

BULLYING BORRELIA: WHEN THE CULTURE OF SCIENCE IS UNDER ATTACK

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ABSTRACT

Although Lyme disease responds to short courses of antibiotics, tick-borne *Borrelia burgdorferi* has been advanced by some as a frequent explanation for medically unexplained symptoms such as continual fatigue, musculoskeletal pains, and subjective neurocognitive dysfunction. Often called “chronic Lyme disease” by adherents of this philosophy, it is loosely defined, and practitioners liberally prescribe nostrums, including prolonged antimicrobial therapies, in a belief that this eradicates suspected infection. Perhaps due to the lack of supportive data, proponents of this theory have developed their own meetings, literature, activist groups, and substantial internet activities to advance their views. Forces motivating this movement are explored, as are tactics used to advance non-scientific ideas that have included legal action and garnering legislative endorsement. While neither logical nor evidence-based, “chronic Lyme disease” harnesses corrosive energies that taint modern medicine and society.

INTRODUCTION

The agent of Lyme disease in North America, *Borrelia burgdorferi*, is recognized as the most common vector-borne infection within the United States. More than 20,000 cases have been reported annually since 2002, although it remains mostly a regional disease with 12 states in New England, the Mid-Atlantic, and the upper Midwest accounting for 94% of cases (1). Transmitted by *Ixodes* species ticks, the infection most frequently presents as an acute illness that includes a characteristic rash (erythema migrans) at the bite site. If untreated, neurologic, cardiac, or musculoskeletal problems may develop. Effective treatment of Lyme disease uses a single antibiotic for durations that range from 10 to 28 days depending on the disease manifestation. The Infectious Diseases Society of America (IDSA), a professional organization of clinicians and researchers

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numbering more than 10,000 members, first issued these recommendations in a guideline statement in the year 2000 with an update in 2006, using an evidence base derived from peer-reviewed studies (2).

Studies examining whether a longer duration of initial antibiotic therapy impacts response rates have not shown benefit because only a minority of treated patients continue to have persistent or episodic symptoms. An analysis of 14 studies examining early Lyme disease therapy indicated that 0% to 23% of patients experienced subjective complaints such as fatigue, myalgia, arthralgia, headache, sleep disturbance, or neurocognitive difficulties for 6 to 24 months after the initial infection (3). Although these symptoms resolve for most patients, with less than 1% going on to have chronic fatigue or persistent pain syndromes, their etiology is poorly understood, and they have become the focus of an often rancorous debate as to whether Lyme disease may account for a wider spectrum of illness than customarily believed, perhaps due to a chronic focus of infection (4).

In an effort to address whether additional antimicrobial treatment helps such patients, four National Institutes of Health (NIH)–sponsored, randomized, placebo-controlled trials have examined whether long-term antibiotic therapy benefits previously treated patients who have had authentic Lyme disease followed by persistent subjective complaints (5–7). No study found any evidence of chronic infection, and none showed significant or durable benefit in the antibiotic arms. Post-Lyme disease syndrome (PLDS) has been advanced as a descriptive term for these non-specific complaints in patients who have no evidence of an active infection or an alternative explanation at least 6 months after symptom onset (2).

In stark contrast and contrary to evidence in hand, over the last 20 years, a number of healthcare providers (mostly private practitioners), patients, and patient advocacy groups have embraced the concept of chronic Lyme disease as an explanation for long-standing fatigue, musculoskeletal pains, and neurocognitive dysfunction. These individuals attribute such symptoms to persistent *B. burgdorferi* infection that they believe can only be effectively treated with antimicrobials, often taken in combination for months or years. Why this approach has gained traction and remained forceful within certain sectors of the medical community and the lay public rests on a number of elements that are far from the traditional venues that use grounded scientific evidence and sound clinical judgment.

