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Prevention and treatment of pressure ulcers/injuries: The protocol for the second update of the international Clinical Practice Guideline 2019

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ABSTRACT

Aim: The European Pressure Ulcer Advisory Panel, the Pan Pacific Pressure Injury Alliance, and the National Pressure Ulcer Advisory Panel are updating the 'Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline' (CPG) in 2019. The aim of this contribution is to summarize and to discuss the guideline development protocol for the 2019 update.

Methods: A guideline governance group determines and monitors all steps of the CPG development. An international survey of consumers will be undertaken to establish consumer needs and interests. Systematic evidence searches in relevant electronic databases cover the period from July 2013 through August 2018. Risk of bias of included studies will be assessed by two reviewers using established checklists and an overall strength of evidence assigned to the cumulative body of evidence. Small working groups review the evidence available for each topic, review and/or draft the guideline chapters and recommendations and/or good practice statements. Finally, strength of recommendation grades are assigned. The recommendations are rated based on their importance and their potential to improve individual patient outcomes using an international formal consensus process.

Discussion: Major methodological advantages of the current revision are a clear distinction between evidence-based recommendations and good practice statements and strong consumer involvement.

Conclusion: The 2019 guideline update builds on the previous 2014 version to ensure consistency and com-

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parability. Methodology changes will improve the guideline quality to increase clarity and to enhance implementation and compliance. The full guideline development protocol can be accessed from the guideline website (http://www.internationalguideline.com/).

1. Introduction

According to the latest definition of the Institute of Medicine in the United States 'Clinical practice guidelines (CPGs) are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.' [1]. CPGs are widely used in many areas of medicine and healthcare to support clinical decision making and to improve patient care and outcomes [2].

One of the first CPGs about pressure injury (PI)[1] prevention was published by the United States Agency for Health Care Policy and Research more than two decades ago [3]. Since then numerous other CPGs addressing PI prevention and treatment have been published and many are regularly updated [4–8]. In 2009, the National Pressure Ulcer Advisory Panel (NPUAP) in the United States and the European Pressure Ulcer Advisory Panel (EPUAP) published the first international CPG for the prevention and treatment of PIs [9]. The Pan Pacific Pressure Injury Alliance (PPPIA) joined this successful collaboration and all three organizations published the first update in 2014 [10,11]. Since publication, this document has been cited nearly 100 times in Web of Science (August 2018), the summary version (Quick Reference Guide) has been downloaded from the International PI CPG homepage (http://www.internationalguideline.com/) approximately 200,000 times, and translations into 13 languages are freely available from the EPUAP homepage (http://www.epuap.org/). This document is due for revision in 2019.

In order to be accurate, reliable, and useful, the development of CPGs must be standardized and meet methodological quality standards [1,12–14]. In addition, the science and methods of CPG development are constantly evolving. For instance, the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Working Group introduced a systematic and explicit approach to develop evidence based recommendations for CPGs in 2004 [15]. Since then, this framework was further developed and Evidence-to-Decision frameworks are now proposed to help guideline developers use evidence in a structured way to inform guideline recommendations [16,17]. A number of adapted and alternative guideline development approaches exist in parallel [18–20], but there is international agreement on key components of high-quality and trustworthy guidelines [14].

The 'Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline' of 2014 [10] is due for revision in 2019. The three organizations EPUAP, NPUAP and PPPIA agreed to collaborate and update this third edition. A guideline governance group (GGG) was formed in 2017 consisting of four representatives of each organization who are the authors of this manuscript. With the assistance of the methodologist, Emily Haesler, PhD, this group is responsible for overseeing the CPG revision process. The CPG development protocol has been adapted and updated based on experiences from the previous 2014 work, feedback and discussions about development methods [11,21,22], and latest methodological developments [17]. The overall objective of the GGG, on behalf of EPUAP, NPUAP and PPPIA, is to develop a high-quality and trustworthy PI guideline and to improve PI care worldwide. The aim of this paper is to summarize and discuss the guideline development protocol for the 2019 CPG update. Possible changes to the guideline development methods described in this protocol will be made explicit in final guideline document.

