SSB 5448: Concerning the Treatment of Lyme Disease

A Report of the Effects Long-Term Antibiotic Therapy has on certain Lyme Disease Patients

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Executive Summary

Each year, the Department of Health receives reports of seven to 23 cases of Lyme disease among Washington residents. Fewer than three of the reported cases each year are from a bite that occurred within Washington. Most of patients acquired the disease following tick bites that occurred in the Northeast and Upper Midwest states, where Lyme disease is more common.

Some patients have lingering symptoms from what is known as post-treatment Lyme disease syndrome. Substitute Senate Bill 5448, which became law in 2015, directs the Medical Quality Assurance Commission to address concerns about treatment of the syndrome. This report examines those concerns, concluding that potential benefits from long-term antibiotic treatments do not offset possible risks to patients. The Medical Commission policy committee hosted opportunities for public comment regarding this issue on May 14th 2015, June 25th 2015 and August 20th 2015.

This report includes five sections. The Medical Commission concludes:

A. The most common treatment for a patient with acute Lyme disease is a 14-day course of doxycycline, an antibiotic.
B. Patients treated with long-term antibiotic therapy for Lyme disease have had severe adverse responses, including death. Other reactions include bloodstream infections, pulmonary embolism, septic thrombophlebitis, and gastrointestinal bleeding.
C. Long-term antibiotic therapy has not proven to provide any long-term benefits to patients with post-treatment Lyme disease syndrome. Benefits appear to last only as long as the treatment continues. When treatment concludes, symptoms return, indicating an underlying, undiagnosed cause of symptoms.
D. Clinical trials show no benefit to long-term therapy in comparison to the initial 14-day treatment plan for acute Lyme disease. Long-term antibiotic treatment of “chronic Lyme disease” – a term

the medical community doesn't find meaningful – is not in patients' best interest. Most patients with medically unexplained symptoms who received a diagnosis of post-treatment Lyme disease will require more than antibiotics to manage their symptoms. These patients should consult with their physician regarding a treatment plan that also includes emotional support, nutritional guidance and physical therapy. Practitioners should openly address any concerns and should reassure patients. Antibiotics are no substitute for sympathetic listening and explanation.

E. The benefits associated with long-term antibiotic treatments do not outweigh the risks to the residents of Washington. Evidence-based science has not determined the best long-term treatment option for post-treatment Lyme disease syndrome. Evidence-based treatments should remain the standard in Washington to ensure our residents' safety. The Medical Commission strongly recommends not adding standard of care and related language to statute because of the evolving nature of science and medicine. Effective treatments must be free from statutory constraint if Washington practitioners are to deliver evidence-based, high-quality care to the state's citizens. Physicians and Physician assistants should not fear disciplinary action from the Commission for ordering, prescribing, dispensing or administering treatments, for a legitimate medical purpose and in the course of professional practice. The Medical Commission has no evidence of disciplinary actions taken against practitioners for either diagnosing or treating Lyme disease.

Antibiotics that are commonly used, prescribed, and administered for the long-term treatment of Lyme disease

Section A

Summary

The most common course of treatment for a patient diagnosed with acute Lyme disease is a 14-day course of orally administered doxycycline. After treatment concludes, there are instances where patients experience lingering symptoms, including fatigue and body aches, known as post-treatment Lyme disease syndrome (PTLDS). There is a lack of evidence to support the benefits of extending antibiotic treatment for the lingering symptoms of Lyme disease.

Acute Lyme disease is caused by the bacterium *Borrelia burgdorferi*. Typical symptoms include fever, headache, fatigue, and a characteristic skin rash called *erythema migrans*. Acute Lyme disease is diagnosed based on symptoms, physical findings (e.g., rash), and a history of possible exposure to infected ticks (CDC, 2015). Laboratory testing may be helpful if used correctly and performed with validated methods. Most cases of acute Lyme disease can be treated successfully with an appropriate course of antibiotic therapy (see Table 1 and Table 2). Doxycycline is an antibiotic used to treat many different types of bacterial infections including those caused by mites, ticks, or lice. It is the most common antibiotic used for Lyme disease treatment.

Studies and Dosage Recommendations

A study by Nadelman, et.al. (1992) compared treatment with placebo versus a single 200-mg dose of doxycycline in 482 people who had removed attached *I. scapularis* ticks from their bodies within the previous 72 hours. Objective extracutaneous (outside the skin) signs of Lyme disease did not develop

in any subject. These data suggest that a single 200-mg dose of doxycycline given within 72 hours after an *I. scapularis* tick is removed can prevent the development of Lyme disease.

