SCOTTISH HEALTH PROTECTION NETWORK
Promoting and Supporting Good Practice

Scottish Health Protection Network Guidance Group (SHPN-GG)

(Version 2.0 FINAL)

Protocol for the Development of Consensus Based Recommendations

Table of Contents

1. Summary

Evidence is required for producing public health and clinical guidance. Evidence resulting from systematic literature reviews is generally preferred to assist in the decision-making process. However, for certain topics, literature reviews may return insufficient or provide low quality evidence. In circumstances where there is lack of evidence, or where evidence is conflicting, consensus-based methods offer a valid approach for public health guidance production. Consensus-based methods can also be used more generally to assist in the process of drawing conclusions and developing recommendations. There are, however, recognised limitations associated with consensus-methods which include the potential for introducing bias.

This document provides a generic approach for assisting in developing public health recommendations based on consensus of expert opinion, within the '*SHPN Framework for Health Protection Guidance Development'*. The protocol is intended to assist in the production of SHPN Evidence Based Guidelines (EBG) or SHPN Good Practice Guidance (GPG), as outlined in the *SHPN Evidence Based Guideline Methodology* and the *SHPN Good Practice Guidance Methodology* respectively – particularly if a formal approach to consensus is indicated. If an SHPN sponsored guidance document does make use of a consensus approach to developing recommendations, it is expected that this protocol will be used.

2. Background

Guidance can be produced internally under the badge of SHPN, or externally by recognised public health organisations outside Scotland (e.g. Public Health England [PHE], the European Centre for Disease Control [ECDC], the US Center for Disease Control [CDC], the World Health Organisation [WHO]) and approved for use by the SHPN.

The '*SHPN Framework for Health Protection Guidance Development'* outlines the categorisation and methods employed by the SHPN, encompassing:

- The development of new guidance;
- Reviewing and updating existing SHPN guidance; and
- Reviewing guidance produced externally to SHPN, for acceptability of use in Scotland.

The '*SHPN Framework for Health Protection Guidance Development'* outlines two categories of health protection guidance in Scotland:

- Evidence Based Guidelines (EBG) - type A and A*
- Good Practice Guidance (GPG).

The SHPN has also produced four methodology documents to promote and support consistent implementation of the Framework:

- Evidence Based Guideline Methodology
- Good Practice Guidance Methodology
- Guidance Review and Update Methodology
- Review of External Guidance for Acceptability of Use in Scotland Methodology

Two further protocols have also been produced by the network to assist in guidance development:

- Protocol for the Rapid Development of Guidance
- Protocol for the Development of Consensus Based Recommendations

The SHPN considers that the latter refers to SHPN endorsed protocols intended to support guidance development, but are not comprehensive.

Consensus-based protocols provide an alternative way to generate advice, especially where published evidence is inadequate or non-existent. They provide an approach to harness the expertise of key experts (defined as individuals with extensive in-depth knowledge and/or research experience in their field) and enable agreement on generating recommendations. While consensus protocols are susceptible to criticism (e.g. bias given that recommendations reflect the opinions of a single group), they provide a transparent, reliable and valid approach in situations where guidance is needed in the absence of robust evidence.

3. Document Aims

The aim of this document is to provide a brief summary of possible methods, particularly based on expert opinion and consensus, which may assist in generating public health recommendations.

Within the '*SHPN Framework for Health Protection Guidance Development*', this document is known as the '*Protocol for the Development of Consensus-Based Recommendations*'. It is intended to assist the production of SHPN Evidence Based Guidelines (EBG) or Good Practice Guidance (GPG), as outlined in the '*SHPN Evidence Based Guideline Methodology*' and the '*SHPN Good Practice Guidance Methodology*', respectively. The protocol can also be used to assist in the development of other documents (other than SHPN guidance), where reaching consensus is required. Further advice can be sought from the SHPN-Guidance Group and Healthcare Scientists, who may help decide which method to adopt.

