

EDITORIAL

Guidelines should be guidelines: Time to leave the terms “consensus” and “position” for other purposes

Clinical guidelines 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]. Clinical guidelines are increasingly becoming a part of neurology clinical practice, most probably because they may improve patient clinical outcomes [2,3]. Methods and strategies intended to increase guideline availability include electronic and computable guidelines integrated into process-oriented information systems with clinical decision support tools [4]. The increased availability and the possibility of continuous update (living guidelines) [5] will likely contribute to promoting compliance with guideline recommendations and to the overarching success of guidelines in improving the quality of care in the near future.

The expected benefits of guidelines [6] are influenced by different factors, including dissemination and implementation challenges, organizational and resource issues, and factors related to physicians, patients, and the guideline themselves. Concerning factors directly related to guidelines, the clinical relevance of the topic addressed and their methodological quality are key factors influencing guideline applicability, acceptance, and adherence, and ultimately the confidence of end users [7].

Scientific societies usually define clinical practice guidelines according to the standard definition [1], differentiating them from other statements or advisory documents, with different purposes and methodology (see Table 1 for a typology of documents produced by some scientific societies).

One of the guideline-related factors that may adversely influence their impact is the misunderstanding of the meaning, intention, and purpose of a guideline versus a consensus or position paper. This can occur at the level of guideline development and/or of the end user. The lack of clarity on this matter may influence the interpretation of the document, the attitude and behavior toward the recommendations, and the clinical decision itself.

Therefore, the Guideline Production Group (GPG) of the European Academy of Neurology (EAN) believes that clarification on the different meanings and purposes of a position paper, clinical consensus statement, and clinical practice guideline is timely and could benefit both the EAN guideline developer community and end users.

POSITION PAPERS

A position paper is a document that presents an opinion about an issue, typically that of the authors or another specified entity.

Position papers are published in different domains, from academia to politics, and can have different formats/structures [8]. Position papers can be used by organizations to communicate their specific beliefs and recommendations. Position papers promote discussion on emerging topics for which evidence is lacking or uncertain, and point to original research needed to be developed so it can be included in a guideline or presented in an academic paper. Position papers are most frequently conceived and written by working groups and subsequently reviewed by a society board.

Two examples of position papers are:

- (i) The position paper on patient involvement in research published in 2020 by the European Federation of Neurological Associations (EFNA) [9]. This document captures the insights from an EFNA workshop held in Brussels in December 2019. Attended by over 50 representatives of patient and health professional organizations, careers, research and industry partners, and other experts, the workshop served to inform EFNA's strategic plan for 2020–2025, particularly in its focus area of “Promoting patient empowerment for more meaningful involvement and engagement.”
- (ii) The position paper on how sex and gender might be crucial determinants of clinical heterogeneity in Alzheimer's disease, with implications for diagnosis, treatment, prevention, and clinical trial design, published in 2020 by the Dementia and Cognitive Disorders Panel of the EAN [10]. This document was created as an overview of existing literature and knowledge on sex and gender differences.

Although this second example relies on opinion, the authors made use of selected evidence to support their conclusions and recommendations (for example, developers should consider including sex in clinical trial design).

Minimal methodological requirements suggested for the development of an EAN position paper are reported in Table 2.

CLINICAL CONSENSUS STATEMENTS

According to the Council of Europe, a “medical consensus” is a public statement on a particular aspect of medical knowledge that is generally agreed upon as evidence-based, state-of-the-art knowledge by a representative group of experts in that area [8]. Its main objective is

TABLE 1 Typology of documents produced by scientific societies (websites accessed on 2 March 2021)

