

Report of the Lyme Disease Subcommittee of the
Maryland Vector-Borne Disease Interagency Task Force
to the Maryland Department of Health and Mental Hygiene

**Recommendations for the Development of a Strategic Plan for
Lyme Disease Prevention and Control in Maryland**

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Introduction

A relatively new but rapidly growing body of knowledge about Lyme disease (LD) has emerged in recent years. Human Lyme disease was first recognized in 1977 with the identification of similarities in cases of juvenile rheumatoid arthritis in Lyme, Connecticut. It was recognized that the rash resulting from an insect/arthropod bite was associated with later symptoms of other organ systems, and, in particular, with arthritis, and was experienced by people who lived where animals were more likely to be found carrying *Ixodes scapularis* ticks, the vector commonly associated with LD. By 1981, a scientist named William Burgdorfer along with colleagues had identified a spiral-shaped bacterium found both in the midgut of *Ixodes scapularis* and in skin lesions and body fluids of LD patients.

Lyme disease is responsible for significant morbidity in the population and imposes a considerable financial and social burden on society. The Immunization and Infectious Diseases section of Healthy People 2010, refers specifically to the public health issues represented by Lyme disease (LD):

*The direct and indirect costs of infectious diseases are significant. ... **A typical case of Lyme disease diagnosed in the early stages incurs about \$174 in direct medical treatment costs. Delayed diagnosis and treatment, however, can result in complications that cost from \$2,228 to \$6,724 per patient in direct medical costs in the first year alone.** " ¹*

LD is the most commonly reported tick-borne illness in Maryland and in the United States. In 2005, Maryland reported an incidence of 22.1 cases per 100,000 population compared with a nationwide incidence of 7.9 cases per 100,000 population. The disease burden of LD is clustered in the northeast and north-central regions of the US, and 2005 incidence rates in some states have been observed to be as high as the Delaware rate of 76.6.

The rise in prevalence of LD depends upon many elements, such as the ecological factors maintaining the propagation of the *Ixodes* vector and the increased exposure to humans, as well as the enactment of a mandatory reporting statute. The geographic distribution of the *Ixodes* vector is maintained primarily by mammalian hosts: with mice as the host in the tick's early developmental stage, and deer as the host during the mature late stages of development. The increased risk of LD to humans is linked to the rise of residential development in semi-wooded areas inhabited by increasing populations of mice and deer, as well as increased outdoor recreational activities.

This report represents the work of the Lyme Disease Subcommittee of the Vector-borne Disease Interagency Task Force and was written in advance of the commitment of funding. Additional efforts are needed to develop strategic and operational plans. The implementation of the various plan objectives can proceed only to the extent that new funding is appropriated for this purpose.

History of Lyme Disease in Maryland

The Centers for Disease Control and Prevention (CDC) initiated systematic surveillance of LD in 1982 in 11 states, and by 1988 nearly all states were reporting LD cases. During 1982-1988, the numbers of reported LD cases increased steadily as active surveillance captured a truer incidence rate.

The Maryland Department of Health and Mental Hygiene (DHMH) received the first patient report of LD in 1985. With changes to the Maryland disease reporting regulations, it became a formally reportable disease for Maryland providers in 1989. Statute changes in 1996 required laboratories to also report LD test results.

The following table shows the annual numbers of confirmed LD cases in Maryland during the last sixteen years:

Year	1990	'91	'92	'93	'94	'95	'96	'97	'98	'99	2000	'01	'02	'03	'04	'05
Cases	238	283	185	207	343	336	423	494	659	899	688	608	738	691	891	1235

The 1,235 confirmed cases in 2005 represent a sizeable increase when compared to the numbers of confirmed cases documented in previous years of Maryland LD surveillance. While this increase may be attributable to improved surveillance, heightened public awareness and better informed health care professionals may have also contributed to the rise in the number of confirmed cases.

Vision of Maryland's Lyme Disease Program

Our ultimate goal is to develop an integrated public health program that reduces the incidence of Lyme disease and strengthens control measures, as evidenced by the following:

- LD is recognized as an ongoing health hazard to human beings that needs to be better understood and prevented. However, it is recognized that the causative agent of LD and its vectors are well established in the environment. Although their total elimination is not feasible, mitigation is possible. In the absence of a vaccine, public education about tick avoidance and control and disease management at the early signs of LD must be emphasized. Cooperation among public health, healthcare organizations, and patient support and advocacy groups will be needed to ensure that the messages about LD reach the widest possible audience. Research into effective vector control methods will be encouraged to support prevention recommendations.
- Within public health in Maryland, responsibility for LD will include not only communicable disease and veterinary public health programs, but also chronic

disease prevention programs, minority disparity elimination programs, cardiovascular disease prevention programs, and professional licensing boards, and others, to provide an integrated, comprehensive LD program for the State.

