



*Commonwealth of Massachusetts*

# Lyme Disease in Massachusetts

**A Report Issued by the Special Commission  
to Conduct an Investigation and Study of the  
Incidence and Impacts of Lyme Disease**

**February 28<sup>th</sup> 2013**

## **Members of the Commission**

Commissioner of the Department of Public Health	.	Dr. Catherine M. Brown (Designee)
Commissioner of the Division of Health Care Finance & Policy	.	Ms. Jen Gorke (Designee)
Director of the State Laboratory Institute.	.	Dr. Linda Han (until 9/13/2012)
House 1	.	Representative David P. Linsky
House 2	.	Representative Carolyn Dykema
House Minority Leader's Appointment	.	Representative Bradford R. Hill
Infectious Disease Specialist	.	Dr. Sam T. Donta
International Lyme and Associated Disease Society	.	Dr. Sheila Statlender
Local Board of Health 1.	.	Dr. Louis E. Fazen
Local Board of Health 2.	.	Ms. Joanne Martel, RN
Local Board of Health 3.	.	Dr. Barbara Roth-Schechter
Lyme and Other Tick-Borne Diseases Organization 1	.	Ms. Patricia McCleary
Lyme and Other Tick-Borne Diseases Organization 2	.	Ms. Brenda J. Boleyn
Public 1 (Patient or Family Member of Patient) – Senate	.	Ms. Kristen Alexander
Public 2 (Patient or Family Member of Patient) – House	.	Ms. Lisa Donahue
Senate 1	.	Senator Susan Fargo
Senate 2	.	Senator Daniel A. Wolf
Senate Minority Leader's Appointment	.	Senator Richard J. Ross
State Epidemiologist	.	Dr. Alfred DeMaria Jr.
Treatment or Research of Lyme Disease Expert 1	.	Dr. Sam Rountree Telford III
Treatment or Research of Lyme Disease Expert 2	.	Dr. Thomas N. Mather

**Massachusetts House Post Audit and Oversight Committee Staff**  
Katelyn Kelly

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## **EXECUTIVE SUMMARY**

In accordance with Section 181 of Chapter 68 of the Acts of 2011, the Commonwealth of Massachusetts established the Special Commission to Conduct an Investigation and Study the Incidence and Impact of Lyme Disease. The twenty-one member Commission was comprised of individuals from a wide variety of backgrounds and was put in place in order to provide the most comprehensive overview and insight into the various issues that surround this disease. The members ranged from state legislators and state agency representatives to experts in treatment and research to members of the public and Lyme disease activists. Upon the formation of the Commission the members broke into five sub-commissions; State Surveillance and Reporting, Education and Awareness, Funding, Prevention, and Insurance and Liability Issues in order to address all tasks issued to the Commission under the Massachusetts General Acts of 2011. The sub-commissions met on a regular basis and the full Commission came together once a month to discuss each group's findings. The following is a compilation of each sub-commission's report and it presents an overview of the Commission's findings and recommendations for the state to enact and enforce in order to ensure that the Lyme disease epidemic is controlled and that future infections can be prevented.

The Commission discovered that the current state laboratory reporting is an obvious strength for statewide surveillance in helping to gain a better idea of trends across the Commonwealth. However, it fails to capture reports of Lyme disease for which laboratory testing is not routinely reported or is not performed at the appropriate stage of the disease. The Commission believes in the importance of enhancing current Lyme disease surveillance methods in order to better determine disease burden, geographic distribution, risk groups, clinical features, and changes in epidemiology over time, which then can be translated into data to assist the Massachusetts Department of Public Health (MDPH) in targeting high-risk areas. The recommendations of the Commission include evaluating the current laboratory-reporting practices in order to gather more pertinent information surrounding the disease by updating the current forms, as well as updating the reporting systems to an electronic format in order to provide more easily presented and accessible data. Having school nurses provide surveillance information regarding students would be another useful tool in surveillance. An all-payer claims database analysis would also help determine the costs associated with the treatment of this disease. Improved laboratory diagnostic methods are necessary in ensuring accurate diagnosis and therefore that accurate treatment plans are being prescribed and seroconversion studies might help identify whether the quality and completeness of surveillance data is proportional to the amount of resources invested in the collection of data.

The most important focus of the Commission is the education and awareness of Lyme disease. Educating the public for prevention is the key aspect in helping to prevent transmission and therefore avoiding many of the difficulties that can arise for patients following infection. The Commission recommends that appropriate knowledge, attitudes, and practices (KAP) surveys are developed in order to establish a basis for targeting education and for the development of an engaging and educational health promotion campaign to be distributed in communities. State funding and advertisement subsidies should be provided to towns for tick bite protection and tick-borne disease (TBD) prevention promotions. Recommendations for education of the medical community include that healthcare providers be apprised of the spectrum of Lyme disease (especially regarding relapsing or persisting symptoms), be made aware that currently published recommendations and guidelines regarding treatment of Lyme disease are based on limited data,

that recommendations regarding antibiotic treatment of patients with persisting or relapsing symptoms are based primarily on the results of one clinical trial, and remind physicians of the Physician Protection Act; Section 12DD of Chapter 112 of the Massachusetts General Laws, which protects doctors from facing disciplinary action should they choose to diagnose and treat according to clinical criteria.

In order to educate physicians and other healthcare providers the Commission recommends that this report be sent to each provider from provider-enrolled organizations, the report be disseminated in medical publications and be accessible online. There should also be support for professional educational forums across the state. It is also recommended that MDPH communicate the limitations of laboratory testing to healthcare providers in Massachusetts and regularly review its educational materials relative to new information pertaining to Lyme disease. Although there is general agreement that published guidelines have never been intended to replace clinical judgment, the differences in approach to treatments have led to a continuing controversy that has significantly impacted the delivery of care for Lyme patients in Massachusetts. This controversy underscores the compelling need for serious national investments in scientific research directed at diagnosis and treatment options; both better Lyme diagnostics through testing that is not dependent upon the production of antibodies and more clinical research relative to treatment protocols. Establishing partnerships between local boards of health and community spaces is important in ensuring the distribution of this material. The implementation of an advisory committee is also essential in fulfilling these recommendations.

