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Crafting practice guidelines in the world of evidence-based medicine

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Abstract

Background—In the era of exponential increase in the medical literature, physicians and health policy-makers are relying on well-constructed, evidence-based practice guidelines to help assure that the care given to patients is based on valid, scientific data. However, the construct of practice guidelines may not always adhere to accepted research protocol.

Methods—In this paper, we will detail the steps required to produce effective, evidence-based practice guidelines.

Results—We presented the 7 essential steps in crafting a practice guideline: (1) Defining a topic, (2) Selecting a workgroup, (3) Performing a literature review, (4) Writing the guideline, (5) Peer review, (6) Making plans for review and revision and (7) Dissemination.

Conclusions—Given the importance of practice guidelines in supporting everyday practice, this paper strives to provide a practical guide in the development of this key component of evidence-based medicine.

Keywords

practice guideline; guide; research; principles; evidence-based medicine

As recently as the early 1990's, medical treatment was practiced as it had been for centuries: if a treatment seemed logical and worked, it became part of the common practice.(1) Randomized controlled trials and other high-level evidence scientific studies were an afterthought. However, in today's changing economic climate, evidence-based medicine has become an important movement in American medicine to improve quality of healthcare and decrease cost.(2, 3) Although making patient-care decisions based on high-impact evidence is a desirable goal, with Medline adding over 600,000 new articles a year (nearly 2000 a day!)(4), it is nearly impossible for any physician to keep abreast of all the relevant evidence from the existing literature. Practice guidelines aim to bridge the gap between research and

practice by doing what few physicians have time to do - staying current with the literature. Most physicians are unable to read all the relevant literature and synthesize the results into recommendations to achieve best practice. Practice guidelines embrace evidence-based medicine by rigorously distilling the highest level of evidence from the literature in an effort to help physicians in the compassionate and scientific treatment of patients.

Practice guidelines are a series of condition- and population-specific recommendations, often published by professional specialty societies such as the American Society of Plastic Surgeons, for patient management. Guidelines can provide recommendations on which diagnostic tests to use, which treatments or medication to provide or they may recommend that no action be taken at all. They provide evidence-based guidance to physicians who have not had the time to read all the literature. Practice guidelines are created with the goal to reduce inappropriate variations in medical practice by assuring all patients experience consistent, efficient, high-quality care. Decreasing practice variations, which is the genesis of the outcomes movement, can reduce morbidity and mortality, improve patient quality of life, and promote equality in treatment.(5, 6) Despite these potential benefits, there are physicians who oppose the creation of guidelines. They claim that practice guidelines promote “medical laziness,” encourage “cookbook medicine” and compromise the art of medical practice.(7, 8) These views are contrary to the intent of evidence-based medicine and the practice guidelines. In contrast to quality measures that seek to distinguish between good and poor quality practices in order to assess rewards and penalties, practice guidelines only make recommendations regarding what constitutes the best evidence in the practice.(9) Table 1 illustrates the differences between practice guidelines and quality measures.

Rather than a strict set of steps, as in quality measures, the use of practice guidelines is analogous to consulting a cookbook to guide the creation of a dish. The recipes in a cookbook do not prevent a cook from tossing a handful of basil into a dish if the cook feels it would improve the flavor. Along the same concept, practice guidelines only suggest the best practice for treating a particular condition.(9) Practice guidelines are not a stand-in for the knowledge that one gains from meaningful patient interaction. Only the treating physician knows the quirks and circumstances of a particular patient. Ultimately the treatment decision must be a shared decision-making process between the physician and the patient by using the best scientific evidence from the literature.

Practice guidelines have the potential to have substantial impact. They may be disseminated on a national, or even international, scale or become part of quality of care metrics, even though practice guidelines serve as guides and are not meant to be quality measures. Nevertheless, because any guideline may be used in these ways, practice guidelines should be carefully constructed. (Figure 1) This process takes time, often months rather than days or weeks, and can be costly, if performed correctly. Throughout this manuscript, we will be referring to the process used to develop the American Academy of Orthopedic Surgeons’ (AAOS) September 2008 Clinical Practice Guideline on the Treatment of Carpal Tunnel Syndrome as an example.(10) The senior author (KCC) was part of the panel in constructing this practice guideline, and the practical experience obtained in this structured process can be instructive in crafting future projects. The guideline writing process is intensively

methodical, but the production of high-quality, evidence-based practice guidelines is a process that must be deliberate and thoughtful.

Define the Topic

Because of the extensive amount of effort required, the practice guideline topic of interest should be as clearly defined as possible. It should be a condition for which there are variations in treatment.(7) There is no reason to go through the guideline building process if there are no other treatment alternatives. Additionally, there must be publications of sufficient scientific quality to warrant consideration. Breast reconstruction, for which there are four different surgical techniques, along with a copious number of publications, is an excellent topic for guideline preparation. If different populations are affected by this condition (i.e. adult patients versus pediatric patients), the population in question should be defined as well. In other words, the condition of interest for a particular affected population must be stated unambiguously during the planning process. For example, the AAOS Work Group wrote their guidelines to focus on idiopathic carpal tunnel syndrome, which was presumed to be caused by mechanical compression of the median nerve by the transverse carpal ligament, a condition for which there is considerable literature available. Careful and complete definition of the condition in question will make the literature search process go much more smoothly.