Scientific society	Clinical practice guidelines developed declaring compliance with standards [1]	Documents with EBM tools required for some steps	Documents without EBM tools	Reference/source
American Academy of Neurology	Yes	Comprehensive systematic reviews Focused systematic reviews Practice advisories	Case definitions Position statements	https://www.aan.com/policy-and-guidelines/guidelines/about-guidelines2/
American Heart Association/American Stroke Association	Yes	Scientific statements	Science advisory Policy statements	https://professional.heart.org/en/guidelines-and-statements/methodologies https://professional.heart.org/en/guidelines-and-statements/publication-development
American Thoracic Society	Yes	Technical statements	Policy statements Research statements	https://www.thoracic.org/statements/document-development/
European Respiratory Society	Yes	Statements Technical standards	Position statements	Brusselle GG, Gaga M. ERS guidelines, statements and technical standards published in the ERJ in 2014: a year in review. <i>Eur Respir J</i> . 2015;45:863-866.
European Society of Cardiology	Yes	Consensus and position papers	Consensus and position papers	https://www.escardio.org/Guidelines/Clinical-Practice-Guidelines
European Society of Medical Oncology	Yes	Consensus conference	Consensus conference	https://www.esmo.org/guidelines/esmo-guidelines-methodology
European Stroke Organization	Yes	Consensus and position papers	Consensus and position papers	https://eso-stroke.org/guidelines/eso-guideline-directory/ Ntaios G, Bornstein NM, Caso V, et al. The European Stroke Organisation Guidelines: a standard operating procedure. <i>Int J Stroke</i> . 2015;10(Suppl A)100:128-135.
International League Against Epilepsy	Partially		ILAE position papers	https://www.ilae.org/guidelines/guidelines-and-reports/procedure-for-publishing-reports Sauro KM, Wiebe S, Dunkley C, et al. The current state of epilepsy guidelines: a systematic review. <i>Epilepsia</i> . 2016;57:13-23. Sauro KM, Wiebe S, Perucca E, et al. Developing clinical practice guidelines for epilepsy: a report from the ILAE Epilepsy Guidelines Working Group. <i>Epilepsia</i> . 2015;56:1859-1869.
Movement Disorders Society	No	Evidence-based medicine review	MDS task force and committee papers	https://www.movementdisorders.org/MDS/Resources/Publications-Reviews/EBM-Reviews.htm https://www.movementdisorders.org/MDS/Resources/Publications-Reviews/MDS-Task-Force-and-Committee-Papers.htm

Abbreviations: EBM, evidence-based medicine; ILAE, International League Against Epilepsy; MDS, Movement Disorders Society.

TABLE 2 Minimal methodological requirements suggested for the development of clinical practice guideline, clinical consensus statement, and position paper documents within the European Academy of Neurology

Phase	Clinical practice guidelines	Clinical consensus statement	Position paper
Scope ^a	Broad	Usually narrow	Narrow
Multidisciplinary panel	Yes	If necessary	If necessary
Clinical question generation (PICO tool)	Yes	Desirable	If necessary
Outcome importance voting (GRADE method)	Yes	No	No
Systematic review for each PICO	Yes	Desirable	No
Grading the quality of studies (various methods)	Yes	Desirable	No
Grading the quality of evidence for each outcome and overall (GRADE method)	Yes	No	No
Direction and strength of a recommendation (GRADE method)	Yes	No	No
Reaching consensus with formal methods	If necessary	If necessary	Desirable

Abbreviation: GRADE, Grading of Recommendations, Assessment, Development, and Evaluations.

^aThe scope of a guideline corresponds to the definition of the target condition and/or the patients, the intended audience and practice settings, the clinical questions (e.g., diagnosis, treatment), the types of interventions and treatments, and the main outcomes [24]. A scope can be defined as “broad” or “narrow” depending on how the abovementioned aspects are covered. For example, a document narrow in scope may not provide the full range of options for the management/treatment of the condition, or cover only a particular age, setting, or aspect of a condition [25]. On the other hand, a clinical guideline should have a broad scope, covering many aspects of the management of a condition and a broad spectrum of patients.

to counsel physicians on the best possible and most acceptable way to address a particular decision-making area for diagnosis, management, or treatment. Other clinical aspects can also be covered under clinical consensus statements (e.g., causation, prognosis, screening, technical standards). Consensus statements synthesize new information, largely from recent or ongoing medical research that may have implications for re-evaluation of routine medical practices. The consensus constitutes the expression of the opinion of the participants and does not necessarily imply unanimity. Because consensus statements provide a “snapshot in time,” they must be re-evaluated periodically.