[1] The terms pressure ulcer, pressure ulceration and pressure injury are used synonymously in this text.

2. Clinical Practice Guideline development protocol

The full guideline development protocol for the third edition of the CPG was finalized in June 2018 and updated in November 2018 [23]. It can be accessed from the International PI CPG website (http://www.internationalguideline.com/). This paper is a summary of the full guideline development protocol and it provides additional background information and references to justify the current approach.

2.1. Scope and clinical questions

The guideline will briefly summarize the state-of-the-science of PI aetiology, prevention and treatment and will provide evidence based recommendations and good clinical practice statements covering PI prevention and treatment, for all age groups, in all healthcare settings, irrespective of the medical diagnoses, comorbidities and/or other health characteristics. The CPG is intended to be used by healthcare professionals and will provide guidance for caregivers and individuals at PI risk and those with existing PIs.

PI prevention includes topics such as risk factors and risk assessment, skin and soft tissue assessment and protection. PI treatments will include topics such as PI assessment and monitoring of healing, pain management, local wound care strategies, and surgery. Nutrition, support surfaces and repositioning, which are elements of both PI prevention and treatment, will also be addressed. Per topic, specific clinical questions have been developed to guide the evidence searches and to make recommendations. The complete list of all specific clinical questions can be seen in Appendix 1 of the full Methodological Protocol for the CPG (third edition) [23].

In addition to the general recommendations, the unique needs of specific populations such infants and children, individuals with spinal cord injuries and individuals with obesity will be addressed. Additional special populations and healthcare settings include individuals in the following settings: operating room, palliative care, critical care and community care settings. However, specific recommendations will only be provided, if the intervention is unique to this special population.

2.2. Guideline development team

The organizational structure of the CPG development is shown in Fig. 1. The Member Organizations overseeing development and sponsoring this update are EPUAP, NPUAP and PPPIA. Four representatives of each organization form the GGG, which monitors all steps of the CPG development and dissemination.

Fifteen international Associate Organizations that share the mission of the GGG support the work and share expertise and perspectives to complement EPUAP, NPUAP or PPPIA. These organizations, who met criteria, were selected after a formal application and selection process by the GGG.

Small Working Groups (SWGs) are formed to review the evidence, and to review and draft recommendations and guideline content. The SWG participants are selected based on the principle of equal contribution from the member organizations and representation from at least one Associate Organization. As well as the participants' expertise in the SWG content area and knowledge of research methods.

An experienced guideline methodologist (Dr. Emily Haesler) oversees the development process. The methodologist assists the SWG members in implementing the methodology, appraising and summarizing the evidence, revising the 2014 guideline recommendations and developing new recommendations. The methodologist will also manage

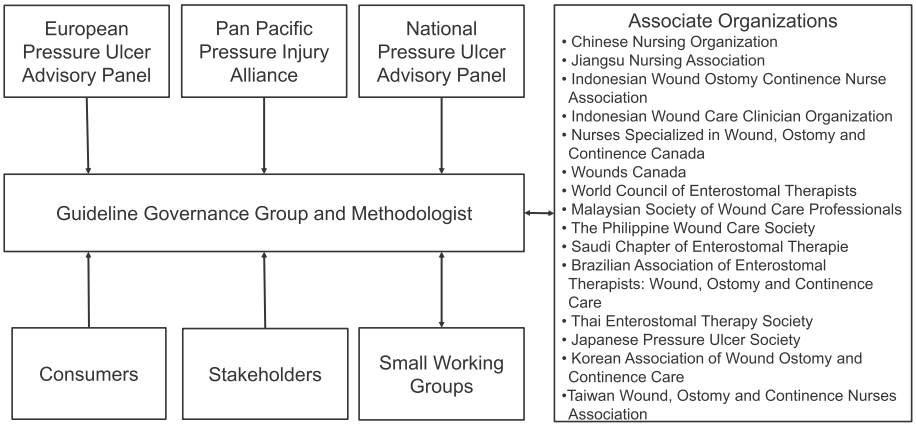

Fig. 1. Organisations and stakeholders.

the consumer survey and the confidential consensus voting process for assigning the Strength of Recommendations. Furthermore, she provides the link between the GGG, Associate Organizations and the SWGs.