- Health care research on LD advances to the point where there is strong scientific support for regimens to manage all stages of LD, and, in particular, the stage(s) characterized by ongoing symptoms after antimicrobial treatment.
- Healthcare providers and provider associations will be aware of recent recommendations about LD clinical diagnosis, the possible role of laboratory testing, if indicated, would use appropriate antibiotics if needed, and would counsel patients about risk factor reduction and later stages or consequences of LD.
- Healthcare providers and consumers will be informed about the various approaches to management of LD treatments, and the therapeutic approach chosen for each care plan would meet the provider's accepted standard of care as well as the patient's need to provide informed consent.
- Healthcare providers will report all LD-like illnesses promptly to local health department communicable disease staff, and respond to requests for follow-up information from public health investigators. A Case Report Form is available online to all healthcare providers and contains links to professional-level LD information.
- Public health staff members at local health departments will investigate every case of LD received, and analyze the epidemiologic characteristics of any LD report which is not "confirmed" by the public health case definition.
- A system to provide real-time information about LD reports in Maryland will be available to the public. Using this information, a geographic information system can be used to highlight high-risk areas in the State.
- Maryland residents will use appropriate personal protection techniques to prevent tick contact, and to look for and locate ticks on the body before they become embedded. Maryland residents will know the early signs of tick-related diseases, and will promptly seek healthcare attention and if needed, treatment. An interactive program geared to young children (5 - 8 years of age) and to their parents will be developed to provide key LD prevention messages.
- Harm reduction programs will be developed, based on survey research among households in high-risk areas, to educate the public and physicians about LD manifestations that may occur months to years after initial infection, and about medical evaluation techniques.
- Land use planning for future residential development in Maryland should include considerations to reduce interactions among people, companion animals and potential vectors of LD.

Maryland Public Health: Strengths, Challenges, and Opportunities

Maryland's public health system currently consists of a health department structure established at both the State and local level. Each of the 24 Maryland jurisdictions (23 counties and the City of Baltimore) maintains a full service health department to focus on disease prevention and health promotion, with particular focus on the challenges to public health in that jurisdiction.

Each local health department is staffed by a local health officer and a professional staff that includes epidemiologists, sanitarians, and communicable disease professionals, who implement Maryland regulations, policies and guidelines for disease investigation and control. These requirements are consistent with the recommendations of the national communicable disease authorities, such as the Centers for Disease Control and Prevention (CDC) of the United States Public Health Service, and also with Maryland statutes.

Strengths

Current strengths of Maryland's Lyme disease program at the State and local levels include:

- A strong organizational support system through the Center for Veterinary Public Health within the DHMH Office of Epidemiology and Disease Control Programs.
- Trained public health epidemiologists who regularly provide consultation to local health department staff members.
- An informative Maryland Lyme Disease Web page that features general LD information, educational resources, and statistics about LD in Maryland as well as links to related LD sites.
- A standardized case investigation and classification process, based on the CDC case definition for LD.
- An automated disease database that is utilized to collect and track information about LD and other communicable diseases reported in the State.
- Adherence to the statutory requirement for LD reporting by medical laboratories, and to regulations requiring reporting by physicians and healthcare facilities.
- Partnerships and support from various groups, including other State government agencies, academic centers, medical providers, and LD advocacy and patient support groups in Maryland.
- A well-established continuing education program provided by major medical and nursing educational facilities throughout the State.

Challenges

Current challenges relating to Lyme disease at State and local public health agencies and related health/healthcare organizations in Maryland:

- Rising LD activity in several regions of Maryland and in other States in the Mid-Atlantic region (especially Pennsylvania, Delaware, and New Jersey).

- Staffing shortages in some local health departments that severely limit the investigation of reports of Lyme disease.
- A widening disparity between the increasing volume of requests for DHMH consultation and assistance with communicable disease issues and the limited number of DHMH staff available to handle these requests.
- A functional yet developing surveillance system for LD in Maryland.
- Limited provider awareness about proper reporting and follow up with local public health investigators.
- Limited patient knowledge and awareness in seeking early screening and prompt treatment for tick-borne illness.
- Frequent difficulty in clinical recognition and laboratory assessment of LD, due to absence of typical LD clinical signs at presentation, or presentation with late LD symptoms.
- Varying approaches within the medical community regarding best practices for the treatment of LD due to the absence of a consensus.
- Provider reluctance to treat patients for LD due to concerns about licensing penalties or adverse legal actions.
- Absence of federal support for LD surveillance programs and research studies in Maryland, coupled with funding cutbacks for other communicable disease control efforts.
- Property development and expansion in rural areas of Maryland that places people in close contact with LD vectors.