Table 1
Antibiotic Period of Treatment for patients with Lyme Disease

Drug	Acute Erythema Migrans (Lyme Disease)	Long-Term Lyme Disease
Amoxicillin	14 Days	28-40 Days
Doxycycline	14 Days	20-28 Days
Cefuroxime Axetil	7-10 Days	N/A
Ceftriaxone	N/A	28 Days
Cefotaxone	N/A	Daily over many weeks as determined by provider

Often called "chronic Lyme disease," persistent symptoms of Lyme disease are properly known as post-treatment Lyme disease syndrome (PTLDS). PTLDS is defined as continuing or relapsing non-specific symptoms in a patient previously treated for Lyme disease (Marques, 2008). The exact cause of PTLDS is not yet known, but most medical experts believe the lingering symptoms are the result of residual damage to tissues and the immune system that occurred during the acute infection. PTLDS is characterized by the lingering symptoms of fatigue, pain, or joint and muscle aches after a patient completes treatment (CDC, 2015). The association of vague systemic symptoms with proven *Borrelia burgdorferi* infection (Lyme disease) is not strongly supported by scientific literature. In instances where the physician and patient agree to extend treatment for Lyme disease, doxycycline had been used to treat certain cardiac, nervous system, and joint manifestations for up to 30 days (U.S. National Library of Medicine). Other specific manifestations of Lyme disease can be treated with intravenous antibiotics, most often ceftriaxone (2 gm twice daily for 14 to 30 days) (National Institute of Health, 2011). Ceftriaxone injection is used to treat certain infections caused by bacteria such as gonorrhea, pelvic inflammatory disease, meningitis, and infections of the lungs, ears, skin, urinary tract, blood, bones,

joints, and abdomen (NIH, 2011). However, while not on the Food and Drug Administration's (FDA) list of drugs recommended for treatment of Lyme disease, ceftriaxone has been used to treat Lyme meningitis, neuroborreliosis, arthritis and severe cardiac manifestations.

Table 2

Recommended antimicrobial regimens for treatment of patients with Lyme disease.

Gary P. Wormser et al. Clin Infect Dis. 2006;43:1089-1134

Drug	Dosage For Adults	Dosage for Children
Preferred Oral Regimens		
Amoxicillin	500 mg 3 times per day [a]	50 mg/kg per day in 3 divided doses (maximum, 500 mg per dose)[a]
Doxycycline	100 mg twice per day [b]	• Not recommended for children aged younger than 8 years • For children aged 8 years or older. 4 mg/kg per day in 2 divided doses (maximum, 100 mg per dose)
Cefuroxime axetil	500 twice per day	• 30 mg/kg per day in 2 divided doses (maximum. 500 mg per dose)
Alternative Oral Treatments		
Selected macrolides [c]	For recommended dosing regimens, see footnote *d*	For recommended dosing regimens, see footnote d
Preferred Parenteral Regimen		
Ceftriaxone	2 g intravenously once per day	50-75 mg/kg intravenously per day in a single dose (maximum, 2 g)
Alternative Parenteral Regimen		
Cefotaxime	2 g intravenously every 8 h [d]	150-200 mg/kg per day intravenously in 3-4 divided doses (maximum. 6 g per day) [d]
Penicillin G	18-24 million U per day intravenously, divided every 4 h [d]	200,000 - 400,000 U/kg per day divided every 4 h [d] (not to exceed 18-24 million U per day)

[a] Although a higher dosage given twice per day might be equally as effective. In view or the absence of data on efficacy, twice-daily administration is not recommended.

[b] Tetracyclines are relatively contraindicated in pregnant or lactating women and in children younger than 8 years of age.

[c] Because of their lower efficacy. macrolides are reserved for patients who are unable to take or who are intolerant of tetracyclines, penicillins, and cephalosporins.

[d] Dosage should be reduced for patients with impaired renal function.

Side effects associated with long-term antibiotic therapy

Section B

Summary

Severe adverse effects such as death, catheter-related bloodstream infections, pulmonary embolism, septic thrombophlebitis, and gastrointestinal bleeding have previously been reported in patients treated with long-term antibiotic therapy for Lyme disease (Fallon (2008), Krupp (2003), Klempner (2001)).