While the Physician Protection Act protects physicians from liability, it is not a guarantee of treatment. Therefore, mandatory Lyme disease insurance coverage needs to be enacted in Massachusetts. The Commission also recommends that a mechanism be devised to oversee potential violations of the insurance mandate, should it be adopted, and to investigate reports of potential discrimination against patients with Lyme disease.

In addition to education, other modes of prevention can provide protection from infection. The Commission believes that the Pesticide Bureau should add specific tick-relevant training though the pesticide licensing exam materials; look into spraying to control ticks; implement a study to be conducted the State Reclamation Board to determine what extra funds would be needed for each mosquito control district to expand the scope of their work to include tick control measures; have the Department of Conservation and Recreation examine options for reducing tick habitat; conduct a study to determine how to ensure compliance for tick control on school properties; have MassWildlife study the costs and benefits of expanded access to crossbow hunting; and have the Massachusetts Division of Fish and Wildlife explore the costs and benefits of changing the archery safety zone to 150 feet of an inhabited dwelling to allow greater access to sites for deer management.

The Commission recommends that state provide funding to provide the public and medical community the most up-to-date materials regarding prevention, as well as diagnostic tools and treatment practices and that the Commonwealth support state and federal funding for tick-borne disease research.

It is important to note that the Commission members participated as individuals, and as such, have voted to move the aforementioned recommendations forward. However, their identification as Commission members does not imply full endorsement of all recommendations or the official positions of agencies or organizations for which they work.

## GLOSSARY OF TERMS

### Merriam – Webster’s Dictionary and the Center of Disease Control

**Acaricides**- pesticides that kill mites and ticks

**Acute Lyme Disease** – an initial infection caused by *Borrelia burgdorferi*; it may be present as non-specific “flu-like” symptoms, and/or presence of typical erythema migrans rash or atypical rash

***Amblyomma americanum*** – more commonly known as the lone star tick. May transmit pathogens of ehrlichiosis, tularemia, and STARI

**Anaplasmosis** – a tick-borne disease caused by the bacterium *Anaplasma phagocytophilum*. It was previously known as human granulocytic ehrlichiosis (HGE) and has more recently been called human granulocytic anaplasmosis (HGA). Anaplasmosis is transmitted to humans by tick bites primarily from the black-legged tick (*Ixodes scapularis*) and the western black-legged tick (*Ixodes pacificus*). Typical symptoms include; fever, headache, chills, and muscle aches

**Antibiotics** – medications used to treat bacterial infections such as Lyme disease, including tetracyclines, doxycycline, penicillin-based derivatives, and erythromycin analogues

**Antibiotic prophylaxis** - antimicrobial therapy to prevent the development of disease, e.g. Lyme disease following short-term attachment and removal of a tick

**Babesiosis** – is caused by microscopic parasites that infect red blood cells and are spread by certain ticks. In the United States, tick-borne transmission is most common in particular regions and seasons: it mainly occurs in parts of the Northeast and upper Midwest and usually peaks during the warm months. Although many people who are infected with *Babesia* do not have symptoms, for those who do effective treatment is available.

**Bartonellosis** - a disease or infection caused by bacteria of the genus *Bartonella*. The bacteria attack red blood cells and may cause severe anemia and high fever followed by skin eruption.

**Behavioral Risk Factor Surveillance system (BRFSS)** - The Behavioral Risk Factor Surveillance System (BRFSS) is a state-based system of health surveys that collects information on health risk behaviors, preventive health practices, and health care access primarily related to chronic disease and injury

***Borrelia burgdorferi*** - the causative agent (spirochete bacterium) in Lyme disease. The organism is transmitted to humans by tick vectors, primarily *Ixodes scapularis*

**CDC positive Lyme disease test** - CDC currently recommends a two-step process when testing blood for evidence of antibodies against the Lyme disease bacteria. Both steps can be done using the same blood sample. The first step uses a testing procedure called “ELISA” (enzyme immunoassay) or rarely, an “IFA” (indirect immunofluorescence assay). If this first step is

negative, no further testing of the specimen is recommended. If the first step is positive or indeterminate (sometimes called "equivocal"), the second step should be performed. The second step uses a test called an immunoblot test, commonly, a "Western blot" test. Results are considered positive only if the ELISA/IFA and the immunoblot are both positive.

**Chronic Lyme Disease** – Lyme disease that has persisting or relapsing symptoms

**Clinically Diagnosed Lyme Disease Cases** - diagnoses based on medical history, symptoms, physical examination. May, or may not, be confirmed by lab tests.

**Ehrlichiosis** – is the general name used to describe several bacterial diseases that affect animals and humans. Human ehrlichiosis is a disease caused by at least three different ehrlichial species in the United States: *Ehrlichia chaffeensis*, *Ehrlichia ewingii*, and a third *Ehrlichia* species provisionally called *Ehrlichia muris-like* (EML). Ehrlichiae are transmitted to humans by the bite of an infected tick. The lone star tick (*Amblyomma americanum*) is the primary vector of both *Ehrlichia chaffeensis* and *Ehrlichia ewingii* in the United States. Typical symptoms include: fever, headache, fatigue, and muscle aches. Usually, these symptoms occur within 1-2 weeks following a tick bite. Ehrlichiosis is diagnosed based on symptoms, clinical presentation, and later confirmed with specialized laboratory tests

**Erythema (chronicum) migrans** – a rash due to the bite of a deer tick that spreads into a bulls-eye rash

**Hyperendemic** - exhibiting a high and continued incidence—used chiefly of human diseases

**Infectious Disease Society of America (IDSA)** - represents physicians, scientists and other health care professionals who specialize in infectious diseases

**International Lyme and Associated Diseases Society (ILADS)** - is a nonprofit, international, multi-disciplinary medical society, dedicated to the diagnosis and appropriate treatment of Lyme and its associated diseases.