Summary of Key Points

- Evidence is ideally required to inform guidance production.
- A systematic literature review and critical appraisal of the literature is the gold standard in considering evidence for guidance production; however, this process is generally very resource intensive, and sometimes results in insufficient (or even contradictory) information.
- Consensus protocols, where experts come to an agreement on recommendations, provide an alternative approach to develop guidance where scientific evidence is either insufficient or conflicting.
- The most common (formal) approaches to consensus development that have been used in the healthcare and clinical fields are: the Delphi method; the nominal-group technique; and the consensus-development conference. The Delphi method and the nominal-group technique being the most appropriate in the context of SHPN guidance development.
- The protocol outlined here, and the approaches detailed, are flexible, so that they can be modified to meet the needs of a given situation.
- The approach used should always be clearly stated in the guidance documentation, should a consensus-based protocol become part of the development of guidance.

4. Consensus based approaches

The approaches outlined below are only intended to highlight the variety of methods that might be considered while developing public health guidance, particularly in circumstances where scientific evidence is conflicting or not sufficient, and where reaching expert consensus is needed. Additional info on consensus is provided in the references section, at the end of this document.

Please refer to the '*SHPN Evidence Based Guideline Methodology*' and the '*SHPN Good Practice Guidance Methodology*' for further details on each of the steps required to generate EBG and GPG respectively.

When a Guidance Development Group (GDG) embarks on the production of guidance and establishes that there is insufficient evidence available in the published literature to produce recommendations, then the GDG may use consensus methods as an alternative approach to generate recommendations.

Consensus methods require a group or panel of experts to agree on recommendations. The GDG – which is a group of individuals with expertise in the area (see the '*SHPN Framework for Health Protection Guidance Development*' for further details) – would be ideally placed to conduct the consensus process. The group would have an appointed Chair who could act as facilitator of the consensus process, or the group could decide to appoint a separate facilitator. Depending on the circumstances, it may be appropriate, however, to create a separate working group/panel with a Chair and/or facilitator, specifically, to carry out the consensus process and keep this separate. Both, the Chair and the facilitator, should be selected based on their communication, group management and conflict resolution skills, and should not have strong academic/healthcare sector bias.

Criteria for the GDG or the "consensus process working group" membership should include:

- Extensive in-depth knowledge and experience of the topic in question; or access to external expert level support if no members of the group can claim to have specific expertise;
- No existing conflict of interest that would prohibit ability to make a balanced judgement relating to the topic in question.

In Stage 4 of EBG or GPG development (Formulation of Recommendations and Drafting) (see '*SHPN Evidence Based Guideline Methodology*' and the '*SHPN Good Practice Guidance Methodology')* the GDG will consider the selected evidence available (scientific and/or non-scientific) and interpret this in order to adequately address the proposed guidance key questions. At this point, the GDG will consider how to formulate recommendations, either:

- by adopting an *informal* approach to consensus; or
- by pursuing a more *formal* approach to reach consensus.

The decision on adopting either a formal or an informal approach, will depend on the nature of the available evidence (characteristics of studies), and on of the need for rigour in the decision-making process.

Informal approach to consensus

An informal approach to consensus can be used on either EBG or GPG development. However, it may be the default choice in the development of GPG (as outlined in 5.4.1. of the '*SHPN Good Practice Guidance Methodology'*).

The term *deliberative process* has been used in the literature to describe the efforts among a body of experts, to discuss the interpretation and use of heterogeneous evidence, with the view to informally reach consensus. A *deliberative process* allows an informal approach to consensus but it is an active participatory platform for experts and stakeholders, to engage face-to-face to assess all available evidence.

While applying the *deliberative process* (particularly in relation to developing GPG) , GDG members should take into account the *colloquial* and *other types of non-scientific evidence*, while acknowledging the wide range of knowledge, experience, expertise and views that professionals, stakeholders, potential users and beneficiaries of the guidance might bring. All of these are essential in the decision-making process, prior to the formulation of recommendations.

The GDG would ideally document how they moved from the available evidence to each recommendation, and should document the decision-making process. If this is not documented in the guidance document itself, it should be recorded in the GDG meeting records. It is recommended that the GDG document the quality of the considered evidence, any identified uncertainties, and other issues on context (i.e. resources, training needs, etc.) that were elements of judgement.

Formal approach to consensus

If formal consensus is the chosen approach to formulate recommendations, the GDG or the "consensus process working group" should consider which method would be the most appropriate to follow, in order to meet the needs of the topic of the guidance or the situation that is being addressed. The most common formal approaches to reaching consensus that have been used in the healthcare[1] and clinical fields are:

- the Delphi method;
- the RAD/UCLA Appropriateness Method (RAM)
- the nominal-group technique; and
- the consensus-development conference.

