

THE HUMAN DIMENSION OF LYME AND OTHER TICK-BORNE DISEASES: THE PATIENT PERSPECTIVE

The National Capital Lyme & Tick-Borne Disease Association

Draft background paper written to stimulate discussion
for the Institute of Medicine Committee on Lyme Disease and Other Tick-Borne
Diseases: The State of the Science

workshop entitled:

"Critical Needs and Gaps in Understanding Prevention, Amelioration, and Resolution of
Lyme and Other Tick-Borne Diseases: The Short-Term and Long-Term Outcomes"
Washington, D. C., October 11-12, 2010

The responsibility for the content of this article rests with the author(s) and does not
necessarily represent the views of the Institute of Medicine or its committees and
convening bodies.

THE HUMAN DIMENSION OF LYME AND OTHER TICK-BORNE DISEASES: THE PATIENT PERSPECTIVE

Submitted by: The National Capital Lyme & Tick-Borne Disease Association

“Courage is what it takes to stand up and speak; courage is what it takes to sit down and listen.”

Winston Churchill

When one family member is infected with *Borrelia burgdorferi* (*Bb*), the entire family is affected. Life as previously lived comes to a screeching halt. The focus of the family turns to survival of a disease that drains the energy, ability and hope from the patient and replaces it with pain, weakness and helplessness.

The unfortunate patients who fail the 2-4 week course of antibiotics are often reassured by their doctor they need no further treatment. They fall further into the progressive illness that includes facial paralysis, cognitive processing delays, difficulty walking, slurred speech, pain, and the loss of their former life and self. Prescription bottles and IV poles become the norm in the home. The roles of parent and spouse disappear as the victim of the disease can no longer fulfill responsibilities that once had been second-nature. Child patients often require individualized education plans, accommodations and special education. Some children must be home-schooled because they cannot get out of bed to participate in a regular classroom curriculum.

Months and years of illness march on and the patient grows wearier of any possibility of recovery. While the medical community spends its time arguing over whether to provide promising additional treatment, the patient faces a daily battle alone with the medical safety net stretched thin. Doctors, family and friends, who long since have had no viable answers, continue to be at a loss to know how to help and stop communicating. The fortunate patients who respond to aggressive antibiotic treatment face a slow climb back to their former life and health. Extensive treatment, however, comes with a price tag that for most patients means the obliteration of their retirement plans and, for some, becoming a financial burden to their children. When the IV pole has been moved from the bedroom to the garage, the question remains: “Do we give it away, or might we need it again?” Tick populations and their related illnesses are increasingly creating epidemics in neighborhood after neighborhood. Each year, more and more new cases are tabulated, documented and stored somewhere . . . **and the band plays on.**

OVERVIEW

Lyme borreliosis, commonly referred to as Lyme disease, alone or concurrent with other tick-borne infections, can be a debilitating illness that severely diminishes a person’s health and quality of life. The more inclusive term "Lyme borreliosis" is used in this paper, rather than

Lyme disease, to include patients with persistent and relapsing infections of the *Borrelia burgdorferi* bacterium after initial therapy. This paper documents the impact of tick-borne infections on patients and their families. It draws on survey data, patient testimonies, and scientific research to examine symptom manifestation, chronicity of illness, and the human and economic costs of tick-borne infections. Children account for a significant number of Lyme borreliosis cases, and this paper examines how tick-borne infections disrupt their development into productive adults. Despite years of research on Lyme borreliosis, understanding of this infection and its impact on patients remains inadequate. This paper identifies gaps in research and medical care. The overwhelming consensus of Lyme patients and their families is that neither the government research community nor the medical community gives sufficient credibility to this disease or devotes adequate resources to combating it. The paper concludes with recommendations that include future research and policy changes needed to combat the serious and growing problem of tick-borne diseases in the United States.

ONSET OF ILLNESS AND PROBLEMS OF DIAGNOSIS

The beginning of patients' struggle with Lyme borreliosis can be confusing and frightening. Misperception about tick bites, tick-related rashes, and the variety of symptoms leaves the patient feeling bewildered with a medical system that does not produce answers. As the mother of a 15-year-old patient from New Jersey described the situation, "The most worrisome thing was not knowing what was afflicting my daughter – not knowing who the enemy was for lack of a diagnosis." Worry returns when doctors offer no explanation for the recurrence of symptoms after a short course of treatment.

Patients are fortunate if they observe the telltale erythema migrans (EM) or bull's-eye rash at the time of their tick bite, which alerts them to seek immediate antibiotic treatment. As few as 44 percent of Lyme patients with chronic illness recall seeing a rash and only 29 percent recall seeing a tick bite (Donta, 1997). Unfortunately, many of those patients who do seek care for a rash do not always receive accurate or appropriate medical advice. Physicians unfamiliar with the many variations of EM rashes may miss the diagnosis of Lyme disease. Only 19 percent of rashes resemble a classic bull's-eye rash (Tibbles and Edlow, 2007), and as many as 15 percent of EM rashes were misdiagnosed, most often as spider bites but also as cellulitis and shingles (Aucott et al, 2009).

Sister of Patient A from Virginia, Ill for 6 years!

"She told the doctor of her fear of Lyme and showed him the bulls-eye rash and she was ignored. We went to doctors located in Virginia where my sister resides and was bitten who said, "Lyme doesn't exist here. We will not treat." My beloved twin began a horrible spiral that has gone downhill ever since. She, a woman who worked in healthcare 17 years helping people with HIV, became a victim of a system she used to believe in."

One of the most common patient experiences is the misuse of the Centers for Disease

¹ Patient testimonies were obtained from various sources, including email requests from various Lyme support patient groups, stories collected by Lyme advocates, and published sources. To ensure patient anonymity, patients are identified only by their state of residence and years of illness.

Control and Prevention's (CDC) Lyme disease surveillance case definition for diagnostic purposes. Many doctors are not aware that the CDC's case definition opens with the warning, "This surveillance case definition was developed for national reporting of Lyme disease; it is not intended to be used in clinical diagnosis" (CDC, 2010a). Despite such admonitions, many doctors refuse to diagnose and treat unless the patient meets the CDC's recommended two-tier testing criterion which requires a positive ELISA or IFA before use of the Western blot. When the ELISA is negative, patients are routinely refused the more specific Western blot test. As a patient from New Hampshire reports, "All of my five Elisa tests were negative. I was sick with fatigue, headaches, and cognitive issues for a year and a half and missed a whole year of school. When a Western blot was finally done it was CDC positive for Lyme disease."

Moreover, the tests for Lyme disease are notoriously unreliable due to the lack of sensitivity and specificity. Studies have found the sensitivity of the ELISA test for *Bb* infection to vary from 59 to 95 percent (Depietropaolo et al, 2005), meaning that tests can miss up to two-in-five of all cases. The authors found that two-tier testing further decreases test sensitivity, resulting in more missed diagnoses. Unreliable testing hampers both surveillance and patient care when the CDC criteria, designed for patient surveillance purposes, are being misused to deny treatment to patients.

The two-tier testing for *Bb* infection is not recommended since testing is unreliable until several weeks after the onset of illness as the test reflects antibodies in the blood that are not produced until that time (Aguero-Rosenfeld et al, 2005; Depietropaolo et al, 2005). Many patients report that they are tested prior to 4-6 weeks; and when their ELISA comes back negative, they are not re-tested, and their infection goes undiagnosed. Since early diagnosis and treatment greatly improve outcomes, it is a tragedy that so many patients do not receive a timely diagnosis.

