviews (Tier 2) and meets the eligible systematic review inclusion criteria.

Selecting additional supporting evidence

Other forms of evidence (e.g., observational studies using designs not eligible for inclusion, other clinical guidelines, qualitative research, etc.) will be eligible for inclusion to support:

- additional judgments on the EtD framework (e.g., resource requirements, health inequalities, acceptability to stakeholders and feasibility),
- good practice statements,
- implementation considerations, and
- research priorities.

This evidence will not be critically appraised. It is acknowledged that some of these types of evidence are subject to internal and external bias by nature of the research designs used. However, these forms of evidence often provide unique sources of clinical information that are relevant for consideration regardless of their score on a critical appraisal tool.

Addressing Risk Factors for Pressure Injuries and Their Assessment

Both the 2014 and the 2019 editions of the International Guideline included comprehensive evaluations of the evidence on patient characteristics that increase the probability of PI development. These editions both extended a systematic review by Coleman et al. (2013) on PI risk factors. In both the 2014 and 2019 editions of the International PI Guideline, the reliability and validity of the more commonly used PI risk assessment scales were reported based on data from prospective studies.

Prognostic factor research evaluating specific risk factors are useful for building (and testing) prognostic models and tools for PI risk, and for developing interventions to address modifiable factors (Foroutan et al., 2020; Riley et al., 2013; Steyerberg et al., 2013). Prognostic models (e.g., PI risk assessment tool scores) are used to predict the probability of future events in individuals or groups (Altman et al., 2009; Foroutan et al., 2020). Clinically, risk assessment is used as a basis for risk-based prevention, making the true prognostic value of the test less meaningful. As noted above, diagnostic accuracy studies are those in which results of index tests are compared with results from reference standards at the same point in time (Bossuyt et al., 2003; Schünemann et al., 2013). Most studies in PI risk research are not classic diagnostic accuracy studies, because the measured PI risk is often compared with subsequent PI occurrence. However, these designs resemble those of prognostic studies or diagnostic accuracy studies with imperfect reference standards (Rutjes et al., 2007). The Methodology Taskforce developing this methodology protocol consider that the evidence on patient-specific risk factors has been comprehensively addressed in the previous editions of the Guideline, in systematic reviews, and in studies using the best possible research designs. There is little practical value in re-examining prospective studies identifying risk factors for different populations, particularly when it is well established than many risk factors are non-modifiable. There is also little practical value in conducting predictive validity analysis of risk assessment scales when it is acknowledged that such scales are neither predictive nor diagnostic of PIs. Therefore, the clinical questions for the fourth edition of the International PI Guideline will focus on the effectiveness of strategies to identify and mitigate modifiable risk factors.

Evaluating the Evidence

The methodological quality of each study will be evaluated by two members of the CRG. Where discrepancy in opinion is noted, the reviewers will discuss the appraisal and reach agreement. If agreement cannot be reached a third reviewer will evaluate the paper.

The methodological quality of each study will be assessed using recognized tools that evaluate the internal and external validity of the studies. The following broad criteria will be considered for intervention studies: 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 to be used, as recommended by GRADE methods (Foroutan et al., 2020; Schünemann et al., 2013), are listed in Table 2.3.

Table 2.3: Critical appraisal tools

Study design	Tool	Access to tool
Systematic reviews	AMSTAR 2 (Shea et al., 2017)	http://www.bmj.com/content/bmj/suppl/2017/09/21/bmj.j4008.DC1/sheb036104.wf1.pdf
Randomized trials	Cochrane RoB 2 (Sterne et al., 2019)	https://sites.google.com/site/riskofbiastool/welcome/rob-2-0-tool/current-version-of-rob-2
Non-randomized studies Quasi-randomized trials Controlled clinical trials Cohort studies Controlled before-after study Interrupted-time series study Repeated measures study	ROBINS-I (Sterne et al., 2016)	https://sites.google.com/site/riskofbiastool/welcome/home/current-version-of-robins-i
Diagnostic accuracy studies	QUADAS-2 (Whiting et al., 2011)	https://www.bristol.ac.uk/media-library/sites/quadas/migrated/documents/quadas2.pdf
Prognostic studies	QUIPS checklist (Hayden et al., 2013)	https://www.ncbi.nlm.nih.gov/pubmed/?term=23420236

Data extraction and synthesis

Included references will be obtained and made available to the Core Review Group for conducting data extraction and data synthesis. 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 in the form of effects estimates; and limitations.

Meta-analysis will be performed by the Core Review Group using RevMan software and the findings will be imported into GRADEPro software into SoF tables (see *Appendix 2*).

Studies that the Core Review Group appraise as not meeting inclusion criteria for the evidence-based recommendations will be re-considered by the Panel Groups for supporting good practice statements and implementation considerations.

Evaluating the certainty of evidence

The CRG will then evaluate the forest plots and SoF tables using GRADE methods to determine the GRADE Certainty of Evidence (CoE). Consideration will be given to the following categories when coming to a decision on the CoE:

- risk of bias,
- inconsistency,
- indirectness,
- imprecision,
- publication bias,
- magnitude of effect,
- opposing plausible residual bias or confounding, and
- dose-dependent gradient.

Judgments about the above characteristics will lead to decreasing or increasing the CoE consistent with the GRADE principles are summarized in Figure 2.2. Full descriptions on the considerations related to each of the categories above is included in the GRADE Handbook (Schünemann et al., 2013) and should be referred to ensure the CoE is determined in a consistent manner. Confidence in the body of evidence will be increased or decreased using the GRADE principles detailed in Figure 2.3 to determine a final CoE. The final outcome of the evaluation will be summarized on the EtD framework (see *Appendix 3)*. At least three members of CRG

will review the SoF table and EtD framework for each clinical question and reach consensus on the representation of the body of evidence before the content is reviewed and refined by the Panel Groups.

Figure 2.2: GRADE Certainty of Evidence evaluation (JBI Adelaide GRADE Centre, 2021)

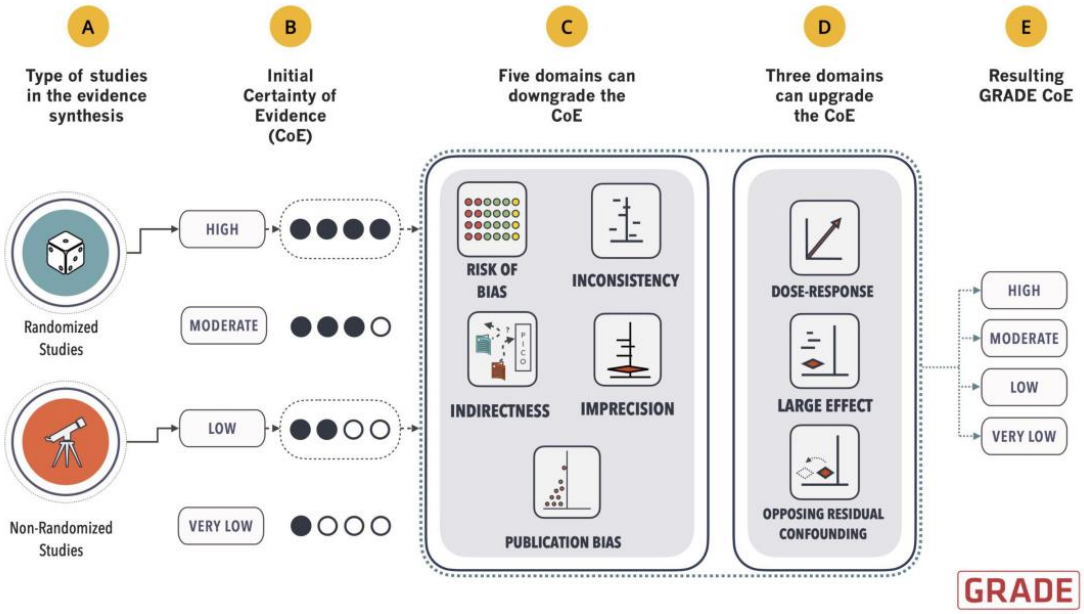
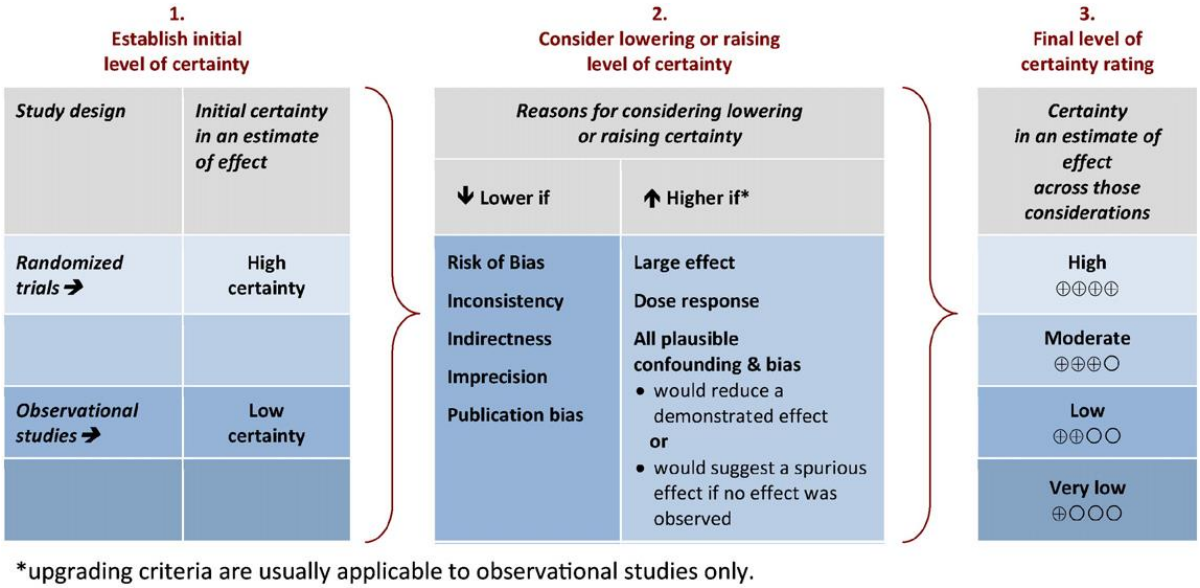


Figure 2.3: GRADE approach to developing Certainty of Evidence ratings across body of evidence (Morgan et al., 2016)



This process will determine the grade of the body of evidence relevant to a specific clinical outcome. The grade given to the evidence reflects the extent of confidence the Guideline Development Team has that an estimate of the effect is adequate to support a particular recommendation (see Table 2.4).