***Ixodes scapularis*** – the blacklegged tick or commonly known as a "deer tick", can transmit the organisms responsible for anaplasmosis, babesiosis, and Lyme disease. This tick is widely distributed in the northeastern and upper Midwestern United States. *I. scapularis* larvae and nymphs feed on small mammals and birds, while adults feed on larger mammals; both can attach to humans.

**Knowledge, Attitudes, and Practices Survey Instrument (KAP)** – a tool used to gather information in order to assess levels of understanding regarding illness in particular areas or regions

**Late Lyme Disease** – the occurrence of objective signs of Lyme disease (e.g. joint swelling, Bell's palsy, meningitis, carditis) weeks to months after the initial infection

**The Physician Protection Act** – Massachusetts enacted Section 12DD of Chapter 112 of the General Law in 2011 which protects the freedom of doctors to prescribe long-term antibiotic therapy for the treatment of Lyme disease

**Post-Lyme Disease** – persisting or relapsing symptoms of Lyme disease after 1-2 months of antibiotic treatment. The persisting symptoms can also be termed chronic Lyme disease

**Seroconversion** - the change of a serologic test from negative to positive, indicating the development of antibodies in response to infection or immunization

**Serology** - the study that deals with the properties and reaction of serums especially blood serum

## **TASKS WITH WHICH THE COMMISSION IS CHARGED**

In accordance with Section 181 of Chapter 68 of the Acts of 2011, the Commonwealth of Massachusetts established the Special Commission to Conduct an Investigation and Study the Incidence and Impact of Lyme Disease. Section 181 of Chapter 68 of the Acts of 2011 states;

There shall be a special commission to conduct an investigation and study of the incidence and impacts of Lyme disease and other tick-borne diseases in the commonwealth including, but not limited to, anaplasmosis<sup>1</sup>, babesiosis<sup>2</sup>, bartonellosis<sup>3</sup>, and ehrlichiosis<sup>4</sup>.

The commission shall consist of 21 members: 3 members of the senate, 1 of whom shall be appointed by the senate minority leader; 3 members of the house of representatives, 1 of whom shall be appointed by the house minority leader; the commissioner of the department of public health or a designee; the commissioner of the division of health care finance and policy or a designee; the director of the state laboratory institute or a designee; the state epidemiologist or a designee; 2 public members who shall be patients or family members of patients, 1 of whom shall be appointed by the senate and 1 of whom shall be appointed by the house of representatives; and 9 members to be appointed by the governor, 1 of whom shall be a physician specializing in infectious diseases, 1 of whom shall be a professional member of the International Lyme and Associated Diseases Society, 2 of whom shall be experts in the treatment or research of Lyme disease, 2 of whom shall be members of Lyme and other tick-borne diseases organizations representing diverse regions of the commonwealth and 3 of whom shall be members of local boards of health from different Lyme endemic areas of the state.

The study shall include, but not be limited to, a cost-benefit analysis of: (i) conducting a Lyme disease public health clinical screening study in high risk regions; (ii) developing education materials and training resources for detecting signs and symptoms of tick-borne illnesses in school-aged populations, to be used by clinical providers and school health personnel; (iii) statewide surveillance and testing for tick-borne diseases in both *Ixodes scapularis*<sup>5</sup>, or the black-legged deer tick, and *Amblyomma americanum*<sup>6</sup>, or Lone Star ticks; and (iv) educating the medical community about research on all aspects of Lyme disease, both acute<sup>7</sup> and chronic<sup>8</sup>. The commission shall also investigate the availability of grants and federal funds for the study of Lyme disease and other tick-borne diseases to determine if future action is feasible and warranted to support Lyme and tick-borne diseases research in the commonwealth. The commission shall review mandatory reporting procedures to promote improved compliance both for CDC-positive<sup>9</sup> and clinically diagnosed<sup>10</sup> cases of Lyme disease and associated tick-borne co-infections.

The commission shall report the results of its investigation and study, together with drafts of legislation, if any, necessary to carry its recommendations into effect, by filing the same with the clerks of the senate and house of representatives, who shall forward the same to the joint committee on public health and the house and senate committees on ways and means on or before April 1, 2012.

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<sup>1</sup> a tick-borne disease caused by the bacterium *Anaplasma phagocytophilum*

<sup>2</sup> is caused by microscopic parasites that infect red blood cells and are spread by certain ticks

<sup>3</sup> a disease or infection caused by bacteria of the genus *Bartonella*.

<sup>4</sup> is the general name used to describe several bacterial diseases that affect animals and humans

<sup>5</sup> the blacklegged tick or commonly known as a "deer tick", can transmit the organisms responsible for anaplasmosis, babesiosis, and Lyme disease.

<sup>6</sup> more commonly known as the lone star tick. May transmit pathogens of ehrlichiosis, tularemia, and STARI

<sup>7</sup> an initial infection caused by *Borrelia burgdorferi*; it may be present as non-specific "flu-like" symptoms, and/or presence of typical erythema migrans rash or atypical rash

<sup>8</sup> Lyme disease that has persisting or relapsing symptoms

<sup>9</sup> CDC currently recommends a two-step process when testing blood for evidence of antibodies against the Lyme disease bacteria. Both steps can be done using the same blood sample. The first step uses a testing procedure called "ELISA" (enzyme immunoassay) or rarely, an "IFA" (indirect immunofluorescence assay). If this first step is negative, no further testing of the specimen is recommended. If the first step is positive or indeterminate (sometimes called "equivocal"), the second step should be performed. The second step uses a test called an immunoblot test, commonly, a "Western blot" test. Results are considered positive only if the ELISA/IFA and the immunoblot are both positive.