Patient B from North Carolina, Sick for Unknown years:

"I continue to deteriorate, now so weak I couldn't go any real distance without a wheelchair . . . I experienced violent muscle jerks that left me sore afterwards, as if I had been beaten up. I went into long coma-like sleep lasting 20 hours a day, waking up lethargic, as if I never slept. I started to have impaired short term memory loss, difficulty multitasking or concentrating and forgetting how to do the simplest tasks, like how to take off my seatbelt. As I'm knee deep in this hell, my dogs start to get sick one right after the other. Their tick titers came back positive for ehrlichiosis, Lyme, and Rocky Mountain spotted fever. It was then I researched Lyme for myself and found all my seemingly unrelated symptoms. Excited I had found the answer, I went back to my doctor and told him to test me for Lyme. We did the Elisa which was negative, so he confidently proclaimed, "You do not have Lyme. We do not have it in North Carolina."

Even positive test results are sometimes dismissed by doctors as irrelevant without additional investigation into the cause of their illness. As one Virginia patient states, "Even with a positive ELISA and Western Blot and 23 symptoms I am being told by Infectious Disease [doctor] I am negative. I am being told we are not sure what you have had for 7 years but it is not Lyme." This common experience indicates a perception of unreliability of *Bb* tests in the medical community, and therefore Lyme borreliosis should remain a clinical diagnosis. Far too many patients never hear about the possibility of Lyme borreliosis. A Johns Hopkins study found that 54 percent of patients were misdiagnosed when they did not present with a rash (Aucott et al,

2009). Other patients see a number of specialists who are unable to determine the proper diagnosis.

Mother on behalf of Patient C from Illinois, Sick for 10 years:

“He saw 21 doctors who ran numerous tests. He was getting sicker, missing school and no one was putting it all together . . . the contact with friends diminished. At times he wondered what he has to live for.”

Lyme borreliosis is often not considered in the differential diagnosis of a patient’s worsening symptoms. Rather, patients are offered a diagnosis such as chronic fatigue syndrome or fibromyalgia, conditions for which there is no known cause or cure. Eventually, depression may also be diagnosed and antidepressants prescribed. Rarely do antidepressants relieve symptoms that Lyme patients experience.

Patient D, Sick for More than 5 years:

“Sometimes I wonder if things would have been different had I been diagnosed earlier and received treatment at a younger age. This illness has destroyed my quality of life. Before my illness, I was a very active person capable of working long hours, jogging, tennis, running a household, and active in my church and community activities. It destroyed 2 marriages and I was not able to have children. It is not only costly, it is demoralizing to not be able to take care of yourself on a daily basis.”

Some patients with enough observable signs and symptoms are diagnosed with multiple sclerosis, lupus, or amyotrophic lateral sclerosis (ALS). Steroids are prescribed, which have the effect of worsening the Lyme patient’s infection through immune suppression, a finding reflected in rhesus monkey studies (Pachner et al, 2001). While the possibility of Lyme borreliosis is overlooked or outright rejected, patients are given seemingly unrelated diagnoses as varied as postural orthostatic tachycardia syndrome (POTS), gastroparesis, autonomic dysfunction disorder, hypoadrenalism, sleep apnea, obsessive compulsive disorder, Aspergers, Tourette syndrome, blood clotting disorders or cyclic vomiting syndrome.

Patient E from California, Sick for 7 years:

“My father had unknowingly contracted Lyme, Babesia, and Bartonella. Six years later, he began to lose strength and felt like he was losing muscle. His HMO doctor ignored his complaint for over a year. A neurologist diagnosed him with ALS. My brother urged our father to pursue Lyme testing and a Western blot came back positive. The HMO agreed to put him on IV antibiotics for one month. After thirty days, Dad could stand up again but [the HMO] refused to continue IV antibiotics citing IDSA treatment guidelines. The HMO insisted Dad had ALS not Lyme Disease, ignoring the fact Dad gained back the use of his legs. [The HMO] also insisted that he had tongue atrophy and put him on a feeding tube. We were told to take Dad home to die and call Hospice. We chose to take our father out of [the HMO hospital] and put him in a nursing home under the care of a physician who would treat him for advanced Lyme Disease. An occupational therapist found that our father did not have tongue atrophy and he began to eat three meals a day. In the next eight months, my father was walking, off the ventilator, and off the feeding tube.”

Reaching the correct diagnosis of Lyme borreliosis can be a long and arduous process. A

survey of patients conducted by the California Lyme Disease Association (CALDA) in 2009 found that 35 percent of patients consulted 10 or more doctors before receiving the diagnosis of Lyme borreliosis and 36 percent reported a delay of six years or more between onset of illness and diagnosis. Lack of public and physician awareness leads to significant diagnostic delays. Like the correct diagnosis itself, the search for a knowledgeable physician proves extremely difficult for 58 percent of patients surveyed.

Mother on behalf of Patient F from Virginia, Sick for 13 years:

“My son was diagnosed with chronic Lyme at age 18 after being misdiagnosed with chronic sinus infections and Chronic Fatigue Syndrome. He started having chronic headaches, fatigue and low fevers at age 9, and would improve on antibiotics, but then relapse a couple months after discontinuing them. He saw a CFS/FM specialist and was treated symptomatically for 5 years. He had to be home schooled the whole time due to his severe fatigue. He also acquired a severe sleep disorder, severe POTS, tremors, sound and light sensitivity, and severe cognitive issues (primarily brain fog, concentration problems and word retrieval difficulty.) He lost 35 lbs. At age 18, he was diagnosed with chronic Lyme disease. At age 22 after long-term Lyme treatment, he is improved enough to attend college part-time.”

OTHER TICK-BORNE INFECTIONS

Joseph Piesman, who oversees the tick-borne disease program at the CDC, notes that, “The more people study ticks, the more new pathogens are discovered” (Landro, 2010). More than a dozen tick-borne diseases have been documented to cause serious illness in humans. “Ticks can be infected with bacteria, viruses, or parasites. Some of the most common tick-borne diseases in the United States include: Lyme disease, babesiosis, ehrlichiosis, Rocky Mountain Spotted Fever, anaplasmosis, Southern Tick-Associated Rash Illness, Tick-Borne Relapsing Fever, and tularemia. Other tick-borne diseases in the United States include Colorado tick fever, Powassan encephalitis, and Q-fever” (CDC, 2010b). A tick study from southern Connecticut found that 20 percent of the 230 *Ixodes scapularis* ticks collected were infected with *Bb*, and of these ticks 68 percent were co-infected with one or more additional pathogens (Sapi et al, 2009). Consequently, a person bitten by a tick is at risk for being infected with multiple tick-borne diseases.

The National Capital Lyme and Tick-borne Disease Association (NatCapLyme) conducted an online survey in July 2010 on Lyme disease for 10 days.² A total of 1,438 subjects, elicited via e-mail from patient support groups across the country, participated in the survey. Such a large response in so short a time demonstrates that those affected with tick-borne infections want serious consideration and recognition of the impact of the disease.