Antibiotics, even used for short periods, let alone for long-term therapy, raise the issues of both toxicity and the emergence of bacterial antibiotic resistance. A side effect of long-term antibiotic therapy is that bacteria become increasingly antibiotic-resistant. Consequently, the resistant bacteria will not respond to the antibiotic in the future. The FDA warns against prescribing antibiotics in the absence of a proven or strongly suspected bacterial infection, or else the treatment is unlikely to benefit the patient and increases the risk of developing drug-resistant bacteria. The FDA further warns that when antibiotics are prescribed to treat a bacterial infection, patients should be told that, while it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by injectable Ceftriaxone or other antibacterial drugs in the future (CDC, 2014).

Side Effects Found in Clinical Trials

In the clinical trials conducted by Dr. Fallon at Columbia University Medical Center, five of the 37 patients dropped out because of adverse effects from long-term intravenous antibiotic treatment: two

because of thrombus, one because of an allergic reaction, one for worsening joint pain and one because of staphylococcal infection (Fallon, Keilp, et al., 2007). Four patients remained in the study despite adverse events but eventually did have to terminate the study early. Of the four, two patients were terminated early because of allergic reactions, one with abdominal pain and one because of hospitalization for a cholecystectomy. It is the opinion of Fallon, Keilp, et al. (2007) that the adverse reactions of seven of these nine cases were directly related to the study treatment.

The study conducted by Klempner et al. (2011) found at least one study-related adverse side effect for 25 percent of their patients. Most of the adverse events, which included rash, diarrhea, and vaginal pruritus, were minor and resolved without intervention. However, there were two patients with whom a study-related serious adverse event occurred. During intravenous treatment, one had a life-threatening pulmonary embolism and the other had fever, anemia, and gastrointestinal bleeding (Klempner et al., 2011).

Colostridium difficile[1] (*C. difficile*) most often infects patients with conditions that require long-term treatment with antibiotics. Long-term therapy of Lyme disease has been linked to many cases of *C. difficile* because of the long-term antibiotic therapy diminishing the effectiveness of the body's natural digestive system bacterial flora. In 2009, the Minnesota Department of Health investigated a woman's death due to *C. difficile.* In June 2009, the woman sought care for symptoms of fatigue, insomnia, achy joints, memory loss, and confusion. These symptoms had been present for 15 years and had worsened in the past two years. She received a diagnosis of a relapse of depression. In August, on the basis of responses to a Lyme disease questionnaire, Lyme disease serologic tests were performed and came back indeterminate. Nevertheless, she was placed on a five-week course of doxycycline. The patient's symptoms improved but then worsened after completion of antibiotic therapy. Both her primary physician and a rheumatologist found no objective evidence of Lyme disease in October. In November, without

[1] Clostridium difficile (C. difficile) is a bacterium that causes inflammation of the colon, known as colitis (CDC).

further Lyme disease testing, another physician prescribed oral cefuroxime and telithromycin for a planned two to four month treatment. Five weeks after initiating this therapy, the patient developed diarrhea for three days and received a diagnosis of *C. difficile colitis*. The patient was started on oral metronidazole therapy but was hospitalized two days later with severe abdominal pain. The next morning, she experienced cardiac arrest twice and succumbed to cardiac arrest during an emergency colectomy. Pseudomembranous colitis was noted in the colon, and *C. difficile* was isolated from stool. In the absence of confirmatory laboratory evidence, such as positive IgG findings by Western blot testing, symptoms lasting 11 months are not likely due to Lyme disease (Holzbauer, Kemperman & Lynfield 2010). Longstanding nonspecific symptoms unaccompanied by objective evidence of infection do not warrant long term antibiotic treatment for Lyme disease (Feder et al., 2007). This death due to fulminant *C. difficile* serves as yet another example of the severe adverse outcomes that can result from inappropriate antibiotic therapy for presumptive Lyme disease.

