Questions & Answers

Medical Guidelines and Reviewing Medical Records
Perry Hookman, MD FACP FACG

Q: What should the LNC know about medical guidelines when reviewing medical records?

A: “Guidelines” may be extensively quoted by medical experts on both sides, both the plaintiff and defendant. What you may not hear from most medical experts is that many of the clinical guidelines are non-evidence-based. But worse yet, some guidelines may be biased.

Guidelines - or more properly Clinical Practice Guidelines (CPGs) - are systematically developed statements that aim to help physicians and patients reach the best health care decisions. According to Field et al. (1990), good guidelines have many attributes, including validity, reliability, reproducibility, clinical applicability and flexibility, clarity, development through a multidisciplinary process, scheduled reviews, and documentation.

Guideline development involves many steps:
1. A topic must be identified and refined. A guideline panel is then convened. This panel should consider all reasonable management strategies for dealing with the problem. Medical specialty societies are the most common sponsors.
2. The next step is to perform a systematic review to identify and appraise the available evidence.
3. A critical appraisal of this evidence must be then translated into a guideline.
4. The guideline must then be disseminated to the relevant audience and implemented.
5. Finally, the impact of the guideline should be prospectively assessed using meaningful and measurable outcomes.

The nation’s Institute of Medicine defined CPGs as “systematically developed statements to assist the practitioner and patient decisions about appropriate healthcare for specific circumstances.” Kohn et al. (2000) state that CPGs are essentially consensus statements created by various entities and experts, both public and private, to outline what may be appropriate treatment for a specific medical condition, group of symptoms, or an approach at disease prevention. According to Moses (2008), “contemporary development of CPGs involves the use of evidenced based medicine (EBM) that proposes the model under which medical decisions and practice are based on the best available evidence.”

Unfortunately, the quality of guidelines varies considerably. The development of CPGs and the EBM approach is a science that continues to evolve. Guidelines rely on both evidence and opinion. They are neither infallible nor a substitute for clinical judgment. They do, however, go beyond systematic reviews to recommend what should and should not be done in specific clinical circumstances. Some are widely respected by physicians. They have helped to standardize care, diminish local variation, and improve health outcomes.

Q. Can the LNC depend upon CPGs to support medical opinions of the medical experts?

A. Yes, as long as the LNC is aware that CPGs have problems, especially EBM-developed CPGs. Many are of low quality because of:
- Peer-reviewed literature can be incomplete dealing with a particular guideline;
- Most guidelines are developed for the “textbook patient,” which is not of the real world; and
- Many guidelines are often developed without knowing their acceptability to physician, patient, or health care system. Thus there is low compliance with published guidelines (Kane et al., 2006). Most guidelines should be graded as to quality and accuracy.

Q. Where should the LNC research guidelines?

A. The medical literature is awash with guidelines (Fried et al, 2007). More than 2,000 guidelines are currently represented in the National Guideline Clearinghouse.
(www.guideline.gov). But the LNC should know where those guidelines came from, as well as the quality of what the expert is quoting to allegedly support the expert’s medical opinion. Among the guideline efforts in the United States that are generally considered successful are those of the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices, and the National Academies, as well as the treatment guidelines for sexually transmitted diseases issued by the Centers for Disease Control and Prevention. Efforts outside the United States include those of the World Health Organization and the National Institute for Clinical Excellence (NICE), in the United Kingdom.

But what is most important about what you see and hear as “evidence” and supporting medical expert opinions are not just “guidelines” but those guidelines backed by evidence in the peer reviewed medical literature that is valid and accurate. Medical organizations that create guidelines face difficult challenges and guidance is needed (Steinbrook, 2007).

According to Hookman (2007), if guidelines are to be truly evidence-based, all recommendations of those guidelines should be supported by up-to-date systematic reviews. Guidelines are classified by the U.S. Preventive Services Task Force in decreasing grade order from I, II-1, II-2, II-3, and III. In addition, the levels of evidence upon which these guidelines are based are classified in decreasing levels of quality from A, B, C, and D. Every medical expert or LCN who uses guidelines and clinical studies to support a medical opinion will be asked by the questioning attorneys: What is the grade of the recommendations? What is the grade of the evidence? If the attorney does not elicit and bring out the quality of these guidelines to the jury, he is either not doing his job well or covering something up. If the medical expert on either plaintiff or defense side does not do this, he either does not know what he should know or is obfuscating.