<sup>10</sup> Some doctors consider a bull's-eye rash diagnostic and don't require further tests. Others, however, require laboratory confirmation before treatment. Culture is the "gold standard" test for identifying bacteria. A sample of the organism is taken from the patient is allowed to grow in a medium and then identified. Culture is accepted as proof of infection. While culture is used to diagnose many infections, it is not practical for Lyme because the bacteria grow too slowly. There are no commercially available culture tests for Lyme disease



In the Fiscal Year 2013 budget outside Section 149: “The second paragraph of section 181 of said chapter 68 is hereby amended by striking out the figure "2012" and inserting in place thereof the following figure:- 2013” was adopted, which extended the reporting deadline of this Commission to April 1, 2013. The twenty-one members of the Commission were appointed and officially sworn in on April 24<sup>th</sup> 2012. The Commission was then broken up into five sub-commissions; State Surveillance and Reporting, Education and Awareness, Funding, Prevention, and Insurance and Liability Issues. The sub-commissions met regularly and reported to the full Commission monthly.

## **Massachusetts State Surveillance and Reporting**

### ***Massachusetts Department of Public Health Lyme Disease Surveillance Activities***

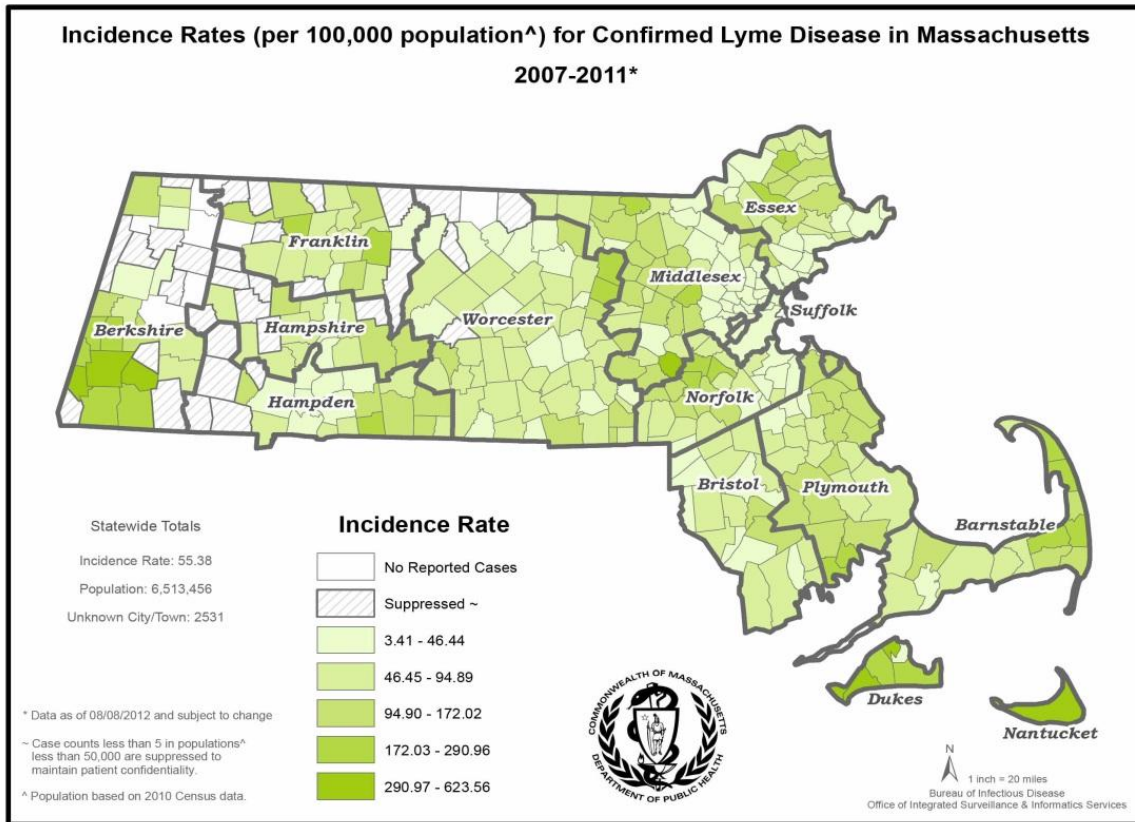
Statewide Lyme disease surveillance is performed by the Massachusetts Department of Public Health (MDPH) Bureau of Infectious Diseases (BID). MDPH receives Lyme disease reports from healthcare providers and from clinical laboratories. Positive Lyme disease laboratory test results are reported electronically, with each positive result generating a request to the ordering healthcare provider for the patient’s clinical information. Both clinical and laboratory reports are captured by the MDPH surveillance informatics system (MAVEN). Currently, MDPH receives approximately 12,000-14,000 Lyme positive lab reports per year. Sufficient clinical information is obtained to classify only approximately 2,000 to 4,000 confirmed, and up to 1,000 probable, Lyme disease cases per year. MDPH estimates a 5 – 10 fold under-reporting rate for Lyme disease.

The laboratory reporting system is an obvious strength of this statewide surveillance system. It allows for identification of most laboratory-confirmed Lyme cases, using an automated system that minimizes errors and effort. Laboratory-based reporting, however, will fail to capture reports of Lyme disease for which laboratory testing is not routinely performed [ie, erythema migrans (EM)] or is not performed at an appropriate stage of disease (i.e. antibody testing performed shortly after symptom onset). Laboratory results are difficult to interpret in the absence of clinical data, which can be obtained only with the cooperation of a health care worker. In addition, the quality of testing and the quality of tests performed varies between laboratories, even though compliance with laboratory quality standards is required of clinical laboratories by the US Centers for Medicare and Medicaid Services Clinical Laboratory Improvement Amendments (CLIA). Lack of standardization of lab results reported by different laboratories also presents a challenge for lab test result interpretation. Although the MDPH surveillance program is able to make efficient use of automated lab-based reporting and can process several hundred reports per day, it still runs a backlog of about 3,000 reports.

