Approach to assessing and using clinical practice guidelines

Melissa J. Armstrong, MD, MSc, and Gary S. Gronseth, MD

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Correspondence

Dr. Armstrong
Melissa.Armstrong@neurology.
ufl.edu

Abstract

Clinical practice guidelines are produced in ever-increasing numbers by the American Academy of Neurology (AAN) and other developers, with over 1,000 guidelines currently in the National Guideline Clearinghouse. Knowing when to use guidelines in clinical practice requires neurologists to assess the rigor of published guidelines and understand how guideline recommendations are best applied in individual patient encounters. This review briefly describes guideline definitions and the AAN process for guideline development, outlines key elements for assessing guideline quality, and details a practical approach for incorporating guideline recommendations when partnering with patients in shared decision-making.

Clinical practice guidelines are produced in ever-increasing numbers. The National Guideline Clearinghouse has over 1,000 entries.¹ The American Academy of Neurology (AAN) published an average of 6 guideline products annually over the last 5 years. Neurologists also use guidelines from subspecialty societies and other organizations. In clinical scenarios, neurologists must decide when guideline recommendations are relevant and how best to apply them.

What are guidelines?

Before online databases such as MEDLINE enabled high-volume searching of scientific publications, guidelines often reflected experts' opinions on how to best evaluate or manage a medical condition. Current high-quality clinical practice guidelines, though, are anchored in a thorough review of medical evidence. The Institute of Medicine (IOM) recommends that the term "clinical practice guideline" be reserved to describe "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."² This is in contrast to documents that are society policy statements or expert opinion statements provided without a full review of available research or offered in the absence of informative studies. The focus on clinical optimization of patient care is also separate from payer policy decisions and AAN products that focus on coverage issues, such as payment policy perspectives and coverage policies.

Guidelines include 2 summary statement types: conclusions and recommendations. In the AAN approach,³ conclusions summarize the systematic review evidence and the confidence in that evidence by using the vocabulary of "highly probable," "probable," and "possible." Confidence in a conclusion is based on the number of studies reviewed, the study Class (risk of bias), and application of a modified Grading of Recommendations Assessment, Development and Evaluation (GRADE) process, which incorporates elements such as precision, directness/generalizability, and magnitude of effect.

Department of Neurology (MJA), University of Florida College of Medicine, Gainesville; and Department of Neurology (GSG), University of Kansas, Kansas City.

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Recommendations are statements intended to guide high-quality care. In the AAN methodology based on the 2011 IOM standards, recommendations are based upon more than evidence. They are developed by transparently combining systematic review conclusions, other strong related evidence that was not part of the systematic review, principles of care, and inferences. This is consistent with how clinicians make good clinical decisions, incorporating more than just direct evidence alone. The “level of obligation” for a recommendation—affecting the “must,” “should,” and “may” vocabulary—is based on whether the recommendation rationale is well-supported and logical, the balance of the potential benefits and risks of following a recommendation, and an assessment of the importance of the outcomes, patient preferences, feasibility, and patient costs.³

What guidelines are not

Clinical practice guidelines do not tell clinicians what to do in a specific patient encounter, which is one reason that they should not be used in malpractice litigation. Patient-centered care decisions are best made through shared decision-making, where patients and clinicians (and sometimes caregivers or family members, either by patient need or choice) partner to consider the best medical evidence alongside a patient’s values and preferences to make the best decision for that patient in that circumstance.⁴ Guidelines are valuable in informing one part of that process—reviewing the best medical evidence.

Level A recommendations—the strongest recommendations—are recommendations that will improve health-related outcomes in almost all circumstances and are recommendations that almost all patients in the relevant circumstance will choose to follow.³ The “almost all” language acknowledges that there are still patients who choose paths different from the recommended course, but this is expected to be rare. Level A recommendations are uncommon.

Level B recommendations denote recommendations that most patients will want to follow and for which adherence is expected to improve health-related outcomes in most circumstances. Following level C recommendations—the weakest recommendations—might improve health-related outcomes in some circumstances.³

High-quality guidelines highlight limitations in the evidence and variations in patient preferences. They also emphasize the importance of patient and physician judgment in medical decision-making. Guidelines are thus not rules for practice or cookbook medicine, but rather summaries of the best medical evidence, limitations in that evidence, and the pros and cons of different options to help clinicians and patients make optimal decisions.

Is a guideline trustworthy?

Various standards exist for developing systematic reviews and clinical practice guidelines, including those from the IOM^{2,5} and the Guidelines International Network.⁶ The most commonly used tool to assess guideline quality and reporting is the Appraisal of Guidelines Research & Evaluation Enterprise II (AGREE-II) instrument. The AGREE-II tool has 6 domains including scope and purpose, stakeholder involvement, development rigor, applicability, and editorial independence.⁷ While different formats emphasize different elements of quality guideline development, key concepts overlap (table).

Are the recommendations valid?

Prior to using guideline recommendations, one must determine whether the recommendations are valid.⁸ This is similar to critical appraisal of research prior to application. Guideline assessment starts with an assessment of methodologic quality (table). Peer review prior to publication is an additional measure of rigor,⁸ overlapping with the idea of external stakeholder review (table). In addition, underlying assumptions (e.g., what was considered a minimal clinically important difference on a scale) must be evaluated. When recommendations are based on more than evidence alone (as recommended by the IOM), readers should evaluate the premises in the recommendation rationales. Are “principles of care” well-accepted axioms? Is cited related evidence strong? In the AAN process, the type of premise for each sentence in the recommendation rationales is indicated in the on-line appendices for thorough assessment.

