

Evidence-based medicine: multiple perspectives

Dr. Oster is responding to Dr. Brand's article in a previous issue. We offered Dr. Brand an opportunity to reply, and fortuitously, Drs. Bransfield and Shepler had posted opinions on the same topic in the internet group Mental Health and Illness (MMI). We begin with Dr. Oster's letter.

I wish to commend your publication of commentary by thoughtful physicians, contributing objective information in an area such as Lyme disease, which harbors so much anecdote. Dr. Brand's commentary (*Reporting some doctors may protect others, Winter 2001/Spring 2002*) leaves open the difficult issues concerning patients who demand treatment for undetermined causes, and desire to receive reimbursement for same. While empiric treatment for a diagnosis of exclusion is frequently carried out for more specific symptoms, such as asymmetric polyarthritis, studies have clearly shown that this approach is not beneficial for the subtle syndromes that most of your audience concern themselves with. This is because most of those cases are likely to be due to some thing other than Lyme disease. The risk of empiric therapy outweighs the potential benefits in those situations, as exemplified by the increasing concern regarding acalculous cholecystitis and other complications of long-term ceftriaxone therapy. Additionally, therapeutic trials should not be permitted to create a false sense of security where the diagnosis remains in doubt. Lastly, the professional (and legal) standard of care is the established boundary, not the point of view of the lobbyist or political activist. Those demanding leading edge or anecdotal therapy, may well be first in line for redress should there be an adverse outcome. For these reasons, and many others, I applaud evidence over anecdote.

Henry A. Oster, MD
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Dr. Brand replies:

Everyone applauds "evidence over anecdote." With regard to Lyme and related diseases, our knowledge base is limited, and there is not enough universally acceptable "evidence" to address the suffering patients who remain untreated by legions of "evidence-based" physicians.

The concept of "evidencebased medicine" was developed by managed care firms to avoid paying for treatment. If the highest standard of care was absolute adherence to evidencebased medical studies, we would not need doctors, as computers could read test results and prescribe more efficiently than mere humans.

Experience, and careful attention to our patients' stories, teaches us things more subtle, less quantifiable, and creates the substrate for optimum care. You are correct that some patients may be adversely affected by IV antibiotic treatment. Some patients also die from aspirin every year. There is a benefit-risk ratio to every decision in medicine. My practice is to describe that ratio to patients so they may make the most informed decision about their own lives. I do not make the decisions for them. You are also correct that IV antibiotic treatment carries a greater risk and should not be considered until other treatments are tried or the urgency of the symptoms demand such action.

Oral and IM antibiotics are usually quite well tolerated and provide help without having to consider the IV route until further down the hierarchy. Regrettably, many patients are denied these as well, without adequate explanation.

Since you specifically addressed ceftriaxone, I would like to know your position on the full spectrum of treatments for patients with symptoms of unproven etiology that fall into the categories we are discussing here. As a psychiatrist, I treat a dozen unprovable diseases

each day and am accustomed to providing care when the diagnosis is descriptive rather than quantitative. I am more comfortable than you to treat when evidencebased medicine proves inadequate to address suffering, as it often does.

The choice of a physician faced with such matters is whether to play it safe and let the patient suffer, to "do no harm," or to courageously venture ahead of the curve, and treat even when less than absolutely positive about diagnosis. In our litigious and paranoid society this is always a risk, and fainthearted physicians do not treat the more difficult diseases, such as Lyme.

The issue of reimbursement is not a matter for ethical physicians. Insurance companies have no business second guessing doctors, and, if I had any spare time, would consider addressing legally their practicing medicine without examining the patient, and without a license. Patients pay premiums and insurance companies pay bills. Managed care is beneath contempt and I do not deal with such companies in my practice. Neither should anyone.

Evidence-based medicine does not treat Lyme disease except in the most obvious, textbook cases, i.e., those with a bulls-eye rash, aching knees and florid western blot results. Lyme is ubiquitous and should remain on the differential diagnosis list until a proven, evidence-based diagnosis is made. Until that is accomplished, subtle multisystem complaints with unexplained neurological symptoms point to the presumptive diagnosis of Lyme, and we have yet to develop a reliable test that definitively rules out Lyme.