2.3. Conflicts of interest

All individuals engaged in the guideline development (GGG and SWG members) must be free of major competing interests and must not have their primary employment in industry. Potential conflicts of interest (COI) are disclosed using a standardized from (see Supplementary material). A COI arises in any situation in which a group member has a direct or indirect pecuniary or personal (e.g. academic advancement, community standing) interest in the way the guideline is developed, how decisions are made, or how statements and/or recommendations are framed. Not all financial relationships with industry or other funding bodies represent true COIs but nevertheless actual or potential conflicts of interest must be declared to enhance transparency and credibility of the CPG. The standardized form is based on the recommendations of the Guidelines International Network [24] but it is acknowledged that the assessment of possible non-financial COI is less detailed. The declarations will be published with the guideline. Potential COI are declared and managed based on an adapted version of the Guidelines International Network Principles [24]:

(1) Every GGG and SWG member must declare any potential COI according to the Disclosure Form (Supplementary material) on an annual basis during the guideline development.
(2) The COI statements are kept with the Chairpersons of the EPUAP, NPUAP and PPPIA and the methodologist, and are valid for one year. Emergent COI during the year must be declared immediately within the working process or meetings and on an updated COI form.
(3) Every person (SWG member, GGG members and GGG chairs) with a 'moderate' to 'very high' COI according to the International Guidelines Network [24] must:
   - not review and/or critically appraise any papers in the area of the COI
   - be excluded from any group discussions, statements and chapter preparations, and strength of evidence ratings.

Every COI is topic specific. The 'weight' of every potential COI will be evaluated in conjunction with the 'relevance to topic' [24].

2.4. Consumer engagement

Consumer engagement is recognized as a requirement for high quality, international clinical guidelines [14,25–27]. In the context of this CPG, consumer requirements and goals are detailed in Table 1. In accordance with international standards [28] consumers (patients, informal caregivers and representatives) will be invited to engage in the guideline development process and consumers will be recruited to complete a consumer survey, participate in a Consumer SWG and/or register as a stakeholder.

2.4.1. Consumer survey

At commencement of the project, an international survey of consumers will be undertaken to establish consumer needs and their interest in outcome measures and inform development of the clinical questions. Broad consumer input will be sought, with a goal of collecting information from consumers in all geographic regions participating in the guideline. Information collected via the survey will be used to review and revise the list of clinical questions, to contribute to the evidence-to-decision framework, and to develop priorities for consumer education material.

2.4.2. Consumer small working group

A Consumer SWG will be established to review each chapter during the drafting phase. Member and Associate Organizations will recruit and nominate consumers from their geographic region, with a goal of 7–10 consumer representatives from each region. Consumer SWG members will be required to complete COI forms. Consumer SWG members will be asked to provide feedback using a standardized format that will include:

Table 1
Consumer engagement and goals.

Consumer engagement refers to involvement in guideline development from the following groups:
- patient consumers (i.e. individuals with or at risk of a PI),
- informal caregivers (i.e. individuals who provide care in an informal capacity such as family members, friends or community); and
- consumer stakeholders (i.e. professional consumer representatives).

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

Consumer engagement will be invited through:
- Website invitations.
- Invitation via GGG and SWG members.
- Invitations to consumer stakeholder groups, Indigenous groups and patient support network groups (e.g. SCI patient groups) known to GGG members in all geographic regions.
- Social media.
- Recruitment to stakeholder engagement or Consumer SWG will be included in consumer survey.