The current position of the EAN GPG is that clinical consensus statements should be produced only in cases where: (i) the amount of the available evidence is low, but not necessarily the quality (although the quality of the evidence is usually poor in cases where the evidence is scarce); (ii) the available evidence is not appropriate for formal ratings of quality of evidence; and (iii) clinical guidance is warranted.

One example of an EAN consensus statement is the 2020 consensus statement for the management of patients with neurological diseases during the COVID-19 pandemic [11]. This consensus statement provides clear structured recommendations on good clinical practice in patients with neurological diseases during the COVID-19 pandemic. The recommendations were established using a refined Delphi methodology to obtain expert consensus.

Several consensus papers in the field of neurology are still a hybrid between a consensus (state of the art) and a guideline. One example is the EAN consensus recommendations on monogenic cerebral small-vessel diseases [12]. In this example, each working group started by searching the MEDLINE database for relevant studies

published in English. Afterward, a formal method was followed to reach consensus on the list of queries to be voted on (online survey), as well as on the issued recommendation statements (Delphi panel). Another example is the “formal consensus-based guidance for the management of myasthenia gravis” by the Myasthenia Gravis Foundation of America [13]. Following a narrative review of the recent literature by the panel members, the cochairs determined which topics should be subjects for an update or new recommendations, based on the availability of new data. Consensus was reached through formal methods, and recommendations were issued specifying their range of appropriateness according to the opinion of each panel member. Although a formal consensus was reached around the interpretation of the selected evidence and recommendations were issued, many methodological requirements of a guideline were missing in these two examples (e.g., multidisciplinary panel; full systematic review for each PICO question, including independent risk of bias assessment; ascertainment of the level of uncertainty in the evidence using, e.g., the Grading of Recommendations, Assessment, Development, and Evaluations [GRADE] approach).

Minimal methodological requirements suggested for the development of an EAN clinical consensus statement are reported in Table 2.

CLINICAL PRACTICE GUIDELINES

Clinical practice guidelines are recommendations for clinicians about the care of patients with specific conditions. The process for

development of an EAN guideline is well established and follows the GRADE methodology [14,15].

Clinical practice guidelines have historically been categorized by large professional organizations, including EAN, as evidence-based or consensus-based guidelines. The expression “consensus guideline” was only recently deleted from the Guidelines webpage of the EAN website where it referred to guidelines, reading, “The consensus guidelines of the EAN are produced by so-called task forces” [16].

Recently, Djulbegovic and Guyatt highlighted that this distinction represents a fundamental misunderstanding of both evidence-based medicine and the process of moving from evidence to recommendations, and is therefore both misguided and misleading [17]. According to the authors, the key difference between the two approaches appears to be that when the evidence is of high quality, some guideline panels consider that the evidence speaks for itself and the process is evidence-based. On the other hand, when the evidence is of lower quality, the process is consensus-based.

However, when the certainty of the evidence (synonyms: confidence in estimates, quality of the evidence) is only of low quality or very low quality, some guideline panels label their process as consensus-based. These panelists argue that the main difference is that evidence-based recommendations require the judgments to be consistent with underlying evidence, whereas consensus-based recommendations do not. This distinction is both misguided and misleading because (i) all guidelines should be evidence-based, even when the certainty of the evidence is of very low quality [18]; and (ii) all types of evidence require interpretation, and therefore the consensus process around evidence interpretation is always a step in the context of guidelines.

One example of an EAN guideline is the guideline on medical management issues in dementia published in 2020 [19]. This guideline is based on systematic reviews of the evidence carried out by the panel and the use of the GRADE framework for the development of recommendations. One recommendation from this guideline is that individuals with dementia (without previous stroke) and atrial fibrillation should be treated with anticoagulants. The certainty of the evidence was considered very low, and the strength of the recommendation was weak. All recommendations and their strength were decided by consensus around evidence interpretation, following the GRADE approach. Nevertheless, this is not a consensus-based guideline.

