



Susan L. Marra MS, ND

Informed Consent for Treatment

Informed Consent for Treatment of Tick Borne Disease including Acute and Chronic Lyme Disease

There is considerable uncertainty regarding the diagnosis and treatment of Lyme Disease within the medical community. No single diagnostic and/or treatment program for Lyme Disease or any of the tick borne infections is universally successful or accepted. Medical opinion is divided, and two schools of thought regarding diagnosis and treatment exist. Each of the two schools of thought is described in peer reviewed evidence based treatment guidelines. Until we know more about these diseases, patients must weigh the risks and benefits of treatment in consultation with their physician.

My Diagnosis:

The diagnosis of Lyme Disease is primarily a clinical determination made by my physician based on my exposure to ticks or other biting insects, my symptom report, and my doctor's observations of signs and of the disease, with diagnostic testing functioning in a supportive role.

Physicians differ in how they diagnosis Lyme Disease. Some doctors rely on the narrow surveillance case criteria of the Center for Disease Control (CDC) for clinical diagnosis even though the CDC itself cautions against this approach. Physicians who follow this approach may fail to diagnose some patients who actually have Lyme Disease. For these patients, treatment will either be delayed or not occur at all.

Other physicians use broader clinical criteria for diagnosing Lyme Disease. These doctors believe that it is better to error on the side of providing treatment because of the serious health consequences of failing to treat active Lyme Disease. These physicians sometimes use the antibiotic responsiveness of a patient to assist in the diagnosis of Lyme Disease. Since none of the treatments are entirely risk free, use of broader clinical criteria to diagnose disease could in some cases expose patients to increased treatment complications. This approach may result in a tendency to over diagnose and over treat Lyme disease.

My Treatment Choices:

The medical community is divided regarding the best approach for tick borne infections, especially if they become persistent and chronic. At this time, many physicians follow the treatment guidelines of the Infectious Disease Society of America (IDSA) that recommend short term treatment ONLY, and view the long

11782 Sand Point Way NE, Seattle WA 98125
tel: (206) 299-2676 fax: (206) 547-0925
email: info@drsusanmarra.com



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term treatment effects of Lyme Disease as an autoimmune process or permanent tissue damage that is unaffected by antibiotics. Other physicians believe that the infection persists, is difficult to eradicate, and therefore requires long term treatment with oral, intramuscular or intravenous antibiotics, frequently in high and/or combination doses. These physicians follow the guidelines promulgated by the International Lyme and Associated Diseases Society (ILADS).

The following are the April, 2010 IDSA guidelines which strongly recommend AGAINST many of the common treatment approaches used by physicians who follow the ILADS treatment guidelines:

- 1) Selected antimicrobials, drug regimens, or other modalities not recommended for the treatment of Lyme Disease
- 2) Doses of antibiotics, antiparasitics, antifungals and antiviral medication far exceed those standardly used to treat infections.
- 3) Multiple and repeated courses of antimicrobials, antiparasitics, antifungals, and antiviral medication for the same episode of Lyme Disease or a duration of these medications used in a prolonged manner, far exceeding the "standard" treatment course.
- 4) Combinations of antimicrobial, antiparasitic, antifungal and antiviral medication.
- 5) Pulse dosing of antimicrobials, antiparasitics, antifungals and antiviral medication (i.e., medication therapy this is given some days and not others).
- 6) First-generation cephalosporins, Benzethine Penicillin G, Flouroquinolones, Factiv, Carbapenems, Vancomycin, Metronidazole, Tinidazole, Allinia, Rifampin, Trimethoprim-Sulfamethoxazole, Amantadine, Macrolides, Isoniazid, Fluconazole, Albendazole, Mebendazole, and Ivermectin.
- 7) Empirical antibabesiosis therapy in the absence of laboratory documentation of active Babesiosis.
- 8) Empirical antibartonellosis therapy in the absence of laboratory documentation of active Bartonellosis.
- 9) The use of therapeutic hyperbaric oxygen.