- Sensitivity (language) of terms.
- Relevance to individuals with or at risk of pressure injuries.
- Acceptability of interventions (e.g., preferences, cultural considerations).
- How much of the information the consumer would want to know.

Information provided by the Consumer SWG will be used to review the presentation of the Guideline, review and revise the recommendations, develop priorities for consumer education material and contribute to the evidence-to-decision framework.

2.5. Other stakeholders

The process of developing the guideline will be made available to stakeholders, on the guideline website (http://www.internationalguideline.com/). Anyone with an interest in PIs, including organizations, industry representatives, healthcare professionals, consumers and informal caregivers, may register as a stakeholder. In 2014, 698 individuals registered as stakeholders to provide feedback to the second edition of the guideline.

2.6. Methods

2.6.1. Identifying the evidence

As the guideline builds on a previously published body of evidence, the evidence search dates for this 2019 update are 1st July 2013 through 31 December 2017. A last update is planned to include evidence published until 31 August 2018. Some SWGs, particularly those that address evidence in topics newly introduced to the guideline, may extend the search to ensure previously published literature meeting the inclusion and exclusion criteria has been represented. Several electronic databases will be used, such as Medline and Embase, using a sensitive search strategy. References must meet the following general inclusion criteria to be considered eligible:

- The articles must be primarily focused on PI prevention, risk assessment, or PI treatment in human subjects.
- The articles must have been published in a peer reviewed journal.
- The articles must report primary research using empirical research designs.

There will be no language restrictions and as such a pool of translators is available to assist in the translation process. Synthesized evidence such as systematic reviews and meta-analysis meeting the critical domains of the AMSTAR 2 tool [29] will be considered for comparative discussion.

In the 2014 guideline, a systematic review published by Coleman et al. [30] was used and updated to summarize the empirical evidence about PI risk factors. A similar strategy will be used for the Guideline update, extending Coleman and colleagues search to 31 December 2017 and applying the same methodology.

2.6.2. Risk of bias assessment

The risk of bias of each study will be assessed by two reviewers using established checklists (Table 2).

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

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

2.6.3. Levels of evidence

Within this CPG a distinction will be made between ‘direct’ and ‘indirect’ evidence. Studies of patients with PIs and individuals at PI risk are considered ‘direct evidence’ and will be required to support an A or B ‘strength of evidence’ rating (see 2.6.7). Studies in healthy human subjects, human subjects with other types of chronic wounds, laboratory studies using animals, or computational models are regarded as indirect evidence. Indirect evidence will support recommendations with a C ‘strength of evidence’ rating, or GGG good practice statements.

The levels of evidence for individual intervention studies will be assigned to each study containing direct evidence, using a classification system adapted from The Joanna Briggs Institute [35] (see Table 3).

Diagnostic accuracy studies are studies in which results of index tests are compared with results from reference standards, sometimes called gold standard, at the same point in time [38]. Therefore, cross-sectional designs are needed to establish the concurrent existence of both index test and reference standard results. A typical example is the comparison of results of quantitative swab culture (index test) and quantitative tissue culture (reference standard). Adapted levels of

Table 2
Critical appraisal tools for assessing risk of bias.

