

FOX VALLEY WELLNESS CENTER / MIDWEST HYPERBARICS
180 KNIGHTS WAY
FOND DU LAC, WI 54935

REQUIRED DISCLOSURE AND CONSENT FOR DIAGNOSIS AND TREATMENT OF PERSISTENT LYME DISEASE

There is considerable uncertainty regarding the diagnosis and treatment of Lyme disease. No single diagnostic and treatment program for Lyme disease is universally successful or accepted. Current testing for Lyme disease can be problematic and may lead to false results. If you are tested for Lyme disease and the results are positive, this does not necessarily mean that you have contracted Lyme disease. In the alternative, if the results are negative, this does not necessarily mean that you have not contracted Lyme disease. If you continue to experience symptoms or have other health concerns, you should contact your health care provider and inquire about the appropriate of additional testing or treatment.

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, patients must weigh the risks and benefits of treatment in consultation with their doctor.

My Diagnosis. The diagnosis of Lyme disease is primarily a clinical determination made by my doctor based on my exposure to ticks, my report of symptoms, and my doctor's observation of signs of the disease, with diagnostic tests playing a supportive role.

Doctors differ in how they diagnose Lyme disease.

- Some physicians rely on the surveillance case criteria of the CDC for clinical diagnosis. These physicians may fail to diagnose some patients who actually have Lyme disease. For these patients, treatment will either not occur or will be delayed.
- Other physicians use broader clinical criteria for diagnosing Lyme disease. These physicians believe it is better to err on the side of treatment because of the serious consequences of failing to treat active Lyme disease. These physicians sometimes use the antibiotic responsiveness of a patient to assist in their diagnosis. Since no treatment is 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 treating persistent Lyme disease. (1) Many physicians follow the treatment guidelines of the Infectious Diseases Society of America (IDSA) that recommend short-term treatment only and view the long-term effects of Lyme disease as an autoimmune process or permanent damage that is unaffected by antibiotics. (2) Other physicians believe that the infection persists, is often associated with other tick-borne co-infections, is difficult to eradicate, and therefore requires long-term treatment with intravenous, intramuscular, or oral antibiotics, frequently in high and/or combination or pulsed dosing. These physicians follow the guidelines promulgated by the International Lyme and Associated Diseases Society (ILADS), which recognize that commercial diagnostic tests may be insensitive and that diagnosis and treatment must be based on the physician's clinical judgment and that the risk/benefit of any treatment must be individualized.

Potential Benefits of Treatment. Some clinical studies support longer term treatment approaches, while others do not. The experience in this office is that although most patients improve with continued treatment, some do not.

Risks of Treatment. There are potential risks involved in using any treatment, just as there are in foregoing treatment entirely. Some of the problems with antibiotics may include (a) allergic reactions, which may manifest as rashes, swelling, and difficulty with breathing, (b) stomach or bowel upset, or (c) yeast infections. Long term antibiotic treatment can have serious, irrevocable consequences. 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 liver, kidneys, gallbladder, or other organs may occur.

Factors to Consider in my Decision. No one knows the optimal treatment of symptoms that persist after a patient is diagnosed with Lyme disease and treated with a simple short course of antibiotic therapy. The appropriate treatment may be supportive therapy without the administration of any additional antibiotics. Or, the appropriate treatment might be additional antibiotic therapy. If additional antibiotic therapy is warranted, no one knows for certain exactly how long to give the additional therapy. By taking antibiotics for longer periods of time, I place myself at greater risk of developing side effects. By stopping antibiotic treatment, I place myself at greater risk that a potentially serious infection will progress. Antibiotics are the only form of treatment shown to be effective for Lyme disease, but not all patients respond to antibiotic therapy and antibiotic therapy has the risks discussed above. There is no currently available diagnostic test that can demonstrate the eradication of the Lyme bacteria from my body. Other forms of treatment designed to strengthen my immune system also may be important. Some forms of treatment are only 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 include (a) the severity of my illness and degree to which it impairs my quality of life, (b) whether I have co-infections, which can complicate treatment, (c) my ability to tolerate antibiotic treatment and the risk of major and minor side effects associated with the treatment, (d) whether I have been responsive to antibiotics in the past, (e) whether I relapse or my illness progresses when I stop taking antibiotics, and (f) 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 the quality of my life, and I have been responsive to antibiotic treatment in the past, I may wish to continue my treatment. However, if I am not responsive to antibiotics, I may wish to terminate treatment. I will ask my doctor 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.

My doctor has made no written or verbal agreement with me and has made no promise or warranties outside of those outlined in this consent document and has not pressured me as regards my decision. I make this decision as regards my treatment for Lyme disease of my own free will. All of my questions have been answered and I fully understand the decision I must make and the significance of my decision to my health care. _____ **Initial**

I am over the age _____ (age of consent in my state) and I realize that the choice of treatment approach to use in treating my condition is mine to make in consultation with my physician. After weighing the risks and benefits of the two treatment approaches, I have decided: (CHECK ONE)

- To treat my Lyme disease through a treatment approach that relies heavily on 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.
- Only to treat my Lyme disease with antibiotics for thirty days, even if I still have symptoms.
- Not to pursue antibiotic therapy.

I understand the benefits and risks of the proposed course of treatment, and of the alternatives to it, including the risks and benefits of foregoing treatment altogether. My questions have all been answered in terms I understand. All blanks on this document have been filled in as of the time of my signature.

Signature: _____

Date: _____

Print Name: _____

Witness: _____