Table 2.4: GRADE quality of evidence grades (Schünemann et al., 2013)

Grade	Definition
High	We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate	We are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low	Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very Low	We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Completing Evidence to Decision (EtD) Frameworks

GRADE EtD frameworks will be used by the Guideline Development Team to consider the quality of a full body of evidence, noting that this may include different clinical outcomes, each of which may have a different CoE (Alonso-Coello, Oxman, et al., 2016; Alonso-Coello, Schünemann, et al., 2016; Schünemann et al., 2013). The EtD framework for each clinical question includes:

- level of consensus on the value that stakeholders place on the potential benefit of an intervention (i.e., the clinical outcome), noting that this evaluation will be informed by the data from the stakeholder survey and previously collected by the OUTPUTs trial, as well as iterative discussion by the Panel Groups and GGG,
- benefits and risks (as detailed in the SoF tables),
- financial costs, as available in the identified evidence, and
- feasibility and acceptability of an intervention to stakeholders, as available in the identified evidence, as well as iterative discussion by the Panel Groups and GGG.

These consideration are discussed in detail in the GRADE Handbook (Schünemann et al., 2013).

Developing Recommendations and Practice Guidance

Evidence-based recommendations

Based on the identified, appraised and summarized empirical evidence recommendations will be formed. Each Panel Group will formulate conclusions about the body of available evidence based on the SoF tables and EtD frameworks.

After completing the SoF table and the EtD framework, the CRG will discuss the quality of evidence and the balance between different factors as listed above to draft a recommendation addressing the clinical question. The GRADE process defines two strengths of recommendation: strong and weak. Recommendations can be strongly or weakly FOR or AGAINST certain action. Finally, there is a fifth option for making no recommendation; however, GRADE methods suggest this option be used infrequently (Schünemann et al., 2013). For example, the Guideline Development Team may conclude no recommendation could be made when (Schünemann et al., 2013):

- confidence in effect estimates is very low and the recommendation is speculative,
- trade-offs are very closely balanced; values, preferences and resource implications are variable or unknown, or
- two management options achieve very different undesirable consequences and individual preference is likely to be highly varied.

Strong recommendations indicate confidence in the desirable effect outweighing undesirable effects (or for a strong recommendation against doing something, confidence the undesirable effects outweigh the desirable effects). Weak recommendations indicate that there is a likely net-benefit (or net-harm) that may not be appropriate for all individuals (Schünemann et al., 2013). The implications are summarized in Table 2.5.

Draft recommendations will be developed by the CRG and then reviewed by the Panel Groups to attain an overall consensus on the recommendation and its strength. To ensure uniformity and internal consistency in the final Guideline:

- 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.
- Each recommendation should be written in a way that indicates its strength (strong or weak), as per the examples in Table 2.5 (Schünemann et al., 2013).
- Recommendations should be simple, short, declarative statements, free of jargon.
- Break up multiple thoughts into multiple recommendations, good practice statements or implementation considerations.
- Throughout the EtD framework, 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.
    - Consider the relevance of the recommendation for specific subset of individuals.
- Include cost and resource implications when appropriate.
- Consider feasibility of implementing recommendations. This may vary widely between healthcare systems. Data from the stakeholder survey will contribute to this evaluation.

Table 2.5: Five types of recommendations (Alonso-Coello, Oxman, et al., 2016; Alonso-Coello, Schünemann, et al., 2016; Atkins et al., 2004; Guyatt et al., 2008; Jaeschke et al., 2008***)***

Recommendation		Description	Implications	Language (examples)
Do it Strong recommendation for an intervention	↑↑	Indicates a judgment that most well informed people would make.	For patient consumers Most people would want the recommended course of action and only a small proportion would not. For health professionals Most people should receive the intervention. If health professionals choose not to follow the recommendation, they should document their rationale. For quality monitors Adherence to this recommendation could be used as a quality criterion or performance indicator.	Clear statement indicating the Guideline Development Team believe an intervention should be offered when relevant to the individual: • We recommend…. • Health professionals should…
Don't do it Strong recommendation against an intervention	↓↓			Clear statement indicating the Guideline Development Team do not believe an intervention should be offered: • We recommend against… • Health professionals should not….
Probably do it Conditional recommendation for using an intervention	↑?	Indicates a judgment that a majority of well-informed people would make, but a substantial minority would not.	For patient consumers: Most people would want the suggested course of action, but many would not. For health professionals: Examine, and be prepared to discuss, the evidence with patients, as well as their values and preferences. For monitoring of quality: Discussion and consideration of pros and cons of the intervention, and documentation of discussion with individuals by health professionals could be used as a quality indicator.	Statement indicating the Guideline Development Team believe an intervention might be offered in some situations or to some individuals: • We suggest… • Health professionals might… • We conditionally recommend… • We make a qualified recommendation that,,,
Probably don't do it Conditional recommendation against using an intervention	↓?			Statement indicating the Guideline Development Team believe an intervention will generally not be appropriate for most situations or individuals: • We suggest not… • We conditionally recommend… • We make a qualified recommendation that…
No specific recommendation		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.	Clear statement indicating the Guideline Development Team makes no recommendation. • We make no suggestion on…

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 Panel Group.

Following completion of the individual recommendations, the GGG and the methodologist and 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.

Good practice statements

A good practice statement is a clinical recommendation that describes practice for which there is a high level of certainty that the practices will do more good than harm but for which there is not a substantial body of direct evidence (Tugwell & Knottnerus, 2015). Consistent with GRADE methods, the Guideline Development Team will propose good practice statements when there is compelling indirect evidence or linked evidence from indirect comparisons that strongly indicate that the recommended practice would achieve benefits for individuals with or at risk of PIs. A good practice statement is appropriate when (Guyatt et al., 2016; Tugwell & Knottnerus, 2015):

- there are no randomized trials or observational studies providing direct comparisons between one action versus an alternative (or no action),
- the Guideline Development Team has high confidence (e.g., based on ethical value or equitability) that indirect evidence supports a net benefit or several and/or separate bodies of evidence when considered together allow for inferences to be made regarding a net benefit, and
- collecting and reviewing the body of indirect evidence would be onerous and achieve little value for the project.

Prior to finalizing good practice statements, the GGG will evaluate their applicability, using the suggested questions outlined by GRADE methods developers.

Table 2.6: Questions evaluating applicability of making a good practice statement (Guyatt et al., 2016)

Appropriateness of good practice statement vs evidence-based recommendation			
1	Is there a lack of RCTs or observational studies providing direct comparisons between one action versus an alternative?	YES / NO	
2	Is collecting and summarizing the indirect evidence a poor use of a guideline panel's limited time and energy (opportunity cost is large)?	YES / NO	
	Are answers to questions (1) to (2) both yes	**YES** Appropriate to consider a good practice statement	**NO** Good practice statement not appropriate
Appropriateness of including the clinical guidance			
3	Is the statement clear and actionable?	YES / NO	
4	Is the message really necessary in regard to actual health care practice?	YES / NO	
5	After consideration of all relevant outcomes and potential downstream consequences, will implementing the good practice statement result in large net positive consequences?	YES / NO	
6	Is there a well-documented clear and explicit rationale connecting any indirect evidence?	YES / NO	
	Are answers to questions (3) to (6) all yes?	**YES** Appropriate to proceed with a good practice statement	**NO** Good practice statement not appropriate

Implementation considerations

Implementation considerations will be presented to support recommendations and Good Practice Statements. These are suggestions on how to implement the recommendations in the guideline. Implementation considerations aim to provide stakeholders with guidance on how a recommendation should be implemented. 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.

Stakeholder Review

Stakeholders, including patient individuals, informal carers, health professionals, academic, researchers, educators, wound organizations, industry representatives and any other interested parties will be invited to contribute to the International Guideline through:

- participation in a Stakeholder Survey at commencement of the project to provide feedback on areas/topics of interest for inclusion, the clinical questions to be explored and the clinical outcomes they consider important,
- an open invitation to identify research meeting the inclusion criteria for consideration in the Guideline, and
- reviewing the draft Guideline material prior to its finalization, including providing feedback on applicability, feasibility and utility of the recommendations, good practice statements and implementation consideration.

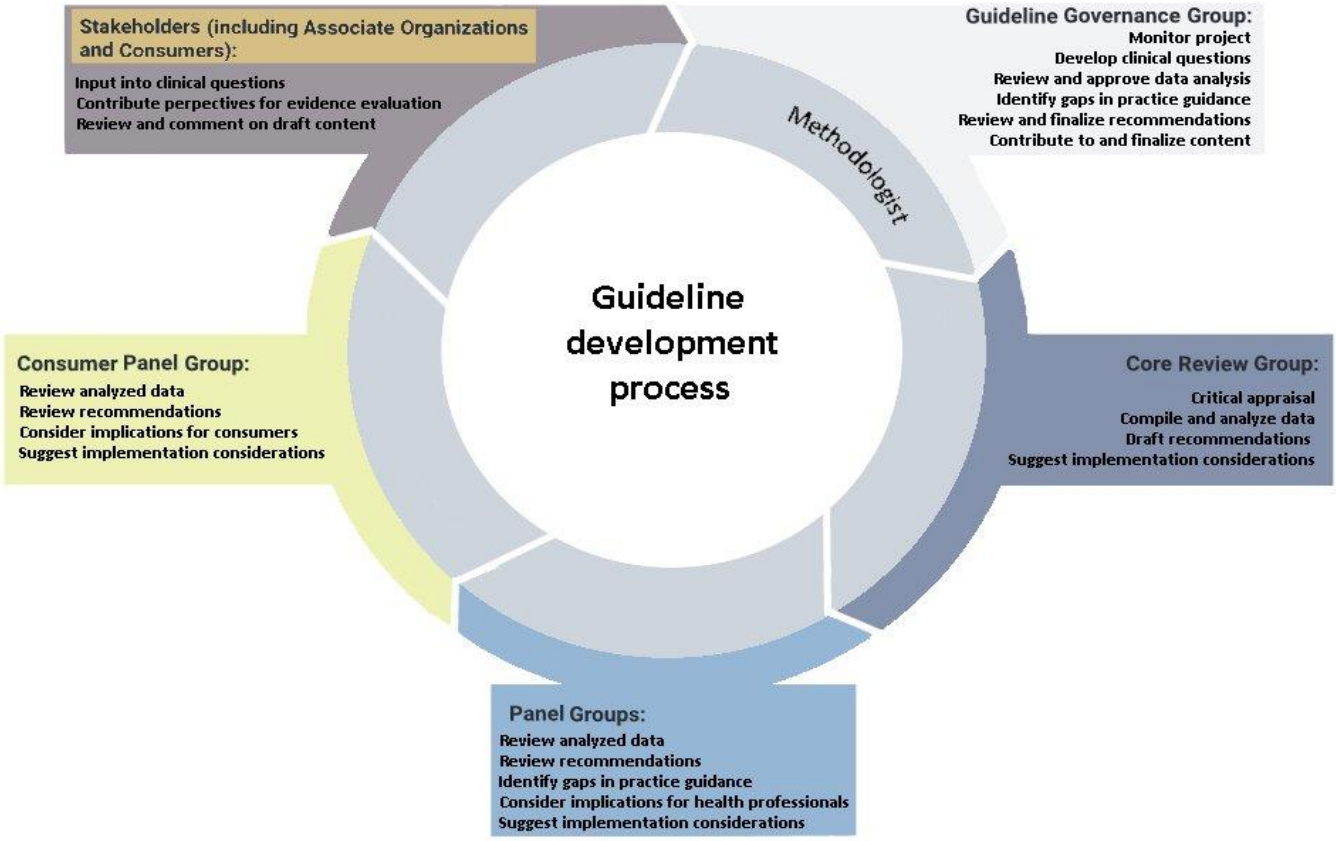
The processes for the Stakeholder Survey are outlined in Appendix 4. Opportunity to identify relevant clinical research for consideration will be provided via the International PI Guideline. The final stakeholder review process is a formal review process, open to all interested parties, to complete the evaluation via a project-specific web platform. In 2019, 699 individuals and organizations registered as stakeholders to provide feedback on the International PI Guideline. In 2014, 698 registered individual and organization stakeholders provided feedback and in 2009, there were 1,049 registered stakeholders. Stakeholders will be invited through open invitations through the Member and Associate Organizations, consumer organizations, industry groups, professional networks, cultural diversity groups and social media.