EAN guidelines sometimes report (good) clinical practice statements. These should not be confused with consensus statements *sensu stricto*, although good practice statements are reached through consensus. Good practice statements are a category of recommendations for implementing a particular course of action. Typically, good practice statements are issued when there is a sufficient body of indirect evidence from multiple sources that guideline panels interpret as allowing inference regarding the net benefit, therefore providing a high level of certainty in support of a particular action [20]. In such cases, why has the guideline panel not followed the GRADE approach? Justifiable reasons include situations where following the GRADE methodology would be an onerous and unproductive

exercise (e.g., true lack of reasonable alternative and compromise of ethical norms), as well as situations where performing a formal rating of certainty is inappropriate. A first consequence is that good practice statements are not GRADE recommendations, and should not be turned into GRADE recommendations by the guideline panels or interpreted as such by the guideline end users. A second consequence relates to the body of evidence behind a good practice statement in a guideline not having been subject to formal quality rating; as such, it cannot be assumed to be of low or very low quality [21]. By definition, the level of subjectivity behind a good practice statement is high, and the format can be very appealing to guideline panels and used abusively. The EAN GPG advocates that this type of recommendation within a guideline should be used carefully and exceptionally, always making explicit the rationale for the guideline panel opting for this format instead of following the formal GRADE approach.

One example of a good practice statement within an EAN guideline can be found in the EAN guideline on medical management issues in dementia [19]. In this guideline, a formal literature search was performed, but the authors found no evidence to answer the question, “should home-living (noninstitutionalized) patients with dementia be offered systematic medical follow-up in a memory clinic setting?” Nevertheless, the panel concluded by consensus that the indirect and linked evidence on this matter strongly supports the net benefit of this action. Therefore, the panel concluded, under a specific heading clearly indicating that this was an ungraded good practice statement and not a GRADE recommendation, that patients with dementia should be offered regular, preplanned medical follow-up.

Minimal methodological requirements suggested for the development of an EAN clinical practice guideline are reported in Table 2.

As pointed out in Table 2, EAN guidelines should have systematic reviews of evidence as background information to provide clear answers to each clinical question. The quality of the systematic reviews, including whether the underlying evidence is still up to date, is a key determinant of the overall quality of the guideline. The EAN board has recently approved a strategic plan to be implemented through the EAN GPG to promote the production of high-quality guidelines. Since 2020, the EAN GPG has received a total of nine new proposals for clinical guidelines. Some of these proposals are joint ventures with other scientific societies. In such cases, additional challenges may occur, as the methodological approach to developing guidelines may be different across societies.

CONCLUSIONS

The terms position paper, consensus statement, and guideline are still frequently employed as if they were interchangeable, but the purpose of such documents and the robustness of advice vary, as the evidence base does not have the same depth in each.

Both clinical consensus statements and clinical practice guidelines provide recommendations and are intended to offer guidance to clinicians and to inform policy decisions. As such, both documents

should be developed using equally rigorous and transparent methods and subjected to high-quality standards. However, there are important differences between them. A clinical practice guideline produces recommendations that are informed by a standardized definition of the clinical questions, a systematic review of the underlying evidence, a ranking of the different outcomes, and an assessment of the benefits and harms of alternative options [1]. A consensus statement is developed by a panel of experts, usually multidisciplinary, convened to review the research literature in an evidence-based manner for the purpose of advancing the understanding of an issue, procedure, or method [22]. The scope is usually narrower than a guideline, and the amount of evidence is usually low. At least in some fields, consensus statements score lower than clinical practice guidelines for rigor of development and editorial independence [23].

Lastly, recommendations offered by both consensus papers and guidelines should be adapted to local clinical practice (regional- or hospital-based clinical pathways), taking into consideration costs and resources, available expertise and technology, and specific circumstances.

We hope that this paper is useful both for task forces developing EAN guidelines and for guideline end users in clinical practice.




CONFLICT OF INTEREST

None.

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