The Delphi method is proposed as the most appropriate technique to use by the SHPN-GG (see 5.4.2. section of the '*SHPN Good Practice Guidance Methodology'*). However, other methods may be used if considered appropriate.

Delphi Method

The Delphi Method [2] is a valid way of seeking and organising judgements where there is little or no existing, conflicting and/or heterogeneous evidence.

Essentially, the Delphi method offers a structured process where a series of questionnaires or 'rounds' are used to gather information from experts (GDG). Each subsequent round is informed by the discussions and conclusions from the previous round. Participants are asked to reconsider their responses in light of the previous round's results. The rounds continue until an appropriate level of consensus is reached[3].

In the Delphi method, a first questionnaire survey allows the group participants / panel members to privately express their opinion on a particular key question. These opinions are then summarised and organised in a limited set of statements, which are then to allow participants to rank their agreement with the statements in the questionnaire. The results are summarised again and circulated to all participants with a repeat version of the questionnaire for a second round of rankings.

As this is an iterative process, the recommendations can be refined by re-phrasing questions in subsequent questionnaires and the process may be repeated a number of times. This, however, may be time-consuming and lead to a delay in producing the final recommendations for the guidance document. A minimum of three rounds is preferred for producing non-urgent draft recommendations.

The final rankings are summarised and assessed for degree of consensus and the participants receive feedback. The opinions of participants can be weighted depending on the expertise of a participant.

The coordination of this iterative process (summarising and circulating surveys) should be carried out by the facilitator of the GDG or panel, or if unavailable, by a project manager or healthcare scientist. Traditionally, the Delphi method is carried out without the participants physically meeting or interacting directly. This can allow a wider pool of experts across a wide geography to be involved. The GDG / panel may decide, however, to meet later on in the process to debate findings or finalise and sign-off recommendations. See Appendix A for a detailed schema of the process[2].

Advantages and Disadvantages of the Delphi Method	
Advantages	**Disadvantages**
• The anonymous voting system allows individuals to express views freely • Dominance by the 'loudest' member/s of the group is limited / everyone can have an opinion • More time to reflect on question, express ideas and make changes • The iterative process allows recommendations to be refined • Numerous and dispersed experts can take part.	• If experts never meet, ideas might be wrongly communicated • The iterative process can be time-consuming • Results depend on group / panel composition and by feedback given during the panel process • Results depend on questionnaire design • Potential for bias in participant selection.

Table 1: Advantages and Disadvantages of the Delphi Method, from Nair et. al 2011

RAND/UCLA Appropriateness Method (RAM)

RAND/UCLA Appropriateness Method [4] is a formal method of consensus, used for combining evidence from the literature with expert consensus. It can be used in developing guidelines where evidence is not sufficient, developing quality of care indicators, determining appropriate use of criteria or the over or underuse of a procedure. It can be used when resources and time are available. There are usually two groups, a core panel and an expert panel. The expert panels can range from 7 to 15 people – an odd number prevents ties. The core panel guides the expert panel through the process. They provide data to the panel which the panel then uses to come to a consensus. The core panel conducts a systematic literature review that provides the panel with information to guide their decision making.

In the first round, a list of clinical scenarios is presented to the panel via email. For each scenario the expert panel will be asked to rate on a Likert scale whether a particular intervention is appropriate – without consideration of the cost and independent of other panellists[5]. The second round is a series of face to face meetings, where panel members are given the results of the other experts' ratings and are given an opportunity to discuss views on each scenario. Panellists can then reconsider and review their original rating. The two-round process is designed to discern whether discrepant ratings are due to real clinical disagreement over the use of the intervention or to fatigue or misunderstanding. Disagreement means a lack of consensus, either because there is polarisation of the group or because judgements are spread over the entire 1 to 9 rating scale. Indications that have been classified as appropriate by the panel may need to be further rated with greater or lesser levels of agreement. Fitch RAND/UCLA user's manual (2001)[4] provides a step-by-step guide on how this method should be carried out. Table 2 illustrates the advantages and disadvantages associated with this method.