The GGG and methodologist will be responsible for reviewing the stakeholder feedback and considering whether the Guideline content requires any revision in response to feedback. The CRG, Panel Groups and Consumer Panel Group will review any changes made to the draft material in response to stakeholder feedback.

Work Process and Content Review

The content of the Guideline will be reviewed across all groups within the Guideline Development Team (see Figure 2.4). The CRG, Panel Groups, Consumer Panel Group and GGG will all review the content prior to editing and stakeholder/peer-review. Although illustrated as a progressive process, the evidence review and content development process is iterative, with the methodologist facilitating communications between the PGMs, CRG and GGG and components of the work being re-reviewed by a group after receiving feedback by another. Each section will usually undergo numerous drafts before being finalized. As each group will progress through the above process at a different rate, there are times when delays can occur. The goal of the Guideline Development Team is to meet the timelines as much as possible. The methodologist will assist in communications and progress.

Figure 2.4 Guideline work process



Terminology in the Guideline

Terms

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

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 carer*' 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). 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.

Guideline Dissemination, Implementation and Update

The Member Organizations and GGG have supported several strategies to increase uptake of previous editions of the International PI Guideline and to evaluate its dissemination and implementation. These include:

- inclusion in the guideline of information on measuring the incidence and prevalence of PIs,
- inclusion in the guideline of quality indicators for use in evaluating the implementation of best practice outlined in the guideline,
- production of an abbreviated Quick Reference Guide (QRG) that summarizes guideline content and is distributed freely via the International PI Guideline website and the sales platform,
- support of translation of both the full Guideline and the QRG into languages other than English to promote dissemination internationally,
- submission to guideline housing /depository platforms (e.g., the ECRI Guidelines Trust® and its medical publishers in the US and the National Health and Medical Research Council in Australia),
- publication and promotion of the International Guideline and associated events (e.g., International Stop PI Day) via the websites/social media of the Member Organizations and the International Guideline website,
- publication of manuscripts focused on guideline development and guideline content,
- presentations at conferences, forums and education events, and
- making the QRG available via Smart Phone platforms in multiple languages, in conjunction with a professional app development team.

Translations

Under the oversight of the Translation Committee, wound organizations are encouraged to undertake translation of the QRG using recognized translation practices (see EPUAP website for more details). The 2019 Quick Reference Guide was translated into 19 languages. The 2009 Quick Reference Guide was translated into 17 different languages and the 2014 Quick Reference Guide was translated into 11 different languages. The GGG will continue to encourage translation of the guideline into languages other than English for maximum international dissemination.

Dissemination

Consistent with Member Organization mission statements, the primary objective of the International PI Guideline is wide-spread dissemination and implementation of evidence-based recommendations to improve patient outcomes throughout the world. Over 250,000 copies of the 2019 Guideline have been disseminated with 96% of the documents provided free of charge. The guideline is also highly cited in the academic literature (Kottner & El Genedy-Kalyoncu, 2022; Kottner & Haesler, 2020).

Implementation

Whilst dissemination efforts have been extremely successful,(Kottner & El Genedy-Kalyoncu, 2022; Kottner & Haesler, 2020) the International PI Guideline can only improve patient outcomes if the evidence-based recommendations are implemented in clinical settings. Recommendations are written with as much clarity and specificity as possible; however, there are some limitations based on the need to provide recommendations that are relevant to multiple international clinical settings and cultures while staying true to the supporting evidence. Carefully selected good practice statements and implementation considerations have helped bridge the gap between the currently available research and the clinician's need for the knowledge and reasoning to guide safe and effective practice. Some recommendations may be directly adopted by clinicians, while others require some adaptation to the local clinical context. The GRADE-ADOLOPMENT approach (Schünemann et al., 2017) facilitates adoption and adaptation of recommendations using the GRADE EtD frameworks and may offer further opportunity to enhance the relevance of recommendations as we develop, disseminate and implement the fourth edition of the Guideline.

Quality Indicators

The GGG will continue to review and develop quality indicators that can be used to monitor the implementation of the guideline. A wide range of clinical indicators are currently used around the world as part of ongoing health service accreditation programs, international benchmarking projects and at local levels for monitoring ongoing quality improvement. The quality indicators will be designed to monitor the specific recommendations for practice that are included in the guideline. They will be selected based on expert opinion on their intrinsic value as an indicator of quality care for prevention and treatment of PIs, 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.

Update

The GGG will continue to monitor the pressure injury literature after the publication of the fourth edition of the Guideline. Another revision is planned for 2029 (or sooner if ongoing literature reviews reveals major advances in pressure injury prevention and treatment prior to 2029).

CHAPTER THREE: GUIDELINE GOVERNANCE GROUP

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 PIs that can be used to guide health professional and patient consumer decisions internationally. This goal is accomplished by reviewing guideline methodology, agreeing on documenting the development process, identifying and critically examining the evidence, applying the principles of GRADE methods, exploring varying opinions and negotiating to achieve consensus (with dissenting opinion recorded) and making recommendations that are based on a rigorous review of the evidence AND have clinical relevance for individuals at-risk of or with pressure injuries.

Guideline Governance Group Membership

The GGG will consist of four voting members selected by each of the Member Organizations (i.e., NPIAP, EPUAP and PPPIA) as their representatives and one consumer representative. When selecting representatives, the Member Organizations will give consideration to promoting representation from a range of professional disciplines necessary to make informed decisions regarding the evidence and its appropriate application to practice. The (non-voting) guideline methodologist will attend and report to meetings.

Although GGG members may represent the views of their Member Organization in financial and business negotiations, the Executive Director/President/Manager of each Member Organization may also be included in these negotiations, but not in determining or influencing the content of the guideline. Any decisions regarding financial and business arrangements must be approved by each Member Organization's governing body.

All GGG members are selected by their respective organizations and should meet the following criteria:

- be free of major competing (or conflicting) interests and undertake to disclose the nature of any minor competing interest and recuse themselves from related decisions (consistent with *Chapter 6: Conflict of Interest Management*). Member Organizations are responsible for screened for potential conflict of interest prior to appointing their representatives. All GGG members' potential conflicts of interest will be declared to the methodologist, disclosed at each meeting and published consistent with *Chapter 6: Conflict of Interest Management,*
- have no employment in industry. (Representatives of industry are excluded from developmental groups but are invited to participate as stakeholders) and
- possess English communication skills necessary to actively participate in written and oral discussions about topics relevant to the project.

In addition to the criteria above, GGG members representing the Member Organizations will meet the following criteria:

- possess expertise in PI prevention and treatment, and
- possess working knowledge of research methods for conducting a quality review/clinical guideline, including an understanding of GRADE methods.

In addition to the criteria above, the Consumer Representative GGG member will meet the following criteria:

- have previous or current experience as a consumer representative within government or counselling bodies in health care, practice, research, or policy,
- awareness of the needs of groups of consumers and ability to objectively represent other views,
- possess an understanding of research methods for conducting a quality review/clinical guideline, including GRADE methods, and

- ability to commit the time to attend meetings, review material and provide feedback.

Guideline Governance Group Chairs

Each Member Organization will appoint a Chair/lead member with authority to lead their Organization's selected GGG members and PGMs and contribution to the guideline. The GGG Chairs will be delegated authority to represent their Member Organization's negotiations regarding financial and business issues. A Member Organization may upon notice in writing to the other Member Organizations change such lead member as it sees fit.

Term of Appointment

Appointment of GGG members is at the discretion of the Member Organizations and consistent with the criteria outlined above. To ensure a core of experienced members and continuity in the guideline process, each Member Organization should, when possible, ensure that at least one of its appointed GGG members previously served as a GGG member.

Once appointed, each GGG member will serve until completion of the project. Additionally, each Member Organization should encourage at least one of its GGG members remains engaged during the interim phase between Guideline editions to oversee issues arising (e.g., methodological reviews).

GGG 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:

- Declaring competing (or conflicting) interests with recusal from GGG discussion and voting as appropriate.
- Developing the guideline scope and purpose.
- Analyzing and approving proposed guideline methodology changes to ensure the reliability, validity, integrity and utility of the Guideline.
- Approving the clinical questions to be addressed in the Guideline with consideration to the results of the stakeholder survey.
- Overseeing the guideline development and revision process to ensure the reliability, validity and integrity of the Guideline.
- Educating, mentoring and guiding PGMs to ensure the reliability, validity and integrity of the guideline development and revision process.
- Reviewing SoF tables, EtD frameworks, draft recommendations, good practice statements, and implementation considerations developed by the CRG and Panel Groups for:
    - comprehensiveness and accuracy of literature reviews,
    - rigor in application of the methodology and analysis of the evidence,
    - applicability to and guidance provided for implementation in clinical practice, and
    - clarity and appropriateness of recommendations, good practice statements and implementation considerations for an international audience.
- Reviewing stakeholder comments and any Guideline revisions as appropriate.
- Approving the final Guideline content as a voting representative on the GGG. Representatives are not required to vote as a block with their Member Organization.
- Serving as an advisory group in financial and business matters with respect to the Guideline.

Meetings of the GGG

Meeting Schedule and Attendance

The GGG will meet on a regular scheduled basis via phone and/or video conference throughout the project. Face-to-face meetings may be arranged as necessary and feasible. GGG members are highly encouraged to attend all meetings.

At times, the GGG may schedule sub-group meetings/working parties of GGG members and/or between GGG members and other groups (e.g., the Core Review Group) to discuss specific issues, but all decisions will be taken back to the full GGG for discussion and voting. The GGG may also schedule meeting of the Guideline Development Team and/or specific Panel Groups at various conferences for the convenience of the project work. These ad-hoc meetings do not constitute official meetings of the GGG and are convened to enhance communication across the full working Guideline Development Team on the guideline.

