What Are Clinical Practice Guidelines?

…And do you really need to follow them?

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A clinical practice guideline is a document that defines a standard of diagnosing care and treatment that is generally accepted and presumed followed by a group of healthcare providers. Radiologists might have a clinical practice guideline for diagnosing and treating breast cancers; so might oncologists. Podiatrists might have their own clinical practice guidelines for treatment of various pedal conditions. Sometimes, organizations might have joint guidelines. Some organizations, such as the New York State Pain Society, could generate guidelines that are multi-specialty in nature. A government agency such as the CDC or Workers' Compensation often generates clinical practice guidelines.

The key is if the guideline is based upon reliable standards and measures. The guideline should present a systematic approach to the subject at hand. It should be based upon reliable research and studies. It should draw upon physicians and healthcare providers who are knowledgeable and experienced in the topic at hand. The inherent value of a clinical practice guideline is the willingness of a physician population to adopt the guideline into their daily clinical practice.

While a guideline might become part of a law or adopted by an organization, in the end, the guideline is only as good as its quality. By quality, we mean applicability in a useful way to the patient. If the guideline presents a paradigm for treatment, can a practitioner reasonably follow it? Does the guideline call upon you to perform reasonable actions? Is the bar set too high before a definitive diagnosis can be made? Often, this can only be determined by taking the guidelines out for a test drive. In other words, good guidelines must work in the real world. Impractical guidelines will soon be ignored by the practitioner.

Clinical practice guidelines may be used to either defend or prosecute a physician administratively, as with the Office of Professional Discipline concerning a podiatrist's license. Since the "rules of evidence" are not adopted at administrative hearings, the administrative law judge has wide latitude as to whether the guidelines can be admitted as evidence. Administrative hearings include the Office of Professional Discipline and hospital hearings. The podiatrist has a better chance of getting them admitted into evidence if her/his attorney can make a showing that the guidelines are accepted by the podiatric community.

Clinical practice guidelines also play a potential role in podiatric malpractice suits. The "rules of evidence" apply. Clinical practice guidelines are hearsay. Hearsay is any statement made by somebody else, to prove the truth of the matter being talked about. An example of hearsay is when an expert witness testifies that Dr. Jones' injection of 1% lidocaine into the trigger point was efficacious or indicated as per the clinical practice guidelines of the "ABCD Society". Can the judge allow this hearsay into evidence? At the risk of sounding like an attorney, "maybe". There are several hearsay exceptions that are permitted. At administrative hearings, arbitration and mediation, hearsay is permitted.

The highest court in New York State is known as the Court of Appeals. Fortunately, the Court of Appeals considered this matter in 2006. There was a medical malpractice case involving an anesthesiologist. As part of that anesthesiologist's testimony, he testified to following a flow chart or paradigm in deciding to allow the surgery to proceed without the patient having a prior cardiac evaluation. The judge allowed the flow chart into evidence. The Court of Appeals agreed. The witness, the treating physician, could use the guide-

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Continued on page 42

Guidelines (from page 41)

lines or paradigm as evidence because he was not using it to prove the truthfulness of the guideline, but just to inform the Court as to the process he took in formulating his medical opinion prior to the patient's surgery. That might seem to be a distinction without a difference, but there it is! A guideline may be admitted into evidence under the proper conditions.

A well-written guideline will promote better and more consistent medical decision-making.

The Court also held that if the treating physician partially (not totally) relied on the guideline in his medical decision-making, the guideline was allowed into evidence. Not only that, but the attorney can ask all sorts of questions to the witness about the guidelines, such as who formulated it, who it is endorsed by, and who else uses it. If the guideline is endorsed by a reliable entity and widely used, it will carry more weight with a jury *(Hinlicky v Dreyfuss*, 6 NY3d 636 Slip Op (2006). It is generally inadmissible for expert, non-treating witnesses to reference clinical practice guidelines. When the defense attorney is cross-examining the plaintiff's expert witness, the defense attorney may ask if the plaintiff's expert considers a clinical practice guideline as authoritative. In the rare instance when the expert admits that he/she considers it authoritative, it may be admissible in a state court. In federal courts, if the judge rules that the guideline in question was established as authoritative, the guidelines may be admitted into evidence. Most, but not all, medical malpractice cases are in state, not federal courts. Each state has its own rules.

The National Practitioner Clearinghouse, part of the Federal Government's AHRQ (Agency for Healthcare Research and Quality) is the website for thousands of clinical practice guidelines that meet stringent federal standards for quality. Frankly, the authors of guidelines that make the cut on this website have jumped through many hoops. Having authored several guidelines that made the cut, I can personally attest to that.

To demonstrate the maze of guidelines that are out there, Type in the search terms “chronic pain” on the National Practitioner Clearinghouse website. 454 different guidelines appear! What is useful, and what is not, often involves common sense. If you practice in New York, the Chronic Pain Disorder Medical Treatment Guidelines from the Colorado Division of Workers' Compensation will not be as helpful to you as compared to the New York version. The ACR Appropriateness Criteria Chronic Foot Pain will apply more to a radiologist than a similar guideline written for a podiatrist.

Clinical practical guidelines are hardly new. They have been around for over 25 years, Of course, guidelines must be updated periodically to keep up with new treatment regimens and scientific discoveries. Depending on the subject, updates might have to be more frequent. For example, guidelines concerning the Zika virus might have to be updated more often as it is currently more thoroughly studied than perhaps the efficacy and dosage of Keflex.

One of the big raps on clinical practice guidelines is that it promotes cookbook medicine. If properly written, a good guideline will leave room for clinical judgment. A well-written guideline will promote better and more consistent medical decision-making.

One might ask what happens if you decide not to follow a generally accepted clinical practice guideline. The short answer is, you better have a good reason for departing from the guideline and you should explain it in that patient's medical record! **PM**

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