CHRONIC LYME DISEASE: (HUMAN) NATURE DOES ABHOR A VACUUM

The definition of a syndrome in clinical medicine rests on recognizable signs and symptoms that can be categorized into a clinical entity that

does not have an understood pathophysiology. Some patients with chronic symptoms of pain, fatigue, and mental inattentiveness, for example, may fall under the syndromic rubrics of chronic fatigue syndrome or fibromyalgia. Clinicians and patients alike are often left with no genuine understanding why these problems arise and persist. Estimates place approximately 2% of the US population as suffering from fibromyalgia or having self-reported severe symptoms (8, 9). The contribution of Lyme disease to this equation is not known but likely would account for only a tiny proportion based on disease distribution and rates of infection. The infrequency with which Lyme is associated with such symptoms is also suggested by the difficulty reported in patient recruitment for the aforementioned NIH trials. Moreover, there are no reports suggesting fibromyalgia or chronic fatigue syndrome epidemiologically clusters as *B. burgdorferi* does in the mid-Atlantic, New England, and upper Midwest United States.

The suggestion that an infectious agent continues to cause chronic symptoms may speak to the observed tendency for patients to develop illusory patterns of perception when they lack control (10). Because an infection paradigm is a generally plausible and tractable concept, it is with no surprise that over the last century a number of descriptors or infectious agents have been offered as an explanation (Table 1). However, Lyme disease may be resisting the typical faddish consideration because another candidate has not yet firmly supplanted this infection as a timeline might suggest.

A necessary cog driving the popularity of chronic Lyme disease is a cadre of healthcare providers who make this diagnosis based on subjective signs and symptoms without valid evidence or history of bona fide *B.*

TABLE 1
*Chronic Fatigue Syndrome Cognomens**

Agnostic Terms
Neurasthenia (19 th –20 th centuries)
Myalgic encephalomyelitis (1950s–)
Chemical hypersensitivity syndrome (1980s–)
Infectious Candidates
Chronic Brucellosis (1930s–1950s)
Chronic Epstein-Barr virus (1960s–1980s)
Chronic candidiasis (1970s–1990s)
Toxic mold (1980s–)
Chronic Lyme disease (1990s–)
Xenotropic murine leukemia virus-related virus [XMRV] (2009–2011)

*Partial list, dates reflects estimates of popular consideration.

burgdorferi infection. This is not a widely held view; one study performed in Connecticut found that only 2.1% of physicians surveyed use this diagnosis (11). A comparison between evidence-based guidelines and those followed by so called Lyme literate medical doctors (LLMDs, who are said to be the only clinicians able to understand chronic Lyme disease) highlights the differences (Table 2). The operational definition of chronic Lyme disease used by the ILADS guideline states that this entity is “inclusive of persistent symptomatology including fatigue, cognitive dysfunction, headaches, sleep disturbance, and other neurologic features, such as demyelinating disease, peripheral neuropathy and sometimes motor neuron disease, neuropsychiatric presentations, cardiac presentations including electrical conduction delays and dilated cardiomyopathy and musculoskeletal problems” (12). Given this wide-ranging case definition, when traditional and accepted definitions are used, for example, many patients who had been told they have Lyme disease do not. Indeed, studies from seven academic medical centers evaluating patients referred for Lyme disease evaluations found that 50% to 88% had no evidence of having had Lyme disease (4).

Given a loose case definition and biological concepts straying far from known concepts in infectious diseases, it is without surprise that reviews of chronic Lyme disease have found no level I, II, or III evidence refuting the positions held by IDSA or 10 European expert panel reports that the entity does not exist (13, 14). Lastly, although advocates offer testimonials to the good works of LLMDs and chronic Lyme disease treatment outcomes, there is little published quality evidence to back their practices or support the hypothesis of ongoing infection. What is present either does not suggest response rates higher than the approximately one-third improvement noted in published placebo-controlled trials or is of low quality, with some of the more highly touted even lacking case definition methodology (5, 15, 16). This lack of good quality evidence and practices has not dimmed efforts to popularize chronic Lyme disease.