Meeting Process

An agenda will be circulated in advance of every meeting. The agenda will usually include a report from the methodologist on the project progress. As the work progresses, the methodologist will circulate draft materials for review by the GGG in each meeting. As the project moves toward completion, it is usual for the draft material for review in each meeting to increase. GGG members should plan additional preparation time in the last 6 months of the project to accommodate the additional reviewing load.

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.

The quorum for all GGG meetings will be seven, with at least two GGG members from each Member Organization. The methodologist (and any non-GGG members invited to attend a meeting) are not counted for quorum purposes.

Key decisions are made by the GGG throughout the project work. These include decisions on arising methodological issues, resolution of any arising project management issues, confirmation of guideline content, financial and business decisions and dissemination plans.

For key decisions, the GGG Chair will call for discussion followed by a GGG vote. The methodologist (and any non-GGG members invited to attend a meeting) do not have voting rights. If a GGG member is absent for an official GGG meeting, voting will still occur at the meeting so that the project 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 GGG members the opportunity to vote in close decisions.

Key GGG Principles

Collaboration

The GGG members agree to participate collaboratively. This includes working constructively together to achieve the overall goal of publishing a comprehensive, evidence-based Clinical Practice Guideline to support the global prevention and treatment of PIs.

Contribution

The GGG members agree to actively contribute to the guideline development. This includes reviewing the SoF tables, EtD frameworks and draft recommendations, good practice statements and implementation considerations and providing feedback in a timely manner.

Conflict Resolution

The GGG members agree to seek resolution of conflict. Revision, addition or deletion of recommendations require a majority vote of the GGG with any dissenting opinions recorded. Conflicts will be resolved through re-examination of available evidence, discussion, and revision of documents to develop an acceptable compromise.

Consumer Participation

The GGG members agree to actively promote participation of patient consumers in the guideline development. Consumer representatives will be invited to both participate in the Guideline development a variety of ways and to provide feedback on the Guideline, as outlined in *Chapter Five: Consumer Participation*.

Consultation

The GGG members agree to actively promote consultation and consideration of feedback from stakeholders. 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.

CHAPTER FOUR: CORE REVIEW GROUP AND PANEL GROUPS

Core Review Group

Purpose and Formation of the Core Review Group

The Core Review Group (CRG) is formed with a purpose of ensuring critical appraisal and data analysis is performed by experienced individuals with a working knowledge of GRADE methods to promote the reliability and validity of the process. The CRG will be co-ordinated by the methodologist and will consist of members appointed by the GGG. The size and composition of the CRG may evolve throughout the project depending on the project requirements.

The CRGs will communicate electronically (e-mail, Skype, phone or video conference) and will undertake guideline work using the web-based platforms outlined in *Chapter 2: Guideline Methodology.*

Core Review Group Role

The CRG is responsible for reviewing the research relevant to each of the PICOT clinical questions. The CRG will work collaboratively to critically analyze the evidence identified as relevant to each PICOT clinical question. The CRG will:

- perform and reach agreement on critical appraisal using the appropriate appraisal tool based on the study design,
- extract data from the research eligible for inclusion for evidence-based recommendations, where relevant conduct meta-analyses, and complete the summary of findings (SoF) table (with consideration to the clinical outcomes defined in the clinical question),
- evaluate and agree on the certainty of the evidence,
- complete the evidence to decision (EtD) frameworks, incorporating the evidence in the SoF tables,
- draft evidence-based recommendations based on the data and decision outcomes in the EtD framework, and
- draft good practice statements and/or implementation considerations arising from the evidence reviewed for the SoF table.

In summary, for each clinical question the CRG will complete a draft SoF table (addressing each clinical outcome) and a draft EtD framework using the processes outlined in *Chapter 2: Guideline Methodology.*

Core Review Group Qualifications

The CRG members should meet the following criteria:

- possess expert knowledge on PI prevention and treatment and the skills to conduct critical appraisal of the relevant PI literature and analysis of the data,
- working knowledge of GRADE methods and/or Cochrane methods to develop draft SoF tables and EtD frameworks,
- be free of major competing (or conflicting) interests and undertake to disclose the nature of any minor competing interest and recuse themselves from related decisions. Potential conflicts of interest will be declared to the GGG and the methodologist and published (further information available in *Chapter 6: Conflict of Interest Management,*
- have no primary employment in industry. Representatives of industry are excluded from the Guideline Development Team but are invited to participate as stakeholders,
- have sufficient computer literacy to use word processing software, the selected web-based platforms for the project, and web-based conferencing applications. CRG members will require their own access to a computer with internet access and onsite support as required.

Panel Groups

The Guideline Development Team will include Panel Groups consisting of health professionals, scientists, academics and educators, and also a Consumer Panel Group. The Consumer Panel Group role, qualifications and process is outlined in *Chapter 5: Consumer Participation*.

Purpose and Formation of the Panel Groups

The Panel Groups are formed with a purpose of ensuring that the evidence-based guidance within the International PI Guideline is clear, appropriate and relevant to the future care of individuals with or at risk of PI throughout the world.

Panel Groups will be formed around a general topic/chapter area (e.g., repositioning, support surfaces etc). The Member Organizations will undertake their own selection process to recruit Panel Group Members (PGMs). Associate Organizations will also undertake their own process to select PGM nominations, who will be submitted to the GGG with the Associate Organization's application. The GGG will review the nominations and determine the final composition of each Panel Group.

Each Panel Group will consist of at least one person (preferably at least two) from each Member Organization, plus additional representatives from Associate Organizations, and will be coordinated by the methodologist. Ideally, Panel Groups should be composed of PGMs representing various scientific and clinical disciplines (particularly those disciplines necessary to make informed decisions regarding the evidence and its application to practice) and representing a range of cultures and geographic locations. This broad representation of expertise enhances the quality of Panel Group discussions and increases the quality, applicability and utility of the Guideline as a whole.

The Panel Groups will meet electronically (e.g., e-mail, Skype, phone or video conference) and access/share information using web-based platforms as outlined in *Chapter 2: Guideline Methodology*.

Panel Group Member Qualifications

The PGMs should meet the following criteria:

- be a member of one of the Member or Associate Organizations (e.g., member, trustee, board member, former trustee/board member [alumni]),
- be invited to participate by one of the participating organizations or the GGG, or self-nominate,
- possess the following expertise, demonstrated in two-page resume submitted to the GGG via their Member Organization's process:
    - expert knowledge in the topic/content area specific to the Panel Group,
    - sufficient knowledge of GRADE methods to analyze the draft SoF tables and EtD frameworks and provide input to the content, and
    - skills to critically read relevant PI literature and apply it to the guideline development process.
- be free of major competing (or conflicting) interests and undertake to disclose the nature of any minor competing interest and recuse themselves from related decisions. Member Organizations are responsible for screening for potential conflict of interest prior to appointing their representatives. All PGMs' potential conflicts of interest will be declared to the GGG and the methodologist, disclosed at each meeting and published. (More information in *Chapter 6: Conflict of Interest Management*),
- have no primary employment in industry. Representatives of industry are excluded from the Guideline Development Team but are invited to participate as stakeholders,
- possess English communication skills necessary to actively participate in written and oral discussions about topics relevant to the project,
- have sufficient computer literacy to use word processing software, the selected web-based project platforms, and web-based conferencing applications. PGMs will require their own 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 PGMs to ensure they have appropriate equipment and

onsite support as required, and to be responsive to communication. It is reasonable to respond to email within five days when working on a collaborative project.

Panel Group Role

The PGMSs should review the methodology and develop an understanding of the GRADE process prior to participating in the guideline development process. The guideline methodologist will advise and assist the Panel Groups to undertake their role to ensure that the guideline process progresses in adherence to the agreed methods.

The PGMs are responsible for:

- Reviewing the clinical questions to be addressed in section of the Guideline for which the Panel Group is responsible.
- Critically reading and extracting data from the evidence assigned to the Panel Group by the methodologist. This evidence will be studies of research designs not eligible for consideration in the SoF table, that might inform additional considerations in the EtD frameworks (e.g., feasibility, applicability and cost-effectiveness) and/or could inform the development of good practice statements or implementation considerations. The methodologist will provide data extraction templates for PGMs to record the significant information from relevant studies.
- Reviewing and drafting any additional content for the SoF tables, EtD frameworks, draft recommendations, good practice statements, and implementation considerations developed by the CRG for:
    - comprehensiveness and accuracy of literature reviews,
    - applicability to and guidance provided for implementation in clinical practice,
    - clarity and appropriateness for an international audience,
    - gaps in the clinical guidance that could be addressed by additional good practice statements and/or implementation considerations.
- Reviewing stakeholder comments and any Guideline revisions as appropriate.

CHAPTER FIVE: CONSUMER PARTICIPATION

Goal of Consumer Participation

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

- patient consumers (i.e., individuals with or at risk of a PI),
- informal carers (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).

Recognizing international standards, the goals of consumer participation in this guideline development process are to (Légaré 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, and
- promote consumer awareness of the International PI Guideline.

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

Processes to Partner with Consumers in Guideline Development

The GGG recognizes the diverse barriers Guideline Development Teams face in promoting consumer participation. The literature identifies many barriers (Armstrong et al., 2017; Légaré 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 these factors in developing a consumer partnership strategy. Strategies to engage consumers in partnership were developed based on recommendations in the literature (Armstrong et al., 2017; Légaré et al., 2011; National Health and Medical Research Council (NHMRC), 2016; Patient-Centered Outcomes Research Institute (PCORI), 2015a) and are outlined in Table 5.1.

Table 5.1: Strategies to promote consumer participation (*Armstrong et al., 2017; Légaré et al., 2011; National Health and Medical Research Council (NHMRC), 2016; Patient-Centered Outcomes Research Institute (PCORI), 2015a)*

Guideline step	Processes to promote patient participation
Recruitment	• Information about the guideline development process will be publicly available. • One consumer representative will be recruited to participate on the GGG, where that member will have voting rights for issues related to guideline content (but not financial and business issues). • Both patient/informal carer consumers and consumer stakeholders will be eligible and invited to participate in a Consumer Panel Group. Individuals with employment in industry will not be eligible for the Consumer Panel Group. • Diverse patient/informal carer consumers will be encouraged through recruitment in the three primary geographic regions of the Member Organizations, with consideration to population groups with specific needs. • Diverse health professionals will be recruited to Guideline Panel Groups to promote consideration of the needs of diverse patient/informal carer consumers. • A methodologist with qualitative research skills will provide moderation support for the Consumer Panel Group.
Preparation	• Patient/informal carer consumers will have the methodologist as a point of contact and will have contact details of the Chair in their geographic region. • Patient/informal carer consumers will receive background information about the guideline, the goals of consumer participation and specific responsibilities of the Consumer Panel Group. • Reading material will be provided in advance of Panel Group discussions.
Logistics	• Methods for providing opportunity for patient/informal carer consumer contribution are pre-identified in this protocol. • The methodologist will co-ordinate consumer participation (e.g., send invitations, administer survey, organize teleconferences, collect written feedback, etc.). • Accessible language will be used for producing background materials, where possible. • Contribution in a variety of formats (e.g., written, verbal, individual, group) will be offered to the Consumer Panel Group. • Contribution from patient/informal carer consumers will be sought in a stakeholder survey, with consideration to simplicity in language, questions, methods of response and time to complete the survey. • Consumer Panel Group communication will be in the English language. It is recognized that this limits diversity of patient/informal carer consumer input. Inclusion of health professionals from areas that speak languages other than English in the guideline development process provides some consideration to non-English speaking consumers. • Consumer Panel Group will have opportunity for teleconference meetings, for those that have access to web-based teleconference software and have time and preference to be involved. • Updates on the guideline development process are published on the International Guideline website.
Reassessment	Evaluation of consumer participation will be undertaken via a survey at the completion of the Guideline project.