Opportunities

Current opportunities include:

- Strong interest of LD patient support and advocacy groups to enhance Maryland's response to LD challenges.
- Heightening public awareness of the advantages of health protective behaviors when engaged in outdoor activities.

Maryland Lyme Disease Subcommittee

DHMH recognized the potential benefits of enhanced collaborative efforts by multiple disciplines in Lyme disease control and appointed a Lyme Disease Subcommittee of the Maryland Vector-borne Disease Interagency Task Force in 2005. Diverse representatives from various State agencies with a professional interest in this disease, as well as from Lyme disease advocacy groups whose primary mission is to aid those persons infected with Lyme and other tick-borne infectious diseases, and medical and public health professionals in related areas, participated. All were brought together to discuss and clarify the burden of Lyme disease in our State, and to draft recommendations for the development of a strategic plan for LD prevention and control.

The LD subcommittee identified six topic areas of particular interest, and it was divided into six Topic Area Groups (TAGs) accordingly. Each topic area was reviewed, and recommendations were made for enhancing the public health response to LD in Maryland. The subcommittee's topic areas included:

1. Surveillance: Monitor and investigate LD disease in Maryland.
2. Ecology: Review human host behavior, the agent of Lyme disease and its direct and indirect vectors, and the environment in which they all interact. Mobilize community partnerships and actions to identify and solve health problems.
3. Public Awareness and Provider Education: Inform and educate the public and medical providers about the causes and risks of LD.
4. Diagnosis: Ensure competence of public and private health care providers and availability of laboratory testing services.
5. Treatment: Link persons seeking assistance with sources of information and personal health care services.
6. Public Policy: Develop policies and plans that support individual and community health efforts. Enforce applicable laws and regulations. Evaluate and assure quality of health care services. Support research to better understand the causes of LD and evaluate the effectiveness of proposed interventions.

Responses to Challenges/Problems Associated with Lyme disease in Maryland

Surveillance: The LD Subcommittee reviewed the status of surveillance of LD and other tick-borne diseases in Maryland.

The following major weaknesses were identified:

- Inconsistent LD case investigation by local health departments in all jurisdictions;
- Ruling out LD prematurely based on incomplete case investigations;
- Problems with physician compliance with local health department requests for additional information;
- Lack of physician understanding of the similarities and differences between the public health LD case definition and the clinical assessment criteria for the disease;
- Lack of feedback to physicians about LD distribution in Maryland; and
- No requirements in law or regulations to report certain other tick borne communicable diseases to public health agencies in Maryland (example: Bartonellosis).

Recommendations for DHMH:

- Add "Southern tick-associated rash illness (STARI)" and "Bartonellosis" as reportable conditions or diseases. Add the term "Anaplasmosis" as a separately listed reportable disease. Change the currently reportable disease group

"Ehrlichiosis" to "Human monocytic ehrlichiosis" [affects Maryland Annotated Code Health General18-205; COMAR 10.06.01.03.].

- Review DHMH and local health department case investigation procedures and practices, including the Maryland LD Case Report Form.
- Assess the need to modify existing case report forms to include additional symptoms, test results, risk factors or exposure history relevant to the more common agents known to co-infect individuals with LD; and
- Identify and remove barriers to appropriate reporting and case investigation of LD and other tick-borne diseases or conditions.

Several LD Subcommittee members recommended that better definitions of federal surveillance case criteria and diagnostic criteria should be made available to health professionals. This recommendation is included under the Public Awareness and Provider Education or Public Policy sections below.

Ecology: This group reported that expanded research and evaluation in this topic area was needed, particularly in areas of vector control, deer population growth, community development and land use planning. The group discussed the possible use of additional educational resources, such as the Connecticut Tick Management Handbook.² Several LD Subcommittee members expressed interest in seeing ongoing discussion of the above topics as well as related topics including tick abundance and personal and professional tick management systems. The group also suggested an expansion of local health department field surveillance efforts to quantify tick vector densities.

Recommendation for DHMH:

Promote research to develop more effective environmentally based control strategies and to promote a better understanding of environmental risk factors for LD among the public health, natural resources, and agricultural communities.