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- 10) The use of fever therapy (with or without malaria induction).
- 11) The use of intravenous immunoglobulins (IVIG therapy).
- 12) The use of Cholestyramine.
- 13) The use of intravenous hydrogen peroxide.
- 14) The use of vitamins, nutritional or herbal management of the chronic illness.
- 15) The use of magnesium or bismuth injections.

Potential Benefits of Treatment:

Some clinical studies support longer treatment approaches while others do not. The clinical experience of Dr. Marra's suggest that although some patients improve with long term treatment, some do not.

Risk of Treatment:

There are potential risks involved in using any treatment, just as there are risks in foregoing treatment entirely. Some of the problems with antibiotics may include: allergic reactions, rashes, swelling, difficulty breathing, stomach or bowel discomfort, or yeast infections. Severe allergic reactions may require emergency treatments, while other problems may require suspension of treatment or adjustment of medication. Other problems such as adverse effects on the liver, kidney, gallbladder, or other organs can occur.

Factors to Consider in my Decision:

No one knows the optimal treatment for symptoms of persistent Lyme Disease, especially if the patient initially had a short course of antibiotics. The appropriate treatment may be supportive therapy without the administration of antibiotic therapy. If additional antibiotic therapy is warranted, no one knows for certain exactly how long to provide the additional therapy. By taking antibiotics for longer periods of time (i.e., months or years), I understand that I place myself at greater risk for side effects. By stopping antibiotics, I understand that I may place myself at greater risk for continued progression of infection. Antibiotics are the only form of treatment known to be effective for Lyme Disease, but not all patients respond to antibiotic therapy. There is no current diagnostic test that can demonstrate the eradication of the Borrelia bacteria from my body so I must rely on my constellation of symptoms. Other forms of treatment designed to strengthen my immune system also may be important. Some forms of treatment are only

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intended to make me more comfortable by relieving my symptoms and do not address any underlying infection.

My decision about continued treatment may depend on a number of factors and the importance of these factors to me. Some of these factors may include: the severity of my illness and degree to which it impairs my quality of life, whether or not I have coinfections which can complicate the treatment, my ability to tolerate antibiotic treatment, the risk of major and minor side effects associated with the treatment, whether I have been responsive to antibiotics in the past, whether I relapse or my illness progresses when I stop taking antibiotics, and my willingness to accept the risk that left untreated, a bacterial infection potentially may get worse.

For example, if my illness is severe, significantly affects my quality of life, and I have been responsive to antibiotic treatment in the past, I may wish to continue treatment. However, if I am willing to accept the risk that infection may progress or if I am not responsive to antibiotics, I may wish to terminate treatment. I will ask Dr. Marra if I need any more information to make this decision and am aware that I have the right to obtain a second opinion at any time if I think this would be helpful.

I realize that the choice of treatment approach to use in treating my condition is mine to make in consultation with Dr. Marra. After weighing the risks and benefits of the two treatment approaches, I have decided the following (please initial next to your choice):

_____ to treatment of Lyme Disease through a treatment approach that relies heavily on Dr. Marra's clinical judgment and may use antibiotics until my clinical symptoms resolve. I recognize that this treatment approach does not conform to IDSA guidelines and that insurance companies may not cover the cost of some or all of my treatment medications.

_____ only to treat my Lyme Disease with antibiotics for 30 days, even if I still have symptoms.

_____ not to pursue antibiotic therapy.



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I may obtain a copy of both the IDSA and ILADS treatment guidelines by going to www.ILADS.org and downloading them.

Signature: _____ Date: _____

Print Name: _____

Parent Signature: _____ Date: _____
(if under age 18)

Spouse Signature: _____ Date: _____
(if under age 18)

Physician Signature: _____ Date: _____

References:

1) The International Lyme and Associated Diseases Society. ILADS Evidence Based Guidelines for the Management of Lyme Disease. Expert Rev. Antiinfect. Ther. 2004; 2(1): S1-S13. Available at www.ILADS.org.