

## Overdiagnosis and overtreatment of Lyme disease leads to inappropriate health service use

**Authors:** M.C. Reid *et al.*

**Title:** The consequences of overdiagnosis and overtreatment of Lyme disease: An observational study.

**Source:** *Ann Intern Med* 1998; 128: 354-362.

**Aim:** The correct diagnosis and treatment of Lyme disease (LD) is of pivotal importance in the USA, where its frequency is estimated to be very high. One problem is the fact that many patients receiving treatment for LD lack firm clinical or serological evidence of the disease. The aim of this work was to study the use of health services and the occurrence of treatment-related illness, disability and distress among patients in whom LD is inappropriately diagnosed or treated.

**Methods:** A 50-item questionnaire was mailed to patients attending the Yale University Lyme Disease Clinic (YLDC) with a presumptive diagnosis of LD made either by the patient, by the referring physician, or both. The questions included: the number of physicians seen and out-patient visits made; the number of serologic tests for LD previously performed; previous treatments and their effectiveness; whether a physician had made the original diagnosis of LD; and other items regarding the number of working days lost and days in which normal activity was reduced, the presence of depressive symptoms, perceived stress, and adverse drug effects. The reliability of the survey responses was assessed by a second questionnaire which contained two items pertaining to the results from the first report (number of previous visits and serologic tests performed for LD). The proportion of observed agreement for these items were respectively 72% and 83%.

The adverse drug events were divided into two groups, i.e. minor and major. The reliability of the determination of adverse drug events was assessed by a second investigation on randomly selected patients. The proportion of observed agreement between raters was 89%.

The patients were divided into those who had LD in the past, those with no previous or current evidence of LD, and patients with active LD. For each patient a clinical history was taken and an examination performed, the duration period of the symptoms was calculated, and an enzyme-linked immunosorbent assay (ELISA) for *Borrelia burgdorferi* was done. Positive sera (1:1200 for IgM or IgG) were tested by Western blot analysis.

All patients were contacted by telephone 3 to 7 months after their visit to determine whether their condition had resolved, or if they had undergone additional therapy or medical visits for LD.

**Results:** 209 of the initial 269 patients evaluated during the 13-month study were available for analysis: 44 (21%) met the criteria for active LD, 40 (19%) had previous but now inactive LD, and 125 (60%) had no evidence of current or previous infection.

The patients with active LD all had good outcomes. It was found that patients with previous or no evidence of LD made

considerable demands on their community's health services: they underwent a median of 11 and 7 out-patient visits respectively, a median of 4 and 4 serologic tests, 75 and 42 days of antibiotic therapy, presented frequent minor adverse drug effects (53 and 55%, respectively), had significant disability (reporting 16% and 18% symptomatic days in which normal activities could not be performed), and presented with high rates of depression (38 and 42%) and stress (52 and 45%). Indeed, 31% of the patients with previous LD, and 20% of the patients with no evidence of LD obtained additional medical evaluations for LD during the follow-up period and 21% and 11% received additional antibiotic therapy, respectively.

**Conclusions:** Many physicians and patients consider LD to be a chronic and often incurable disease that requires multiple courses of antibiotics to control. This work demonstrates that such a view can lead to the over-diagnosis and over-treatment of LD, associated with the inappropriate use of health resources and avoidable drug-related effects, disability and distress.

### Comment

*The problem described by Reid and colleagues is two-fold.*

*First: Overdiagnosis. It is important for patient and physician alike that a specific explanation be found for the patient's malady. When no specific diagnosis presents itself, some physicians literally invent one, often despite evidence to the contrary. Frequently the practitioner's "personal experience" outweighs the peer-reviewed medical literature. Laboratory tests are mis-used and mis-interpreted. Results not in keeping with the a priori biases of the physician are rejected. Unproven tests are adopted. Enthusiasm, regardless of the original motives, replaces science (1).*

*Second: Overtreatment. If the patient does not have Lyme disease, there will be no objective response to anti-microbial therapy (2). Perhaps the patient never had the infection, perhaps it was present at the start but has now been eradicated; in either event the current symptoms are not due to Lyme disease. Lack of response should prompt a re-consideration of the diagnosis, but in situations such as the one under discussion it instead prompts prescriptions for more aggressive therapy. The end result? A patient with a permanent psychological disability (chronic sick role) and a sense of helplessness and hopelessness ("nothing is working"), as well as drug side effects and large pharmacy and physician bills.*

*Why? Abandonment of logic and science in the practice of medicine. Misplaced compassion? Greed? Ego? It makes little difference: the outcome is bad, for no one gains and everyone loses (3).*

L.H. SIGAL, MD

*Division of Rheumatology, UMDNJ - R.W. Johnson Medical School, New Brunswick, New Jersey, USA*

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