The effectiveness of long-term antibiotic therapy of controlling symptoms for patients who have post-treatment Lyme disease syndrome

Section C

Summary

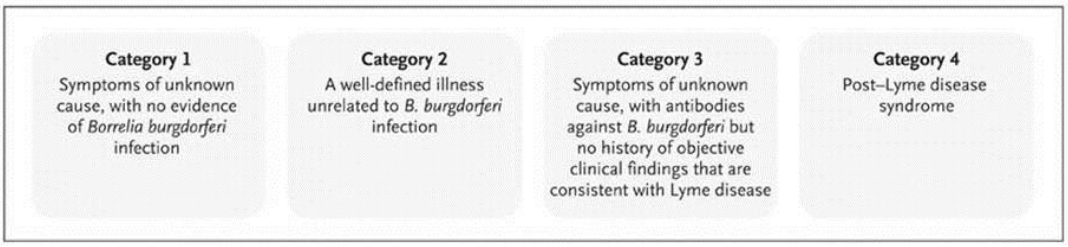
There is a lack of peer-reviewed evidence that supports the effectiveness of long-term antibiotic therapy in controlling the symptoms of post-treatment Lyme disease syndrome. The literature reviewed shows no benefit to a long-term antibiotic treatment plan. The medical community has not come to a consensus on the symptom profile for a patient suffering from post-Lyme disease syndrome. The patient could be put at risk by mandating the prescription of treatment for a disease the medical community has not clearly defined and evaluated. The physician and patient need to determine the treatment that is best for their individual situation. Reluctance from the patient or the provider to consider that the patient's deteriorating state may not be attributed to Lyme disease, and instead may be a separate underlying condition, places the patient's safety in jeopardy.

Manifestations of Lyme Disease

"Chronic Lyme disease" is not a meaningful diagnosis in the medical community. The term "chronic Lyme disease" has been used to describe widely varying symptom complexes and patient populations that should not be grouped together. These include patients with objective manifestations of late Lyme disease (for example, arthritis, encephalomyelitis or peripheral neuropathy), patients with post-Lyme disease syndrome, and patients with nonspecific signs and symptoms of unclear cause who receive this diagnosis based on unproven and/or non-validated laboratory tests and clinical criteria (Marques, 2007). Diagnoses of "chronic Lyme disease" appear to fall predominantly into one of four categories.

Table 3

The Four Predominant Categories of Disease Associated with Chronic Lyme Disease.



Feder HM Jr et al. N Engl J Med 2007;357:1422-1430.

Patients with Category 1 disease do not have objective clinical manifestations or laboratory evidence of *B. burgdorferi* infection, and receive a diagnosis on the basis of the presence of nonspecific symptoms such as fatigue, night sweats, sore throat, swollen glands, stiff neck, arthralgia, myalgia, palpitations, abdominal pain, nausea, diarrhea, sleep disturbance, poor concentration, irritability, depression, back pain, headache and dizziness. Nonspecific symptoms such as these are common. Some occur in more than 10 percent of the general population, regardless of whether Lyme disease is endemic in the area (Feder et al., 2007).

Patients with Category 2 disease have identifiable illnesses or syndromes other than Lyme disease. Such patients may or may not have a history of Lyme disease. They have received either a misdiagnosis or a diagnosis they are reluctant to accept, and have sought an alternative diagnosis from a physician willing to treat them for chronic Lyme disease (Feder et al., 2007).

Data from studies of patients who underwent reevaluation at academic medical centers suggest that the majority of patients presumed to have "chronic Lyme disease" have Category 1 or 2 disease (Feder et al., 2007). Because patients in these two categories do not have evidence of active infection with *B. burgdorferi*, the potential benefit of treating them with antibiotics, beyond a placebo effect, would be attributable to the anti-inflammatory or other non-antimicrobial effects of antibiotics. Antibiotic therapy in these patients is not warranted.

Patients with a Category 3 disease do not have a history of objective clinical findings that are consistent with Lyme disease, but their serum samples contain antibodies against *B. burgdorferi*, as determined by means of standardized assays that were ordered to investigate chronic, subjective symptoms of unknown cause (Feder et al., 2007). These patients have at most only equivocal evidence of *B. burgdorferi* infection, as the predictive value of positive serologic results in this setting is low. Although some clinicians would offer patients with Category 3 disease an empirical trial of two to four weeks of an oral antibiotic, such patients should be told that the diagnosis is uncertain and that a benefit from treatment is unlikely (Feder et al., 2007).

Patients with Category 4 disease have symptoms associated with post–Lyme disease syndrome. In prospective studies of patients with erythema migraines, subjective symptoms of unknown cause were present one year or more after treatment in 0.5 percent to 13.1 percent of patients (Feder et al., 2007). Whether this prevalence exceeds that of such symptoms in the general population is unknown, because none of these studies included a control group.

