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Pulse

In the Lyme Light

The debate over how Lyme disease should be treated has moved to the state Capitol. Should the Legislature have a say?

Senator John Marty hadn't thought much about Lyme disease until several years ago, when he found out a woman he knew had been bedridden for nearly a year with vague symptoms that had gradually worsened. When Marty, a DFL senator from Roseville, next saw her, she was much improved. She told him she had been diagnosed with Lyme disease and credited antibiotic treatment for alleviating her symptoms. More recently, Marty, who chairs the Senate Health Committee, started hearing similar stories from others, including a former colleague and several nurses, who talked about having ongoing problems related to Lyme disease.

"I had been approached by a number of people saying 'You ought to start paying attention to this issue,'" he recalls, adding that the blacklegged tick that carries the *Borrelia burgdorferi* spirochete that causes Lyme in humans is endemic to Minnesota and that the number of cases in the state has been increasing steadily (see Lyme Country).

What Marty didn't realize at the time was how much controversy a tick the size of a pepper flake already had stirred up within the medical community. Doctors had been arguing for years over what it means when symptoms reminiscent of Lyme disease return after antibiotic treatment; whether it is possible to have Lyme without the presence of a bulls-eye rash at the site of the tick bite or laboratory confirmation of the presence of *B. burgdorferi*; and whether it is safe to treat patients with antibiotics for months or longer.

At the urging of a group of physicians who feared being sanctioned for the way they treat patients with Lyme disease, Marty introduced a bill last year that would prohibit the Minnesota Board of Medical Practice from bringing disciplinary action against physicians who prescribe long-term antibiotic treatment for Lyme disease. The bill was not heard in committee earlier this year, but Marty says he and Rep. John Ward (DFL-Brainerd) plan to pursue its passage in 2010.

Two Camps, Two Views

Minnesota isn't the first state to consider legislation regarding the treatment of Lyme disease. Last year, Connecticut, where the disease was first identified in 1975, passed a law protecting physicians who treat Lyme patients with extended courses of antibiotics from disciplinary action. Rhode Island has a similar law; New York, a memorandum of understanding; and California, a law relating to the practice of alternative medicine that does the same.

What's driven these legislative initiatives is rooted in a long-running schism within the medical community that has pitted members of the Infectious Disease Society of America (IDSA), the specialty organization for infectious disease physicians, against those from the International Lyme and Associated Diseases Society (ILADS), a group of physicians who've devoted their practices to treating Lyme disease patients, over whether the IDSA's guidelines for diagnosing and treating Lyme disease are adequate.

Among the many issues where there is fierce disagreement is whether there is such a thing as "chronic" Lyme disease and whether long-term antibiotic treatment is appropriate for patients whose symptoms persist following standard antibiotic therapy. The IDSA guidelines, which are voluntary but used by many practices and insurers to guide treatment and payment decisions, recommend two to four weeks of treatment with oral antibiotics (doxycycline, amoxicillin, or cefuroxime axetil) and two to four weeks of intravenous ceftriaxone, cefotaxime, or penicillin in cases of severe or unresponsive disease.

"There is no information that has been published as a result of scientific studies that have gone through the independent peer review process that have documented that chronic infection persists after standard treatment courses with antibiotics," says Johan Bakken, M.D., Ph.D., an infectious disease specialist at St. Luke's Hospital in Duluth and a coauthor of the IDSA's 2006 guidelines. Bakken cites four prospective studies that found no documented benefit for patients with persistent symptoms who received oral or IV antibiotic treatment beyond the duration recommended in the IDSA's treatment guidelines.

But some physicians argue that some patients do get relief with longer courses of therapy. Elizabeth Maloney, M.D., a family physician in Wyoming, Minnesota, has been a vocal critic of the IDSA guidelines and a supporter of Sen. Marty's bill. "Ultimately, when you're talking about treatment decisions, you have to apply a risk-benefit analysis that is patient-specific," she says. "Guidelines can't do that. They don't know the patient....They don't know what the treating physician knows."

Maloney describes four different studies of patients with late neurological Lyme who were treated for 14 to 30 days—the recommended course. "Treatment was beneficial for some, but outcome rates for complete response were dismally low, between 7 and 35 percent," she says. She also contends that one of the studies Bakken cites is flawed and that patients in two others, who received an additional 30 to 70 days of treatment with ceftriaxone, saw a reduction in severe fatigue.

Bakken contends that patients who do feel better when they're treated with prolonged oral antibiotics often experience benefits related to the drug's anti-inflammatory properties, not its antimicrobial properties. He also argues that patients who have gone through antibiotic treatment and continue to experience symptoms may be experiencing symptoms driven by an activated immune system and not the presence of *B. burgdorferi*. "Components of the immune system that have become activated don't turn off on command and don't turn off just because you institute antibiotic therapy," he says. "So the immune response may persist sometimes beyond the duration of antibiotic administration. Some practitioners erroneously equate that with a continued active infection, when in fact no one has been able to prove that." In addition, Bakken says, the four prospective studies found an increase in adverse events as a result of prolonged IV treatment including infection at the IV catheter site, *Clostridium difficile*-associated diarrhea, sepsis, and venous thrombosis. He adds that prolonged treatment may also create antibiotic-resistant bacteria.

Lyme Country

Minnesota is not an unlikely place for the next showdown over how Lyme disease should be treated. It is, after all, Lyme country.