The NatCapLyme survey found that 46 percent of the respondents had been diagnosed

² The survey was an Internet survey, conducted from July 9 to July 19, 2010. Subjects from the United States, Canada and Europe were recruited by email. Announcements about the survey were posted on Lyme patient support websites. The reported data are for the United States only (1,438 respondents). Respondents who reported that they were infected outside the United States were not included in the analysis (121 respondents). Duplicate response entries were also excluded.

with two or more tick-borne infections. Babesiosis is the most common co-infection, with 41 percent of respondents afflicted. Patients who are co-infected with Lyme borreliosis and other tick-borne infections experience more symptoms and more persistent illness than those with only *Bb* infection (Krause et al, 1996). Because symptoms for other tick-borne infections can be similar to those of Lyme borreliosis, these infections may go undiagnosed, contributing to ongoing illness despite treatment.

Patient G from Virginia, Sick for 13 years:

“After my initial two and a half years of “lyme” treatment, it was believed the lyme was “cured.” Unfortunately, after a couple months, not only did all my symptoms come back, but, I had developed cardiac issues. Sadly, at this time, I was also diagnosed with Babesia and Bartonella by a specialty lab which verified IgG and IgM for Babesia. The physician believed the initial regional test he had performed earlier for Babesia did not include the strain I had, which was WA-1. If the co-infection testing had been accurate back in early 2004, I may not have had the struggle I still face with cardiac issues due to years of infection with Babesia and Bartonella.”

Lyme patients frequently suffer from other infections. The NatCapLyme survey found that fully 39 percent of respondents had been diagnosed with bartonellosis in addition to Lyme borreliosis. The tick study from southern Connecticut found the *Bartonella henselae* bacterium to be present in 30 percent of ticks, suggesting an association with ticks as a vector.

The exact role that other tick-borne diseases and opportunistic illnesses play in the disease course is poorly understood, suggesting the need for more research. Researchers have found that spirochete DNA remains in the circulation longer in subjects co-infected with both Lyme disease and babesiosis, compared to patients with Lyme disease alone, leading them to speculate that “babesial infection may impair human host defense mechanisms, as it does in cattle and mice” (Krause et al, 1996). Tick-borne infections can overwhelm the immune system, making the patient vulnerable to other infections, such as mycoplasma, Epstein Barr virus, yeast, *H. pylori* and *Chlamydia pneumoniae*, etc. Consequently, a downward spiral of health problems may consume the patient’s life and resources.

ONGOING ILLNESS

Some patients report a full or nearly complete recovery following a month or less of antibiotic treatment for Lyme borreliosis. Receiving early treatment is critical, because left untreated, Lyme borreliosis can become a debilitating disease. “When ticks transmit *B. burgdorferi* to humans, a rash develops where the spirochetes enter the skin. Several days to weeks later, there may be symptoms elsewhere in the body, where the spirochetes have spread. The symptoms are more likely to appear in the joints, the nervous system, and the heart than anywhere else in the body. When the symptoms of Lyme disease appear in these parts of the body, the person may be considerably disabled. It is this potential for disability that, understandably, makes people so afraid of the disease” (Barbour, 1996).

Early treatment often fails when medication is discontinued prior to full recovery. Some patients experience a slow, insidious deterioration, while others report an abrupt return of former symptoms as well as new, disturbing ones. A literature review on treatment failure of antibiotic therapy found that after a 2-4 week course of treatment, 10 to 61 percent of patients relapse with

debilitating symptoms that are indistinguishable from those of late Lyme borreliosis (Green, 2009). Further delay in treatment comes when patients wait to call their doctors during the initial relapse because they do not want to complain after being treated with what they have been told should be sufficient treatment. They are naturally bewildered that the therapy ceases before they feel better, since it is common for doctors to repeat a course of antibiotics when a throat or ear infection persists. In the case of Lyme disease, the end of treatment is often dictated by treatment guidelines rather than the resolution of symptoms.

It is well-documented that *Bb* can infect most parts of the body, producing different symptoms at different times (Steere, 1989; Duray, 1989). Early symptoms are easily mistaken as aches and pains attributable to the common flu, stress at work, over-exercising, or simply the natural aging process. The initial dismissal of possible *Bb* infection allows an otherwise more easily treated infection to develop into a full-blown central nervous system infection which is difficult to treat.

One of the more perplexing dimensions of untreated or under-treated infection is the multiplicity of symptoms that seem to change, appear and disappear suddenly, only to reappear. In patients with Lyme meningitis, Pachner (1995) notes that, "Symptoms can be surprisingly variable, so that days of near normality can alternate with days of profound debility." Symptoms can include, but are not limited to, fever, chills, fatigue, body aches, headaches, rash, swollen lymph nodes, stiff neck, pain, meningitis, neurological problems, poor motor coordination, cognitive impairment, heart problems, eye inflammation, skin disorders, gastrointestinal issues, and general weakness. The great range of symptoms can make disease recognition difficult.

Mother of Patient H from Florida, Sick for 15 years:

"One of her doctors told us that if one doesn't want to be bored in the medical profession, one should focus on Lyme disease since every organ in the body is affected. Our daughter has had brain encephalitis, arthritis, vision problems, sporadic rashes, extreme fatigue, a headache that has lasted 11 years, photosensitivity, hyperacusis, tinnitus, skin sensitivity, carditis, autonomic nervous system dysautonomia and much, much more."

Patients choosing to continue their search for a treating physician often report great difficulties finding a doctor who has experience in treating persisting infection. Many patients report that the specialists they consult are focused on their chosen field of medicine and miss the multi-system nature of the disease. When this multi-system concept is understood and patients receive long-term antibiotic therapy, they report benefits. A patient survey found that between 72 and 78 percent of respondents experienced improvement in neuropathy, joint pain, concentration difficulties and fatigue with additional treatment beyond 2-4 weeks (CALDA, 2009).³ Also, two NIH-funded studies on re-treatment of patients with persistent Lyme borreliosis found a statistically significant improvement in symptoms. A study found that 64 percent of patients in the treatment group, versus 19 percent in the placebo group, showed substantial and sustained improvement in fatigue (Krupp et al, 2003). Another study found that patients with more severe symptoms who received an additional 10 weeks of antibiotics reported sustained improvement in pain and physical functioning (Fallon et al, 2008). Although there are treatment failures, long-term, combination antibiotic therapies do return many patients to functional and rewarding lives.

³ The percentages were determined from the survey subsample with the given symptom.

Patient I:

“After 10 weeks of Rocephin therapy, I had regained about 80% of my previous health, and most significantly, the return of my intellect and termination of my depression. . . . Now after 6 weeks on oral antibiotics, I'm approximately at 90% recovered. . . . And the big question: will my improvement hold with the eventual ending of antibiotics?”

A common theme in the patient stories we collected was that patients asked for more effective treatment. More research is needed regarding treatment failures in order to meet the needs of those Lyme borreliosis patients who continue to be ill. Lyme borreliosis can lower the quality of life dramatically. Chronic Lyme borreliosis patients experience deficits in health status of someone with congestive heart failure or osteoarthritis and suffer more impairment than someone living with type 2 diabetes or a recent heart attack (Klempner et al, 2001). A more recent study found the fatigue level in patients with chronic Lyme disease equals that of multiple sclerosis (Fallon et al, 2008).

IMPACT ON WORK

Quality of life for adults with Lyme borreliosis is marked by major declines in vocational, social and recreational functioning, as well as overall deterioration in cognitive and neuropsychiatric impairment. Persistent Lyme borreliosis severely impacts patients' abilities to function in the workplace. A James Madison University survey (Wilcox and Uram, 2009) on the impact of persistent Lyme disease on workplace performance found that patients experience difficulties working. Prior to their illness, all the respondents had been working full-time (a selection criterion), whereas only 28 percent were still working full-time at the time of the survey.

