

FALL-WINTER NEWSLETTER 2007

Tick-borne Infections



Council of North Carolina, Inc

Highlights...

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- **NC State Legislature Gives Money for Tick and Tick-borne Disease Education, Prevention, and Testing**
- **Lyme Disease Found by Vet School in Two Local Dogs**
- **President Bush's Lyme Disease**
- **A bioterrorism lab in Butner?**
- **Columbia University's Study on Chronic Lyme Disease Published**
- **Revisions to the National Surveillance Case Definition for Lyme disease and other tick-borne infections in effect January 1, 2008**

APPROPRIATIONS FOR TICK STUDIES, TESTING, AND OTHER ACTIVITIES

After 25 years of asking for funds Pest Management in the State Department of Public Health received recurring appropriations for tick studies and public education with the help of our organization, TIC-NC. We are now part of an Advisory Committee to help allocate the monies from the first budget item.

Appropriations:

Food Borne/Tick Borne Diseases

1. The governor recommends creating two positions for surveillance, public education, and participation in a demonstration project (in conjunction with DENR) associated with food borne and tick borne diseases.

Appropriation \$340,007 \$374,329

Positions 2.000 2.000

2. Expanded Public Health Lab Testing

The governor recommends funds to conduct tests for Human Papilloma Virus (HPV), food borne diseases, tick borne diseases, and additional HIV testing for pregnant women.

Requirements \$293,632 \$329,895

LYME DISEASE FOUND IN TWO LOCAL DOGS BY NC STATE SCHOOL OF VETERINARY MEDICINE

This summer one dog from Chapel Hill and one from Cary were found to have Lyme disease.(LD) Their tests were further confirmed at Cornell University. The dogs had never traveled away from home. The tick that carries the LD bacteria is known to be in this area as well as the bacteria. However, a study in 2005 in NC of hundreds of state dogs by the vet school did not find any LD except in a few that had traveled to New England. These two cases confirm that the LD organism is present in North Carolina and can be transmitted to warm-blooded mammals.

Bush Treated for Lyme Disease Last Year By JENNIFER LOVEN Associated Press Writer, August 8, 2007

WASHINGTON (AP) -- President Bush was treated for Lyme disease last August, the White House announced Wednesday after failing to disclose the problem for nearly a year.

The treatment was revealed only when the White House made public all the results of Bush's annual physical exam on Wednesday. It showed up in the "past medical history" section and in the summary along with other skin conditions. Bush was treated for what his doctors described as "early, localized Lyme disease" after developing the characteristic bullseye rash.

Lyme disease is a tick-borne infection that, if left untreated, can cause arthritis and other problems. Symptoms can include lethargy, joint pain, fever, limping and loss of appetite. A bacterial disease, it can be eradicated with antibiotic treatment in the early stages, but can become more complicated to treat if not caught early.

White House spokesman Scott Stanzel said Bush's treatment was not disclosed earlier because it happened after his last physical, on Aug. 1, 2006. He said doctors decided not to perform blood tests for Lyme disease because the treatment worked for the one area where the president experienced a rash, and he never progressed to other symptoms or saw a recurrence.

"It was a rash," Stanzel said. "It's not uncommon for the president to have tick bites when he's out biking."

The president's main form of exercise and recreational activity is biking. His doctors advised him to start wearing long pants and long-sleeved shirts and use bug spray in risk-prone areas such as Maine, where he is spending this weekend at his parents' coastal summer home.

Saturday, May 12, 2007

Bioterror lab could be built in N.C.

THE ASSOCIATED PRESS, RALEIGH

Homeland-security officials will visit a site in Butner next week to discuss a \$450 million biocontainment laboratory that is being pursued by North Carolina and 11 other states.

The proposed 520,000-square-foot facility, which could create about 300 lab jobs, will house researchers studying deadly pathogens that could be used in bioterrorism. Researchers also will study ways to protect U.S. livestock from foreign animal diseases.

The U.S. House authorized construction of the lab Wednesday as part of a \$39.8 billion funding bill for the Department of Homeland Security, but the Senate has yet to consider its version. The department has not said how much it will cost to operate the lab.

Other states competing for the lab are Texas, California, Georgia, Kansas, Oklahoma, Maryland, Mississippi, Missouri and Wisconsin. Kentucky and Tennessee are working together for one site in Kentucky.

The new lab would replace a facility on Plum Island, N.Y., and expand its research scope.