Case reports in the state show a stair-step increase from 94 cases in 1986, the first year the Minnesota Department of Health collected data on Lyme disease, to 1,050 in 2008. Originally found in the eastern part of the state, the blacklegged tick that transmits the disease is now found as far northwest as the headwaters of the Mississippi River.

David Neitzel, an epidemiologist with the Minnesota Department of Health who specializes in vector-borne diseases, believes there are a number of reasons for the increase in case reports. One could be the growing deer population. "With deer come their parasites," he says. Another explanation could be more people spending time at second homes in the woods or taking part in outdoor activities such as paintball and ATV trail riding, which can put them in contact with ticks. Minnesota's recent mild winters and wet springs may have also played a role in the increased incidence of the disease. Blacklegged ticks like warm, moist conditions. "If the weather is very hot and dry, it can be difficult for them to feed and survive," he says.

Neitzel says approximately one in three female blacklegged ticks in Minnesota is infected with the Lyme disease spirochete. The Department of

Maloney argues that long-term IV antibiotic treatment is rare and that oral antibiotics have proven safe when given over a long period. "If you had acne, no one would blink an eye over months or years of antibiotics," she says. In her opinion, the real danger of trying to limit how physicians can treat patients for Lyme is that it could drive patients out of state, or even out of the country, to get care. "I don't want people to have to travel out of state or take their dog's doxycycline or get antibiotics from Mexico—all these things that desperate patients go through. I would much rather have them go to physicians who have really studied Lyme disease."

Bakken says by defaulting to long-term antibiotic therapy when a patient has persistent symptoms, physicians may miss the real cause of the problem. "No one is arguing that there isn't a group of patients who will continue to have symptoms," he says, noting that the clinical symptoms could be the result of some other undiagnosed illness. "But one of the problems of endorsing long-term antibiotic therapy is that you become blinded to discovering what's really going on."

Heart of the Matter

So what is really at the center of this debate? Take away the arguments over whether there is evidence that persistent Lyme disease exists or whether long-term antibiotics are safe and effective and what's left is politics.

Maloney, who has written a challenge to the IDSA guidelines that was published in the fall 2009 *Journal of American Physicians and Surgeons*, is quick to point out that the IDSA "is a very powerful organization." "They put forth guidelines that really don't reflect the science, which is unsettled," she says. "Forty percent of the studies cited in the guidelines were written by guideline authors. That makes it difficult for them to judge the true strength of a particular study."

In 2006, Connecticut attorney general Richard Blumenthal filed an antitrust suit charging that the process the IDSA used to develop the guidelines, which were being used by insurers to deny coverage of certain treatments, was flawed because of conflicts of interest on the part of some of the panel members and because of failure to consider alternative opinions or evidence regarding the treatment of Lyme disease. The IDSA agreed to a settlement last year. Under that agreement, the IDSA would allow the document to be reviewed by an independent panel to determine whether the guidelines should stand, be changed, or be retracted.

Members of the new panel were agreed upon by the IDSA and the Attorney General's office and scrutinized by a medical ethicist, who ruled that anyone who derived more than \$10,000 in income from direct treatment of Lyme disease would not be considered for the panel.

The nine-member panel met on July 30 and is expected to make its recommendations by the end of the year.

But will those recommendations end the debate? "I will be very satisfied if they can say treatment decisions really have to be individualized and offer some parameters," Maloney says. "If they give us options, that's moving where we need to go." But she doubts that will happen. "You have a panel that doesn't really know Lyme disease," she says, explaining that the income guidelines used to select panel members excluded physicians who devote even a small portion of their practice to treating Lyme patients. "If you look at the panel and see how many are members of IDSA, you wonder how much movement there will be on this." She would like to see a set of guidelines put forth by ILADS, which allow for clinical judgment for diagnosing Lyme disease and long-term antibiotic treatment, adopted instead.

Bakken, too, believes that the panel's recommendations won't resolve the controversy. "I think

Health also has documented an increase in the number of human cases of two other diseases transmitted by blacklegged ticks, human anaplasmosis and babesiosis. "We think the increases in all three tick-transmitted diseases represents a real increase, rather than some sort of disease-reporting artifact," he says.—**K.K.**

the resolution of the controversies over 'chronic Lyme disease' and prolonged antibiotic administration will affect how the 'Lyme-literate' physicians will survive," he says, adding that those physicians who have based their practice on treating people with Lyme disease will lose revenue if they don't continue to keep up the pressure. "I don't think they will abide by any final settlement by this review panel," he says. "There's a profit motive here that's seldom brought out."

Who Decides?

As these arguments get replayed in St. Paul, they will highlight a bigger concern: Should lawmakers have a say in how doctors practice medicine? "We don't think that it's good health care policy to legislate what the standard of care is," says Rebecca Hafner-Fogarty, M.D., M.B.A., president of the Minnesota Board of Medical Practice. "We would view this bill as the Legislature attempting to set a medical standard of care, and we think the people who should be setting that are in the medical community."

Marty says he understands the board's concerns and is trying to keep the scope of the bill narrow for that reason. "At some point, the medical community will come to consensus as to what is and is not appropriate treatment," he says. "At that time, we won't need things like this. But at this time, some are saying it's a settled matter and others are not, and we want well-trained, professional doctors to be able to use their best judgment."—**Kim Kiser**