### ***Other Statewide Lyme Disease Surveillance Activities***

Two current short-term projects at local boards of health seek to define the extent of Lyme disease regionally in Massachusetts, and the extent of Lyme disease under-reporting. The Martha’s Vineyard Boards of Health are purchasing insurance data on doxycycline prescriptions written to its residents and surveying local pharmacies to assess quantities of doxycycline dispensed on the island. This will be used as proxies for quantifying the frequency of Lyme

disease. This project is expected to be completed over the next 6-12 months. The Dover Board of Health is collaborating with an MDPH intern to field a survey of local health care providers, to assess frequency of Lyme disease diagnoses among their patient population in order to assess the extent of underreporting, and define obstacles to clinician reporting. This project is expected to be completed by the end of 2012.



In addition, previous studies conducted in Massachusetts may also be useful for informing estimates of current Lyme disease incidence and Lyme disease underreporting. Prospective studies that measure seroconversion<sup>11</sup> (incidence) are rare for the country as a whole due to the expense of conducting them. The best such study was a result of the SmithKline Beecham Lymerix Phase II and Phase III trials. For the Phase II, an incidence of 3.4% (95% CI 1.2-9.5) was recorded among 353 subjects on Nantucket, Martha’s Vineyard, and Block Island during 1994-1995. During the Phase III trial of 10,936 subjects enrolled from endemic states from Maine to Maryland, an incidence of 1.5% (95% CI 1.2%-1.9%) and 2.0 (1.6-2.4) were recorded with active case detection (Paddock and Telford, 2010, Institute of Medicine report). A review of ten other small prospective studies reported in the literature suggests a median incidence of 1.5%.

When Lyme disease first becomes established in a habitat, the risk may be great. Lastavica et al. NEJM 320:133, 1989 determined that a median of 4% of 190 residents of Crane Beach,

<sup>11</sup> the change of a serologic test from negative to positive, indicating the development of antibodies in response to infection or immunization

Massachusetts suffered a new case of Lyme disease each year (range 1%-10%) from 1980-1987. Of the 190, 23% had been infected as determined by serology.

Prevalence estimates from cross-sectional studies suggest that about 10%-20% of any coastal New England community has been exposed to *Borrelia burgdorferi*. Estimates have been published for two Massachusetts studies: 15.3% (95%CI 10.0%-19.8%) (Phillips et al. Am J Prev Med 2001; 20:219) for Nantucket and 8% (95% CI 4.6-14.5) for Great Island in 1983 (Steere et al. J Infect Dis 1986; 154:295). The following table comprises unpublished data from the Telford laboratory, which are consistent with these published estimates.

Community	Date	Samples	%Pos (95%CI)	Occupational Group
Martha's Vineyard	1994	39	12.8 (5.6-26.7)	random
Martha's Vineyard	2001	182	12.6 (8.6-18.3)	landscapers
Chappaquiddick	2011	33	12.1 (4.8-27.3)	random
Nantucket	1992-1997	4464	10.7 (9.8-11.6)	hospital visitors
Naushon	1986	117	21.4 (14.6-29.3)	random
Naushon	2011	85	10.6 (5.3-19.6)	random

Although there is concern that visitors to coastal Massachusetts sites such as Martha's Vineyard and Nantucket may become infected during a brief visit and return to the community of their primary residence; the only study to examine this found that only those staying more than two weeks in such sites did so (relative risk 3.7, 95% CI 2.2-6.2) (Daltroy et al. Health Education Behavior 2007). 0.66% of 21,853 questionnaire respondents reported have been diagnosed Lyme disease during their visit to Nantucket. There is no ecologic evidence that transmission of *Borrelia burgdorferi*<sup>12</sup> has changed on Nantucket in the interim and thus the limited data suggests that enhanced surveillance of short term visitors to hyperendemic sites such as the Cape and Islands is not justified.

Prospective studies remain our best means of accurately measuring incidence, as opposed to reported cases. Such studies do not rely solely on serology, but also on active case detection, which would capture EM cases that are treated but for which laboratory confirmation would not be obtained. A prospective study would document the effects of a committed intervention but cannot be done (logistically and economically) except at a community level. Nonetheless, providing the resources for prospective studies of sentinel communities considering a committed intervention would provide concrete data on the effects of intervention.

### ***Potential Benefits of Enhancing Lyme Disease Surveillance***

Among other benefits, Lyme disease surveillance can be useful in defining disease burden, geographic distribution, risk groups, clinical features, and changes in disease epidemiology over time. Enhancing current estimates of Lyme disease case numbers could be useful in (1) measuring the efficacy of disease prevention interventions, (2) justifying funding requests to

<sup>12</sup> the causative agent (spirochete bacterium) in Lyme disease. The organism is transmitted to humans by tick vectors, primarily *Ixodes scapularis*

support Lyme disease research and prevention programs, and (3) identifying high risk areas that may benefit from environmental interventions or more aggressive educational campaigns. However, collection and confirmation of Lyme disease surveillance data can be resource intensive, and the incremental benefits of improving the existing surveillance system must be carefully weighed against the incremental costs associated with implementing additional disease surveillance activities. Massachusetts already reports thousands of cases per year, and is already recognized as one of the states with the highest Lyme disease incidence. As such, the benefits of enhancing existing surveillance activities must also be weighed against the benefits of investing resources in educational efforts and other interventions to curtail disease.

### ***Potential Activities for Enhancing Surveillance of Lyme Disease in Massachusetts***

#### Analysis of MDPH Laboratory-Based Reporting Data

Reports of positive Lyme disease laboratory tests are the primary source of Lyme disease reports at MDPH. This source of data could also provide additional information useful in Lyme disease surveillance efforts, including (1) data to indicate test ordering practices of clinicians in the state (e.g. what Lyme tests are being ordered, how frequently tick-borne disease panels are ordered), (2) data on what types of tests are being performed by various laboratories, and (3) how test results are reported and with what interpretative guidance. Examination of these data might be useful in identifying strategies for improving Lyme disease surveillance. For example, if lack of standardization of lab result reporting practices is found to be widespread, this would need to be accounted for in surveillance measures, and may also indicate a need for providing guidance to clinicians in test result interpretation.