The proposed North Carolina site is the Umstead Research Farm in Butner, about 30 miles north of Raleigh.

A consortium of North Carolina universities, state agencies and private companies are advocating for the facility.

"We have expertise in veterinary sciences, we have medical colleges, research firms and long partnerships with federal agencies such as EPA," said Warwick Arden, dean of the College of Veterinary Medicine at North Carolina State University. "We also offer an attractive place to live." Ed note: In the past, ticks were researched at the Plum Island labs.

CLINICAL GUIDELINES MAY HAVE DUBIOUS ORIGINS

US clinical guidelines often influenced by industry, NEJM says Janice Hopkins Tanne, 1 New York

Many clinical guidelines for doctors in the United States are influenced by the pharmaceutical industry and special interest groups, said an article in the New England Journal of Medicine last week (2007;356:331-3). "The quality of guidelines varies considerably," and some are controversial, says a commentary by the journal's national correspondent, Robert Steinbrook. Meanwhile, the National Institutes of Health (NIH) cancelled a conference that it had planned on guidelines for screening pregnant women for herpes, after it received a protest letter from the Center for Science in the Public Interest. The organization's letter said that **four out of five of the speakers had undisclosed ties to drug firms** that made antiviral drugs (BMJ 2007;334:115).

The letter was signed by Richard Horton, editor of the Lancet; two former editors of the New England Journal of Medicine, Marcia Angell and Jerome Kassirer; 41 other physicians and scientists, including the head . . . [Full text of this article] <http://www.bmj.com/cgi/content/full/334/7586/171>

Columbia University Medical Center Leads First Placebo-Controlled Study of Cognitive Impairment Due to Chronic Lyme Disease

PRESS RELEASE Wednesday, Oct 10, 2007

MEDIA CONTACT: Elizabeth Streich (212-305-6535; cas2125@columbia.edu)

Findings Show Severe Physical Dysfunction Among Patients & Benefit of Repeated IV Antibiotic Therapy to Provide Long-Term Symptom Relief

NEW YORK – Findings from the first placebo-controlled study of chronic cognitive impairment after treated Lyme disease (also known as chronic Lyme encephalopathy) demonstrate that patients report moderate cognitive impairment, physical dysfunction comparable to patients with congestive heart failure, and fatigue comparable to patients with multiple sclerosis. In the study, repeated intravenous (IV) antibiotic therapy was shown to be effective in treating cognitive dysfunction and the debilitating pain, fatigue and physical dysfunction associated with this disease.

The study, titled "A Randomized, Placebo-Controlled Trial of Repeated IV Antibiotic Therapy for Lyme Encephalopathy," will be published on-line by the journal Neurology on Oct. 10, 2007. The study was led by Principal Investigator Brian Fallon, M.D., M.P.H., director of the recently established Lyme and Tick-borne Disease Research Center at Columbia University Medical Center (http://www.cumc.columbia.edu/news/press_releases/fallon_lyme_center.html). The research was conducted jointly at the Columbia University Medical Center and New York State Psychiatric Institute and was funded by the National Institute of Neurological Disorders and Stroke (NINDS).

"These findings replicate results from a prior placebo-controlled trial of post-Lyme fatigue, which found positive treatment results from repeated antibiotic therapy. They also replicate the degree of physical impairment results demonstrated in another prior study of chronic Lyme disease," said Dr. Fallon (*see citations below). "The door should be left open for physicians to prescribe medications as warranted, after a careful discussion with the patient of the potential risks and benefits." Dr. Fallon and his research team identified patients with cognitive problems that developed after being diagnosed with Lyme disease and which persisted or relapsed despite prior treatment, in order to determine whether patients who have already received the "standard" course of antibiotic treatment (three weeks of IV antibiotic therapy),

would benefit from an additional 10 weeks of antibiotic therapy. They also set out to determine whether patients relapse when taken off antibiotics or whether the alleviation of symptoms is sustained or enhanced with time.

Study participants (57 subjects: 37 patients with a history of Lyme disease and 20 controls) were divided into three subject groups: patients with a history of treated Lyme disease who were randomized to IV treatment with an antibiotic called ceftriaxone for 10 weeks; patients with a history of treated Lyme disease who were randomized to IV placebo for 10 weeks; and, healthy controls who were tested at the same time points as the patients to help to control for the practice effect on neuropsychological testing. All patients had to meet criteria for memory impairment at the start of the study and they were also required to have a positive IgG Western blot for Lyme disease at study entry.

