LYME DISEASE SURVEILLANCE SUMMARY

BACTERIAL ZOONOSES BRANCH
DIVISION OF VECTOR-BORNE
INFECTIOUS DISEASES
CENTER FOR INFECTIOUS DISEASES
CENTERS FOR DISEASE CONTROL

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NATIONAL LYME DISEASE REPORTING VIA NETSS

Lyme disease became a nationally notifiable disease beginning January 1, 1991. Through the 11th week of this year, a total of 564 cases of Lyme disease (Figure 1) have been reported by 22 states to CDC via the National Electronic Telecommunications Surveillance System (NETSS). Most of these 22 states are reporting "core" data only (i.e., basic demographic data and a disease code) on each Lyme disease case. In addition, a few states (e.g., Georgia, New York, Missouri) have had software installed which allows them to enter "extended" data via NETSS. "Extended" data are disease-specific, which for Lyme disease can be either the data contained on CDC's Lyme Disease Case Report Form or similar forms customized for individual states. "Extended" Lyme disease data supplied to CDC via NETSS will obviate the need to submit written report forms or case reports on diskette. In addition, states eventually will be able to electronically access this national database for their own purposes.

The Division of Surveillance and Epidemiologic Studies, Epidemiology Program Office (EPO), CDC, is helping states establish the capability to enter "extended" disease-specific data. Site visits by EPO personnel to some states are already scheduled for this purpose. The completion of this project may take as long as 2 years, although many states will have the appropriate software installed within the next several months. For further information on NETSS, please contact Norma Gibbs (404-639-3761) or Robert Fagan (404-639-2709) at EPO, CDC in Atlanta.

NATIONAL LYME DISEASE IN PREGNANCY REGISTRY

Gestational Lyme disease and its effect on the fetus continues to be controversial. Few scientific studies have been reported and many basic questions, including magnitude of risk, remain to be answered. CDC plans to contract for a new epidemiologic study of this issue in the current fiscal year. In addition, CDC is encouraging clinicians to register their Lyme disease patients who are pregnant. The National Lyme Disease in Pregnancy Registry was established in 1985 (MMWR 1985;34:376-384). The registry is anonymous. The essential requirements for registration are a brief clinical history and information on the resulting birth outcome. Culture media and shipping costs will be supplied by CDC for the collection of clinical samples related to adverse birth outcomes. For more information, or to register patients, please contact Dr. Roy Campbell at (303) 221-6474.

MALARIA THERAPY FOR LYME DISEASE

Deliberate infection of patients with malaria parasites (malaria therapy) was widely used in the early part of this century to induce fever as a treatment for a number of illnesses. The suggestion that malaria therapy might be useful for the treatment of Lyme disease is based on the obsolete practice of malaria therapy for neurosyphilis. A review of the literature suggests that the effectiveness of malaria therapy for neurosyphilis was variable and unpredictable. Therapeutic trials were not carried out following strict scientific guidelines, thus making it impossible to compare treatment outcome among individual patients or among reported series of cases. Most importantly, the advent of effective antibiotics eliminated the need for alternative therapies.

Malaria infection has recently been tried for treating persons with late-stage Lyme disease. An article published in the Morbidity and Mortality Weekly Report (MMWR), 1990;39:873-875) reports on the use of malaria therapy in Lyme disease and recommends against it. The CDC position is based on the following concerns: (1) No controlled studies have been conducted demonstrating the effectiveness or safety of malaria therapy in treating patients with Lyme disease; (2) there are substantial health risks to the patient treated in this manner, including the potential for severe illness and death associated with malaria infection itself and risks for acquiring illnesses such as hepatitis B and AIDS from being inoculated with contaminated blood; (3) there is a small but definite risk of mosquito-borne malaria transmission within the United States from patients entering the country with malaria.

CDC does not support the research evaluation of any therapeutic modality that does not follow established safeguards and currently is not aware of the existence of any approved research protocols for the experimental use of induced malaria in the treatment of Lyme disease. According to the Declaration of Helsinki for the protection of human subjects in medical research, and as adopted at the 29th World Medical Assembly in Tokyo in 1975, the design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted to a specially appointed independent committee for consideration, comment and guidance. The type of clinical research exemplified by the experimental use of malaria therapy in patients would normally require approval by the Food and Drug Administration for the use of a new therapeutic approach, institutional review board (committee for the protection of human subjects) clearance, informed patient consent, strict precautions against inducing infection with blood-borne pathogens other than malaria parasites, and monitoring of the course of illness in a hospital setting.