Strategies to Partner with Consumers in the Guideline Development

Consumers (patients, informal carers and consumer representatives) will be invited to partner in the Guideline development process, including surveys, a Consumer Panel Group and the stakeholder review process. Consumer participation will be invited through:

- website and social media invitations,
- invitations via GGG members and PGMs, and
- invitations to consumer stakeholder groups, Indigenous groups and patient support networks (e.g., SCI patient groups) known to GGG members in the geographic regions represented by the Member Organizations.

Stakeholder Survey

At commencement of the project, an international survey of stakeholders, including patients and informal carers, will be undertaken to establish priorities, interests and needs (see *Appendix 4*). Broad consumer input will be sought, with a goal of collecting information from consumers in all geographic regions participating in the guideline. The stakeholder survey will explore:

- clinical topics of priority for inclusion in the next edition of the Guideline,
- clinical outcomes considered important for evaluating treatment options for PIs, and
- additional suggestions for topics to address in the Guideline.

Consumer GGG Representative

At commencement of the project, the GGG will reach agreement on selection of appropriate consumer representatives to join the GGG. Each of the Member Organizations will be invited to put forward one potential GGG consumer representative with an interest in filling the responsibilities of the consumer GGG representative and meeting the criterial outlined in *Chapter 3: Guideline Governance Group*. The GGG will reach agreement on appointment of a consumer representative, with consideration to applicants' skills, track record and business considerations such as the project budget.

Consumer Panel Group

A Consumer Panel Group will be established to review each recommendation and its associated guideline content during the drafting phase. Member Organizations will recruit and nominate consumers from their geographic region, with a goal of forming a Panel Group comprising 7 to 10 consumer Panel Group Members (PGMs).

Consumer Panel Group member qualifications

The Consumer PGMs should meet the following criteria:

- be nominated to participate by one of the Member Organizations,
- possess the following expertise, demonstrated in two-page resume submitted to the GGG via their Member Organization's process:
    - knowledge of the experience of patients with or at risk of PIs and/or their informal carers,
    - sufficient skills to critically read draft Guideline material and provide practical suggestions to represent the perspectives of patients/informal carers,
    - an understanding that rigorous research processes are followed to develop evidence-based recommendations.
- be free of major competing (or conflicting) interests and undertake to disclose the nature of any minor competing interest and recuse themselves from related decisions (consistent with *Chapter 6: Conflict of Interest Management*). Member Organizations are responsible for screening for potential conflict of interest prior to appointing their representatives to the Consumer Panel Group. Potential conflicts of interest will be declared to the GGG and the methodologist, disclosed at each meeting and published consistent with *Chapter 6: Conflict of Interest Management,*
- have no primary employment in industry. Representatives of industry are excluded from the Guideline Development Team but are invited to participate as stakeholders,
- possess English communication skills necessary to actively participate in written or oral discussions about the Guideline content,

- have sufficient computer literacy to participate. Consumer PGMs will require their own 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 PGMs to ensure they have appropriate equipment and onsite support as required and be responsive to communication. It is reasonable to respond to email within five days when working on a collaborative project.

Consumer Panel Group role

Consumer PGMs will be provided with the draft guideline content to review as sections are completed. The Consumer Panel Group will be asked to provide feedback using a standardized format that will include:

- sensitivity (language) of terms,
- relevance to individuals with or at risk of PIs,
- acceptability of interventions and implementation considerations (e.g., preferences, cultural considerations),
- feasibility of interventions from the patient consumer/informal carer perspective,
- additional considerations for sub-populations,
- consumer education material that could support the guideline content.

Opportunity to hear or review other consumer perspectives is recognized as a facilitator to engagement (Légaré et al., 2011). The Consumer PGMs will be given an opportunity to engage with one another via teleconference facilitated by the methodologist to discuss the guideline content and education needs. Consumer PGMs will also be given opportunity to provide input via written correspondence or digital audio recording.

Information provided by the Consumer Panel Group will be used to review the presentation of the Guideline, contribute to completion of the EtD frameworks, review and revise the recommendations, good practice statements and implementation considerations and to identify priorities for consumer education material.

Evaluating Consumer Participation

A post-survey will be conducted with the Consumer Panel Group (and other PGMs) to evaluate the experience of consumer partnership in the guideline development

CHAPTER SIX: CONFLICT OF INTEREST MANAGEMENT

Ensuring there is a rigorous and consistent process for declaration and management of conflicts of interest (COIs) is fundamental to developing a transparent and trustworthy clinical guideline (Qaseem et al., 2019). A COI arises in any situation in which a Guideline Development Team 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. Nevertheless, actual or potential COI must be declared to enhance transparency and credibility of our guideline (Schünemann et al., 2015). All individuals engaged in the Guideline Development Team are required to complete a Conflict of Interest (COI) Disclosure form (see Form 1) in order to be involved and to receive acknowledgement as a member of the team.

Policy on Conflict of Interest

In order to participate in the guideline development all members of the Guideline Development Team **must declare** whether they have any **potential or actual COI** by completing a COI Declaration Form (see *Form 1*). The Guideline Development Team are all required to be free of major competing (or conflicting) interests and are requested to disclose the nature of any competing interest.

Declaring a Conflict of Interest

The COI Declaration form (see Form 1) includes the relevance of the conflict (see Table 6.1) and the weight of the conflict. Every COI declaration is topic specific, as noted on the declaration form. Conflict of interest declarations will be completed:

- on commencement of the project, covering the preceding three years,
- as new conflicts arise throughout the project, on an as-needed basis, and
- a final COI declaration covering the preceding four years (i.e., confirming prior declarations above) made approximately three months prior to publication on the International PI Guideline.

Failure to complete and submit a final COI declaration will render the development team member ineligible for acknowledgement as a participant in the International PI Guideline development.

Management of Conflicts of Interest

The COI statements will be kept by Chairs of the Member Organizations and copies sent to the methodologist. Emergent COI during the process must be declared immediately in working process/meetings and in writing.

Every Guideline Development Team member with a 'moderately high' to 'very high' COI according to the conflict relevance assessment (see Table 6.1) (Schünemann et al., 2015) will be excluded from participating in the following activities in the specific topic area of their COI:

- critical appraisal of the evidence,
- synthesis of the evidence,
- group discussions on the evidence,
- evaluation of the body of evidence,
- development of recommendations, statements and chapter preparation, and
- strength of recommendation ratings.

Reporting Conflict of Interest

Consistent with high quality guidelines, the COI declarations for each member of the Guideline Development Team will be made public in conjunction with the publication of the International PI Guideline. For simplicity, the highest ranking of COI for each participant will be noted, together with a list of all the Guideline Development Team member's declared sources of actual or potential COI.

Form 1: COI Declaration form including COI weight (Schünemann et al., 2015)

Conflict of Interest Declaration Form

Name: Date:

☐ I have **NO INTERESTS TO DECLARE OVER THE PRECEDING THREE YEARS**

or

☐ I have **POTENTIAL INTERESTS TO DECLARE** and have completed them in the table below

Type of Interest	Name of entity	**Weight (1-3)** (see below)	Paid to you (Y/N)	Paid to your institution (Y/N)	List all guideline topics to which COI relates	**Relevance (0-6)** (see page 2)
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 work on this guideline						
Payment for contributing to development or review of this guideline						
Provision of other assistance for guideline development						
Academic interest (e.g., researcher in areas covered by the guideline)**						
Other (specify)						

*Please tick the relevant box(es) covering the period of time XX years proceeding commencement of work on this guideline edition.

WEGHT (rated 1 – 3) **Up to $1,000 weight = 1** **$1,001 to 5,000 weight = 2** **$5001 and more weight = 3**

Include estimated monetary value of non-monetary items (e.g., travel expenses, tickets, computer, etc.)

Table 6.1: Conflict Relevance (Schünemann et al., 2015)

Appendix Table 2. Relevance to the topic.*

User instructions
Step 3. Rate the "Relevance" of a potential conflict of interest by choosing descriptor or number:

TABLE A2. RELEVANCE TO THE TOPIC

Relevance	None 0	Very Low 1	Low 2	Moderate 3	Moderate to High 4	High 5	Very High 6
Description	Topic of interest is not relevant and unrelated to a competing interest			Topic of interest is somewhat relevant and related to a competing interest			Topic of interest is highly relevant or directly related to the declared competing interest
Examples	A statistician involved in conducting meta-analysis on implementing pneumonia guidelines who consulted for a spirometer device company	A methodologist has given a methods focused presentation at an event sponsored by a for-profit organization whose products will be discussed by a guideline panel	A researcher has received personal honoraria for speaking about medications that is produced by a sponsor. Other products of this sponsor will be discussed by a guideline panel	A researcher has received personal honoraria for speaking about a medication that will be the topic of a recommendation in a guideline	A researcher's career is focused on the exploration of a topics about which a recommendation for additional resources will be made to a funding agency	A clinical researcher has received a research grant and/or honoraria from a for-profit sponsor that is related to exploring the efficacy of a medication that will be discussed by a guideline panel. The guideline panel may make recommendations for its use	A researcher is the owner or major shareholder of a company that produces a devise or medication about which a recommendation will be formulated by a guideline panel

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APPENDIX 1: ASSOCIATE ORGANIZATION AGREEMENT

ASSOCIATE ORGANIZATION/COLLABORATION AGREEMENT ON INTERNATIONAL PRESSURE INJURY GUIDELINE

(FOURTH EDITION)

AGREEMENT

This Agreement is made and entered into by:

the Member Organizations: National Pressure Injury Advisory Panel (NPIAP), the European Pressure Ulcer Advisory Panel (EPUAP), and the Pan Pacific Pressure Injury Alliance (PPPIA)

and

the Associate Organization: **TO BE NAMED**

1. This Agreement is entered into to develop the fourth edition of the International Pressure Ulcer/Injury Guideline.
2. The fourth edition Guideline development will be led by the Guideline Governance Group (GGG), made up of representatives from the Member Organizations.
3. The Associate Organization will not have voting representatives on the GGG.
4. The Associate Organization will maintain ongoing communication with the Methodologist, who will liaise between the GGG and the Associate Organization and its Panel Group Members (PGMs).
5. The fourth edition of the Guideline will be developed according to the methodology documented by the GGG in the published Methodology Protocol.
6. For the development of the fourth edition of the Guideline, the Associate Organization will nominate between 3 and 10 members for participation in Panel Groups according to their interest and expertise. These PGMs will review the Summary of Findings Tables and Evidence to Decision Frameworks, critically read scientific literature as assigned by the methodologist and make contributions to recommendations, good practice statements and implementation considerations consistent with the methodology. The role of PGMs is outlined in the Methodology Protocol.
7. All PGMs, including those nominated by the Associate Organization, must complete the Conflict of Interest (COI) process outlined in the Methodology Protocol. The Associate Organization is responsible for collecting COI documentation from its nominated PGMs and submitting it with the application for participation in the project. COI declarations are published in the final Guideline.