Study design	Tool	Version
Case series	Checklist based on a tool reported by Moga, Guo [31]	Version published 2012 (accessed November 2017)
Case control studies	Scottish Intercollegiate Guidelines Network (SIGN) checklist for case control studies	Version accessed November 2017
Cohort studies	SIGN checklist for cohort studies	Version accessed November 2017
Cross-sectional/survey studies	Checklist derived from the SIGN checklists	Developed 2012
Diagnostic studies	SIGN checklist for diagnostic studies	Version accessed November 2017
Implementation research	STaRI checklist [32] **PLUS** an appropriate checklist to study design when applicable	Version published 2017
Qualitative research	Critical Appraisal Skills Programme (CASP) Tool	Version accessed November 2017
Quality improvement reports	Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0) [33] **PLUS** an appropriate checklist to study design when applicable	Version published September 2015
Quasi-experiments	Checklist adapted from the SIGN checklist for RCTs, and consistent with methodology reported by Joanna Briggs Institute [34,35].	Version developed 2012
Prognostic designs (excluding those related to risk)	QUIPS checklist [36]	Version published 2013
Randomized controlled trials	SIGN checklist for RCTs	Version accessed November 2017
Risk factor studies with multivariable analyses	Methodology outlined by Coleman, Gorecki [37]	Version published 2013
Economic evaluations	SIGN checklist for economic evaluations, based on the requirements for submission to the British Medical Journal	Version accessed November 2017
Systematic reviews	AMSTAR 2 checklist [29]	Version accessed November 2017

Table 3
Levels of evidence for intervention studies [35].

Level 1	Experimental Designs • Randomized trial
Level 2	Quasi-experimental design • Prospectively controlled study design • Pre-test post-test or historic/retrospective control group study
Level 3	Observational-analytical designs • Cohort study with or without control group • Case-controlled study
Level 4	Observational-descriptive studies (no control) • Observational study with no control group • Cross-sectional study • Case series (n = 10+)
Level 5	Indirect evidence: studies in normal human subjects, human subjects with other types of chronic wounds, laboratory studies using animals, or computational models

evidence are used for these study designs [39,40] and explained in the full guideline development protocol [23]. Test accuracy and validity estimates are only surrogate measures for clinical effectiveness [41]. The clinical effectiveness of diagnostic test procedures can only be adequately investigated by diagnostic RCTs [39,42]. In case of diagnostic or prognostic RCTs the described level of evidence hierarchy of intervention studies is used.

2.6.4. Data extraction

The full papers of included references will be obtained and made available to the relevant SWGs on a web-based platform (LineGuide) that facilitates critical appraisal and data extraction. A data extraction template will be used to extract relevant data from individual papers, including study design; description of participants; study groups and interventions; outcome measures; length of follow up; study results; and comments and limitations. The technical documents summarizing data extraction of included studies will be made available at the guideline website after the guideline has been published.

2.6.5. Developing recommendations

Each SWG will formulate conclusions about the body of available evidence based on the evidence tables and critical appraisals and levels of evidence. Evidence tables from previous guideline editions will be made available to SWGs to ensure the full body of scientific literature is reviewed. The first draft of recommendations developed by the respective SWGs will be reviewed by the GGG making revisions as necessary, and then will be additionally reviewed by the Consumer SWG.

To ensure uniformity and internal consistency in the final guideline recommendations they must comply with the following rule: Each recommendation starts with a direct action verb and be a simple, short, direct, declarative statement, free of jargon.

2.6.6. Terminology

The term ‘individual’ is used to describe the patient, client, resident, or person with a PI, or at risk for a PI. The terms ‘health professional’ refers to persons with professional qualifications and health professionals and non-professional healthcare workers who provide formal healthcare services to the individual, comprise the ‘interprofessional team’. The roles of professionals/healthcare workers who perform a given service may vary from country to country based on the laws and regulations governing healthcare providers. The term ‘informal caregiver’ is used to describe people providing care to individuals outside the context of formal healthcare services. This generally refers to family members and friends.

Medical devices or drugs for PI prevention and treatment such as dressings, support surfaces, or topical agents available in one country may not be available in another. Therefore, generic names will be used when referring to these products. The CPG will not endorse, nor appear 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 in the CPG text. Descriptions of products used, and possible modes of action in the appraised research, will be used as presented in publications, and more information may be sought from the manufacturer's product information if required. In evidence tables, full product and brand 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.