Organize a Work Group

Because the creation of guidelines is almost always sponsored by a professional society, such as ASPS, or other healthcare organization, the work group will consist primarily of members of these groups. Including experts in other fields may be beneficial as well.(6) For example, the AAOS work group comprised of not only hand surgeons but also non-surgical physicians who diagnose and treat carpal tunnel syndrome. In some cases, including patients or patient-advocates can bring insight to the guideline development process that may have otherwise been overlooked. These individuals will be able speak to patient values and preferences, which may differ from those of clinicians.(6, 11, 12) Patient perspective will prevent the writing of a guideline recommending a treatment regimen that although effective, may not be well-received by patients.

Literature Review

A critical part of the practice guideline creation process is the performance of a meticulous literature search and review. This review should be undertaken as if one is performing a systematic review or meta-analysis, depending on the amount of available data.(13) The inclusion and exclusion criteria for the article search need to be determined *a priori*,(10) which is analogous to the adherence to a study protocol for a prospective study. All efforts should be made to include abstracts presented at conferences and manuscripts that have been accepted for publication but that have yet to be published.(14) Including presented abstracts in the literature search will help avoid publication bias, the tendency for studies showing non-significant or negative results to be published far less often than studies with statistically significant and positive results.(13) Electronic database searches can be

supplemented with manual searches of bibliographies of articles that meet the inclusion criteria and tables of contents of relevant journals.(14)

For topics that have been the subject of a large number of publications, it is not necessary to include all available information. The process of determining which publications to include can be facilitated by the critical appraisal of the literature. The ASPS Work Group employed this process when developing their clinical practice guideline for chronic wounds of the lower extremity, by assigning a level of evidence to each according to the ASPS Evidence Rating Scale.(15) This rating system allows the work group to review only the best available evidence publications for each treatment method. This was the case in the AAOS Work Group's search for relevant carpal tunnel syndrome literature. In this instance, when sufficient Level II data were found for a particular treatment method, Level III evidence publications were not pursued.(10) If Level II data were deficient, then searches for Level III publications would commence.

Once all relevant articles are identified, the various treatment recommendations. This should be done in a standardized way and be done independently by several of the work group members. A data abstraction form is an organized method to assure all relevant data are collect.

Create Guideline

With the data provided by the literature search and review, the work group should vote on which of the diagnostic or treatment methods recommended in the literature will become part of the guideline. When voting on recommendations, group members should keep the practicality of the guideline in mind. A good guideline should be useful, apply to as many members of the patient population as possible and take into account the cost of the recommended tests and treatments.(7, 16)

It is inevitable that at some point, the aforementioned votes will not be unanimous. A plan should be in place to deal with this situation. The AAOS work group utilized the Nominal Group Technique (NGT) to deal with conflicting opinions.(17) In this process, a possible recommendation from the literature is presented for a vote. Group members rate their agreement with including this recommendation in the final guideline from 1 ("total disagreement") to 9 ("total agreement"). Giving a recommendation a rating of 7-9 is considered "agreement." Consensus is reached when the number of members rating a recommendation 1-6 compared to the number of members giving a rating of 7-9 is statistically not significant. The binomial distribution is used to set the allowable number of dissenters (by group size) while still maintaining consensus.(17) (Table 2) For example, in a group of 9 members in the work group, only 2 dissenters are allowed. In the AAOS work group's use of this technique, possible recommendations were first voted on prior to group discussion. If consensus was reached (i.e. there was a permissible number of dissenters), than that recommendation was included in the guideline. If there was not consensus, the group engaged in discussions and additional votes were carried out until a consensus was reached. If after three votes no consensus could be reached, the recommendation was discarded.

Other ways to reach group consensus include the Delphi Technique in which participants anonymously submit which recommendations they believe should be in the completed guideline. A facilitator then provides a summary of all the recommendations submitted. Participants then re-submit their guideline recommendations, changing them as they see fit based on the summaries of previous recommendations. The Delphi Technique relies on the idea that eventually, polarizing ideas will merge into a unified idea that the whole working group will embrace as their own. (18) This method was adopted quite effectively by the RAND group that the senior author participated in, which formulated a quality measure for the treatment of carpal tunnel syndrome.(9) This method can be useful, but is more time-consuming than NGT and requires the use of an impartial facilitator who can manipulate the discussions into reaching a unified goal. Simple voting can also be used to reach recommendation consensus; however, without a plan to deal with disagreement if voting is not unanimous, a stalemate is problematic.