Advantages and Disadvantages of RAND-UCLA Appropriateness Method

Advantages	Disadvantages
• Synthesis of published literature prior to consensus techniques incorporated. • Allows for both confidential ratings as well as group discussion. • Multidisciplinary panel encourage consensus from a wider group. • Reproducibility of RAM ranges from moderate to excellent as determined by different panellists for "appropriate" and "inappropriate" care. • Acceptable predictive validity for a recommendation supported by RCTs.	• Misclassification is expected. • Takes great deal of time from gathering of the evidence to multiple rounds of consensus. • Face-to-face, which can add cost/time delay and lead to highly opinionated individuals in the field dominating the discussion. • Requires third party (core panel) to construct clinical indications for an intervention and analyze/interpret the results from the expert panel meeting. • Requires voting on multiple case scenarios.

Table 2: Advantages and Disadvantages of RAND-UCLA Appropriateness Methods, from Nair et. al 2011

Nominal Group Technique (NGT)

Nominal Group Technique [6] can be used to give priority to questions to be discussed. It consists of face to face structured group meetings where groups of 5-9 panellists are led by a moderator. The session begins with silent, independent ideas generation. There is then a round robin where ideas are shared, then privately and independently ranked – i.e. from 1 to 10. The highest ranking ideas are kept, others discarded. There is no definitive guidance as to what ranking would be considered as acceptable; however, this should be predefined. A facilitator is needed to support the process.

NGT could be modified by generating the initial responses via email, using the Delphi technique. It has been suggested that in an NGT, each person is more likely to generate ideas uninhibited by other participants. By avoiding elaboration during the ideas generation phase, this should reduce the risk of focussing on one particular suggestion. Moreover, this method allows everyone to make a contribution, avoiding dominance of the group by one or two stronger personalities. Additional advantages and disadvantages of this technique are outline in Table 3.

The process can be split into five main stages[7-8]:

- The Ideas stage: Group or panel members should start by writing their ideas or suggestions based on the key questions posed.
- The "Round Robin" stage: Each group or panel member should read out one of their ideas in turn, starting with their best one first. These ideas should all be written down (by a non-participating individual, e.g. the project manager, the secretariat) so that the whole group can see them (e.g. on a white board, projected onto a screen, on a flipchart etc).
- The Clarification / Discussion stage: At this stage each idea is discussed more widely and clarified; duplicate ideas are brought together and the individual ideas are numbered.
- The Voting stage: From the ideas which are numbered, the group needs to prioritise them based on an agreed voting system.
- The Action stage: The group discusses the outcome of the voting stage with the intent of reaching agreement, and produces recommendations to address the key questions.

The Nominal Group Technique is a good stand-alone technique for simple issues but must be combined with other techniques where the issue is more complicated or affects people outside the sphere of influence within the group.

Advantages and Disadvantages of Nominal Group Technique	
Advantages	**Disadvantages**
• Many ideas are generated • Participants meet face-to-face. • All participants have an opportunity to voice opinions. • Design of NGT does not allow any individual to dominate. • Requires only one skilled facilitator • Produces an answer with few resources • Decisions are made at the close of the meeting	• Certain members of the panel can take over discussion. • Limited by time – only a few questions can be discussed and agreed on. • Economic and time costs associated with face-to-face meeting. • Limited to providing a solution to a few problem limits its applicability to multiple scenarios.

Table 3. Advantages and Disadvantages of Nominal Group Technique, from Nair et. al. 2011

Consensus Development Conference (CDC)

Consensus Development Conference [9] is best used to provide guidance on how to proceed in the development of recommendations where an issue involves a controversial public health policy topic; where the issue is of a high degree of public interest; or where it may impact on health care costs. The CDC brings together selected experts and concerned individuals to reach agreement about the safety, efficacy and appropriateness of using various medical procedures, drugs and devices. A consensus statement is then drafted and presented for review by conference attendees. The panel may then modify the statement before it is released to influence healthcare practice and research. Some advantages and disadvantages of this method are outlined in Table 4.

Advantages and Disadvantages of Consensus Development Conference	
Advantages	**Disadvantages**
• Mix of practicing physicians, researchers, consumers, and others to come together and jointly evaluate an existing technology. • Wide circulation through both lay and medical media • Unbiased panel	• Interaction is not structured. • The aggregation methodology used is implicit – a formal feedback system is lacking.