Clinical Trials Investigating Long-Term Antibiotic Therapy

Less than 10 percent of patients adequately treated for Lyme disease develop fatigue, headache, joint pain, paresthesias, cognitive difficulties, and tender points on examination (Bockenstedt & Radolf, 2014). This clinical presentation is very similar to that of chronic fatigue syndrome or fibromyalgia. As outlined by Anthem's medical policy (2015), some physicians believe such patients represent antibiotic treatment failure and recommend long-duration (months to years) oral or intravenous antibiotic therapy. Some of these physicians recommend unusual dosing protocols, such as two doses per week followed by weeks without treatment. The medical policy states that there is no data to suggest that such long-term or unusual regimens are necessary or better than the standard regimens referred to previously. Anthem (2015) also points out that some physicians diagnose such patients as having post-Lyme disease fibromyalgia, or simply post-Lyme disease syndrome, and treat them with anti-depressants, physical therapy, and exercise programs. Studies have reported that post-Lyme disease symptoms do not respond

to antibiotics (Schwartz, 2012). An increasing amount of literature discusses post-Lyme disease symptom persistence (Fallon et al., 2007), possible explanations for persistent symptoms (Klempner, 2002 & Wormser, Dattwyler, et al., 2006), and options for therapy.

In two randomized placebo-controlled trials, as discussed by Fallon et al. (2007), three months of antibiotics conferred no greater benefit than the placebo on the primary mental functional measure or the secondary outcome measure of cognition. Fallon et al. (2007) concluded their findings with the following: "Adverse effects attributed to IV ceftriaxone occurred in 26 percent of patients. Therefore, considering both the limited duration of cognitive improvement and the risks, 10 weeks of IV ceftriaxone and then 14 weeks of no antibiotic is not an effective strategy for sustained cognitive improvement" (pg. 1002).

Klempner et al. recognize that there is considerable impairment of health-related quality of life among patients with persistent symptoms despite previous antibiotic treatment for acute Lyme disease. However, in the two trials of antibiotic treatment in patients with persistent symptoms, treatment with intravenous and oral antibiotics for 90 days did not improve symptoms more than placebo (2001).

There is no convincing biologic evidence for the existence of symptomatic chronic *B. burgdorferi* infection among patients after receipt of recommended treatment regimens for acute Lyme disease. Antibiotic therapy has not proven to be useful and is not recommended for patients with chronic (six months) subjective symptoms after receiving the recommended treatment regimens for acute Lyme disease (Wormser, Dattwyler, et al., 2006).

Other Factors

Some patients treated for post-treatment Lyme disease and the clinicians who prescribe their treatment regard a temporary improvement in symptoms following antibiotic treatment as confirmation of the diagnosis. This temporary improvement in symptoms is most often attributed to the placebo effect. The placebo effect is an instance where patients will experience a positive or negative change in their symptoms, when there is no active ingredient in their medication, because of their perception of the drug

being tested. Commonly used antibiotics[2] have numerous non-antimicrobial properties, including anti-inflammatory, immunomodulatory and neuroprotective effects. These agents may have temporary modifying effects on many disease processes, but all can cause potentially serious adverse effects as well. Paradoxically, many patients treated for post-treatment Lyme disease and the clinicians who prescribe their treatment also interpret worsening of symptoms while being treated with antibiotics as confirmation of the diagnosis, since they believe this to be related to a Jarisch-Herxheimer[3] reaction (Moore, 1987). Some practitioners treating post-treatment Lyme disease assert that these reactions may occur at any time during the treatment course, despite evidence that these reactions are seen only in early disease and then are usually confined to the first 24 hours of treatment (Wormser, Dattwyler, et al., 2006). Reluctance to consider that the patient's deteriorating state may instead be due to a separate underlying condition that was not diagnosed or to a drug-related adverse event places the patient in jeopardy.

[2] Commonly used antibiotics: including tetracyclines, macrolides and certain beta lactams

[3] An increase in symptoms after administration of a drug. The reaction was originally discovered in penicillin treatment of syphilis, but it has been found to occur with other diseases as well (Mosby's Medical Dictionary, 8th edition © 2009).

Concerning whether allowing physicians in Washington State to administer long-term antibiotic therapy for treating Lyme disease would be beneficial to the health and safety of Washington residents

Section D

Summary

Administering long-term antibiotic therapy for treating Lyme disease will not be beneficial to the health and safety of Washington residents. Clinical trials do not show the benefit of long-term therapy in comparison to the initial 14-day treatment plan for acute Lyme disease. Due to improper and unstandardized testing methods, antibiotic treatment of supposed chronic Lyme disease has not been proven to be effective nor in the best interest of the patient. However, a blanket statement that it is never effective would be unwise. Such treatment decisions, like essentially all others, should be based on scientific evidence as it evolves and not codified by statute.