Absence of proof is not proof of absence. Just the opposite. Somehow, the ubiquitous, vague and unprovable "fibromyalgia" and "chronic fatigue syndrome" are universally accepted by the same doctors who rail against the diagnosis of Lyme disease in patients with more specific symptom clusters.

The bottom line: A suffering patient deserves the best treatment we can provide, and it is our duty to develop a hierarchy of reasonable benefit-risk options, beginning with the most effective and least harmful. If the first choice works, fine. If not, we must keep going, always measuring the ratio and letting the patient decide how much risk and adversity they wish to tolerate vs how much disease related suffering they undergo.

While your note addresses what we should not do to help these patients, it fails to mention what we should do, other than refuse treatment.

Richard Brand, MD
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Dr. Bransfield writes:

This discussion touches on a core conflict in the whole managed care crisis. Insurance companies, managed care, "evidence-based" medicine and disease management focus upon welldefined treatments of well-defined diseases. In the every day practice of medicine, most diseases are not well understood and not well defined. We treat patients with diseases: we do not treat diseases. I contend it is malpractice to merely treat a disease. If others accept this view, the whole concept of disease management for the establishment of diagnosis and treatment guidelines would be considered malpractice, and justifiably so, in my opinion. Whenever diagnostic or treatment guidelines are published, there is always a disclaimer of responsibility by those who publish the guideline. No professional society, insurance company or other organization or individual ever assumes responsibility and accountability for diagnostic and disease management guidelines. If the individuals who make these guidelines do not stand behind them, why should we?

Those who take a hypothesis to explain a disease and promote it to an authoritarian view are violating the scientific method when they ignore and dismiss evidence that may undermine their belief as being merely subjective, anecdotal, etc. Since much is not known about medicine, in the real world all treatments are empirical and subject to constant revision if the clinical course is contrary to a prejudged view of the diagnosis and needed treatment.

Back to Lyme disease. At NIH, the diagnosis of Lyme disease, and in particular chronic Lyme disease, is conceptualized as a pyramid. At the apex are the cases that everyone agrees is Lyme disease. At the base are cases that everyone agrees may be some type of condition, but not Lyme disease. In between are cases that some call Lyme disease and some do not. When we perform research or collect epidemiological statistics on any disease, we like to use the apex of the pyramid as a reference point. Insurance companies invariably select the most restrictive (and cheap) diagnostic and treatment criteria and use skewed "evidenced-based" arguments to justify their position. Therefore, they often incorrectly use the epidemiological criteria, research criteria, criteria for Lyme, criteria for arthritis, rather than other manifestations of late stage disease, lab tests with a high cut off point to define the clinical syndrome, etc. Lyme disease, like many conditions is a clinical diagnosis. We make a diagnosis by looking at the weight of evidence in the presentation of any given patient. Often, patients do not fit into a clean diagnostic category. We therefore need to consider their complaints are caused by a presentation of the disease not currently recognized by the currently flawed diagnostic guidelines, some other disease, or some uncategorized disease. We still have a responsibility to treat the patient to the best of our ability, even when it is contrary to someone's view of the nature of any particular disease.

Robert Bransfield, MD
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Dr. Shepler writes:

I am struck by the legal analogies. Note that the vast majority of legal claims of all sorts fail due to lack of "evidence." Doctors are being pressured to gather less and less "evidence" of illness in their use (or lack thereof) of patient histories and physicals and laboratory testing. If no "evidence," the conclusion is that there nothing wrong. Your (health care) claim fails. In law, the justification for having to have fairly high standard of proof (evidence) has to do with issue of justice and fairness—but those concerns don't operate to any meaningful degree in health care, other than the arguments about avoiding waste so that the maximum number of people may benefit. While the argument that avoiding waste so that the maximum number of people can benefit is important and powerful, it would seem that is not the reason why physicians and patients are being forced to provide "proof" of illness. Rather, the end is corporate profit and an attempt to limit the number of individuals who will benefit from health care resources.

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