Table 4. Advantages and Disadvantages of NIH CDC, from Nair et. al. 2011

Werner et. al. conducted an evaluation of a consensus conference that had been conducted online and via telephone. The majority of respondents (who had been expert panel members) stated that they would not have preferred traditional face to face conferences; that they had no technical problems; and that online consensus conferences were equivalent or superior to traditional conferences – indicating that perhaps online conferences could be an acceptable alternative to traditional face to face meetings[10].

Summary of methods of a formal approach to consensus

There are several benefits and limitations to each method. However, common to all methods is that:

- Consensus methods to guidance development should allow equal opportunity to each group / panel member to anonymously provide their opinion. This is to avoid dominance by a single or few members of the group / panel.
- If time allows, the process should also incorporate group interaction and iterative judgment processes by using several rounds of appropriateness ratings and reformulation of statements.
- Consensus methods should provide a controlled and systematic feedback to each group / panel member, indicating how their previous responses compared to the distribution of opinion across the group.
- A summary of results should be provided to each group / panel member and final recommendations drafted.

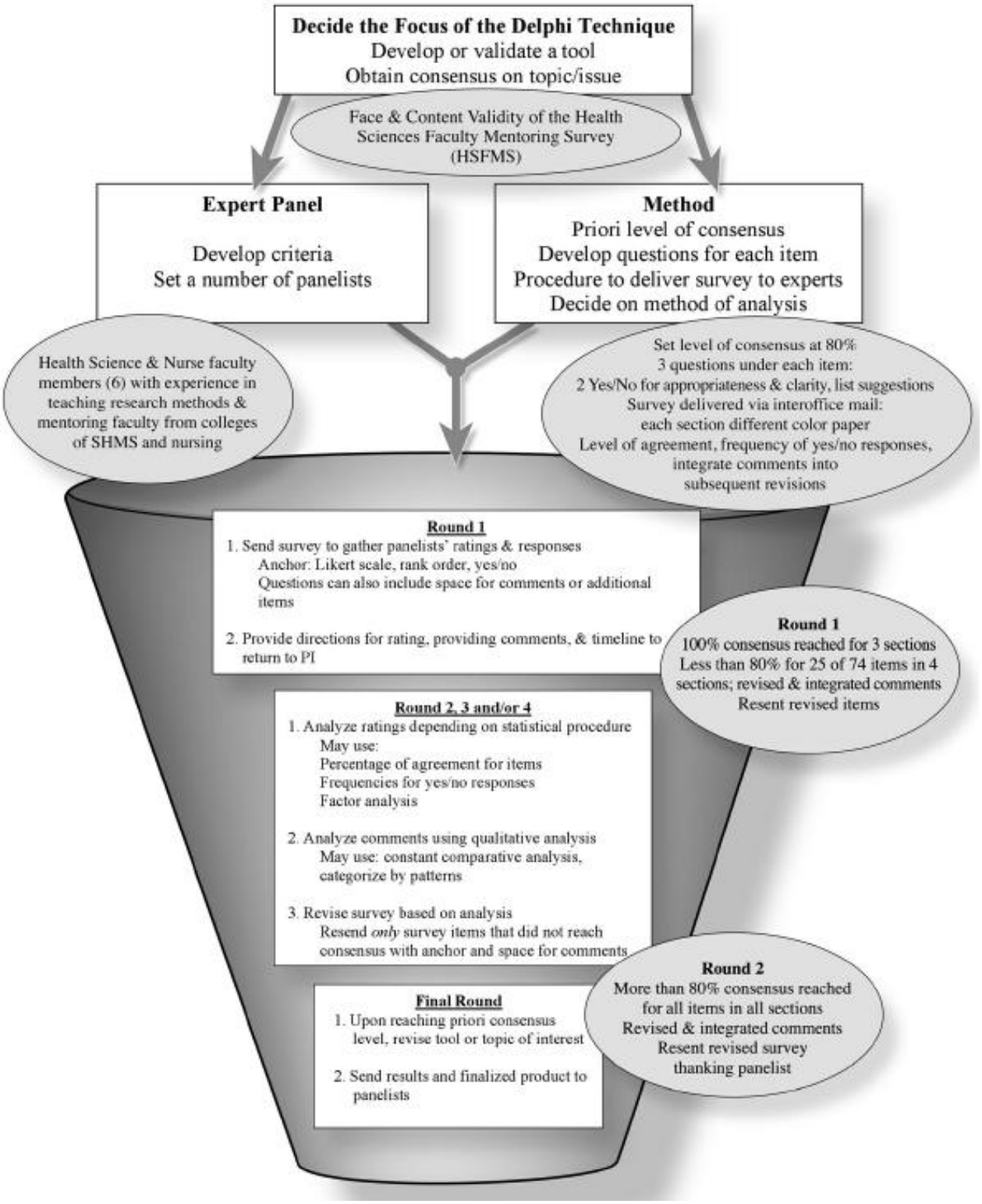
Records of each stage of the process (eg. Delphi) should be kept and should be made available as supporting material to the guideline, if required.