Public Awareness and Provider Education: This group discussed existing efforts in Maryland to educate and inform health professionals and the public about LD.

The following needs were identified:

- Improved physician awareness about Lyme disease diagnosis and treatment options; and
- Patient awareness of Lyme disease early signs and the need for prompt evaluation, especially among minority populations or groups with limited healthcare access.

There was considerable discussion about the best strategies to use for continuing education of physicians and the expected roles and responsibilities of physicians and patients in interpreting medical information. Several members of this group offered examples of educational documents regarding education and prevention issues. The group also discussed the importance of tailoring LD education information to minority populations.

Maryland state health officials provided formal information to medical providers about Lyme disease through a LD surveillance update posted on the Web site of the Medical and Chirurgical Faculty of Maryland (MedChi) in November 2005 at www.medchi.org.

DHMH also recognizes the importance of training public health students in the control of vector-borne diseases. PHASE students from the Johns Hopkins University Bloomberg School of Public Health assisted with the development of educational materials to promote awareness of LD in summer recreational and camp programs.

A Lyme disease and tick ecology educational training session was presented by a DHMH/EDCP epidemiologist to camp inspectors and students. The training presentation and other resources were subsequently made available to DHMH camp inspectors. Educational material was uploaded to the Web site of the Division of Community Services, the DHMH unit which regulates youth camps in Maryland. This Web site serves as a regular source of information and communication for camp counselors and directors.

The annual Zoonotic Disease Update conference coordinated by the Office of Epidemiology and Disease Control Programs (EDCP), Center for Veterinary Public Health serves as another vehicle for disseminating LD information to local health departments. The June 13, 2006 conference included a presentation entitled "Lyme Disease: An Educational Initiative" by Anne Arundel County Health Department officials, and "Tick-borne Rickettsial Diseases" by an EDCP staff member.

Recommendations for DHMH:

- Update the statistical information on the Lyme Disease page on the EDCP Web site (http://www.edcp.org/vet_med/lyme_disease.html), access to downloadable educational materials for health care providers and school-aged children, and links to other Web sites for additional resources.
- Develop an educational flyer targeting school-aged children.
- Promote provider education via information sharing on Continuing Medical Education opportunities.
- Continue LD educational programs for staff of local health departments to maintain their knowledge and skill levels.

Diagnostic Best Practices and Treatment Guidelines:

This group discussed major areas of discordance relating to:

- Establishing a standard of health care for LD, and
- Meeting the standard of health care for LD.

These two TAGs (Diagnosis and Treatment) confronted some of the most difficult aspects of LD surveillance and control: clinical and laboratory diagnosis and clinical management of the disease.

A. Diagnostic methods:

The CDC case definition of Lyme disease, which describes clinical symptoms supported by a positive laboratory test, is used for national LD surveillance. CDC recommends a two-tiered testing protocol of an enzyme-linked immunosorbent assay (ELISA) and Western blotting in the presence of a characteristic clinical picture of Lyme disease. These test results are interpreted according to criteria established by the CDC/Association of State and Territorial Public Health Laboratory Directors.

The difficulty in culturing the LD spirochete (spiral-shaped bacterium) coupled with shortcomings in laboratory testing procedures and many different manifestations of LD often lead physicians to rely indirectly on serological (blood serum) tests to support the clinical presentation of LD. Diagnosis based on blood tests is insensitive early in the infection: it does not differentiate between new and old infections, or between persistent infection and re-infection of Lyme disease, and it is not predictive of the efficacy of antibiotic therapy during the course of treatment. Problems have also arisen concerning the standardization and reproducibility of the results obtained through such serological assays.

Recommendations for DHMH:

- State health officials should encourage research aimed at improving the sensitivity and specificity of existing diagnostic methods, along with the development of a rapid, sensitive and specific diagnostic test to distinguish actively infected individuals from those who were infected in the past. This will be a significant advance for Lyme disease diagnosis. Such a test is needed especially for patients who present with symptoms like fatigue, muscular or neurological aches and pains, and cognitive difficulties that are associated with Lyme disease but are not unique to this infection.
- Remind providers that the CDC surveillance case definition is developed for national surveillance and reporting purposes and is not intended to substitute for the physician's sound clinical judgment.

B. Treatment:

The subcommittee discussed several guidelines currently used by medical practitioners to determine the best treatment approach for LD. The subcommittee recognizes that there is wide variation in treatment options.

Treatment guidelines have been issued by the Infectious Diseases Society of America (IDSA)³ and by the International Lyme and Associated Diseases Society (ILADS).⁴ These two sets of guidelines represent examples of the variety of resources and guidance used by individual providers in formulating individual care plans for their patients.