Key findings from the Neurology paper are as follows:

Cognition

§ There was significantly greater improvement in cognition in the antibiotic treated sample at the primary end point for efficacy (week 12).

§ When patients were retested three months after antibiotic treatment, the initial gains in cognition for the ceftriaxone-randomized sample were no longer present.

§ Patients lose their cognitive improvement when IV antibiotic therapy is stopped.

Pain, Fatigue and Physical Dysfunction

§ Among patients with greater severity at the start of the study, those randomized to ceftriaxone had more significant symptom relief of pain, fatigue, and physical dysfunction at week 12, as compared to those patients who did not receive ceftriaxone.

§ Patients initially randomized to IV ceftriaxone who had greater severity of symptoms at baseline continued to show reduced pain and improved physical functioning at week 24. Improvement in fatigue continued, but was no longer statistically different from placebo at week 24.

§ Repeated IV antibiotic therapy is effective in improving cognition, and among the more impaired, in improving pain, fatigue, and physical dysfunction.

Safety

§ 18.9 percent of the 37 patients had serious adverse effects associated with either the IV line or a reaction to the antibiotic itself. Although all fully recovered, IV antibiotic therapy has the potential for serious risks, such as systemic infection, thrombus formation, or allergic reactions.

Clinical Recommendations

§ Repeated IV antibiotic therapy should be considered a valuable option with long-term benefit for managing the disabling symptoms associated with chronic Lyme disease.

§ Given the risks and benefits associated with IV antibiotic therapy, physicians and patients need to have a thoughtful discussion prior to initiating treatment.

Citations from Recently Published Research

§ The percentage of patients with meaningful improvement in fatigue noted at six months in this Neurology study (66.7 percent for patients treated with ceftriaxone vs. 25 percent for placebo) was comparable to the improvement in fatigue noted after repeated IV ceftriaxone therapy in a prior placebo controlled study (64 percent for drug vs. 18.5 percent for placebo) (Krupp et al., Neurology, 2003).

§ The degree of physical impairment (comparable to congestive heart failure) was comparable to the impairment noted in another chronic Lyme study (Klempner et al., NEJM, 2001). "Future research needs to focus on identifying a treatment approach that either allows not only for acute efficacy, but also long-term cognitive improvement; or, a treatment that could be given after the IV antibiotic therapy that would allow for sustained or enhanced cognitive improvement over time. Our Lyme and Tick-borne Disease Research Center continues to work towards finding these solutions," said Dr. Fallon. "The most important

lesson of this study is that physicians and patients need to collaborate openly to design an individual treatment plan to manage the long-term and complex suffering from symptoms of chronic Lyme disease."

Revisions to the National Surveillance Case Definitions for Tick-borne Infections. Matthew L. Cartter, MD, MPH, Epidemiology Program Coordinator Connecticut Department of Public Health

Revisions of reporting requirements for a number of infectious diseases went into effect on January 1, 2008. Tick-borne diseases include Rocky Mountain Spotted Fever, ehrlichiosis and anaplasma, Lyme disease, and Q fever. These revised TBI case definitions are available at: <http://www.cste.org/position%20statements/searchbyyear2007final.asp>.

Of particular interest are the changes in the reporting requirements for Lyme disease. In the past, all Erythema Migrans (EM) rashes were considered to be Lyme disease. Now only EM cases from endemic counties will be recorded. EM rashes in a county not classified as endemic will require a positive test. Endemic is defined as at least two confirmed cases which have been previously acquired or in which established populations of a known tick vector are infected with *B. burgdorferi*. These and other changes will affect reporting. The CDC feels that the changes will lead to more accurate numbers without overburdening counties. Others feel that they are more restrictive and will result in fewer cases being counted. In our opinion, further study is required to understand and document the effects of these changes.

Newsweek Article on Lyme Disease—August 2007

The Great Lyme Debate: Patients ache as doctors disagree about whether there is a chronic form of the tick-borne malady. By Mary Carmichael, Newsweek

Aug. 6, 2007 issue - There's a debate raging over Lyme disease, although you'd never know it unless you've been paying close attention—because on the surface it sounds like the dullest argument imaginable. Last year, the Infectious Diseases Society of America issued new guidelines saying physicians should treat Lyme with antibiotics for no longer than 30 days. Some docs think that's wrong. It's a seemingly straightforward difference of opinion. So why has the debate dissolved into animosity, with one side suggesting that its opponents have no credibility and the other slinging deeply personal insults on the Web? And why has it now spilled out of medical journals and into the office of a state attorney general? Clearly, something other than ticks is bugging a lot of doctors.