8. The Associate Organization and all its representatives (e.g., PGMs, project managers) agree to maintain confidentiality during the Guideline development period. All material being developed is confidential and will not be shared by the Associate Organization or its representatives outside the development team or used in other projects without express permission from the Member Organizations.
9. Completion of this agreement assigns all ownership interest in contributions to the fourth edition of the Guideline to the Member Organizations. Associate Organizations will hold no ownership interests.
10. All fourth edition Guideline Works, including the fourth edition QRG, the fourth edition CPG and any translation of the works to languages other than English shall be marked © NPIAP-EPUAP-PPPIA. The Associate Organization will not share in copyright of the Guideline Works.
11. All profit from any sales of the fourth edition Guideline Works remains with the Member Organizations.
12. The Associate Organization/will be given first opportunity to negotiate sole rights permitted to translate the Guideline into your requested local language. Associate Organization must enter into a Translation Agreement and undertake translation using the process outlined in the Translation Agreement (to be made available on EPUAP website).
13. The Member Organizations maintain all rights to undertake updates or revision of the Guideline Works in future editions.
14. The Associate Organization agrees to provide its organization logo for use on the International Guideline website and as endorsement within the fourth edition of the Guideline.

This agreement is entered into on **DATE** and accepted by:

Dr Janet Cuddigan GGG Chair, NPIAP	Dr Keryln Carville GGG Chair, PPPIA	Dr Zena Moore GGG Chair, EPUAP

Representatives for the Member Organizations

Name: Position:	Name: Position:

Representatives for the Associate Organization

APPENDIX 2: SUMMARY OF FINDINGS TABLE

Summary of Findings (SoF) tables will be prepared for each clinical question consistent with GRADE methods to facilitate evaluation of the evidence. The SoF tables will include (see Table A2.1):

- a list of the clinical outcomes that were considered for the clinical question,
- the assumed risk, which is a measure of the typical risk at baseline (e.g., baseline score or control group risk),
- the corresponding risk associated with the intervention (i.e., the risk of the outcome in treated/exposed individuals based on the relative magnitude of an effect and the assumed risk),
- the relative effect (i.e., for dichotomous outcomes, the risk ratio, odds ratio, or hazard ratio)
- the number of participants (across studies), the number of studies and their designs
- a rating of the overall quality of evidence for each clinical outcome, and
- footnotes or explanations about information in the table.

A SoF table will be prepared by the Core Review Group for each comparison made in a systematic review/meta-analysis, and where multiple alternative interventions are compared, all outcomes will be presented in one SoF table.

Table A2.1: Example of a SoF table (Schünemann et al., 2013)

Comparison being made
e.g. Intervention 1 versus no treatment for people at risk of pressure injuries

Bibliography: Guideline citation

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk without intervention	Risk difference with intervention (95%CI)
Clinical outcome 1	n participants (n studies) XX years/months	○○○○ indicated by circles +/-			
Clinical outcome example 1	2345 (7 studies) 12 weeks	⊕⊕⊕⊖ **MODERATE**[1,2] due to imprecision	**RR 1.05** (0.75 to 1.46)	**Moderate**	
				27 per 1000	**1 more per 1000** (from 7 fewer to 12 more)
Clinical outcome example 2	0 (1 study) 12 months	⊕⊕⊖⊖ **LOW** due to risk of bias, imprecision	Not estimable	See comment	-

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: Confidence interval; **RR:** Risk ratio;

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

Footnotes provide basis for assumed/baseline risk and comments regarding the evaluation of specific clinical outcomes, as required
1,2 Include comments related to reasons for grading, if the RR includes spectrum of risk and benefit, etc.

APPENDIX 3: EVIDENCE TO DECISION FRAMEWORK

Evidence to Decision frameworks are included in GRADE methods to facilitate reaching recommendation and determining their strength in a transparent manner. The framework (see Table A3.1) is used to summarize the:

- level of consensus on the value that stakeholders place on the potential benefit of an intervention (i.e., the clinical outcome), noting that this evaluation will be informed by the data from the Stakeholder Survey and previously collected by the OUTPUTs trial, as well as iterative discussion by the various groups making up the Guideline Development Team,
- benefits and risks (as detailed in the SoF tables),
- financial costs, as available in the reviewed evidence, and
- feasibility and acceptability of an intervention to stakeholders, as available in the reviewed evidence, as well as iterative discussion by the various groups making up the Guideline Development Team.

After outlining the above information in the EtD framework, the final section of the framework will document conclusions based on this information. This will include:

- the final recommendation made based on this information,
- the strength of the recommendation,
- any considerations for specific sub-populations,
- implementation considerations (i.e., tips, hints and initiatives to successfully implementing the recommendation in different care settings/populations), and
- related priorities for future research.

In the first instance, the Core Review Group will complete draft EtD frameworks. These will be reviewed and elaborated by the relevant Panel Group (by topic), the Consumer Panel Group and the Guideline Governance Group before the content is finalized for the stakeholder review process and eventual finalization by the GGG.

Table A3.1: GRADE EtD framework (Schünemann et al., 2013)

Criteria	Evaluation	Questions	Explanations
Is there important uncertainty about how much people value the main outcomes?	○ Important uncertainty or variability ○ Possibly important uncertainty or variability ○ Probably no important uncertainty of variability ○ No important uncertainty of variability ○ No known undesirable	• *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)?* • *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?*	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'.
What is the overall certainty of the evidence of effectiveness? (The likelihood that the effect will be substantially different from what the research found)	○ Very low ○ Low ○ Moderate ○ High	*What is the overall certainty of this evidence of effects, across all of the outcomes that are critical to making a decision?*	The less certain the evidence is for critical outcomes (those that are ranked as high priority), the less likely that an option should be recommended.

How substantial are the desirable anticipated effects?	○ Substantial ○ Probably substantial ○ Probably not substantial ○ Not substantial ○ Unclear	*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)?*	The larger the benefit, the more likely it is that an option should be recommended.
How substantial are the undesirable anticipated effects?	○ Substantial ○ Probably substantial ○ Probably not substantial ○ Not substantial ○ Unclear	*How substantial (large) are the undesirable anticipated effects (including harms to health and other harms) of the option (taking into account the severity or importance of the adverse effects and the number of people affected)?*	The greater the harm, the less likely it is that an option should be recommended.
Do the desirable effects outweigh the undesirable effects?	○ No ○ Probably no ○ Uncertain ○ Probably yes ○ Yes ○ Varies	*Are the desirable effects large relative to the undesirable effects?*	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.
How large are the resource requirements?	○ Substantial ○ Probably substantial ○ Probably not substantial ○ Not substantial ○ Unclear	*How large an investment of resources would the option require or save?*	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.
Is the option acceptable to key stakeholders?	○ No ○ Probably no ○ Uncertain ○ Probably yes ○ Yes ○ Varies	*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)?*	• The less acceptable an option 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 implementation strategies to address concerns • Acceptability might reflect who benefits/is harmed and who pays/saves); and when any benefits, adverse effects, and costs occur. Unacceptability may be due to some stakeholders: ○ Not accepting distribution of benefits, harms and costs ○ Not accepting costs or undesirable effects in the short term for desirable effects in the future

			○ Attaching more value to the undesirable consequences than to the desirable consequences or costs of an option ○ Morally disapproving (i.e., in relationship to ethical principles)
Is the option feasible to implement?	○ No ○ Probably no ○ Uncertain ○ Probably yes ○ Yes ○ Varies	*Can the option be accomplished or brought about?*	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).

APPENDIX 4: STAKEHOLDER SURVEY

Aim and objectives

The aim of the Stakeholder Survey is to collect perspectives from international stakeholders on topics of interest and outcomes of importance in evaluating interventions for preventing and treating PIs.

The objectives are to collect stakeholder perspectives on PI topics and outcomes to (Schünemann et. al., 2013):

- increase the relevance to all stakeholders of the content (particularly the clinical questions) of the fourth edition of the International PI Guideline,
- measure the values and preferences of patient consumers and their informal carers to assist in developing and grading recommendations,
- understand the needs of specific patient populations groups to assist in selecting guideline content, and
- measure education/information needs of stakeholders to inform the development of resources to accompany the Guideline.

Methods

Data collection

The perspectives of stakeholders, including health professionals, educators, researchers, patient consumers, informal carers, industry representatives and other people with an interest in PIs on the importance of clinical questions and clinical outcomes related to the prevention and treatment of PIs will be collected via a survey. The survey will collect information the following information:

- basic, non-identifiable demographic information (type of stakeholder, geographic region, gender, age and ethnicity identification),
- PI at-risk populations of most interest to respondents (e.g., people with spinal cord injury, older adults and neonates),
- care settings of most interest to respondents (e.g., acute hospitals, aged care facility, and community),
- topics/questions of interest, and
- clinical outcomes of interest.

Participants will be able to access the survey using a QR code or the URL. The survey will include short answer responses, drop-down menus and drag-and-drop options to enable fast response with limited barriers to access. Participants will be able to skip any question to which they do not wish to respond and will be free to withdraw from the survey at any time. Once a participant submits their survey responses it will not be possible for them to withdraw from the survey because the results are anonymous.

Survey questions

The survey questions are provided below.

<u>Priority of clinical questions</u>

The clinical questions used for the 2019 edition of the Guideline will be used to collect information on topics/questions of interest to stakeholders. Participants will be presented with the clinical questions that were explored in the 2019 edition of the Guideline and asked to rank each question on a five-point scale defined within the GRADE methodology (Schünemann et al., 2013):

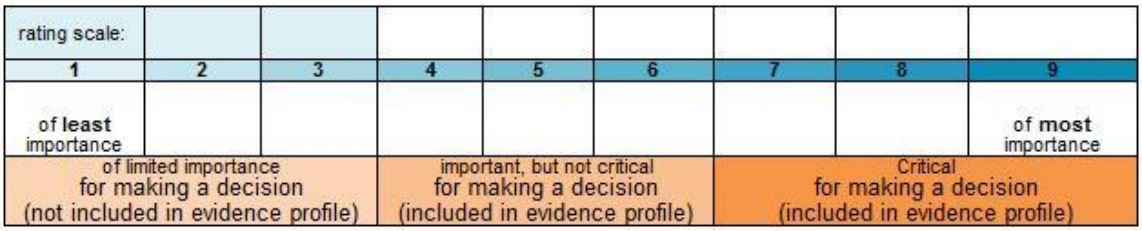
- Considerable priority (Must be included)
- Moderate priority (would be good if included)
- Some priority (may be included)
- Little priority (likely not included)
- No priority (do not bother)

Respondents will be able to identify additional topics in which they are interested in an open-response question.