EFFORTS TO MOVE PUBLIC OPINION

Perhaps because of an inability to persuade academics or mainstream medical practice within the court of scientific opinion, advocates of chronic Lyme disease have used a host of measures in an effort to promulgate their views. Among the most effective have been the increase of rapid, electronic communication and generation of content without high-quality peer review. One survey of Lyme disease-related information on the internet, for example, found considerable inaccuracy (17). Despite the disconnect between valid scientific data and the

TABLE 2
Lyme Disease: Comparison of Evidence-based Guidelines Versus Non-evidence-based Concepts Favored by LLMDs and Advocacy Groups

Description	Evidence-based†	Not Evidence-based‡
Terminology	Late Lyme disease	Chronic Lyme disease
	Post-Lyme disease syndrome	Chronic Lyme disease
Epidemiology	Tick-borne	Sexually transmitted
	Known geography	Geographically unrestricted Congenital infection
Pathophysiology	Not an intracellular pathogen; no evidence of cystic forms <i>in vivo</i>	Chronic infection resistant to antibiotics due to cyst formation or intracellular location
		Stealth mechanisms establish and maintain chronic infection
Clinical	Objective and subjective signs and symptoms	Subjective symptoms only necessary for diagnosis
	Treatment effective for early or late infection	If not treated early, infection may be incurable
	Defined clinical spectrum	Cause of learning disabilities, autism, multiple sclerosis, amyotrophic lateral sclerosis, Parkinson's disease, Morgellons disease, psychiatric disease (Lyme rage), Alzheimer's disease,
		Occasional tick-borne disease co-infections
	Rare reports of death related to Lyme disease	Lethal disease
Diagnostic tests	Negative Lyme serology seen in early infection	Seronegative Lyme disease common, late disease
	IgM immunoblot used for acute illness diagnosis only	IgM immunoblot sufficient to diagnose long-standing symptoms
	FDA approved <i>B. burgdorferi</i> serology	Lyme specialty labs using non-validated tests or test interpretations
Therapy	Single antibiotic course 10-28 days with rare situations to retreat Treated patients with persistent symptoms have no evidence of remaining infection	Use of markers CD57, C4a
		Persistent symptoms demand long-term treatment until resolution of symptoms (months-years) Combination and/or parenteral antibiotics necessary for cure

†Data derived from (2, 3, 36, 37).

‡Data derived from (12, 38, 39).

content of these internet writings, Lyme advocacy groups have flourished, including in states that do not have endemic *B. burgdorferi* infection such as Colorado (18). The appeal of these groups may lie in the information presented in Lyme blogs or on advocacy web sites espousing views that Lyme disease is difficult both to diagnose and to treat, and that mainstream medical opinions are biased due to undocumented conflicted interests or corrupt practices. Such conspiracy views appear to channel practices that have long been used by some movements in American politics, such as McCarthyism, trading on frustration and anger, plying fear of the unknown and paranoia to exploit their point of view (19).

In addition to maintaining a robust internet presence, these Lyme disease advocacy groups and activists have worked to develop a foundation of LLMDs, research and publications, and meetings to promulgate their theories. One of their intentions, for example, is to assert the existence of a vast and under-recognized epidemic of Lyme diseases. Advocates have taken this and other messages to the traditional media who, in turn, have perhaps unwittingly given significant time to the advocates' points of view; these mainstream publications appear to have blunted the rightful characterization of these groups' fringe philosophy and its pseudoscience underpinnings. Beyond undue fair balance, many media pieces trade on testimonials and human interest stories conveying a saga of chronic Lyme disease; those often outshine the counter arguments of sound science (if even presented). This phenomenon may well be exacerbated by the decline of scientific literacy within journalism generally (20). Pseudo-documentaries have been among the latest techniques to launch vitriol against established experts and practices (21).

Given the veneer of legitimacy, advocates have amplified the effects of media campaigns by harnessing political routes. Both Connecticut and Rhode Island have passed legislation to protect practitioners from any disciplinary action in their treatment of Lyme disease, and similar bills have been introduced in at least 11 other states (Diana Olson, personal communication, December 2011). Mandated insurance coverage for long-term and parenteral antibiotics for Lyme disease is now law in New Jersey. Among the more unusual efforts, advocacy groups upset with the newly updated 2006 IDSA Lyme disease guideline have sought legal means to have it withdrawn or altered, largely because of the guideline recommendation against long-term antibiotic therapy for Lyme disease due to ineffectiveness and potentially harmful effects (22).