Cognitive impairment, memory, attention deficiencies, and lack of word fluency interfere with Lyme disease patients' work performance. Eighty-nine percent of the 315 respondents said that their symptoms had either a “moderate impact” or a “severe impact” on their ability to remember facts and details. Moreover, 75 percent said that Lyme disease impacted their ability to understand complex concepts and analyze information. More than half of the respondents reported an adverse impact on their basic skills of reading, writing, and math. Such impaired employees are not the only ones affected. When they cannot fulfill their duties, their colleagues are forced to pick up the slack, which has a complex, negative impact on the workplace itself.

Fatigue, pain and dizziness also negatively affect Lyme patients' ability to work. A study of Lyme patients with persistent symptoms found that 90 percent suffered from fatigue and malaise (Klempner et al, 2001); and nearly all of the respondents (95%) in the work performance survey reported that fatigue made it difficult, and in many cases impossible, to maintain a full-time workload (Wilcox and Uram, 2009). Connecticut biologist Joe Dowhan conducted tick research and brought the first *Ixodes scapularis* ticks to Dr. Allen Steere in 1976. Dowhan struggled to keep up with his work as he developed chronic Lyme disease:

“By the beginning of July (of 1976), I was crawling up the stairs to get home. The other biologists were finally telling me to just stay in the car because it was slowing everyone down. I was incapacitated with the disease. . . . In 1990, I started feeling a generalized malaise, a real fatigue, headaches, neck aches . . . I just had overwhelming fatigue, unrelated to exercise. I would find myself at two in the afternoon absolutely needing to drop my head on the desk. I just

couldn't move. I'd come home. My pockets would be stuffed with notes (to myself); I was having a difficult time remembering things and getting dinged by my bosses for not following through with things, not even remembering phone conversations with them" (Edlow, 2003).

Dowhan's story is repeated in workplaces across the country. Many Lyme patients struggle to adequately fulfill the requirements and responsibilities of their jobs. More than half (52%) of the respondents in the work performance survey changed jobs, usually for a less challenging and less stressful job (Wilcox and Uram, 2009). Many Lyme patients eventually became too disabled to work as their health deteriorated. Half (51%) of the respondents had left the workforce, and 55 percent of those who stopped working were receiving disability benefits.

Patient J from Maryland, Sick for 6 years:

"In 2004, I developed severe left-sided head pain and pressure, and eventually migraine headaches. In November 2006 I collapsed at my job where I was working as a surgical nurse in open heart surgery. I had no feeling from the neck down. I have been on disability since. I had a constant "buzzing" or ringing in my ears, with occasional loud blasts of sounds. Extreme fatigue, blurred vision, floaters in my eyes were next. Tingling and numbness in my legs and eventually my arms. Balance problems were next, stumbling and falling also. I eventually walked with a cane. . . . I could have avoided all of this if I had been treated with oral Doxycycline for 28 days. I would still be working as a registered nurse, a job that I loved. I have been disabled since I was 52. . . . After 3 years of treatment for Lyme Disease, I am better, but very different from a high functioning nurse that I was. I am mentally challenged and every day is a struggle, but I am thankful that I am alive."

FUNCTIONALITY AT HOME

Many Lyme patients have to cut back on usual everyday activities. Cooking, cleaning, and other household tasks become arduous, if not impossible, to perform due to cognitive problems, pain and fatigue. Fifty-six percent of respondents to the NatCapLyme survey said that their ability to cook a meal was "moderately impacted" or "severely impacted" by their illness, and 70 percent said that cleaning the house was nearly impossible.

Patient K from Maryland, Sick for more than 10 years:

"Despite [my husband's] long work days, he was now in charge of meals and most everything else. I was rarely able to do the shopping. I no longer cooked. One morning I decided I wanted scrambled eggs for breakfast. I remember standing at the stove, spatula in hand, looking down at these yellow things in a pan, and very clearly thinking: I DON'T KNOW WHAT THESE ARE."

Many patients have to curtail driving due to dizziness, vision problems and/or cognitive problems. Forty-six percent of the respondents in NatCapLyme's survey said that their driving was impaired. Lyme patients have reported that they have become lost just blocks from their own home, as they are unable to recognize familiar landmarks. One Lyme patient from Maryland wrote, "Cognitive function declined rapidly . . . I would get lost less than a mile from my home that I lived at for thirty years." Consequently, patients become dependent on family and friends for transportation or otherwise find themselves homebound and isolated.

SOCIAL IMPACT

Interpersonal relationships are strained to the breaking point by the challenges of Lyme borreliosis. Sometimes family and friends are sympathetic to the initial illness, assuming that it will pass like a virus or flu. Patience wears thin, however, when a patient cannot resume normal vocational and recreational activities. Being part of a school, work, sports or social event requires accommodations for the patient. Only the immediate family members, who witness the planning required to get ready for simple daily activities, understand the extent of the efforts required to maintain some normalcy. Everyday grooming requires effort. Acting normal requires stamina. Showing up requires mobility. Patients must adopt a “one day at a time” philosophy and have to cancel vacations and other important events at the last minute due to flaring symptoms. Patients feel that repeated comments from family and friends ranging from “You look fine” and “Do you still have Lyme?” to “Why don’t you take some energy pills and get back into life?” invalidate their illness.

Patient L from Virginia, Sick for unknown years:

“At first my children told me that I didn’t have Lyme disease, that it was all in my head, and then they began to make fun of me, and finally, now that I have a doctor and have been under treatment, they tell me I spend too much time focusing on my Lyme disease, that I need to stop thinking about it. . . . I have learned, over the years, to keep it hidden as much as possible, to say nothing, to never ask for help, because when and if I try to talk to them about it, I am quickly silenced or humiliated. Their lack of compassion and understanding is what hurts the most.”

The patients’ testimonies frequently speak about broken engagements, divorces and abandonment by loved ones who have difficulty accepting that the person they once knew has unnaturally changed. Meanwhile, patients suffer a loss of self-esteem due to the burden of their illness being imposed on the family. Marriages are understandably strained. Spouses may be frustrated by their partner’s sudden inability or unwillingness to have children. Disagreements erupt over the patient’s inability to work and care for their children as well as the drain of life savings to pay for treatment. Parents may differ about how to treat an ailing child, and adult children can underestimate the depth of their parents’ suffering.

Mother on behalf of Patient M from Virginia, Sick for 8 years:

“It’s rough on a marriage to have a child sick without a diagnosis for a long period of time. And, it’s even more difficult once there’s a controversial diagnosis that is very expensive to treat. Add to that a sick spouse and the opportunities for implosion are everywhere. Our life turned from activities, work, vacations, individual pursuits, hobbies and pleasures to pain, isolation, pressure to make treatment decisions based on limited understanding, and total exhaustion.”

Many times Lyme borreliosis infects multiple family members. If one or both parents are affected, children reverse roles and become caretakers to their parents at the expense of their own social lives and with undue stress on their personal development. The focus of the entire family is redirected toward daily survival of new and variable symptoms, the reduction of pain, and the potential for emergency room visits. The healthy family members feel the full weight of being the caregivers. Some have to start working multiple jobs to compensate for the patient’s lost income and the added financial burden.