Once the work group decides which recommendations will be included, they are developed into actionable, full-length practice guidelines. The full content of the guideline should indicate the evidence base on which the guideline was developed.(16) It is possible that the guideline will not propose the use of the lowest cost treatment alternative. In this case, a brief justification of the increased cost should be provided, either by a cost-benefit or cost-effectiveness analysis.(19) Because the text for a guideline can become quite long, a shorter summary version should be developed so that the recommendations can be put into action without users having to read the entire document. This summary should contain who the guideline applies to, a brief background, the intended outcome and any additional steps necessary to provide treatment. A visual aid, such as a decision tree may help, if appropriate, to make the steps clearer.(20)

Finally, guidelines should be graded. (Table 3) The grade given and language used when presenting the recommendations indicate confidence of the work group that the recommendations will result in the expected outcomes,(21) as well as the importance of adherence to the recommendation.(10) For example, a recommendation in a guideline given the grade of “A” indicates that there is strong evidence to support this recommendation. Although following the recommendations given in practice guidelines is always elective, a physician can be confident that the recommendations are among the best available. On the other hand, a recommendation given a grade of “C” does not have as strong an evidence base behind it and the recommendation can be seen as simply providing options for treatment. The crafted practice guideline should be peer-reviewed for clarity and applicability. Following reviews, all comments were responded to and addressed, and the final guideline was submitted for approval by the guidelines committee of the organization overseeing the guideline’s development.

Set Plan to Review and Update

Before a guideline is released for use, a plan should be put in place to review, to update or to rewrite the recommendations at regular intervals. New research evidence is being published all the time, making planned, regular reviews of guidelines imperative for up-to-date relevance. Out-of-date guidelines are one of the most frequent reasons given by oncologists

when asked why they do not adhere to guidelines.(22) Guidelines have an average “shelf-life” of just under 6 years.(23) This means that every 6 years, the complete guideline development process should be repeated.(23) But this does not mean that guidelines do not require attention sooner. Guidelines should be “living documents” evolving to the changes in the scientific community.(24) A sub-committee of work group member should be appointed to review new literature for its effect on the guideline recommendations. The intervals at which any guideline will need to be reviewed for the inclusion of new evidence will depend on the field. Guidelines for some conditions may require review much more often than others, due to the rapid release of new research information.

Dissemination

Practice guidelines can be disseminated in a variety of manners, with publication in a relevant peer-reviewed journal, such as this one, or distribution through a professional society being the most popular method. In addition, the Agency for Healthcare Research and Quality maintains a National Guideline Clearinghouse (NGC).(25) The NGC currently contains nearly 2400 individual guidelines on a variety of topics, from the treatment of ingrown toenails to the management of post-transplant lymphoproliferative disease following solid organ transplant in pediatric patients. The guidelines are submitted by professional societies in the US and abroad, as well as by patient advocacy and other non-profit organizations.(25)

Summary

We should stress that crafting useful practice guidelines is not a simple task that can be undertaken quickly. The process takes time and money to be completed correctly. For example, the AAOS carpal tunnel guidelines cost approximately \$200,000 over the course of several months to create.(10) Several organizations have developed methodology to assure quality and practicality of the guideline working process, but a review of published guidelines found that only about half of guidelines adhere to these standards.(26) In addition, only 8% of guidelines studied reported the use of a systematic review or meta-analysis to examine existing data.(26) The process of clinical practice guideline development should be undertaken with care and thorough consideration of the far-reaching effects that the resulting guidelines may have. When conducted appropriately, practice guidelines are essential tools in managing the complexity surrounding medical decision-making processes today.

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Figure 1.

The steps required in practice guideline writing. Note the iterative nature of literature review, guideline writing and dissemination.

Table 1

Practice Guidelines vs. Quality Measures

	Practice Guidelines	Quality Measures
Developed using systematic review	✓	✓
Developed using group consensus	✓	✓
Represent best practices of care	✓	
Represent basic standards of care		✓
Discriminates between higher and lower quality care		✓
Optional Recommendations	✓	
Mandatory, when associated with penalties or rewards		✓

Table 2Number of permissible dissenters based on work group size^{*}

Group Size	Number of Permissible Dissenters
3	Dissenters not permissible
4-5	Dissenters not permissible
6-8	1
9	2

^{*} Adapted from AAOS Clinical practice guideline on the treatment of carpal tunnel syndrome(26)

Table 3

Grading of guidelines

Grade	Descriptor	Evidence Quality	Level of Evidence	Language
A	Strong Recommendation	Good	Level I studies, or consistent finding from multiple Level II, III or IV studies	We recommend Treatment X...
B	Recommendation	Fair	Level II, III or IV studies with consistent findings	We suggest Treatment X...
C	Option	Poor	Level II, III, or IV studies, but findings are inconsistent	Treatment X is an option...
D	Option	Insufficient or conflicting evidence	Level V	N/A

Adapted from "Scale for Grading Practice Recommendations." American Society of Plastic Surgeons, 2009.