In his role as Connecticut Attorney General, Richard Blumenthal launched an investigation into the 2006 IDSA guideline with allega-

tions of undisclosed conflicts of interest among the authors and the complaint that alternative therapies addressing chronic Lyme disease were not considered. This action was roundly criticized since the Federal Trade Commission and the courts have opined in the past that such voluntary medical guidelines do not limit fair trade, and actions against them have no legal basis (23). The American Medical Association also passed a resolution stating guideline development should remain independent (24).

After 2 years of maneuvering, a mutual agreement reached between the IDSA and the Connecticut Attorney General resulted in an independent review panel which reviewed more than 1,205 references and also convened a public hearing. The independent panel's analysis concluded that the 2006 IDSA recommendations were valid without an immediate need for revision; moreover, they found no conclusive evidence within controlled studies to support either the existence of chronic Lyme disease or a need to incorporate such a concept into the IDSA guideline statement (25). This taxpayer-sponsored investigation resulted in defense costs summing more than \$550,000 to the IDSA as well as countless volunteer and staff hours (Diana Olson, personal communication, December 2011). Although vindicated and without any findings of conflicted interest among guideline authors, the wide divide has continued to be a wedge issue for chronic Lyme disease advocates to pitch stories and angles to media and politicians as a tainted process that was in violation of voting agreements (26). By co-opting political and legal means to advance their cause, Lyme disease activists have taken on the overt tones of a business or public interest group rather than an authentic medical entity.

POLITICALIZATION OF LYME DISEASE: COLLATERAL DAMAGE

Some may argue that in a free society such as the United States, such efforts by believers in chronic Lyme disease have little harm and merely contribute to the debate about this infection. These efforts have likely gained traction as a result of the dynamics of significant numbers of people who suffer from poorly understood problems that are neither easily categorized nor treated by the medical profession. Indeed, the stigma of syndromic diagnoses and/or interactions with dismissive, non-empathetic physicians citing somatic explanations for otherwise unexplained symptoms no doubt fuel the movement.

While the increase of personal computer usage coincided with the first identification of Lyme disease in the 1970s, the expansion of

internet-based communication in the 1990s allowed patients with maladies to seek and exchange information among many newly formed organizations, postings, and blogs. Aided and empowered by these web-based modalities, advocacy groups have secured celebrity endorsements, fundraising mechanisms, and political lobbies. In addition to the impacts described above, these advocacy groups are also affecting mainstream medicine. For example, some healthcare providers now come to understand Lyme disease in terms provided by patients who have investigated information on the internet, citing half-truths such as a need for long-term antibiotic therapy for treatment, or the poor sensitivity of *B. burgdorferi* serological testing (27). Indeed, although antibody formation can take 4 to 6 weeks to manifest in acute infection (leaving erythema migrans as the main marker of early disease), serology is helpful in rendering Lyme disease as unlikely in patients with long-term symptoms who are seronegative (28, 29).

Over-diagnosis of Lyme disease can harm an individual patient in ways that include diagnostic delay and the repercussions of not receiving timely, appropriate care. Further, treatment of non-existent Lyme disease with long-term antibiotics has caused death, *Clostridium difficile* colitis, and adverse drug reactions, and it may drive the emergence of antibiotic-resistant organisms (4, 30). From a larger public health perspective, erroneous diagnoses lead to unnecessary consumption of resources including testing, drugs, and professional services that may or may not be covered by insurance because many LLMDs have cash-based, fee-for-service practices. When clinical studies indicate no advantage with the use of long-term antibiotics, the ethical question of whether LLMDs are serving well their patients without conflict of interest might also be raised (31). When questioned, typical arguments offered by LLMDs include critiques of these studies as inadequate and/or rebuttal references of low quality (32). Many also either offer untested theories or rely on anecdotal experience to guide their practice (Table 2).

The argument of whether current scientific and clinical data support or refute chronic Lyme disease has itself consumed considerable energies. The debate may be side-tracking efforts to research the causes and treatment of these poorly understood problems. Critics claim that an open mind should be maintained about chronic Lyme disease. Allowing this entity to secure any significant footing, however, will only add fuel to the forces that have corrupted public opinion in similar veins; examples of such assaults on sound science include discredited assertions regarding the MMR vaccine effecting autism, as well as homeopathy as an effective therapeutic modality (33, 34).

