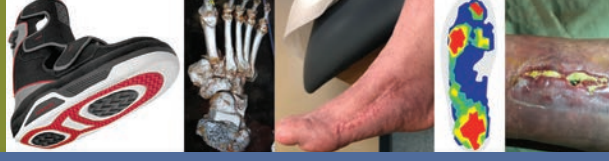

Clinical Practice Guidelines and the Diabetic Foot

These can be useful in following evolving treatment changes.

BY LAWRENCE F. KOBAK, DPM, JD

An effective clinical practice guideline is a text that describes a standard of diagnosing care and treatment that is largely accepted and presumed followed by a group of healthcare providers, such as podiatrists. The guideline can be multi-disciplinary. Care and treatment of the diabetic foot is a classic example of where a multi-disciplinary approach to patient care is generally considered preferable.

Clinical practice guidelines are hardly new. They have been around for over 30 years. Specialty societies will create them. Charitable organizations might have them drafted. Governmental departments might even get involved in their manufacture.

One of the criticisms of clinical practice guidelines is that they promote the practice of "cookbook medicine." But the best evidence-based guidelines allow room for clinical judgment. They are a "guideline", not a rigid pathway.

Reliable Criteria and Procedures

A good practice guideline should be based on reliable criteria and procedures. It should present a systematic approach to the subject at hand, in this case the care and treatment of diabetes of the foot. The guideline should be based upon trustworthy research and studies. It should be drafted by healthcare providers who are both knowledgeable and experienced in the topic at issue. The value of such a guideline rests in the commitment of the healthcare providers who treat the diabetic foot to embrace the guideline into their daily treatment of such patients. The value of the guideline rests in its quality. All clinical practice guidelines should be updated from time to time.

The IDF Guideline

The guideline must be applicable in a suitable way to the diabetic patient. The practice guideline presents an algorithm for treatment that must be practicable for the healthcare provider to follow. For example, if the guideline requires diagnosis of a condition by using an extremely expensive instrument that is not readily available, that will not promote use of that clinical guideline. As an example of a clinical practice guideline, let's use the 2017 IDF Diabetic Foot Guidelines.

The IDF Guidelines are the official guidelines of the International Diabetes Federation.

These guidelines were authored by Lawrence B. Harkless, DPM, Jonathan Labovitz, DPM, as well as several medical doctors, professors of diabetes, and PhDs with extensive knowledge and experience in the diagnosis, care, and treatment of the diabetic foot. It is evidence based.

The IDF Guidelines are the official guidelines of the International Diabetes Federation. The IDF is an international organization that heads over 240 diabetes associations all over the world; the American Diabetes Association is a member of the IDF.

Before we go any further, any guideline purporting to be applicable to the entire world would have the tremendous burden of being applicable in Africa, Asia, as well as North America. While the basic principals of diabetes and its associated conditions do not change, other things such as diet, exercise, local traditions, government, and availability of medical equipment and medication are far from uniform. This must be considered in the utility of any clinical practice guideline. The analysis of this guideline will study its applicability only in North America.

The IDF Guideline is subdivided into diabetic peripheral neuropathy, peripheral arterial disease, ulcers, diabetic foot infection, and Charcot neuro-osteoarthropathy. This is a useful categorization of most of what is dealt with by the North American podiatrist.

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Each section is replete with a robust list of references using peer reviewed journals. Each section is really a clinical guideline of its own subsection. Each subdivision has its own unique layout. Each is clear and easy to follow. Each subdivision discusses the cause, the diagnosis, and the treatment involved. In total, this guideline has 70 pages which are full of colorful charts, photographs, and instructive pathways for diagnosis, care, and treatment of diabetic podiatric patients.

Diabetic Foot Ulcer Guidelines

Another example of an evidence-based diabetic foot care practice guideline is the evidence based 2016 clinical practice guideline concerning the diabetic foot ulcer. It was produced by a joint effort of the APMA, the Society for Vascular Medicine, and the Society for Vascular Surgery. It is 19 pages in length with a full reference section of peer reviewed journal articles. Both medical doctors and podiatric physicians of note in the diabetic world have authored this guideline that is limited to the subject of the diabetic foot ulcer. This guideline also has a two-page summary of recommendations that exponentially increases the ease and usefulness of it.

There are many more practice guidelines that encompass the diagnosis, care, and treatment of the diabetic foot and its various aspects. There are no universally accepted practice guidelines. However, depending upon where you practice, a particular guideline might be favored, or even required. Perhaps your practice insists upon following a particular paradigm in a particular area of diabetic foot care. If so, it should be followed, absent some good reason not to. Your hospital may have adopted a treatment algorithm. Your state's administrative bodies might use a particular set of practice guidelines, such as with Workers' Compensation.