CDC supports appropriately conducted research on diagnosis and treatment of Lyme disease, but is concerned with the public health implications of purposeful induction of malaria infection.

UNITED STATES NATIONAL TICK COLLECTION

The World's largest tick collection, representing 90% of all known tick species, has been established at the Institute of Arthropodology and Parasitology at Georgia Southern University in Statesboro, Georgia, under the direction of Dr. James H. Oliver, Jr. The collection, which is the property of the Smithsonian Institution, is on a long-term collection enhancement loan to the University. The costs of moving, operations and staffing for the collection are provided by a five-year grant awarded from the National Institute of Allergy and Infectious Diseases. Dr. James E. Keirans, an authority on tick classification, continues as curator for the collection and has joined the Georgia Southern faculty.

The collection originated as a result of research on Rocky Mountain spotted fever in the Bitterroot Valley of Montana. U.S. Public Health Service Researchers studying the cause of spotted fever began collecting local tick species. By the outbreak of World War II, species had been collected from all over the U.S., Canada and Mexico. During that war, researchers serving in the U.S. military all over the world sent specimens back for the collection. In the following years, the Montana collection has been combined with that of the Smithsonian and the extensive international collection of the late Dr. Harry Hoogstraal (who worked at the Naval Medical Research Unit in Cairo, Egypt) to form the National Tick Collection.

Over 300 type specimens are available for study at the Georgia Southern facility. This facility contains laboratories, a tick reference library and conference room, preparation rooms, and staff offices. The collection can now house live specimens as well as preserved materials and is more accessible to researchers than in previous locations.

CONCERNS ABOUT LYME DISEASE VACCINE FOR CANINES

During February 1991, the National Association of State Public Health Veterinarians (NASPHV) sent a letter to the United States Department of Agriculture outlining the Association's concerns about scientific issues related to the recent approval for marketing of a canine vaccine for Lyme disease. The issues raised included the following:

- The company's nationwide advertising campaign is misleading. It is not made clear that this is a provisionally licensed vaccine for which safety and efficacy data are incomplete. Ads state that Lyme disease is found in 44 states without distinguishing between areas of high endemnicity and areas where it is rarely diagnosed. Furthermore, no distinction is made between imported and native cases. Reference to transmission via body fluids is based on limited experimental data and is overstated in the informational brochure supplied by the pharmaceutical company. The unsubstantiated implication is that the canine vaccine will indirectly protect human health.

- The testing protocol and unpublished data provided to the scientific community by the company are not sufficient to evaluate the efficacy of the vaccine, especially

under conditions of natural challenge. Much information and data are claimed as proprietary, thus unavailable for verification and challenge by colleagues in the scientific community.

- Use of the vaccine may give people a false sense of security and result in less emphasis on vector control and other public health measures which provide significantly greater protection to the public.

- There is a clear need to properly evaluate the vaccine, but no plan apparent to do so. In essence, NASPHV members feel that an uncontrolled field trial is being conducted at the expense of the pet owners.

- The use of canine serosurveys as part of the surveillance for Lyme disease may be precluded by the widespread use of this vaccine. This is of particular concern in transitional areas where Lyme disease is not endemic and public health officials are maintaining vigilance for the spread of Borrelia burgdorferi.

- The package insert recommends annual boosters, although the challenge trial was apparently done at 156 days. There was no documentation that immunity will last a year.

- If demyelination and arthritic consequences of Lyme disease are immunologically mediated, might the vaccine produce similar problems over time?

Editorial Note: Transmission of Lyme disease to humans by body fluids of humans or animals has not been established in the scientific literature, and we know of no data which suggest that prevention of Lyme disease in dogs by a vaccine would prevent human Lyme disease cases. Claims by the vaccine manufacturer of direct dog-to-dog transmission in one of its study populations have yet to be published. The issues raised by NASPHV make it clear that substantial questions remain about the efficacy and safety of this canine vaccine in the prevention of Lyme disease in dogs.

Lyme Disease Surveillance Summary (LDSS) is edited by Drs. Robert Craven and David Dennis. If you have information to contribute or wish to receive a LDSS, please contact them at:

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FIGURE 1
REPORTED LYME DISEASE CASES, U.S., 1991