CONCLUSIONS

Although science has not supported the concept of chronic Lyme disease, the entity has continued to draw favor among some patients, healthcare providers, media, and politicians despite, or perhaps due to, the controversy. Although one can have understandable empathy for an individual's suffering regardless of the cause, it is clear that such Lyme disease activists are strongly waging a war against evidence-based medicine. Further study or findings that do not hew to the theories advanced for chronic Lyme disease are unlikely to staunch the ire against and criticism of traditional medicine. It is of paramount importance that key decision makers for both patients and public alike understand that fairness and balance have no place in medicine, and that this sort of discourse is best waged in the arena of scientific debate. Consequences otherwise may mean that many will fall victim to poor and harmful practices.

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DISCUSSION

Barondess, New York: Thank you very much for that, Paul. It strikes me that there is, in the ambient environment, a population of people who are chronically fatigued with aches, pains, and a variety of other symptoms; some of whom are interested if it’s Lyme disease, others wondering if it’s a murine leukemia virus, and others who don’t know what it may be. Nevertheless, a universe of people are symptomatic, frustrated, and, to some extent at least, militant. I doubt very much this fight is going to be resolved by trying to bring more scientific evidence that their difficulties are not due to persistent Lyme disease. I think that’s the wrong question. One approach might be to examine subsets in chronically fatigued and achy people and see what demographics exist between one group of people and another. What profiles or other questions can be deduced to refine questions and approaches, therefore—approach it on a somewhat more rational basis? You are never going to settle this in this way and it’s very disturbing that it’s already moved in the direction that chiropractic went many years ago, which was to establish itself to attorneys general and state legislatures. That was also an incorrect path, but it seems to me that some fresh approach to these people who are genuinely symptomatic, not to mention mad as hell, would be a more productive approach.

Auwaerter, Baltimore: Well, I think you’ve hit it spot on. Logic and science will not persuade this group because they’ve decided not to use that equation to get to the diagnosis of chronic Lyme disease. They are, in fact, fighting the notion of evidence-based medicine. I agree that certainly these patients should be studied. The Centers for Disease Control has conducted studies for a number of years, and there are infections that clearly seem to propagate a post-infectious, chronic fatigue-like syndrome—for example, infectious mononucleosis and Ross River virus infection. In my view, Lyme disease offers a good model for this, although only a small number of people are afflicted with chronic and severe symptoms after treated infection. The trouble is the funding for this in the sense that this is probably such a heterogeneous disorder, I think has stymied many from devoting lots of resources, but it is something which I think the other side has tapped. This anger and angst from these patients are seeking definitive answers and treatments, and these LLMDs are providing that.

M. Gershon, New York: There is a parallel organization out there representing parents of children with autism, and they are having an effect on the distribution of

vaccines and the effect is extremely negative. It's not just in the United States, although it's particularly malignant in parts of this country. It seems to me that in your last slide that you put up, should that be an offense? It seems to me that these people are spreading disease. There has to be an offense. Money is drying up to provide medical care for many groups in our society and money is short. There just isn't time to put up with this kind of nonsense. It's like saying, "We have to let typhoid fever spread." That's what these people are; they are spreaders of disease. I know it's very traumatic to deal with them. I've testified at Congress on the issue whether measles, mumps, and rubella vaccination causes autism. At one point during my testimony when the chairman of the committee raised his gavel, I thought he was going to throw it at me. It becomes extremely passionate, as you said, but we have got to find a way about it. It seems to me that not every politician is infected by the chronic Lyme or autism nonsense. It is the vaccine advocates' approach to educate widely receptive people who have not yet been contaminated. I mean, you can't talk to Richard Blumenthal, but there are other attorney generals, although he is now a senator. He's only one of 99.

Auwaerter, Baltimore: Well, I think you're right. It is something, though, that has taken on really a non-evidence or solely faith-based attribute, so you have likeminded people or politicians. It is they who really facilitate this. I testified in front of the Virginia Governor's Lyme disease task force, and it seemed to me that the majority of the group was chronic Lyme disease proponents. The panel was, at times, hostile, and did not appear to me to be conducting itself in an impartial manner. So, I think the politics of this will continue until there is an alternative, catchier explanation.