- IDSA guidelines offer information on the full spectrum of disease, but with respect to antibiotic use, limit treatment to 10 to 28 days, with a possible second

course in some cases. IDSA guidelines consider “antibiotic-refractory Lyme disease” to be best approached with symptomatic therapy.

- ILADS guidelines focus on the treatment of all stages of disease, with emphasis on “persistent, recurrent and relapsing symptoms of *B. burgdorferi* infection,” and include use of prolonged or repeated courses of antibiotics.

In addition to differences in the use of medications for patients with ongoing manifestations of LD symptoms, these guidelines vary in their reliance on laboratory diagnostic tests, diagnosis and treatment of other tick-borne co-infections, and their use of complimentary or supportive therapies including diet, probiotics, vitamins and other supplements, physical therapy, joint infusions, surgery, and acupuncture.

Presentation of recurrent infection or late or persistent symptoms in Lyme disease can be identical or similar to that of other multisystem disorders. Issues concerning management of patients with recurrent or persistent symptoms demonstrate that the practice of medicine is not an exact science. A need exists for the medical community to improve its understanding of approaches to addressing the complications of Lyme disease.

A consensus was reached that considerable scientific work remains to be done in order to clarify the best approach to treatment uncertainties and that continuing discussion is needed on all aspects of the Lyme disease spectrum.

A consensus was also reached that providers and patients would be well served by open discussions of treatment options before venturing into the more controversial aspects of LD care. Providers will benefit from opportunities for patients to advise them of their understanding of the disease process and their possible preference for a particular option. Patients should be encouraged to solicit information and answers to their questions and either agree to the treatment as offered or state their interest in identifying a provider with a different approach. Although ideally the provider and patient would reach consensus of opinion on a course of treatment, it is unlikely that this will happen in each instance. Providers are encouraged to document in the patient record the discussion of options, the rationale for recommended therapy, and the patient’s concerns and/or agreement with the provider’s recommendations.

The subcommittee made no recommendation concerning either of the two treatment guidelines discussed above.

Recommendations for DHMH:

Ultimately, it was recommended that DHMH and its partner agencies enhance provider and patient education in the following areas:

- Primary care providers in endemic areas should be familiarized with all aspects of this disease and should understand both the characteristics and limitations of the laboratory tests commonly used to diagnose Lyme disease.

- Primary care providers should be made aware of challenges in the clinical recognition of the erythema migrans rash and its varying manifestations in ethnic and minority patients.
- Patients and providers should be made aware of and should communicate about available treatment options; physicians should exercise clinical discretion and should individualize medical decision-making.

Public Policy Issues:

A public policy topic area group was not assembled. However, the subcommittee members discussed related public policy issues. Concern was raised that the Maryland Board of Physicians would follow the lead of similar agencies in several other states in which legal action was initiated against providers who chose to practice according to ILADS guidelines. In its Fall 2005 Newsletter⁵, the Board clarified that:

- It does not target or restrict the treatment of LD.
- It does not support the concept of “immunization” of any physician from scrutiny because of the particular disease, patients treated or location of practice.
- The Board does not create, promulgate, or endorse in advance specific guidelines regarding any disease state.

Summary

This document reviews the background and historical information about Lyme disease in Maryland. A vision of a more comprehensive approach to preventing the disease is presented along with the current picture of Maryland’s public health strengths, challenges, and opportunities for combating LD. The efforts of the LD Subcommittee are presented in the topic areas of surveillance, ecology, public awareness and provider education, diagnostic best practices and treatment guidelines, and public policy issues along with specific recommendations. These recommendations address: 1) enhancements to surveillance for LD and other tick-borne illnesses for a more accurate portrayal of the burden of disease in Maryland, 2) public education about tick population control and the need for additional research on the effectiveness of certain host control measures, 3) increased information sharing for the public and providers to enhance easy access to current diagnostic and treatment information, and 4) availability of educational materials and programs for school-aged children and campers. The recommendations also support heightened awareness by providers and patients of the spectrum of treatment approaches, increased provider-patient communications, as well as prompt evaluation, early recognition and treatment of LD signs and symptoms. Greater clarification to providers is needed about the role of licensing entities (e.g. Maryland Board of Physicians) in regulating practice and licensing matters. Taken together, these recommendations form the basis for the strategic approach to be taken by DHMH, partner agencies and providers, individuals and organizations on collaboratively achieving enhanced LD prevention and control programs in Maryland.

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