The Lyme Wars: Guidelines, Controversy, and Informed Consent

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Medical societies issue guidelines to establish a standard of care. When restrictive guidelines do not provide room for treatment variation or clinical judgment, there may be legal ramifications. An underlying assumption of practitioners is that guidelines are based on evidence and were developed in a fair process.

However, medical specialty societies control their guideline development process and typically limit their panels to like-minded folk. These are not robust, inclusive, discursive, or even transparent democratic processes, and those most affected may have no voice in the process.

Fifty percent of medicine is practiced in the grey zone of uncertain evidence.[1] Most guidelines rely on a consensus of the expert opinions of those on their panels to fill the holes in the evidence gaps.[1] For example, a study of the guidelines of the Infectious Diseases Society of America (IDSA) found that only one in seven of their guideline recommendations was based on strong evidence.[2] More than half the recommendations relied solely on expert opinion or anecdotal evidence. Faced with low quality evidence, different guideline panels may arrive at conflicting recommendations because the panels hold different viewpoints.[3,4]

The National Guidelines Clearinghouse lists 25 medical conditions with conflicting guidelines.[5] However, the Institute of Medicine notes that the controversy surrounding the competing Lyme disease guidelines of the IDSA and the International Lyme and Associated Diseases Society (ILADS) is among the most contentious.[4] It also highlights the IDSA Lyme guidelines as an example of a flawed guideline development process.[4]

The scientific evidence base regarding treatment of chronic Lyme disease is not robust. Only three NIH funded randomized controlled double blind studies exist. All used very small sample sizes (fewer than 57 patients completed the largest trial) and yielded conflicting results on the value of extended antibiotic treatment, with two finding improvement of fatigue.[6-8] Other *observational* trials do support further treatment, but are discounted by the IDSA.[9-15]

Currently available diagnostic tests are unable to monitor treatment progress or demonstrate eradication of the Lyme bacteria from a patient. Many patients remain severely ill after short term treatment. Forty percent of those with chronic Lyme report being unable to work due to Lyme disease, and 24% of patients with chronic Lyme disease report being on disability at some point in their illness.[16,17] No other treatment options are available to patients.

The essence of the controversy, which is framed differently by the two organizations, is the question of whether to intervene with treatment when science is unsettled. The IDSA contends that the existing evidence base is too weak to warrant intervention. ILADS, in contrast, contends that given the poor quality of life of those with Lyme disease, the evidence is strong enough to support treatment.

Hence, the critical question becomes *who* decides the appropriate course of treatment for the patient. Who should assess the risks and benefits of treatment? Whose values count? Who bears the consequences of the decision?

Under the medical ethical principle of autonomy, the treatment decision among viable options belongs to the patient. Hence, organizations like the American Medical Association require physicians to disclose and discuss with the patient the risks and benefits of the proposed treatment as well alternative treatments (regardless of cost or insurance coverage).[18] For example, patients with prostate cancer (where significant uncertainty exists regarding long-term treatment outcomes) may choose between watchful waiting, radiation and surgery.

The legal doctrine of informed consent also requires physicians to inform patients of material treatment options. The doctrine is inherently vague, but the seminal decision of Canterbury states that informed consent requires that physicians disclose to the patient:

> *"recognized serious possible risks, complications, and anticipated benefits involved in the treatment . . ., as well as the recognized possible alternative forms of treatment, including non-treatment.*[19]

Treatment choices involve trade-offs between the risks and benefits of treatment options that only patients – who know the risks they are willing to run and the quality of life outcomes that matter to them – are uniquely suited to make.[20] Without adequate information about treatment options, their probable outcomes, and the risks and benefits associated with each, patients cannot act autonomously.

From the medico-legal perspective, while informed consent does not provide a complete shield against malpractice or unprofessional conduct allegations, it plays a critical role. In addition, failure to appropriately obtain consent may create legal liability.

From the patient's perspective, informed consent is a moral imperative. For a patient who may be too ill to work, choosing to wait and/or failing to intervene is not a value-neutral proposition. Patients with chronic Lyme disease surveyed by LymeDisease.org overwhelmingly state that they would not elect to be treated under the restrictive IDSA guidelines. Not all patients elect continued antibiotic therapy, but they believe the choice should be their own.[17]

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