Lyme disease—the most common insect-borne ailment in America, with roughly 20,000 cases diagnosed each year and more undetected—is transmitted mostly by a well-known pest, the deer tick. But the real culprit is something even nastier, a bacterium called *Borrelia burgdorferi* that lives in the tick's gut. When *Borrelia* infiltrates the human body, it can cause a suite of distinctive symptoms, most notably a flulike feeling and a red rash like a bull's-eye. Sometimes, though, it causes no symptoms at all, and that's more dangerous, because the early signs are the only warnings doctors have. If Lyme is left undiagnosed and untreated, its consequences can be serious, including arthritis, meningitis, heart problems and inflammation of the brain. "The real secret," says Dr. Michael Zimring, director of the Center for Wilderness and Travel Medicine at Mercy Medical Center in Baltimore, "is to be able to recognize the disease early enough."

Zimring would know. Several years ago his wife felt fluish and came down with an oval-shaped rash. Zimring wasn't sure what she had, but "knowing our backyard is loaded with

ticks was enough," he says. He started his wife right away on one of the classic, effective antibiotics used to treat Lyme. When her medical tests came back, they proved him right. "I treated her for three weeks," he says, "and that was it. No problem."

Unfortunately, not all Lyme patients recover so easily. And that's what's at the heart of the debate—some docs think patients who are treated inadequately can develop a chronic form of the disease, while others deny that it's possible. Dr. Rafael Stricker, president of the International Lyme and Associated Diseases Society, believes in "chronic Lyme disease," and he says that in his clinical experience about 70 percent of patients with it get better if they're treated long term with the same drugs used to treat early infection. But the doctors who made the new IDSA guidelines on treatment say there's no such thing as chronic Lyme, because in most patients who complain of it, *Borrelia* isn't detectable in the body. Dr. Gary Wormser, who chaired the IDSA panel, prefers the term "post-Lyme syndrome." Treating that syndrome with high-dose antibiotics for months—as some physicians did before the new guidelines—can only hurt patients, he says. It can give them gallstones and infections and lead to antibiotic resistance while not curing anything. "The majority of patients treated for 'chronic Lyme' do not have post-Lyme," he says, "and in fact never, ever had Lyme disease at all."

This does not sit well with thousands of patients who believe they do have chronic Lyme and badly want antibiotic treatment for it. "The IDSA is basically saying to them, 'We're right, you're wrong, we don't want to listen to you, just take some antidepressants and go away'," says Stricker. The IDSA is a highly respected group of doctors. But it's facing formidable opposition, not just from Stricker's group (and angry patients who've taken to Internet message boards) but also from the attorney general's office in Connecticut, the state with the country's highest incidence of Lyme disease. A.G. Richard Blumenthal has launched an investigation of the IDSA panel, looking into whether it ignored any research that would support long-term antibiotic treatment (the guidelines cite more than 400 studies). "Our question basically is whether the guidelines were formulated through a process that was proper, without self-interest or conflicts of interest," Blumenthal says, noting that some of the panel members have financial interests in treatments and vaccines. Blumenthal also worries that the new guidelines might be used by insurance companies looking to avoid paying for Lyme drugs. The investigation is at "an important juncture," he says.

Meanwhile, Wormser is baffled. "How could the interests of the patient be served by treating with unnecessary and potentially dangerous therapies?" he says. "The guidelines represent the best that medical science has to offer." The question, then, is whether that's good enough. © 2007 Newsweek, Inc.

RHODE ISLAND'S CENTER FOR VECTOR-BORNE DISEASE HAS RECEIVED \$100,000

SOUTH KINGSTOWN — A private foundation has donated \$100,000 to the University of Rhode Island's Center for Vector-Borne disease, university officials announced yesterday.

The money will support the center's public health education program for preventing tick bites and Lyme disease, according to a university statement.

URI plans to expand the center's tick education Web site, www.tickencounter.org, adding animations to illustrate appropriate bite-prevention strategies and a tool to calculate a person's risk of being bitten.

Tick-Borne Infections Council of North Carolina is a non-profit organization formed to improve the recognition, treatment, control, and understanding of tick-borne diseases in North Carolina. We are all-volunteer and appreciate donations.

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