#### Detailed Surveys for a Subset of Lyme Disease Cases

Currently, the MDPH Lyme disease surveillance program requests only a limited set of data for each reported Lyme case. Collection of additional information from case patients and their providers on a subset of Lyme cases in Massachusetts could be useful for better defining exposures and risk factors, clinical manifestations and sequelae, and overall morbidity and burden of disease. This mechanism for enhancing disease surveillance would build off an existing structure and is readily implemented. However, additional personnel at state and local public health departments would be needed to support this intensified level of data collection.

#### Behavioral Risk Factor Surveillance Survey

The MDPH Health Survey Program operates the Behavioral Risk Factor Surveillance System (BRFSS)<sup>13</sup> in Massachusetts. The BRFSS is an annual telephone survey that collects data on emerging public health issues, health conditions, risk factors and behaviors. Although the survey does not routinely include questions regarding Lyme disease, applications to include disease-specific modules can be made, and could be used to assess Lyme disease incidence in individuals and their family members, as well as knowledge, attitudes, and beliefs pertaining to Lyme disease prevention. The 2000 MDPH BRFSS included several questions pertaining to Lyme disease. Although the sophisticated data collection methods used by BRFSS are effective for collecting statistically well-characterized data from thousands of Massachusetts residents on a statewide basis, use of the BRFSS system is associated with a significant cost. Specifically, a

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<sup>13</sup> The Behavioral Risk Factor Surveillance System (BRFSS) is a state-based system of health surveys that collects information on health risk behaviors, preventive health practices, and health care access primarily related to chronic disease and injury

module of five survey questions costs approximately \$42,500. In addition, modules can be submitted to BRFSS for consideration and prioritization only once a year. Proposed survey questions must be prioritized for inclusion in the survey, since there are a limited number of questions included in the survey per year.

#### School Nurse Surveillance Capacity

MDPH has a School Health Services unit in the Bureau of Community Health and Prevention, which routinely collects information on pediatric conditions observed by school nurses in the schools. School nurses collect information on causes of student absenteeism and illness, and are involved in administration of medications to students. This existing data collection system could be tapped to collect data to provide an indication of Lyme disease incidence in students statewide, at minimal cost. Additionally, school nurses could be surveyed at the beginning of the school year to assess indicators of Lyme disease impact on students (since cases of early Lyme disease can occur prior to school opening) and the overall burden on the school age population they serve. Potential disadvantages to this include increased burden on school nurses and a lack of standardized data collection methods between school districts.

#### Electronic or Fax Reporting of Clinical Diagnosed Cases

One major source of disease underreporting is clinician underreporting of cases of erythema migrans (EM), which is the most common clinical manifestation of Lyme disease. Since these cases often are not associated with a positive laboratory result, electronic laboratory test reporting cannot be relied upon as a mechanism for reporting.

The current clinical case reporting process is inadequate, in that there are no MDPH online reporting forms or instructions. In the past, MDPH had facilitated clinician reporting by allowing clinicians to report cases in a roster format. However, this practice would require more MDPH data entry staff than currently exist. Existing staff already cannot keep up with report processing. An alternative reporting mechanism could be to physically distribute or make electronically available case report optical character recognition forms that providers could complete and fax to DPH for automated data entry. The primary advantage is the minimal cost. The primary disadvantage is that the success of this strategy is dependent on its acceptance and consistent use by clinicians, for whom disease reporting is only one of many competing priorities. Small-scale pilot tests of both the roster format and physical distribution of the case report forms were not readily embraced by healthcare providers.

#### Analysis of All-Payer Claims Database

Analysis of state insurance claims could provide another estimate of Lyme disease burden via examination of the frequency and costs of antibiotic utilization, clinician visits, diagnostic tests, and hospitalizations associated with Lyme disease or management of tick bites. This approach to Lyme disease surveillance takes advantage of an existing data collection system that could provide an indication of the economic burden of Lyme disease. However, processes for release of claims data are still being established and the accessibility and utility of these data for Lyme disease surveillance have not yet been evaluated. Furthermore, funding would be necessary to conduct these analyses. It is too soon to adequately define the costs and benefits of this approach to Lyme disease surveillance. Nevertheless, this approach might prove valuable in the long term, and should continue to be considered as an option in the future. It is also important to identify

that this is a means by which to provide more of an estimate of the amount that Lyme disease treatment is costing rather than the number of people infected since many pay out of pocket; this data would not be a good representation of total number.

#### Development of Improved Laboratory Diagnostic Methods

Current FDA-approved Lyme disease antibody tests are valuable in the diagnosis of Lyme disease but have limitations and their results must be interpreted appropriately. Development of new tests could address a number of diagnostic gaps, and could include (1) improving direct methods for detecting *Borrelia burgdorferi* (as opposed to antibody-based tests), (2) improving the current serology diagnostic testing algorithm or developing single serology tests, (3) improving test sensitivity, specificity, and rapidity throughout all stages of disease, and (4) developing tests that can be used to measure response to treatment. Improving test methods could improve disease surveillance. However, test development requires significant investment and resources, and occurs in academic and/or commercial settings, rather than within the state government or public health laboratory setting.

At the very least, existing modalities should be standardized for all laboratories providing clinical laboratory support in Massachusetts. In addition, health care providers should be educated on the limitations of serology, particularly on the concept of pre-test probability and its influence on predictive value.

#### Seroconversion Studies

Seroconversion studies based on laboratory-confirmation of Lyme cases have been useful for defining Lyme disease prevalence in the setting of phase 3 vaccine trials. These studies are, in effect, active surveillance systems that provide determinations of Lyme disease prevalence that are more comprehensive and accurate than can be achieved by more passive surveillance systems. However, they are extremely labor and resource intensive, and cost-prohibitive in most settings. Seroconversion studies illustrate how the quality and completeness of surveillance data is often proportional to the amount of resources invested in the collection of data. While the value of high-quality surveillance data is obvious in regions of high Lyme disease incidence, aggressive efforts to improve rates of disease reporting in these settings may be less valuable than improving the quality of data reported, and may be less valuable than investing resources on disease prevention activities.