Your state's professional practice board may favor various clinical guidelines. Unfortunately, by the time you might find out which guideline they favor, it is usually too late. The best practice is to stick with guidelines that are generally recognized and that are evidence-based. This way, you are relying on "science" to defend your actions.

Most courts consider such guidelines, in and of themselves, to be hearsay.

Malpractice Situations

What about using Clinical Practice Guidelines to defend yourself in a medical malpractice situation? Most courts consider such guidelines, in and of themselves, to be hearsay. Hearsay is any statement made by somebody else to prove the truth of the matter being talked about. An example of this is when an expert witness testifies that Dr. Smith debrided a diabetic foot ulcer down to viable tissue in the fashion as indicated by the Clinical Practice Guidelines as delineated by the "XYZ" Society. Some state courts will accept the expert's testimony if they state they relied upon those guidelines when coming to their expert opinions being offered in court; others will not. Of course, if you claim you practiced by using a particular set of clinical practice guidelines, you will be allowed to testify about its use in your practice and why you came to use them.

Unlike a judicial trial, administrative hearings, such as with professional discipline, mediations, and arbitration of podiatric malpractice cases, do not abide by the rules of evidence and generally allow hearsay evidence; that would include the use of clinical practice guidelines. However, be warned that each of these types of hearings can apply their own degree of reliability to each clinical guideline.

Documentation

Assuming you have a clinical guideline that you are following to treat the diabetic foot: how do you go about documenting that you are following the guideline? How do you go about explaining why you are not following the guideline?

First, let's take an example of when you chose not to follow the guideline. Your patient, who is diabetic and has a pedal infection, appropriately has a culture and sensitivity taken by you. The results come back with the information that a cephalosporin has the greatest sensitivity to the organism causing the infection. The treatment, according to the guideline, would require a prescription for a cephalosporin, being proven the most sensitive by the culture and sensitivity that you took. However, your history of this patient clearly elicited that she has an allergy to cephalosporins. The patient told you that she broke out in hives the last time she ingested it. Instead, you prescribe an antibiotic that had the second highest sensitivity. Clearly state in your patient chart why you did not prescribe the cephalosporin and why you prescribed the antibiotic that you did prescribe.

The accepted appropriate examination and treatment of your patient will likely change over the years.

In the case of when you follow the guideline, there is no need to state you are following the guideline. What is necessary is to include the reasons for why you are doing what you are doing when you are doing it. Why did you debride the ulceration? What is the size and depth of the ulceration? Describe precise location of the ulceration. Describe how deep you debrided the ulceration. Compare

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the progress of your treatment to the prior visit(s). Is there an odor? Drainage? If there is drainage, is it clear or purulent? What is the neurologic status around the ulcer site? What is the vascular status of the area? A chart with this level of documentation, with an appropriate course of treatment, will suffice.

The accepted appropriate examination and treatment of your patient will likely change over the years. Treatment of the diabetic patient is not exactly the same as it was when I started in podiatry back in 1976. There were no CAT scans or MRIs in those days. The antibiotics at the disposal of podiatrists differed back then. Digital x-rays were not available. That is why clinical practice guidelines must be updated as necessary. Technology and knowledge evolves.

Prior to 2018, the federal government had a wonderful website under the rubric of the federal Agency for Healthcare Research and Quality, known as the Nation Guideline Clearinghouse. Unfortunately, the government stopped funding this program then. There were literally thousands of "approved" clinical practice guidelines. They had to pass rigidly set rules to make the cut. Again, more than one set of guidelines was listed in various areas of practice. There is no one set of guidelines that is accepted as the end of the conversation. That is a good thing. If there was, medicine would be static. The science of medicine and podiatry could not advance. With the advent of new technology, acceptable care and treatment change.

The Inevitability of Evolution

I have by my side a copy of the 1925 book entitled *Practical Chiropody*. Some of the suggested treatments, to say the very least, are dated. Some have withstood the test of almost a century. Surely, nobody would suggest that this 160-page book be followed as a clinical guideline for any aspect of footcare. Guidelines should evolve. Your mode of care and treatment should evolve. The clinical practice guideline is a tool to help make that happen. **PM**

Dr. Kobak is Senior Counsel in Frier Levitt's Healthcare Department in New York. Larry has extensive experience representing physicians in connection with licensure issues, as well as successfully defending physicians before Medical Boards, OPMC, OPD investigations, as well as Medicare Fraud, Fraud & Abuse, Hospital Actions, RAC Audits, Medicare Audits, OIG Fraud, Healthcare Fraud, Medical Audits, and Health Plan Billing Audits. As a licensed podiatrist prior to becoming an attorney, he served as the international president of the Academy of Ambulatory Foot and Ankle Surgery.