Guidelines have also been questioned when pharmaceutical and medical-device companies with a financial stake in the outcome provide substantial funding for their development and implementation. At present, the financial ties between guidelines panels and industry are extensive. A survey of 685 disclosure statements by authors of guidelines concerning medications found that 35% declared a potential financial conflict of interest. Taylor and Giles (2005) found that in 57% of guidelines, prescribing drugs have extensive financial connections with the pharmaceutical industry. Public-health experts say that the results of the Taylor and Giles survey, which is the largest of its kind, suggest that drug companies are distorting decisions about how their products are being prescribed.

In the United States, the NIH Consensus Development Program (www.consensus.nih.gov), which was started in 1977, sponsors evidence-based assessments of important medical issues. Each assessment includes a systematic literature review, prepared through the Agency for Healthcare Research and Quality (AHRQ), a public conference that features research presentations, and a consensus statement that is disseminated widely. The public conferences use a system of jurors and witnesses. Panel members can have neither financial nor other potential conflicts, and panels are independent of both the NIH and the Department of Health and Human Services. The consensus statements reflect the conclusions of the panels, not those of the institutes. The conference speakers, by contrast, may have industry ties, but if they do, those ties are disclosed. Despite its rigor, however, the process has limitations: it takes about 18 months from conception to completion, each assessment costs about $500,000, and only three or four conferences are held each year.

Q. So what should the LNC do when presented with CPGs?
A. Each LNC should remember the following:

• CPGs are intended only to assist the physician in decisions about appropriate health care for specific clinical circumstances—not to be the definitive plan of treatment for every case.

• The EBM approach to establishing CPGs increases objectivity in their development but does not imply that CPG recommendations are absolute and without problems.

• Physician compliance with CPGs in general is still low.

• CPGs should be used selectively. They do not apply to every patient. Each patient is unique so it is necessary to factor in the patient’s competing medical problems and medications, general health and well-being, and values.

• Always consider the source of a CPG to determine its potential bias favoring the drug companies who profit by approach to the companies drug, or the insurance company who profits by delaying or entirely withholding certain procedures.

Q. What should the LNC look for in the medical records?
A. Although physicians may decide whether or not to follow a CPG, and to what degree, the doctor not adhering to the published CPG must indicate his knowledge of the CPG in the medical records. The LNC must adequately review each document in the patient’s record to see if the reasons for not following the CPG are documented. The doctor should clearly state the limitation of that particular CPG for his individual patient’s treatment based on the available research as it applies to his patient in that particular circumstance.

References

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Perry Hookman, MD, in active practice, is Board Certified in both Gastroenterology and Internal Medicine. He has authored/coauthored more than 50 publications in peer-reviewed medical literature on topics in Internal Medicine and Gastroenterology. He is the author of the new book *Medical Malpractice Expert Witnessing: Introductory Guide for Physicians & Medical Professionals* (available at www.hookman.com).

He received his training in Internal Medicine and in Gastroenterology at The Johns Hopkins Hospital in Baltimore, Maryland. He currently holds a Medical School faculty appointment and is on the teaching medical staff of a large community hospital. He has served on the Editorial Board of several medical journals. Hookman has been elected to fellowship in the American Gastroenterology Association, the highest level of membership. He is also a Fellow of the American College Of Physicians, the American College Of Gastroenterology, the American College Physician Executives, and The American Society of Gastrointestinal Endoscopy. Among his awards are Knighthood from the Archbishop of the Greek Orthodox Church of North and South America, the Physician of the Year Medal “for community leadership and devoted humanitarian efforts,” and the Annual Award of Merit from the United Jewish Federation “for outstanding achievement and service.” He can be reached at hookman@hookman.com.

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