2.6.7. Strength of evidence ratings

‘Strength of evidence’ ratings will be assigned to recommendations. This rating identifies the strength of the cumulative body of evidence supporting each recommendation. Critical appraisals of quality and levels of evidence for studies in a recommendation's cumulative body of evidence will be considered in ‘strength of evidence’ ratings. Table 4 outlines the strength of evidence rating system to be used for the 2019 guideline edition (adapted from NHMRC methodology) [27].

The SWGs will summarize the evidence supporting each recommendation. An explicit link between the recommendation and supporting evidence is expected. The strengths and limitations of this body of evidence will also be clearly described. All recommendations with a ‘strength of evidence’ rating of A or B will require an explicit summary of one or more studies conducted with human subjects with PIs or at risk for PI development. The ‘level of evidence’ for each study and its quality rating will also be identified.

The GGG good practice statements (Table 4) will be only made when they are perceived to be necessary. They should help clinicians to take appropriate actions in areas of uncertainty [43]. The GGG good practice statements will not be given a strength of recommendation, consistent with current best practice in guideline development [43]. Evidence gaps will be explicitly identified and will serve as an agenda

Table 4
Strength of evidence rating for each recommendation (adapted from NHMRC) [27].

A	• More than one high quality Level I study providing direct evidence • Consistent body of evidence
B1	• Level 1 studies of moderate or low quality providing direct evidence • Level 2 studies of high or moderate quality providing direct evidence • Most studies have consistent outcomes and inconsistencies can be explained
B2	• Level 2 studies of low quality providing direct evidence • Level 3 or 4 studies (regardless of quality) providing direct evidence • Most studies have consistent outcomes and inconsistencies can be explained
C	• Level 5 studies (indirect evidence) e.g., studies in healthy human subjects, humans with other types of chronic wounds, animal models • A body of evidence with inconsistencies that cannot be explained, reflecting genuine uncertainty surrounding the topic
Good practice statement	• Statements by the GGG that are not supported by a body of evidence as listed above but considered significant for clinical practice.

Table 5
Five types of recommendations [15,45,46].

Recommendation	Symbol	Description	Implications
Do it: Strong recommendation for an intervention **Don't do it:** Strong recommendation against 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.
Probably do it: Conditional recommendation for using an intervention **Probably don't do it:** Conditional recommendation against 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 quality monitors*—Clinicians' discussion and consideration of pros and cons of the intervention, and documentation of discussion, could be used as a quality indicator.
No specific recommendation: Conditional recommendation for either the intervention or the comparison	↔	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'.

for future research efforts.

2.6.8. Strength of recommendations

The 'strength of evidence' ratings identify the strength of cumulative evidence across studies supporting the recommendation. In addition, 'strength of recommendation' grades are assigned (Table 5). The recommendations are rated based on their importance and their potential to improve individual patient outcomes. The 'strength of recommendation' is the extent to which a health professional can be confident that adherence to the recommendation will do more good than harm. The grading of importance is not necessarily related to the strength of internal or external evidence. The overall aim is to help health professionals to prioritize interventions. The following points will be considered when assigning the strength of recommendation [44–48]:

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

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

- How strong is the confidence that estimated probabilities improve clinical decision making, treatment decisions and subsequent patient outcomes? [41,42,49].

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

The process will be facilitated using an evidence-to-decision framework that will be finalized by the GGG. An evidence-to-decision framework presents relative pros and cons for interventions and ensures individuals voting on recommendations do so with a more complete understanding of the evidence and implications of recommendations. For each recommendation to be evaluated using the adapted-GRADE process, voters will be presented with a tabulated summary of the evidence relevant to questions about desirable and undesirable anticipated effects, the overall certainty of evidence, resource requirements, feasibility of implementation, and values of consumers.

After reviewing the evidence-to-decision table, voters will be asked to select a 'strength of recommendation' grade from the options presented in Table 5 and an additional option to abstain from voting (with reason provided). Votes will be recorded and calculated using a software program designed for the purpose. Participants will be able to nominate a 'strength of recommendation' for as few, or as many recommendations as they prefer, but will be strongly encouraged to vote on all recommendations.

