



Lyme Disease: Two Standards of Care

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The central difficulties in the diagnosis and treatment of Lyme disease stem from the lack of sufficiently sensitive and reliable biological markers of the disease. Without such markers, it is difficult to determine who has the disease, the effectiveness of a course of treatment, and the end point of treatment. The ideal antibiotics, route of administration, and duration of treatment for persistent Lyme disease are not established. No single antibiotic or combination of antibiotics appears to be capable of completely eradicating the infection, and treatment failures or relapses are reported with all current regimens, although they are less common with early aggressive treatment. [1-3]

Opinion within the medical community is deeply divided regarding the best approach for treating Lyme disease, particularly persistent Lyme disease that is not cured by short-term protocols. This split has resulted in two standards of care. Both viewpoints are reflected in peer-reviewed, evidence-based guidelines. Some physicians treat patients for 30 days only and assume that remaining symptoms reflect a self-perpetuating autoimmune response. [4] Other physicians assume that the persistent symptoms reflect on-going infection and gauge the duration of treatment by the patient's individual clinical response. These physicians believe that there is insufficient evidence at this point to adopt standardized treatment protocols. [5]

While each viewpoint has a strong underlying hypothesis, the scientific evidence supporting either viewpoint is equivocal. Outcomes research is limited and conflicting. The NIAID has only funded three double-blind, placebo-controlled treatment outcome studies for long-term treatment of persistent Lyme disease. The findings of two studies (Klempner and Krupp) are contradictory, with one indicating that continued treatment is beneficial for treating fatigue and the other indicating that it is not.[6-8] The third NIAID-funded study has recently been completed and preliminary results support continued antibiotic treatment for patients with persistent Lyme disease.[9] The findings of five non-controlled studies support continued treatment.[1, 10-13] The existence of limited or conflicting controlled studies is not uncommon in the practice of medicine. Where this is the case, the unique clinical course of the patient, of necessity, bears the laboring oar in treatment decisions.

Insurance companies have placed the full weight of their economic clout behind the less expensive short-term treatment protocols. More expensive longer-term treatment options are discredited as "experimental" or "not evidence-based." The point, of course, is that the science underlying both the short-term and the longer-term treatment options is equally uncertain (like prostate cancer). The appropriate response to equivocal research findings in healthcare outcomes is to fund more research. It is estimated that only 20% of medicine practiced today is rooted in double-blind studies.[14] The bulk of medicine today is practiced in the grey zone. Evidence-based medicine requires only that medicine be practiced in accordance with the evidence that currently exists, not that treatment be withheld pending research.

Insurance companies have adopted guidelines reflecting short-term treatment approaches. However, the legal standard of care for treating a condition is determined by the consensus of physicians who actually treat patients, not by treatment guidelines.[15] Moreover, more than one standard of care may exist. A number of surveys have found a fairly even split among treating physicians. One survey found that 57% of responding physicians treat persistent Lyme disease for three months or more.[16] Fallon notes that for over 3400 patients screened for the Columbia University study of persistent Lyme disease, the mean duration of IV treatment was 2.3 months and the mean duration of oral antibiotic therapy was 7.5 months.[6] In another survey, "50% of the responders considered using antibiotics for a time greater than one year in a symptomatic seropositive Lyme disease patient. Almost that same number would extend therapy to 18 months if needed." [17] For treating early Lyme disease, there are conflicting surveys. Most

physicians responding to one survey specified short-term treatment [18], while 43% of those responding to another survey would treat erythema migrans-positive Lyme disease for three months or more.[16] All jurisdictions that have considered the matter have found two standards of care in the treatment of Lyme disease.[19]

When more than one standard of care exists, the critical question becomes *who* decides the appropriate course of treatment for the patient. Under the medical ethical principle of autonomy, the treatment decision belongs to the patient. Hence, the American Medical Association requires that the physician disclose and discuss with the patient not only the risks and benefits of the proposed treatment, but also the risks and benefits of available alternative treatments (regardless of their cost or the extent to which the treatment options are covered by health insurance).[20] For example, patients with prostate cancer (where significant uncertainty exists regarding long-term treatment outcomes) must elect between watchful waiting, radiation and surgery. The legal doctrine of informed consent also requires that patients be advised of material treatment options. Treatment choices involve trade-offs between the risks and benefits of treatment options that only patients—who know the kinds of risks they are willing to run and the types of quality of life outcomes that matter to them—are uniquely suited to make.

Sound health care policy follows suit, with healthcare costs generally witnessing a reduction when the patient's preference is supported. Patient preference exists whenever there is more than one acceptable treatment approach. When inefficiencies in the Medicare system were analyzed by looking at small area variations in medical practice, most variation in preference-sensitive care was found to reflect physician opinion. In patient preference situations, patient and provider values are often in conflict and public healthcare researchers recommend reducing the medical practice variations in these situations by “reduc[ing] scientific uncertainty through outcomes research.... and establish[ing] shared decision-making for preference-based treatments.”[21]

Respect for the basic autonomy of the patient is a fundamental principle of medical ethics. Without adequate information about treatment options, their probable outcomes, and the risks and benefits associated with each, patients cannot act autonomously. Today, however, many patients are either denied treatment by their HMO physicians who follow actuarial treatment protocols generated to keep treatment costs down, or they must find an independent physician to treat them, with the all but forgone conclusion that coverage for this treatment will be denied by their insurer based on cherry-picked (economically favorable) guidelines. Moreover, HMO physicians generally do not advise their patients that treatment alternatives exist.

Scientific uncertainty about Lyme disease has resulted in more than one treatment approach (like prostate cancer). We agree with the AMA, ACP and other professional medical organizations interested in promoting informed patient consent and want to make sure that:

- Physicians, insurers, patients and governmental agencies are educated that two treatment approaches exist;
- Physicians give patients sufficient information about treatment options to enable patients to make a meaningfully informed choice and respect the autonomy of that choice;
- Insurance reimbursement be provided for treatment rendered in accordance with either standard of care; and
- Government agencies provide unbiased information and remain neutral regarding both standards of care and treatment approaches.

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