Importance of clinical outcomes

The question related to clinical outcomes of interest to stakeholders will be based on a rapid overview of the research that was included in the 2019 edition of the Guideline. For this survey, only clinical outcomes related to treatment of PIs will be included. Recent work has already been conducted to collect the perspectives of stakeholders on clinical outcomes associated with preventing PIs (Lechner et al., 2022; Lechner et al., 2019; Lechner et al., 2021).

The clinical outcomes associated with treatment of PIs that were reported in the 2019 edition of the Guideline will be presented to survey respondents for rating on a nine-point scale defined within the GRADE methodology (Schünemann et al., 2013):



Adapting the survey questions for different respondent groups

The survey will be presented with two question sets – one question set for health professionals, academics, educators and industry representatives, and second version developed specifically for patients and informal carers. The smart survey design will present the appropriate set of questions based on the respondent's selection for 'type of stakeholder'.

The patient/informal carer survey questions will use less technical language and aim to have a reading level of Grade 5/6 (where possible without losing meaning) and will be enhanced with explanatory text to describe more technical terms (e.g., explanation of clinical assessment tools). Consultation will be undertaken with a consumer representative before the survey questions are finalised.

Recruitment

Participants will be recruited via open invitation promoted by the Member Organizations through their social media, newsletters and websites, and through the International PI Guideline website. Invitations will be sent to health professionals via the Member Organization mailing lists, including identifying the opportunity for the survey link to be openly shared with any potentially interested individual (e.g., the health professionals' patients, health consumers and colleagues). All health professionals who have been involved in the development of the third edition of the Guideline and all the registered stakeholders (individuals, organizations and industry groups) for previous edition of the Guideline will also be sent individual e-mail invitations to participate in the Stakeholder Survey.

Ethics

This is considered a low risk (opt-in, anonymous with no sensitive information collected) quality improvement initiative and a component of the Guideline development process. The Stakeholder Survey will collect perspectives from guideline stakeholders on its content, in the same way a draft guideline is presented to stakeholders for their review prior to publication. The proposed survey was evaluated by the University of Nebraska Medical Center, Institutional Review Board, Office of Regulatory Affairs (Nebraska, US) and it was determined this project does not constitute human subject research and was therefore exempt from seeking ethics approval.

Data analysis

Demographic data will be tabulated. Data reflecting the interests of respondents regarding care settings and population groups will be presented graphically. Data describing the priority ranking assigned to clinical question topics will be analyzed and graphically presented as the median rankings by stakeholder category (patient and informal carers, researcher/academic/educators, health workers and all stakeholders). The data describing the ranking of importance of clinical outcomes for evaluating PI treatment will be reported as

analyzed and graphically presented as the median rankings by stakeholder category (patient and informal carers, researcher/academic/educators, health workers and all stakeholders). Open responses on additional topics and innovations that stakeholders consider relevant to address in the Guideline content will be grouped (by stakeholder type) according to the general themes arising.

Stakeholder Survey

Initial Public Consultation Survey

About this Survey

The European Pressure Ulcer Advisory Panel (EPUAP), National Pressure Injury Advisory Panel (NPIAP) and Pan Pacific Pressure Injury Alliance (PPPIA) released the International Guideline on the Prevention and Treatment of Pressure Ulcers/Injuries in November 2019 after an extensive and rigorous review of the available evidence. Now these same organisations are preparing start work on a new edition of the Guideline and are seeking stakeholder feedback.

The survey is designed to collect information about the stakeholder opinion on the content of the next guideline version. The survey will ask about:

- Simple information about you
- What you use the guideline for
- Questions you would like answered
- Things important to you for deciding if you would use a treatment

THIS SURVEY WILL CLOSE ON 16th June, 2022.

> **Institutional Review Board Waiver**
>
> The University of Nebraska Medical Center, Office of Regulatory Affairs (ORA) determined this project does not constitute human subject research as defined at 45CFR46.102. Therefore, it is not subject to the US federal regulations. No further action is required. No Application needs to be submitted.

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Privacy - Terms

☐ I consent to compilation of my survey responses with other stakeholder responses and understand that my individual responses are non-identifiable.

Do The Survey | No Thank You

Demographics

1. What country do you currently live in?

2. Which of the following best describes you? ---

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- ---
- Health professional/health worker
- Researcher/academic/educator
- Industry representative
- Person who has or previously had a pressure injury
- Person concerned about getting a pressure injury
- Family/friend caregiver trying to look after a pressure injury
- Family/friend caregiver trying to prevent a pressure injury

Populations of Interest

Rank the following populations from most interested in (1) to least interested in (10).

You must rank at least four options.

Unranked Options
Neonates
Children
Elderly
Overweight and obese individuals
Individuals living with spinal cord injury
Individuals living with other disabilities
Individuals receiving life-saving critical care
Individuals receiving end-of-life care
Individuals with COVID-19/other infectious diseases

Drag and drop options into your ranking.

	Ranked Options
1	
2	
3	
4	
5	
6	
7	
8	
9	

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Settings of Interest

Rank the following settings from most interested in (1) to least interested in (10).

You must rank at least four options.

Unranked Options
General acute care
Critical care
Operating room/theatre
Emergency department
Rehabilitation Care
Long term care/Nursing home/Aged care
Skilled nursing care
Palliative Care
Outpatient Clinic
Individuals in community settings

Drag and drop options into your ranking.

	Ranked Options
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	

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Main Interests

The following screen presents broad topics related to pressure injuries. Rank the following topics from most interested in (1) to least interested in (5). Your response to this question will determine the order you receive the next questions in this survey.

Unranked Options

Drag and drop options into your ranking.

	Ranked Options
1	Assessments associated with pressure injuries
2	Pressure injury risk
3	Preventing pressure injuries
4	Treating pressure injuries
5	Stakeholder engagement, knowledge and skills

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Topics of Interests Introduction

The Guideline Governance Group (GGG) is commencing the development phase for the 4th edition of *Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline*. In preparation, the GGG will develop clinical questions relevant to stakeholders. The first step in developing the new clinical questions, is finding out what are considered priorities by our stakeholders. Stakeholders are health professionals, patients, informal carers and anyone else with an interest in the next edition of the guideline.

The following screens present topics that were considered for *Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline* 3rd edition, 2019).

Please rank the topics according to **your priority for their inclusion in the next guideline edition.**

You do not need to answer every item.

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Assessments Associated with Pressure Injuries

Please rank the topics according to **your priority for their inclusion in the next guideline edition.**

	Considerable Priority (Must be included)	**Moderate Priority** (Would be good if included)	**Some Priority** (May be included)	**Little Priority** (Likely not included)	**No Priority** (Do not bother)
What are accurate and effective methods for pressure injury classification?	●	●	●	●	●
What are accurate and effective methods for pressure injury assessment?	○	○	○	○	○
What are accurate and effective methods for skin and tissue assessment?	●	●	●	●	●
What are accurate and effective methods for assessing nutritional status of individuals with pressure injuries?	○	○	○	○	○
What are accurate and effective methods for assessing nutritional status of individuals at risk of pressure injuries?	●	●	●	●	●
What are accurate and effective methods for assessing heel skin and tissue?	○	○	○	○	○
What are accurate and effective strategies for evaluating/monitoring pressure injury healing?	●	●	●	●	●
What are accurate and effective strategies for assessing pressure injury pain?	○	○	○	○	○
What are accurate and effective strategies for assessing infection and biofilms in pressure injuries?	●	●	●	●	●
What are accurate and effective strategies for selecting an individual for surgical intervention for a pressure injury?	○	○	○	○	○

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Risk of Pressure Injuries

Please rank the topics according to **your priority for their inclusion in the next guideline edition.**

	Considerable Priority (Must be included)	**Moderate Priority** (Would be good if included)	**Some Priority** (May be included)	**Little Priority** (Likely not included)	**No Priority** (Do not bother)
What factors put people at risk for pressure injury development?	●	●	●	●	●
What are accurate and effective methods for pressure injury risk assessment?	○	○	○	○	○
What factors put people at risk for heel pressure injury development?	●	●	●	●	●

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Preventing Pressure Injuries

Please rank the topics according to **your priority for their inclusion in the next guideline edition.**

	Considerable Priority (Must be included)	**Moderate Priority** (Would be good if included)	**Some Priority** (May be included)	**Little Priority** (Likely not included)	**No Priority** (Do not bother)
What skin and soft tissue interventions (e.g. skin care, moisture or friction reduction interventions) are effective in preventing pressure injuries?	●	●	●	●	●
What nutritional interventions are effective in preventing pressure injuries?	○	○	○	○	○
What local management strategies are effective in preventing device related pressure injuries?	●	●	●	●	●
What support surfaces are effective in preventing pressure injuries?	○	○	○	○	○
What repositioning interventions are effective in preventing pressure injuries?	●	●	●	●	●
What early mobilization interventions are effective in preventing pressure injuries?	○	○	○	○	○
What are effective local management strategies (e.g., skin care, moisture or friction reduction interventions) in preventing heel pressure injuries?	●	●	●	●	●
What interventions are effective in preventing heel pressure injuries?	○	○	○	○	○
What are effective biophysical agents for preventing pressure injuries (e.g., electrical stimulation, ultrasound etc.)?	●	●	●	●	●

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Treating Pressure Injuries

Please rank the topics according to **your priority for their inclusion in the next guideline edition.**

	Considerable Priority (Must be included)	**Moderate Priority** (Would be good if included)	**Some Priority** (May be included)	**Little Priority** (Likely not included)	**No Priority** (Do not bother)
What nutritional interventions are effective in supporting pressure injury healing?	●	●	●	●	●
What support surfaces are effective in supporting pressure injury healing?	○	○	○	○	○
What repositioning methods are effective in supporting pressure injury healing?	●	●	●	●	●
What factors affect healing of heel pressure injuries?	○	○	○	○	○
What strategies are effective in preventing pressure injury pain?	●	●	●	●	●
What strategies are effective in treating pressure injury pain?	○	○	○	○	○
What local pressure injury treatments are effective for treating pressure injuries (i.e., cleansing, debridement, topical agents, wound dressings, etc.)?	●	●	●	●	●
What are effective strategies for preventing and treating infection and biofilms that interfere with pressure injury healing?	○	○	○	○	○
What are effective biophysical agents for treating pressure injuries (e.g., electrical stimulation, ultrasound and negative pressure wound therapy etc.)?	●	●	●	●	●
What strategies are effective in preparing and managing an individual undergoing surgical intervention for a pressure injury?	○	○	○	○	○

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Stakeholder Engagement, Knowledge and Skills

Please rank the topics according to **your priority for their inclusion in the next guideline edition.**

	Considerable Priority (Must be included)	**Moderate Priority** (Would be good if included)	**Some Priority** (May be included)	**Little Priority** (Likely not included)	**No Priority** (Do not bother)
What are effective strategies for engaging patients and their family caregivers in pressure injury prevention?	○	○	○	○	○
What are effective strategies for engaging patients and their family caregivers in pressure injury treatment?	○	○	○	○	○
What are effective strategies for promoting quality of life for people with or at risk of pressure injuries?	○	○	○	○	○
What valid and reliable assessment methods are available to evaluate health professional knowledge of pressure injury prevention and treatment?	○	○	○	○	○
What interventions are effective in attaining sustained improvements in health professional knowledge of pressure injury prevention and treatment?	○	○	○	○	○
What interventions are effective in attaining sustained improvements in health professional competency in pressure injury prevention and treatment?	○	○	○	○	○
What institutional level interventions are effective in preventing pressure injuries?	○	○	○	○	○

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Additional Questions

Do you have any suggestions for emerging innovations you think are a priority to address in the new guideline?