The patient's personality may undergo significant changes due to the illness. Previously vibrant people become confused, scared, and angry. A mother from New Jersey wrote: "In his teen years his health and personality changed. He was having problems with anger that were uncharacteristic for him. Over several years he became homicidal, suicidal, and was in jail." Patients who were independent before their illness become dependent on family and friends for everything. Friendships are hard to maintain, and many patients feel isolated and alone. Feeling they are a burden to their loved ones makes it difficult to face another day of suffering. Seven percent of the respondents in the NatCapLyme survey said they had attempted suicide after contracting Lyme disease and 42 percent had suicidal thoughts.

Patient N from Kansas, Sick for 9 years:

"Last September, I tried to commit suicide. I ended up in the hospital due to my wounds for two weeks. Everyone thought I just had a bad case of post-partum depression. But I knew the truth, I wasn't depressed, I was absolutely terrified about how lyme was destroying my body, and I just could not take the pain anymore. Slowly I have gotten better on antibiotics. It has almost been a year . . . I have come a long way from where I was, and I am able to function as wife and mother again."

As patients seek understanding on how to deal with the multi-faceted issues related to having Lyme disease, support groups can play an important role in helping patients regain their health. Struggling with bewildered family members and the lack of support from physicians and insurance companies, they turn to Lyme disease support groups to learn more about their illness and how to cope. Support groups provide life skills in how to deal with daily challenges, illness-related social problems, and disability and insurance issues. As former U.S. Surgeon General, C. Everett Koop, MD, explained: "I believe in self-help as an effective way of dealing with problems, stress, hardship and pain. . . . Mending people . . . is no longer enough; it is only part of the total health care that most people require."

FINANCIAL IMPACT

As the illness stretches into months and then years, health care costs accumulate. NatCapLyme's survey asked respondents for their "best estimate" of the total costs of their Lyme-related treatments. Forty-six percent said that they and their insurance company paid \$50,000 or more for treatment. Many patients find their insurance coverage is inadequate to cover their growing health care needs (Jorgensen, 2010). Patients also report that their health insurance company has denied coverage of antibiotic therapy for persistent Lyme borreliosis based on the Infectious Diseases Society of America's (IDSA) 2006 treatment guidelines on Lyme disease. A patient from Virginia, sick for over a year, explains, "Not only do Lyme patients have to battle the medical community for a proper diagnosis, but they are forced to battle the insurance companies for treatment." Treatment that falls outside the guidelines is deemed "to exceed the standard of care" or is considered "experimental" and therefore is not covered. Thirty-five percent in the NatCapLyme survey responded that they were denied either insurance coverage or treatment due to IDSA treatment guidelines. A husband of a patient from Virginia who has been sick for 3 years states, "I have paid medical insurance premiums for more than 50 years but today's medical system allows my insurance carrier to deny coverage of lyme treatment. Big insurance is allowed to practice medicine without a license." Insurance denial

leaves Lyme patients with the choice of either paying for treatment out of pocket or being condemned to a life of persistent illness.

Patient O from Iowa, Sick for 6 years:

“Our insurance company to this date refuses to pay for the treatment and antibiotics citing them to be experimental and not medically necessary. We exhausted all appeals with the insurance company, put a mortgage on our home and cashed out our retirement funds to pay for the medical bills. We currently have a case pending before the Supreme Court of Iowa pertaining to medical coverage denied by our health insurer.”

Most health care costs could be avoided if the infection were diagnosed in a timely manner and treated aggressively. According to a CDC study on the economic impact of Lyme disease, the estimated average annual costs, both medical and non-medical, per patient with late-stage Lyme disease are \$18,880 (in 2009 dollars). That amount is 10 times higher than the per patient costs for early-stage Lyme disease (Zhang et al, 2006).

Lyme borreliosis poses a serious financial strain on families. Numerous patients with persistent Lyme borreliosis are forced to cut back on work, modify their career goals, or stop working altogether. Parents may have to curtail work hours to care for a sick child. According to the JMU work performance survey, 37 percent of the respondents had lost \$100,000 or more in income and wages from onset of illness to the time of the survey. Job loss usually means health insurance coverage is lost as well. Families often deplete savings accounts, run out of personal resources, and lose their homes to pay for medical care. Many patients must depend on government assistance. Twenty-five percent of respondents in the CALDA survey had been on public support or received disability benefits for their illness.

The loss of income has a staggering effect on Lyme patients and represents a burden on our economy. The CDC estimates the national annual economic impact of Lyme disease to be \$295 million (in 2009 dollars) (Zhang et al, 2006).⁴ This figure underestimates the true economic impact for several reasons. First, the CDC acknowledges significant underreporting (by a factor of 6 to 12) in the number of Lyme disease cases under their case definition (CDC, 2004). This means that the actual number of new Lyme disease cases could be over 300,000 per year. Secondly, the CDC’s economic impact study looked at a narrow set of economic variables. It excluded the costs of loss in productivity resulting from spouses and parents taking time off from work to care for a family member. Other economic costs, such as those associated with childcare services and adults needing in-home or assisted living services also were not included. A 2007 study on the economic burden of persistent disease found that caregivers’ lost productivity can add fully 7 percent to economic costs (DeVol and Bedroussian, 2007). Not only does the disease affect patients’ financial stability, it has the potential to impact the financial security of generations to come.

Patient P from Maryland, Sick for more than 20 years:

“If the doctors had met their most basic obligations, or cared at all, I would have been

⁴ The total economic costs figure was based on the CDC’s estimate of \$203 million (in 2002 dollars) by Zhang et al., converted into 2009 dollars, using the Consumer Price Index (CPI-U) and adjusted for the increase in the number of reported cases from 23,763 in 2002 to 28,921 in 2008.

cured decades ago. . . . They have decided I do not have value as a human being and am not worthy of a healthy, happy life.”

YOUTH

According to the CDC, children 5 to 14 years of age face one of the highest risks of *Bb* infection (CDC, 2006). This risk is likely due to the amount of time children spend playing outdoors, and a lack of awareness of the importance of finding and removing ticks. While children experience the same range of symptoms as adults, they often do not have the capacity to express and understand what they are feeling. Parents and doctors often dismiss non-specific symptoms of headaches, fatigue, gastrointestinal issues, and behavioral changes as a part of growing up. Such dismissal often results in delayed diagnosis, thereby allowing dissemination of the infection and consequent long-term illness.

Studies have revealed a long-term impact of Lyme borreliosis on a child’s physical and intellectual functioning. Researchers at Columbia University found “deficits in visual and auditory attention, or in working memory and mental tracking” in children with cognitive problems associated with Lyme disease. They concluded that [their] study demonstrates that children whose diagnosis and treatment are delayed may suffer considerable impairment” (Tager et al, 2001).

The education of children with persistent Lyme borreliosis becomes compromised, leading to inconsistent school attendance and performance. According to the NatCapLyme survey, 45 percent reported that their children with Lyme borreliosis missed school more than one day a week, and 42 percent reported that their children were tardy more than once a week. Studies on the long-term impact of Lyme borreliosis on children’s physical and intellectual functioning have documented behavioral changes, forgetfulness, cognitive deficits, and partial complex seizure disorder (Bloom et al, 1998; Tager et al, 2001). Teachers notice changes in play behavior, declining school performance, excessive sleepiness and frequent trips to the school nurse. At home, parents notice that some children present with cognitive and behavioral issues, nightmares, trouble falling asleep, difficulty concentrating and learning difficulties.