Safety Concerns Washington Residents

Data from three double-blind, randomized, placebo-controlled trials have shown substantial risk, with little or no benefit, associated with additional antibiotic treatment for patients who have long-standing subjective symptoms after appropriate initial treatment for an episode of Lyme disease (Feder et al., 2007)

Antimicrobial resistance is one of our most serious health threats. Infections from resistant bacteria are now too common, and some pathogens have even become resistant to multiple types or classes of antibiotics. The loss of effective antibiotics will undermine the ability of Washington health providers to fight infectious diseases. Physicians must be especially careful in managing infectious

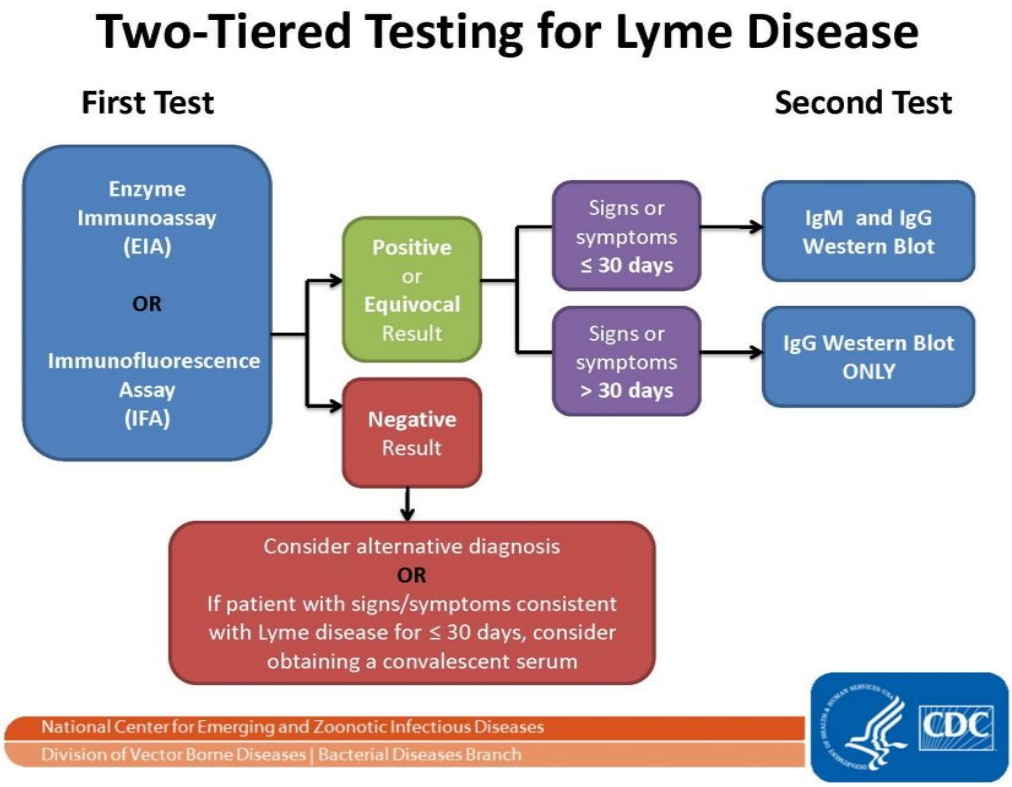
complications common in vulnerable patients undergoing chemotherapy for cancer, dialysis for renal failure, and surgery, especially organ transplantation, for which the ability to treat secondary infections is crucial (CDC, 2015).

The guidelines set forth by the Infectious Disease Society of America (2009), state that "Due to a lack of demonstrated efficacy in controlled studies, absence of supporting data, or the potential for harm to the patient, the following are not recommended for treatment of patients with any manifestation of Lyme disease: first-generation cephalosporins, fluoroquinolones, carbapenems, vancomycin, metronidazole, tinidazole, amantadine, ketolides, isoniazid, trimethoprim-sulfamethoxazole, fluconazole, benzathine penicillin G, combinations of antimicrobials, pulsed-dosing (i.e., dosing on some days but not others), **long-term antibiotic therapy**, antiBartonella therapies, hyperbaric oxygen, ozone, fever therapy, intravenous immunoglobulin, cholestyramine, intravenous hydrogen peroxide, specific nutritional supplements, and others (Wormser, Dattwyler, et al., 2006 pg. 1904) ." Evidence shows that long-term antibiotic therapy for chronic Lyme disease poses substantial risk to the patient.