#### Ecologic Surveillance

Although there is some public perception that risk maps may be generated by collecting and analyzing ticks for evidence of infection, such maps are snapshots of a dynamic situation. Tick populations are very focally distributed; often one yard on a street will have most of the ticks with the other yards yielding none. Such a pattern is also characteristic at higher scales of distribution: although Nantucket is said to be hyperendemic<sup>14</sup>, there are many sites where there are few or no ticks. Such attributes also differ from year to year. Within a single transmission season, one site on Nantucket (taken as representative of any endemic site) may differ with respect to tick density from another but the pattern may be reversed the following year. “Infection rates”, regardless of mode of testing, are usually reported as proportions with no estimates of the possible variability around that estimate due to sampling issues. Indeed, when

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<sup>14</sup> exhibiting a high and continued incidence—used chiefly of human diseases

95% confidence intervals are calculated for “infection rates”, such rates generally overlap between sites and years [The 95% confidence interval provides a range of values that would include the estimate of interest, proportion infected, for 95 out of 100 samples obtained from the same site using the same methods at the same time. Although not conceptually identical to the true population prevalence (a sample estimate is not necessarily representative of that of the underlying population) it is assumed that the 95% CI would include the true population estimate if such a thing was able to be measured]. Although it is possible that resources could be made available to allow for rigorous sampling of sentinel sites, the most useful information is whether deer ticks are present or not; when Lyme disease is the infection of interest. Wherever deer ticks are present, evidence of *Borrelia burgdorferi* transmission may be found. The density of infected ticks is poorly associated with measures of human risk, probably because of imprecision in measuring as well as issues of scale (case reports come from towns, tick sampling is from representative sites within a town). There is some suggestion that risk is paradoxically great in sites with fewer ticks because people are less aware of ticks and do not engage in preventive behaviors. In sum, the benefit of providing resources for ecologic surveillance is not clear.

## **Education and Awareness**

The scourge of Lyme disease in the Commonwealth has been described as having reached epidemic proportions and as endemic in all of Massachusetts. “Regions of particularly high incidence include Cape Cod and the Islands, as well as some areas in Norfolk, Middlesex, Essex, and southern Berkshire Counties.” Although annual reports through MDPH may fluctuate, the trend is not encouraging; the incidence of tick-borne disease (Lyme + co-infections) is on the rise, both numerically and geographically. Massachusetts ranks among the most highly endemic states, with incidence rates that placed it in second place in the nation in 2008.

### ***Education for Prevention***

These diseases can be prevented. A significant dent in these numbers may be achieved by preventing tick bites. Given the extraordinary ‘payback’ from preventive measures, the Commission recommends strong emphasis and investment in education for prevention. The goal here is to provide information that will empower individuals to protect themselves and to convince them to do it.

The five recommendations outlined below are presented in an order that would be ideal chronologically. However, the Commission acknowledges that funding availability will steer these objectives. It is also recognized that a number of organizations are already effectively engaged in the work of the third recommendation

1. Development of an appropriate knowledge, attitudes and practices (KAP)<sup>15</sup> survey instrument of current tick bite protection and disease prevention strategies, and then implementing the KAP survey to a broad cross-section of residents throughout the Commonwealth. The KAP survey not only would provide a “road map” for targeted education and health promotion programming going forward but also would serve as a baseline measure for assessing metrics of disease prevention programming effectiveness.

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<sup>15</sup> a tool used to gather information in order to assess levels of understanding regarding illness in particular areas or regions

2. Development of an engaging educational health promotion campaign to run annually with seasonally appropriate prevention messages. This campaign should have a consistent message and be available through a variety of channels (internet, mass media, local media, public health, etc.). Desirable elements of the campaign would include:
  - a. Provides for a distinctive Massachusetts brand (e.g. Get TickSmart/MA) based on URI model ([www.tickencounter.org](http://www.tickencounter.org)). Other resources include the BLAST program ([www.ridgefieldct.org](http://www.ridgefieldct.org)) and The Report of Newtown Tick-borne Disease Action Committee ([www.newtown-ct.gov](http://www.newtown-ct.gov))
  - b. Contains core call-to-action messages
  - c. Includes strategies for removing implementation barriers
  - d. Uses stakeholder-appropriate messaging (school-age children, adults working with school-age children, outdoor workers, homeowners, pet owners, people engaging in higher tick risk recreational activities, etc.)
  - e. Takes a theory-based approach (eg. Health Belief Model or others; such a model examines incentives/disincentives that determine personal action taken toward a health outcome)
  - f. Strategies to maximize reach and engagement
  
3. That important campaign messages include: tick reduction/avoidance strategies, vector control strategies, tick-bite management strategies, tick identification resources, decision support for taking prevention action. Ideally, the campaign would help all Massachusetts residents and visitors know:
  - a. Where they are at risk and the likelihood of tick encounters
  - b. The habitats and activity seasons of vector ticks
  - c. Disease associations with different types of ticks
  - d. How to conduct daily tick checks
  - e. How to safely remove a tick
  - f. How to most effectively repel ticks
  - g. How to effectively reduce tick encounter risk in the home environment
  - h. How to protect pets from ticks and how to keep pets from carrying ticks to people
  - i. The role of wildlife in propagating ticks and disseminating disease agent
  - j. That a single tick can carry concurrently more than one disease agent
  
4. That state funding be developed to provide cooperative promotion and advertisement subsidies to towns related to tick bite protection and TBD prevention promotion
  
5. That a coordinator or a coordinating committee be established to help implement the educational campaign (Note that later it is recommended that an “Implementation Advisory Committee” be appointed).