Adolescents present special diagnostic and treatment challenges, since their new-found desire for privacy, normalcy and independence may prevent full-body tick checks by parents and compliance with keeping doctor appointments and taking prescribed medications. Lyme borreliosis can cause symptoms including fatigue, slurred speech, and confusion which can be misinterpreted as resulting from illegal drug or alcohol use. Although some school districts offer generous support through Individualized Educational Plans and home instruction, others resist. Sadly, some teenagers do turn to street drugs and alcohol to self-medicate unmanaged neurologic and rheumatologic pain.

Many teenagers, overwhelmed by the illness and socially isolated, find it increasingly difficult to cope with life. Parents of children 8 to 16 years old reported in the Columbia University study that 41 percent of their children had expressed suicidal thoughts and 11 percent had made a suicidal gesture (Tager et al, 2001). Among the most disturbing results of the NatCapLyme survey were that 54 percent of the respondents reported that their children with Lyme borreliosis suffered from depression and 13 percent reported that their children had attempted suicide. Such suicidal ideation arises from an understandable weariness from chronic

illness. Most poignant is the simple statement from a Lyme-infected child, “I just don’t want to live anymore.”

Patient Q, age 13 from Missouri, Sick for 4 years:

“The kids at school pick on me because I am now in a wheelchair. I have a pic line in my arm . . . I am very sad. I can’t play sports and I am very tired all the time. Sometimes I wish I were not alive. I really have no friends. Who wants to be a friend of someone in a wheelchair or with an illness like mine?”

Relationships with friends and family become strained for some young people with Lyme borreliosis. Some children are confined at home by their illness. Their participation in normal activities, such as athletics or hobbies, becomes a vague memory. Persistent illness affects youths' ability to participate in normal rites of passage.

Mother on behalf of Patient R from Florida, Sick for more than 10 years:

“Since R was not able to attend school for so many years, receiving home-bound tutoring through the school, she missed out on the normal social growth of a teenager. I think one of the most difficult moments for me was the night her only two friends brought their dates over to show off their prom finery, with the limo waiting outside. I thought my heart would break when my Cinderella ran upstairs after the kids left.”

Parents understandably suffer along with their children. During periods when symptoms abate, hope of recovery rises, only to be dashed when symptoms return. Parents must make unimaginable decisions about putting their children on powerful painkillers or pursuing experimental treatments. They spend sleepless nights weighing the risks and benefits of committing their own child’s life to one of the opposing treatment philosophies.

Mother of Patient S from Virginia, Sick for more than 8 years:

“The treatment decisions often boil down to the lesser of two evils. I worry constantly about the potential long-term effects of all of these medications on her developing body, her reproductive capacity.”

Parents wonder why there is a narrow focus of concern from physicians regarding the dangers of curative antibiotics while little concern is expressed regarding the dangers of all the other medications including painkillers and "black-box" medications for the treatment of symptoms. As the mother of an eight-year-old Maryland patient states, “There is also, as a parent, guilt . . . Tremendous guilt if we make what later turns out to be the wrong choice.”

Most parents share the goal of guiding their children to a happy, healthy, productive adulthood. To that end, many parents of children suffering from Lyme borreliosis stretch their resources of time, energy and money to the limit. When young adults expect to launch their independence via college and career, ongoing illness interferes with this natural process. As the years of illness accumulate, hopes of becoming a productive adult and having a family fade. Too many of these young people are forced to create new life plans, but how does one plan for life under these circumstances?

Patient T, young adult from Virginia, Sick for more than 10 years:

“Lyme has taken what was supposed to be my decade of life, promise, and opportunities

and turned it into a decade of intense struggle, betrayals, and constant disappointment. While I once celebrated the highest academic achievements, strove to draw that perfect sound from my instrument, and worried which boys' words rang true, I now celebrate making it to the bathroom, strive for ways to diminish my ever growing medical costs, and worry this time the insurance company will reject my claim because I'm too expensive and growing too weak to fight back. And when Lyme traps me in a twitching body that gasps for air, tries to vomit and feels crushed by an elephant all at the same time, I remember my past filled with promise, ponder my present filled with doctors who say if they can't figure out what's wrong it doesn't exist and family that says if you just try hard enough all problems will disappear, and then contemplate my future - wondering if there is still any hope left in it. They say that adversity builds character, but Lyme weaves darker paths in life that I hope my friends will never need to travel."

CONCLUSION

Lyme borreliosis erodes every facet of an individual's life, decimates marriages, and causes children to leave the educational system. Life never returns to normal for many patients, as they must accommodate activity restrictions and ongoing health concerns. Recovery is further complicated by physicians who do not acknowledge the possibility of ongoing illness, and medical policymakers who do not consider additional avenues worthy of scientific exploration, in spite of mounting evidence of persistent infection.

Research remains inconclusive about optimal treatment. Yet state medical boards routinely penalize doctors for deviating from the Infectious Diseases Society of America's (IDSA) guidelines for treatment of Lyme disease (Wormser et al, 2006) by subjecting them to investigations and disciplinary procedures rarely visited on physicians treating other diseases. Consequently, a growing numbers of patients lose their doctors, who stop treating Lyme disease in fear of losing their licensing. Physicians are reluctant to treat Lyme and other tick-borne infections in a manner that contradicts the IDSA guidelines. This phenomenon appears to be unique to Lyme borreliosis. The government-sanctioned medical society favoring one treatment philosophy over another places an unnecessary burden on patients who are left to fend for themselves. In an ironic twist of the medical axiom "First do no harm," patients are left to wonder why the harm they endure from failure to receive treatment is not a rejection of that cherished standard.

The patient testimonies submitted illustrate that the conventional medical wisdom is seriously disserving Americans with tick-borne infections. They also support the frequent allegation that Lyme and associated tick-borne infections are major life-debilitating diseases that should be taken very seriously. Disease manifestations and treatment responses vary among patients. Some patients who are diagnosed and treated early respond well to IDSA-recommended treatment. Patients, whose diagnosis and treatment are delayed, often benefit from long-term or intermittent antibiotic therapy, which is why patients should have the right to pursue all treatment options.

Lyme patient support groups are encountering a growing number of people who were healthy prior to contracting Lyme borreliosis and have not returned to their former level of functioning after treatment. Patients across the United States report innumerable treatment failures. Worse yet, some people never receive treatment. It is unconscionable that so many people suffer for lack of an accurate diagnosis or effective treatment.

A recent study on the use of guidelines in medical negligence litigation in England and Wales concluded that, “there is a danger in applying the generalized prescription of guidelines in a rigid fashion to every patient” (Samanta et al, 2006). The authors noted that this interference with clinical freedom can result in “cookbook medicine” “In medical practice, many situations arise where the art of identifying patient problems and the application of clinical acumen to individual patient's needs remain removed from the science and technological advances of the discipline. Evidence-based medicine cannot fully capture the art of medical practice, and there remains a need for clinical judgment and discretion” (Samanta et al, 2006). Weak research data undermine the validity of treatment guidelines.

Clearly a serious gap between the conventional medical community's acknowledgment and patient reality is evident. Harvard Medical School professor Dr. Jonathan Edlow states in his book, *Bull's-Eye*, “We still have a lot to learn about Lyme disease, and more importantly, we still have a lot to learn about the scientific process” (Edlow, 2003). Patients hope that the Institutes of Medicine's (IOM) Workshop will lay the foundation by bringing university and private-sector scientists and practicing physicians from different viewpoints together to collaborate on solving the problems of treatment failures and persistent illness. We must utilize the scarce resources available to reach out to new thinkers, to explore fresh approaches that will give us the answers to find a cure for all victims of *Borrelia burgdorferi*.