Do you have any other suggestions for new topics related to assessment, prevention and/or treatment of pressure injuries?

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Clinical Outcome Measures (part 1)

The final sections are more technical in nature and relate to the way that interventions to treat pressure injuries/ulcers are evaluated and reported in research studies.

To help patients and other health professionals make decisions about treatments, we need evidence about what works best. Treatments are developed and tested by researchers to make sure they work and are safe. To do this, researchers look at the effects those treatments have on patients. Researchers do this by measuring an "outcome". Outcomes are treatment effects. For example, a dressing applied to a pressure ulcer/injury is the treatment, healing may be an outcome. However, many other outcomes may be measured as well (e.g., pain, quality of life), depending on the what the treatment was designed to do. For the purposes of this survey, assume there is a good match between the treatment and the outcome.

Outcomes have to be relevant to patients and health professionals. This information is helpful to guideline developers because it provides an indication of what evidence the guideline developers should look at.

The next pages list outcomes that have been reported in the research on treatments for pressure injuries/ulcers. They have been compiled from all the studies reported in the previous edition of the International Pressure Injury/Ulcer guideline. Not all of these outcomes are necessarily important for evaluating every pressure injury/ulcer treatment. For example, healing or lowering pain reduction might be more relevant for patients compared to reduction in microbial counts or technical properties of dressings.

Please rate the outcomes on how important you consider the outcome is for making a decision about whether or not you would use a specific treatment reported in research. **When making your evaluation please assume the outcome is relevant to the intervention.** In the guideline critical outcomes will be given highest priority.

You do not need to answer every item.

How important do you consider it is that researchers evaluate and report the following outcomes for studies on pressure injury/ulcer treatments?

	Critical for making a decision			**Important but not critical for making a decision**			**Of limited importance for making a decision**		
	1. (Of Most Importance)	2.	3.	4.	5.	6.	7.	8.	9. (Of Least Importance)
1. Improved scores on a validated wound assessment tool designed to monitor progress toward healing (e.g., PUSH Tool, BWAT, DESIGN-R) more info	○	○	○	○	○	○	○	○	○
2. Change in size of the pressure injury/ulcer	○	○	○	○	○	○	○	○	○
2a. Change in length and/or width	○	○	○	○	○	○	○	○	○
2b. Change in depth	○	○	○	○	○	○	○	○	○
2c. Change in surface area	○	○	○	○	○	○	○	○	○
2d. Change in volume of wound	○	○	○	○	○	○	○	○	○
2e. Change in tunneling and undermining measurement	○	○	○	○	○	○	○	○	○
3. Percent decrease in wound size (surface area)	○	○	○	○	○	○	○	○	○
3a. 25% decrease in wound size	○	○	○	○	○	○	○	○	○
3b. 50% decrease in wound size	○	○	○	○	○	○	○	○	○
3c. 75% decrease in wound size	○	○	○	○	○	○	○	○	○
3d. 100% decrease in wound size (complete healing) only	○	○	○	○	○	○	○	○	○

	Critical for making a decision			Important but not critical for making a decision			Of limited importance for making a decision		
	1. (Of Most Importance)	2.	3.	4.	5.	6.	7.	8.	9. (Of Least Importance)
4. Time it takes the pressure injury/ulcer to heal	○	○	○	○	○	○	○	○	○
4a. Time to complete healing only	○	○	○	○	○	○	○	○	○
4b. Decrease in size at 2 weeks	○	○	○	○	○	○	○	○	○
4c. Decrease in size at 4 weeks	○	○	○	○	○	○	○	○	○
4d. Decrease in size at 2 months	○	○	○	○	○	○	○	○	○
4e. Decrease in size at 3-6 months	○	○	○	○	○	○	○	○	○
4f. Decrease in size at 7-9 months	○	○	○	○	○	○	○	○	○
4g. Decrease in size at 10-12 months	○	○	○	○	○	○	○	○	○
5. Improvements in the type of tissue in the wound	○	○	○	○	○	○	○	○	○
5a. Decrease in percent necrotic tissue (eschar)	○	○	○	○	○	○	○	○	○
5b. Decrease in percent slough	○	○	○	○	○	○	○	○	○
5c. Increase in percent healthy granulation tissue	○	○	○	○	○	○	○	○	○
5d. Epithelialization only	○	○	○	○	○	○	○	○	○

	Critical for making a decision			Important but not critical for making a decision			Of limited importance for making a decision		
	1. (Of Most Importance)	2.	3.	4.	5.	6.	7.	8.	9. (Of Least Importance)
6. Decrease in exudate	○	○	○	○	○	○	○	○	○
6a. Change in exudate score on a validated wound assessment tool more info	○	○	○	○	○	○	○	○	○
6b. Number of times wound dressing changes required	○	○	○	○	○	○	○	○	○
7. Decrease in wound odor	○	○	○	○	○	○	○	○	○
8. Change in signs and symptoms of inflammation and infection	○	○	○	○	○	○	○	○	○
8a. Change in cardinal signs and symptoms of infection (heat, erythema, edema, purulent discharge)	○	○	○	○	○	○	○	○	○
8b. Change in local signs and symptoms of infection on a recognized infection assessment tool	○	○	○	○	○	○	○	○	○
8c. Microbial counts from tissue biopsy	○	○	○	○	○	○	○	○	○
8d. Microbial counts from quantitative swab	○	○	○	○	○	○	○	○	○
8e. Biofilm detection by tissue biopsy and high-resolution microscopy	○	○	○	○	○	○	○	○	○
8f. Change in markers of inflammation (e.g., C-reactive protein, matrix metalloproteinase, etc.)	○	○	○	○	○	○	○	○	○
8g. Change in bacteria fluorescence in the wound bed	○	○	○	○	○	○	○	○	○

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	Critical for making a decision			Important but not critical for making a decision			Of limited importance for making a decision		
	1. (Of Most Importance)	2.	3.	4.	5.	6.	7.	8.	9. (Of Least Importance)
9. Change in levels of wound-related pain	○	○	○	○	○	○	○	○	○
9a. Change in pain score on a recognized pain assessment tool	○	○	○	○	○	○	○	○	○
9b. Subjective assessment of comfort (patient)	○	○	○	○	○	○	○	○	○
10. Change in severity as defined by Category/Stage	○	○	○	○	○	○	○	○	○
11. Change in pressure injury condition (e.g., improved/deteriorated) based on clinical judgment	○	○	○	○	○	○	○	○	○
12. Subjective assessment of ease of use of product/intervention	○	○	○	○	○	○	○	○	○
12a. Assessment by patient	○	○	○	○	○	○	○	○	○
12b. Assessment by health professional	○	○	○	○	○	○	○	○	○
13. Cost of intervention	○	○	○	○	○	○	○	○	○
13a. Cost to patient	○	○	○	○	○	○	○	○	○
13b. Cost to health professional or facility	○	○	○	○	○	○	○	○	○
14. **Cost-benefit analysis**	○	○	○	○	○	○	○	○	○

Thank You

Your survey responses have been submitted.

Thank you for input. Your contribution will help ensure the next edition of the guideline better serves the needs of all stakeholders.

Done

APPENDIX 5: CORE OUTCOMES

Core Outcomes – Prevention of Pressure Injuries

The core outcomes to be considered for clinical questions related to prevention of pressure injuries are those defined in the OUTPUTs study (Lechner et al., 2022; Lechner et al., 2019; Lechner et al., 2021).

Table A5.1: Core outcomes for reporting PI prevention interventions (Lechner et al., 2022)

Core outcome	Description
1. Pressure ulcer occurrence	Pressure ulcers that develop anywhere on the body (reporting pressure ulcers specifically for defined body sites or device-related pressure ulcers will be decided at a later stage)
2. Pressure ulcer precursor signs and symptoms	Early pressure ulcer warning signs and symptoms including pain (not restricted to the skin)
3. Mobility	Patient's ability to move (e.g. turn over in bed and/or walk)
4. Acceptability and comfort of intervention	How well the patient accepts the prevention technique and the patient's comfort or discomfort
5. Adherence/compliance	Adherence and compliance of patients. Do patients use prevention techniques in the way they are intended to?
6. Adverse events/safety	Harmful or negative events that occur during the trial, for example injuries, falls, skin irritation or allergic reactions

PANEL GROUP NOMINATION FORM

Name: _____

Email: _____

Organization you are seeking to represent:

NPIAP EPUAP PPPIA Assoc Org (name): _____

Full Postal Address: _____

Health discipline: _____

Current employment and professional role:_____

Topics of expertise (use check boxes to nominate a maximum of three topics):

☐ Pressure injury risk
☐ Skin and soft tissue assessment and treatment

☐ Device-related pressure ulcers/injuries
☐ Nutrition
☐ Support surfaces
☐ Repositioning and mobilization
☐ Heel pressure injuries
☐ Pressure injury prevention bundles

☐ Assessment of pressure injuries/ulcers and methods to monitor healing
☐ Pressure injury pain
☐ Topical wound care and wound infection
☐ Wound dressings
☐ Biophysical agents
☐ Pressure injury surgery

☐ Health professional education
☐ Consumer focused issues: quality of life, involvement in care and education

Specific population of expertise: (use check boxes to nominate a maximum of two populations):

☐ Individuals receiving end-of-life care
☐ Individuals with spinal cord injury
☐ Children and neonates
☐ Individuals in critical/intensive care settings
☐ Individuals in community/home care settings
☐ Individuals in the operating room
☐ Individuals with darker skin tones