Applying a guideline

High-quality clinical practice guidelines must still be assessed for appropriateness of use prior to application within any given clinical scenario. Guideline currency is best assessed first. While guideline developers should have a plan for update (table), few developers currently have mechanisms for living guidelines that constantly add new literature. The AAN reviews guidelines every 3 years for currency (and upon notification of new relevant high-quality publications) and makes determinations regarding whether guidelines should be reaffirmed, updated, or retired.³

Next, clinicians must determine if high-quality and current guidelines are applicable to their specific clinical scenario. At its most basic level, this is straightforward. The AAN

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Table Elements of high-quality clinical practice guidelines

Quality standard	References	Sample questions to ask when reading the guideline
Transparent and explicit development methodology	2,6,7	Does the methods section transparently explain development steps and/or are these steps described in an available manual? Does the guideline describe the funding source(s)?
Guideline scope and objectives are specified	6,7	Does the guideline specifically describe the objectives, scope, and relevant population(s)?
Author panel includes relevant stakeholders	2,6,7	Does the author panel include various relevant medical experts, guideline specialists/methodologists, and patients/caregivers?
Conflicts of interest are addressed	2,6,7	Is there a process for assessing and reporting potential conflicts of interest and are possible conflicts of interest described and managed? Is it clear that the guideline funder has not influenced the content?
Use of systematic review	2,6,7	Is the guideline based on a systematic review (a comprehensive review using prespecified scientific methods to find, choose, assess, and summarize all studies addressing a specific scientific question)? Are the results well-described? Is there a description of the level or strength of evidence?
Processes for developing recommendations	2,6,7	Is the process for moving from evidence to recommendations described? Does the guideline include a description of potential benefits and harms? Does the guideline include cost considerations? Is there a rating for the strength of the recommendation?
Recommendation clarity	2,6,7	Are recommendations easy to identify? Is the meaning of the recommendations clear? Can compliance with the recommendations be evaluated (especially for strong recommendations)?
Review by external stakeholders	2,6,7	Was the draft guideline reviewed by external stakeholders prior to final publication (e.g., by experts not involved in guideline development, external organizations, public comment processes)?
Applicability	7	Does the guideline describe or provide tools or advice for implementing the recommendations? Does the guideline describe barriers and facilitators to implementation? Does the guideline consider resource implications?
Plan for update	2,6,7	Does the guideline (or referenced manual) include a specific plan for assessing guideline currency and performing updates?

guideline for treatment of essential tremor⁹ is applicable for patients with essential tremor but not other tremor syndromes. Recommendations for survivors of out-of-hospital cardiac arrest¹⁰ are of uncertain relevance to patients with in-hospital cardiac arrest.

Clinical practice guidelines, though, are by their nature dependent on systematic reviews of published research. Just as clinicians must decide if clinical trial results are relevant to an individual patient, they must decide if a guideline based on clinical trial results (in the case of therapeutic guidelines) are relevant to an individual patient. Steroid treatment studies for Bell palsy typically exclude individuals with diabetes, so recommendations for treating Bell palsy with steroids, even if Level A,¹¹ must be considered in that light. Guidelines should ideally acknowledge applicability of recommendations to special populations, as was done in the Bell palsy guideline: “Although there is strong evidence that steroid use increases the probability of good facial functional recovery in patients with Bell palsy, it does not necessarily follow that all patients with Bell palsy need to take steroids. For example, it would be reasonable for a clinician to opt not to use steroids in a patient with brittle diabetes mellitus.”

When current, high-quality, and population-relevant guidelines are available for a specific clinical scenario, clinicians must determine how to best use a guideline with the patient. Both systematic review conclusions and recommendations can be used for reviewing best medical evidence with patients. Discussion of options within shared decision-making includes describing details of the different possibilities (e.g., mechanism of administration, cost, potential benefits, and side effects)¹² and the evidence underlying the different possibilities. The AAN creates guideline summaries for patients and families (available at aan.com/guidelines/) and these lay summaries can be helpful tools for reviewing guideline evidence and recommendations. These summaries are not formal decision aids for guiding patients and clinicians through the decision process, but they are helpful in describing guidelines in patient-friendly ways and educating patients.

For example, when choosing a first treatment for a person with restless legs, a clinician could use the AAN Treatment of Restless Legs Syndrome in Adults guideline summary for patients and families.¹³ This summary highlights pharmacologic and nonpharmacologic options, the related strength of evidence, and common adverse events (AEs). Clinicians

would also discuss considerations such as mechanism of administration (e.g., oral vs patch) and expected cost (e.g., due to availability of generic options). Patient preferences informing the decision—relating to pharmacologic vs non-pharmacologic strategies, mechanism of administration, insurance coverage, risk of augmentation or other AEs—are then incorporated with other values¹⁴ and guideline evidence to make the best decision.

Conclusions

Clinical practice guidelines are routinely published by the AAN and others with the goal of improving high-quality patient care and outcomes. Ease of use may increase as guidelines are incorporated into electronic health records. Using guidelines effectively involves understanding development processes and purposes, assessing guideline quality, determining relevance in specific clinical scenarios, and effectively using guidelines within shared decision-making.

Author contributions

M.J. Armstrong: design/conceptualization of manuscript, analysis/interpretation of concepts, drafting of manuscript, revision of manuscript for intellectual content. G.S. Gronseth: analysis/interpretation of concepts, revision of manuscript for intellectual content.

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Practical Implications

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