Testing Methods and Limitations

From the research reviewed, a sizeable proportion of patients diagnosed with chronic Lyme disease will have received positive results from laboratories that used either non-validated methods or unproven criteria to interpret the results; both lead to a high rate of false-positive results. The poor reliability and the low positive predictive value of such findings should be indicated to patients before testing. Fluid from the patients' spine or joint and blood samples are used to test for Lyme disease. This is a two-tier test (Figure 1) and the CDC (2015) does not recommend skipping the first test and only completing the Western blot. In doing so, there is an increase in the frequency of false positive results that may lead to misdiagnosis and improper treatment. The CDC does not recognize any other tests at this time due to lack of performance and consistency (CDC, 2015).

Figure 1



The diagnosis of post-treatment Lyme disease is often based solely on clinical judgment rather than on well-defined clinical criteria and validated laboratory studies, and it is often made regardless of whether patients have been to areas where Lyme disease is endemic or whether there is a history suggestive of acute Lyme disease having occurred. It is dangerous for physicians to make a diagnosis of post-treatment Lyme disease based on elevated levels of Lyme serology, when there is an absence of any history suggesting that acute Lyme disease was contracted. The intravenous treatments commonly used in long-term treatment are dangerous to the health of the patient and should not be used without a firm diagnosis of Lyme disease. Furthermore, if a physician prescribes long-term therapy without exploring a diagnosis other than "chronic Lyme disease", they may have overlooked a serious underlying condition. Most patients with medically unexplained symptoms who have received a diagnosis of post-treatment Lyme disease will require emotional and psychological support in addition to symptomatic management. For example, many patients with post-Lyme disease syndrome fear that their symptoms are indicative of a

chronic infection that may cause neurologic damage. These concerns should be openly addressed and the patients reassured. There is no substitute for sympathetic listening and explanation.

Aspects of long-term antibiotic therapy that the commission deems important for the health and safety of patients who may receive these treatments

Section E

Conclusion

This report does not intend to suggest that cases where patients feel better after long-term treatment do not exist; there are isolated cases where people are pleased with the outcomes of long-term antibiotic therapy. This report discourages outlining treatment in statute. The Medical Commission bases its investigations on whether the standard of care was met between the provider and patient after a complaint is filed. There is a lack of evidence to support the validity of long-term antibiotic therapy for the treatment of post-treatment Lyme disease syndrome.

Evidence-Based Medicine

Evidence-based medicine is the integration of best research evidence with clinical expertise and patient values. While there is anecdotal evidence of patients experiencing symptom relief after long-term antibiotic therapy, these instances should not be a baseline for the validity of long-term Lyme disease treatment. The patient and physician should determine the treatment path. Mandating or forbidding a course of treatment by statute is counterproductive to the evolving nature of evidence-based medicine. The legislature should not enshrine disease treatment methods or modalities in statue, since evidence-based medicine continually progresses with the availability of new information. A high number of patients will be placed at risk by mandating the prescription of treatment for a disease that has not been clearly defined and evaluated on an ongoing basis by the medical community. This Commission recommends that medical practices for Lyme disease, or any other disease, never be mandated by statute.

Medicine is an ever evolving profession, rooted in evidence and scientific trials. The citizens of Washington cannot benefit from the latest medical science if their treatment plan is mandated by statute.

Communication between the Patient and the Physician

The existing literature documents a vast amount of inconsistency, a lack of evidence to support the benefits to long-term antibiotic therapy, and the adverse effects to the patient are numerous and life altering. The evidence indicates it is not in the best interest of people suffering from Lyme disease to undergo long-term antibiotic therapy. Treatment decisions must be made at the discretion of the patient and provider. Patients who choose long-term antibiotic therapy should be counseled on the risks associated with the treatment, as well as the scientific evidence against the concept of "chronic Lyme disease". The patient should be thoroughly evaluated for other medical conditions that could explain the symptoms. If a diagnosis for which there is a specific treatment cannot be made, the goal should be to provide emotional support and management of pain, fatigue, or other symptoms as required.

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