“The controversy in Lyme Disease research is a shameful affair. And I say that because the whole thing is politically tainted. Money goes to people who have, for the past 30 years produced the same thing . . . Nothing.”

~ Willy Burgdorfer, Entomologist who first identified the bacterial spirochete responsible for causing Lyme disease (Wilson, 2009).

RECOMMENDATIONS

The National Capital Lyme and Tick-borne Disease Association recommends:

1. Improve surveillance by effective, thorough national oversight of tick-borne infections. Tick-borne infections are a serious health concern, and effective national surveillance of these diseases is needed in order to improve public awareness, prevention and diagnosis. Develop a more inclusive surveillance case definition that reflects the actual experiences of practicing physicians confronted with patients presenting with symptoms consistent with Lyme borreliosis. Suggestions to accomplish this are:
 - Broaden the case definition for surveillance to include advanced late-manifestations of Lyme disease.
 - Abandon the two-tier testing approach by eliminating the ELISA as a prescreening requirement before advancing to the Western Blot. The ELISA is too unreliable to be used as a preliminary screening test, given its extremely low sensitivity.
 - Standardize national reporting forms by issuing brief, automated forms that will enable treating physicians to report cases easily. Reports should be held confidential and not disclosed to state medical boards or insurance companies and their service organizations in order to remove the physicians' fear of adverse consequences from treating patients

with Lyme borreliosis.

2. Differentiate between the criteria for surveillance and clinical diagnosis. Once sufficient data have been gathered to form valid conclusions with respect to symptoms of Lyme borreliosis, develop a working clinical case definition for broad application within the medical community. Immediately, the CDC should inform all health service providers and health departments that the surveillance case definition is not intended to be used in clinical diagnosis.
3. Improve diagnostics by developing definitive, reproducible tests with a sensitivity of 95% or higher, that can detect active and latent infection of *Bb* and other tick-borne infections. The test should be reliable enough to be part of an annual physical examination.
4. Design a national survey. While both NatCapLyme and CALDA have conducted informal surveys which yielded useful information, their results point to the need for an unbiased national scientifically valid survey that collects reliable data on the experience of those suffering from Lyme and other tick-borne infections. Include the patient community in designing the survey.
5. Broaden clinical trials to include patients with persistent Lyme borreliosis. These patients are at the heart of the Lyme controversy. Broaden the entrance criteria for government-funded clinical trials to include entire classes of Lyme patients, whose disease expression and treatment response are poorly understood.
6. Base research grants for tick-borne infections on a non-biased approach. Given the recognized controversy over treatment of Lyme and other tick-borne infections, priority should be given to fund new researchers with innovative ideas and methods that would help to settle this controversy.
 - Many in the Lyme community believe that the Bayh-Dole Act of 1980 ultimately hindered advancement in Lyme disease research. Notably, the Alzheimer's disease Neuroimaging Initiative (ADNI) researchers recently discovered significant new biomarkers. Under the ADNI, researchers agree to share all data, make every finding public immediately, and renounce ownership and patent rights accruing to any individual researcher. According to Dr. John Trojanowski, a researcher at the University of Pennsylvania, "... we all realized that we would never get biomarkers unless all of us parked our egos and intellectual-property noses outside the door" (Kolata, 2010). NatCapLyme strongly advocates adoption of this model in the field of Lyme disease research.
 - Conduct treatment trials that better mirror the variety of treatment regimens actually used by treating physicians.
 - Research the unique attributes of *Bb* including multiple life forms and the incredible survivability of this organism in the host, genetic complexity, cell-wall deficient forms, its capacity for intercellular sequestration, antigenic variation, immune suppression, and the possible role of borrelial colonies and biofilms.
 - Research the complex disease resulting from multiple tick-borne infections.

7. Create dialogue among the scientific research community, health agencies, medical societies, and the full spectrum of treating physicians, including those who view Lyme borreliosis and tick-borne diseases as a potential persistent and infectious process. The NatCapLyme encourages all parties interested in Lyme and tick-borne diseases to work together to find solutions. NatCapLyme believes that true solutions to the dilemma of Lyme and tick-borne infections may be found only when all parties are willing to consider the views that each seeks to contribute.
8. Respect patients' right to choose treatment. Medical guidelines are designed to provide recommendations and not mandates. No monolithic treatment solution should be offered for such an unresolved area of medical research. While the overuse of antibiotics is a concern to all, some Lyme patients are reporting benefit from longer-term and combination antibiotic therapy.
9. Design a National Informed Consent Form to protect the patients' right to choose as well as protect the doctors' right to treat. The consent form should reflect fair and balanced treatment options and the benefits and risks of both short-term and long-term treatment choices. The committee that writes this should include medical and legal professionals who hold varied and conflicting points of view. This consent form must not favor any single treatment protocol. It should only include information necessary for fully informed patients to exercise their right to choose treatment.

Our committee would be happy to discuss further these recommendations and the experiences of Lyme and tick-borne disease patients that led to our conclusions. We were asked to provide the IOM committee with insight into the patient experience. We concluded that a simple cathartic expression of the angst and suffering of patients and their families would be useless, unless it was combined with insights into the research and science that further illuminates that experience. There is an urgent need to broaden our understanding of tick-borne infections. It is our hope that the scientific community will address the chronic forms seriously and effectively, so that many more of their victims will be able to return to useful, productive lives and the pursuit of happiness.

The National Capital Lyme and Tick-borne Disease Association thanks the Institute of Medicine committee members for allowing us to offer you the experience, thoughts, concerns, and needs of Lyme patients. Our hope is that the work of this committee will result in better care for patients and continued research to find a cure for this disease. We look forward to continuing to work with all governmental agencies and the medical community in hopes of finding successful treatment for all patients with tick-borne diseases.

The NatCapLyme Working Group: Monte Skall, Executive Director, NatCapLyme; Don Boileau, Professor; Barbara Cohen, Psychologist; Cindy Eisenhart, School Librarian; Susan Green, Attorney; Janis Ivicic, School Teacher; Helene Jorgensen, Economist; Linda Lobes, Advocate; Bill Merrigan, Legislative Attorney; Mimi Segal, Clinical Social Worker; Gregg Skall, Attorney; Lisa Torrey, Tick-Borne Disease Advocate; Joy Walker, Law Student; Judith Weeg, former CDC Health Educator; Sharon Whitehouse, Editor; Diane Wilcox, Professor.

Acknowledgment: We would like to thank the following organizations for their contributions to this paper: Lyme Disease United Coalition, Judith Weeg, President; Michigan Lyme Disease Association, Linda Lobes, President; National Tick-borne

Disease Advocates, Lisa Torrey, President; and Parents of Children with Lyme.