If agreed by the GDG, and feasible, it would be convenient to look for an online tool to support the consensus process, but in any case, running the process should be possible by email.

Once a summary of results is recorded and recommendations drafted, the GDG should continue the guidance development process, as in the '*SHPN Good Practice Guidance Methodology'* (from stage 5).

Appendix A: Detailed schema of the Delphi method

Delphi technique funnel decision-making model, from Falzarano and Pinto Zipp, 2013



References

[1] MK Murphy et al. Consensus development methods, and their use in clinical guideline development. Health Technology Assessment. 1998;2(3). Available at: https://www.journalslibrary.nihr.ac.uk/hta/hta2030#/abstract

[2] Falzarano M, Pinto Zipp G. Seeking Consensus Through the Use of the Delphi Technique in Health Sciences Research. *Journal of Allied Health*. 2013;42(2):99-105. Available at: https://www.ncbi.nlm.nih.gov/pubmed/23752237

[3] Keeney S, McKenna H, Hasson F. *The Delphi technique in nursing and health research*: John Wiley & Sons; 2010. Available at: https://onlinelibrary.wiley.com/doi/abs/10.1002/9781444392029.ch1

[4] Fitch K, Bernstein SJ, Aguilar MD, Burnand B, LaCalle JR, Lazaro P, Loo MVH, McDonnell J, Vader JP, Kahan JP. *The RAND/UCLA Appropriateness Method User's Manual.* RAND 2001, Arlington. Available at: https://www.rand.org/content/dam/rand/pubs/monograph_reports/2011/MR1269.pdf

[5] Nair R, Aggarwal R, Khanna D. Methods of Formal Consensus in Classification/Diagnostic Criteria and Guideline Development. Seminars in Arthritis & Rheumatism. 2011;41(2):95-105. Available at: https://www.sciencedirect.com/science/article/pii/S0049017210002544?via%3Dihub

[6] Nair R, Aggarwal R, Khanna D. Methods of Formal Consensus in Classification/Diagnostic Criteria and Guideline Development. *Seminars in Arthritis & Rheumatism*. 2011;41(2):95-105. Available at: https://www.sciencedirect.com/science/article/pii/S0049017210002544?via%3Dihub

[7] DS Sink. Using the nominal group technique effectively. National Productivity Review. 1983;2(2):173-184. Available at: https://onlinelibrary.wiley.com/doi/pdf/10.1002/npr.4040020209

[8] Scottish Executive Health Department (SEHD). NOMINAL GROUP TECHNIQUE, Involving People website on Scottish Health. Available at http://www.sehd.scot.nhs.uk/involvingpeople/methodologies/individualmethodologies/Ngt.htm.

[9] Halcomb E, Davidson P, Hardaker L. Using the consensus development conference method in healthcare research. *Nurse Res*. 2008;16(1):56-71. Available at: https://www.ncbi.nlm.nih.gov/pubmed/19025106

[10] Werner RN, Jacobs A, Rosumeck S, Nast A. Online consensus conferences for clinical guidelines development - a survey among participants from the International Guidelines for the Treatment of Actinic Keratosis. Journal of Evaluation in Clinical Practice. 2014;20(6):853-6. Available at: https://onlinelibrary.wiley.com/doi/full/10.1111/jep.12159