



Tick-borne Infections Council of North Carolina, Inc.

Lyme Disease and Two Standards of Care

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 reflected in peer-reviewed, evidence-based guidelines. Some physicians treat patients for up to 30 days only and assume that remaining symptoms reflect a self-perpetuating autoimmune response. [1] Others assume that the persistent symptoms reflect on-going infection and gauge the duration of treatment by the patient's individual clinical response. The latter believe that there is insufficient evidence at this point to adopt standardized treatment protocols. [2]

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. [3-5]

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.[6-8] The preliminary results of the recently completed third NIAID-funded study support continued antibiotic treatment.[9] The findings of five non-controlled studies support continued treatment.[1, 10-13]

Insurance companies have generally 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." It is estimated that only 20% of medicine practiced today is rooted in double-blind studies.[14] 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]

In Lyme borreliosis a number of surveys have found a fairly even split among treating physicians between longer and shorter treatment. (6, 16-18) 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 (AMA) 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]

As with certain other diseases (for example, prostate cancer), scientific uncertainty about Lyme disease has resulted in more than one treatment approach. We agree with the AMA, the American College of Physicians, and other professional medical organizations interested in promoting informed patient consent. We need to ensure that:

- Physicians, insurers, patients and governmental agencies understand 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.

Adapted from "Lyme disease: Two Standards of Care" by Lorraine Johnson, JD, MBA, Executive Director, CALDA. The full-length article can be accessed at www.lymedisease.org January 2006

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