Correspondence: Monte Skall, Executive Director, National Capital Lyme and Tick-borne Disease Association; phone: 703-821-8833; e-mail, Natcaplyme@natcaplyme.org

REFERENCES

- Aguero-Rosenfeld, M. E., G. Wang, I. Schwartz, and G. P. Wormser. 2005. Diagnosis of Lyme borreliosis. *Clinical Microbiology Reviews* 18(3):484-509.
- Aucott, J., C. Morrison, B. Munoz, P. C. Rowe, A. K. Schwarzwald, and S. West. 2009. Diagnostic challenges of early Lyme disease: Lessons from a community case series. *BMC Infectious Diseases* 9(79):1-8.
- Barbour, A. 1996. *Lyme disease: The cause, the cure, the controversy*. Baltimore and London: The Johns Hopkins University Press. xiii.
- Bloom, B. J., P. M. Wyckoff, H. C. Meissner, and A. C. Steere. 1998. Neurocognitive abnormalities in children after classic manifestations of Lyme disease. *Pediatric Infectious Disease Journal* 17(3):189-96.
- CALDA (California Lyme Disease Association). 2009. *Lyme Policy Wonk: CALDA survey results are in!* (Attachment titled [Surveysummary_09102009_blog_attach_872443128.pdf](http://www.lymedisease.org/news/lymepolicywonk/198.htm)). <http://www.lymedisease.org/news/lymepolicywonk/198.htm> (accessed July 15, 2010).
- CDC (Centers for Disease Control and Prevention). 2004. Lyme disease-United States, 2001-2002. *Morbidity and Mortality Weekly Report* 53(17):365-9.
- CDC, Division of Vector-Borne Infectious Diseases. 2006. *Average annual incidence of reported cases of Lyme disease by age group and sex, United States, 1999-2004*. http://www.cdc.gov/ncidod/dvbid/lyme/ld_MeanAnnualIncidence.htm (accessed July 2, 2010).
- CDC, National Center for Public Health Informatics. 2010a. *Lyme disease (Borrelia burgdorferi). 2008 case definition*. http://www.casedef/lyme_disease_2008.htm (accessed July 17, 2010).
- CDC, National Institute for Occupational Safety and Health. 2010b. *NIOSH Safety and Health Topics: Tick-borne diseases*. <http://www.cdc.gov/niosh/topics/tick-borne/> (accessed July 28, 2010).
- Depietropaolo, D. L., J. H. Powers, J. M. Gill, and A. Foy. 2005. Diagnosis of Lyme disease. *American Family Physician* 72(2):297-304.
- DeVol, R., and A. Bedroussian. 2007. *An unhealthy America: The economic burden of chronic disease*. Santa Monica, CA: Milken Institute.
- Donta, S. T. 1997. Tetracycline therapy for chronic Lyme disease. *Clinical Infectious Diseases* 25(Suppl 1):S52-6.
- Duray, P. H. 1989. Clinical pathologic correlations of Lyme disease by stage. *Reviews of Infectious Diseases* 11(Suppl.6):S1487-93.
- Edlow, J. A. 2003. *Bull's-eye: Unraveling the medical mystery of Lyme disease*. New Haven and London: Yale University Press. 197-8, 253.

- Fallon, B. A., J. G. Keilp, K. M. Corbera, E. Petkova, C. B. Britton, E. Dwyer, I. Slavov, J. Cheng, J. Dobkin, D. R. Nelson, and H. A. Sackeim 2008. A randomized, placebo-controlled trial of repeated IV antibiotic therapy for Lyme encephalopathy *Neurology* 70(13):992-1003.
- Green, C. 2009. Challenge to the clinical definition of late Lyme disease and post-Lyme disease syndrome. Unpublished paper. Los Altos, CA: Green Oaks Medical Center.
- Jorgensen, H. 2010. *Sick and tired: How America's health care system fails its patients*. Sausalito, CA: Polipoint Press.
- Kolata, G. 2010. Sharing of data leads to progress on Alzheimer's. *The New York Times*, August 13. <http://www.nytimes.com/2010/08/13/health/research/13alzheimer.htm> (accessed August 13, 2010).
- Klempner, M. S., L. T. Hu, J. Evans, C. H. Schmid, G. M. Johnson, R. P. Trevino, D. Norton, L. Levy, D. Wall, J. McCall, M. Kosinski, and A. Weinstein 2001. Two controlled trials of antibiotic treatment in patients with persistent symptoms and a history of Lyme disease *New England Journal of Medicine* 345(2):85-92.
- Krause, P. J., S. R. Telford, A. Spielman, V. Sikand, R. Ryan, D. Christianson, G. Burke, P. Brassard, R. Pollack, J. Peck, and D. H. Persing. 1996. Concurrent Lyme disease and babesiosis. Evidence for increased severity and duration of illness *JAMA* 275(2):1657-60.
- Krupp, L. B., L. G. Hyman, R. Grimson, P. K. Coyle, P. Melville, S. Ahnn, R. Dattwyler, and B. Chandler. 2003. Study and treatment of post Lyme disease (STOP-LD): A randomized double masked clinical trial. *Neurology* 60(12):1923-30.
- Landro, L. 2010. More tick infections begin at home. *The Wall Street Journal*, August 2. <http://online.wsj.com/article/SB10001424052748703999304575399234058978228.html?KEYWORDS=Landro> (accessed August 2, 2010).
- Pachner, A. R. 1995. Early disseminated Lyme disease: Lyme meningitis *American Journal of Medicine* 98(4A):30S-43S.
- Pachner, A. R., K. Amemiya, M. Bartlett, H. Schaefer, K. Reddy, and W. F. Zhang 2001. Lyme borreliosis in rhesus macaques: effects of corticosteroids on spirochetal load and isotype switching of anti-borrelia burgdorferi antibody. *Clinical and Diagnostic Laboratory Immunology* 8(2):225-32.
- Samanta, A., M. M. Mello, C. Foster, J. Tingle, and J. Samanta 2006. The role of clinical guidelines in medical negligence litigation: A shift from the Bolam standard *Medical Law Review* 14(3):321-66.
- Sapi, E., J. Bober, M. Montagna, M. Raman, M. Reddy, M. Hessberger, and A. Melillo 2009. *Prevalence of tick-borne pathogens in Ixodes scapularis ticks from southern Connecticut*. Unpublished paper. New Haven, CT: New Haven University, CT.
- Steere, A. C. 1989. Lyme disease. *New England Journal of Medicine* 321(9):586-96.
- Tager, F. A., B. A. Fallon, J. Keilp, M. Rissenberg, C. R. Jones, and M. R. Liebowitz. 2001. A controlled study of cognitive deficits in children with chronic Lyme disease *Journal of Neuropsychiatry and Clinical Neurosciences* 13(4):500-7.
- Tibbles, C. D., and J. A. Edlow. 2007. Does this patient have erythema migrans? *JAMA* 297(23):2617-27.

Wilcox, D. M., and C. Uram. 2009. *The impact of chronic Lyme disease on workplace performance: A survey of chronic Lyme patients*. (Addendum of tables and charts). Paper presented at the International Lyme and Associated Diseases Society Conference 2009, National Harbor, MD.

Wilson, A. A. 2009. *Under Our Skin*. Open Eye Pictures, Inc.
<http://underourskin.com/blog/?p=191> (Accessed August 5, 2010).

Wormser, G. P., R. J. Dattwyler, E. D. Shapiro, J. J. Halperin, A. C. Steere, M. S. Klemperer, P. J. Krause, J. S. Bakken, F. Strle, G. Stanek, L. Bockenstedt, D. Fish, J. S. Dumler, and R. B. Nadelman. 2006. The clinical assessment, treatment, and prevention of Lyme disease, human granulocytic anaplasmosis, and babesiosis: Clinical practice guidelines by the Infectious Diseases Society of America. *Clinical Infectious Diseases* 43:1089-134.

Zhang, X., M. I. Meltzer, C. A. Pena, A. B. Hopkins, L. Wroth, and A.D. Fix 2006. Economic impact of Lyme disease. *Emerging Infectious Diseases* 12(4):653-60.

DRAFT