Rules for determining 'strength of evidence' were determined based on previous applications of the adapted GRADE process, and a desire to obtain significant consensus. Determination of the final 'strength of recommendation' will be made according to the following rules:

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

As can be seen in Table 5, the thumb sign used in the 2014 CPG has been replaced by arrows. From a conceptual point of view it does not matter whether symbols, letters or numbers are used [50]. However, this decision has been made to avoid any potential cultural issues.

3. Discussion

The EPUAP, NPUAP and PPPIA are currently developing the third edition of the International CPG for the prevention and treatment of PIs according to the methods described in this protocol. Overall, the development is similar to the previous version to ensure consistency and comparability. However, some changes were considered necessary to

improve the CPG quality and to make this document more powerful.

3.1. Strength of evidence ratings and good practice statements

In the 2014 CPG a slightly different strength of evidence hierarchy was used. Expert opinion was considered as one source of evidence to support the lowest strength of evidence level C, for the 2019 update, expert opinion has been identified more transparently. The GGG believes that expert opinion is of major importance to inform clinical practice, because scientific evidence is either indirect or widely missing in many different areas of PI prevention and treatment [11]. However, in a strict sense, formal strength of evidence and strength of recommendation ratings are inappropriate for expert opinions [43]. Instead, good practice statements will be developed. These statements typically represent situations in which evidence is missing but the GGG considers this significant for clinical practice. At the same time good practice statements will be used only when they are necessary, that is, without such a statement, clinicians might fail to take the appropriate action [43].

This adapted methodology will have several advantages: the overall number of guideline recommendations will be reduced, enhancing the clarity and readability of the document. A clearer distinction will be made between evidence based formal guideline recommendations and crucial best practice statements. The reduction of trivial statements, length and complexity is considered as one measure to enhance compliance with this guideline [51]. Because of the changes to methodology, the ratings given to studies in previous editions of the CPG will also be reviewed. For recommendations supported by direct evidence, the addition of evidence-to-decision frameworks will more explicitly link the evidence to decisions regarding evidence-based based recommendations.

3.2. Special populations

The focus on specific populations is important and takes the special PI risk and treatment challenges for each group into account. However, in the 2014 edition this led to a number of repetitions of guideline recommendations in the special populations' chapters. The GGG believes that key PI preventive and treatment interventions are similar across populations. Therefore, attention will be paid in this edition to avoiding unnecessary repetitions, and to develop only those recommendations and/or good practice statements, that are unique to the given populations. This, will reduce the overall number of recommendations and make this edition of the CPG more concise. The needs of individuals in community settings will be examined for the first time in the 2019 Guideline.

3.3. Consumer engagement

Insufficient consumer engagement was a weakness in the 2014 CPG. Therefore, several measures are implemented to engage consumers via various channels. The consumer survey is available July 2018 through October 2018; with over 1200 respondents to date. In addition to informing the clinical questions and the guideline content, the results of this survey will be a major source for directing future PI research and development of patient consumer resources.

3.4. Dissemination and implementation

In addition to the hard copy version, the CPG will be disseminated as an electronic version as a downloadable pdf. The Quick Reference Guide (QRG) has been available in both paper and electronic forms since 2009. As with previous versions of the Guideline the GGG will work with individuals willing to translate the Guideline into languages other than English. Implementation tools and guides will be developed by the GGG and sponsoring organizations in order to meet the cultural and unique practice needs of different regions of the world.

4. Conclusions

Based on the previous experiences and latest methodological developments, the GGG and methodologist has improved the CPG development methods as described in this protocol. This will result in an enhanced quality CPG which is expected to be implemented more widely than previously, improving the quality of PI prevention and treatment worldwide.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jtv.2019.01.001.

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