The role of the schools is essential in this effort. In 2007 the MDPH issued a six page Public Health Advisory to the public schools with information about the risk of diseases spread by mosquitoes and ticks, including “Tick-borne and Mosquito-borne Disease Prevention Procedures and Activities for Schools – Guidelines for school committees, administrators, teachers, and school nurses.” We recommend that this document be revised where needed (eg. field-trip



information, preventive landscape practices), and that it be made available on the MDPH website.

The MDPH website ([www.mass.gov/dph](http://www.mass.gov/dph)) has some excellent educational resources, but it is often difficult to navigate the pathways to locate them. We recommend that funding be provided to secure the professional expertise needed to update the content and to make it easier to navigate the website. We also believe that the website can be strengthened with links to external sites for additional educational information on tick-borne diseases (TBD's) such as but not limited to the Lyme and Tick-borne Disease Research Ctr., Columbia Univ. Medical Center ([www.columbia-lyme.org](http://www.columbia-lyme.org)) or the International Lyme and Associated Disease Society ([www.ilads.org](http://www.ilads.org)) for physician training as well as Lyme Disease Association, Inc. ([www.lymediseaseassociation.org](http://www.lymediseaseassociation.org)), LymeDisease.org ([www.lymedisease.org](http://www.lymedisease.org)), Lyme Research Alliance ([www.lymeresearchalliance.org](http://www.lymeresearchalliance.org)), and Tick-borne Disease Alliance ([www.tbdalliance.org](http://www.tbdalliance.org))

### ***Education for the Medical Community***

1. It is most important that healthcare providers be apprised of the spectrum of Lyme disease, especially regarding relapsing or persisting symptoms, even after one of two courses of “standard” antibiotic treatment over a 1-2 month period of time. This condition may/can be much more frequent than has been previously acknowledged or appreciated, and the recent (2011) report of the Institute of Medicine (IOM), National Academy of Sciences (the nation’s most highly regarded scientific body) attests to the difficulties surrounding the diagnosis and management of this complication of Lyme disease (*Critical Needs and Gaps in Understanding Prevention, Amelioration, and Resolution of Lyme and Other Tick-Borne Diseases: The Short-Term and Long-Term Outcomes: Workshop Report*). Regardless of whether this continued symptomatology is termed post-Lyme disease or chronic Lyme disease, the cause of the persisting symptoms has yet to be delineated, and there are currently no tests to determine that the causative organisms are still present or absent in a given individual; the currently available antibody-based tests cannot be used to determine that one no longer has, or does have Lyme disease, or to assess response to treatment. Clinical judgment and assessment of all available information remain the keys to appropriate management of all patients with Lyme disease. This point is made by the Centers for Disease Control & Prevention (CDC) ([www.cdc.gov](http://www.cdc.gov)) and is noted on laboratory testing information, yet many physicians incorrectly rule out Lyme disease solely on the basis of a “negative” lab test.
2. Healthcare providers need to be aware that currently published recommendations and guidelines regarding treatment of Lyme disease are based on limited data. For example, the recommendation that one does not need treatment for a tick bite if the tick has not been imbedded for more than 48 hours was not based on testing in humans. Patients need to be counseled to be aware of what are often only subjective symptoms (fatigue, aches and pains, ‘brain fog’) that may occur several weeks to a few months after having been bitten by a deer tick (*Ixodes*). It should be noted that these symptoms may be inappropriately dismissed, or mischaracterized as psychiatric or stress-related. Guidelines for antibiotic prophylaxis<sup>16</sup> are also based on limited data. The recommendation that a

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<sup>16</sup> antimicrobial therapy to prevent the development of disease, e.g. Lyme disease following short-term attachment and removal of a tick

single day's treatment with doxycycline for an imbedded deer tick bite can prevent Lyme disease has some published support; however, this approach may not always be effective, and some physicians believe that it is ill-advised. Patients who have taken a prophylactic dose need to be counseled to be aware that if symptoms develop over the subsequent few months, they should seek medical attention. They should be made aware that antibody production may be abrogated as a result of early dosing, thus potentially making laboratory testing even more problematic in these situations.

3. Healthcare providers need also to be made aware that the recommendations regarding antibiotic treatment of patients with persisting or relapsing symptoms are based primarily on the results of one clinical trial. There have been a few other controlled treatment trials, which did not show either any, or any sustained, benefit following treatment. But the failure of the antibiotics used in these trials cannot be used to conclude that use of different antibiotic regimens and durations of treatment would not be effective; there is published information, in addition to physician experience, that suggest there are other antibiotic regimens that may be effective. Until there are additional controlled treatment trials to prove or disprove other antibiotic regimens, healthcare providers should make themselves aware of available alternative regimens so that their patients can be provided the opportunity to resolve their persisting symptoms.
4. Physicians should also be reminded of the Physician Protection Act<sup>17</sup>, which protects them from any disciplinary action should they choose to diagnose and treat according to clinical criteria, relying on history and symptoms even in the absence of positive lab results. This may include prescribing antibiotics over a prolonged period of time when warranted by the patient's presentation.

It is recommended that these approaches be taken in order to enable the education of physicians and other healthcare providers as described above:

- a. The Commission report, including the recommendations regarding education of physicians and other healthcare providers, should be sent to each provider from provider-enrolled organizations, e.g. the Massachusetts Medical Society and the Massachusetts Chapter of the American Academy of Pediatrics. If a government agency is desired, the list-serve from the Massachusetts Board of Registration in Medicine could be used.
- b. The Commission report should be published in the New England Journal of Medicine as an informational article. And/Or – There should be broad distribution of the report using multiple avenues including, but not limited to, online and printed methods.
- c. There should be support for educational forums in various state locations, similar to ones that have taken place in Barnstable County over the last more than 10 years, carrying Continuing Medical Education (CME) accreditation (until 2007 these had been supported by state funding). Agendas should address uncertainties and gaps in knowledge regarding tick-borne diseases and include current divergent view points in the medical community.

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<sup>17</sup> Massachusetts enacted Section 12DD of Chapter 112 of the General Law in 2011 which protects the freedom of doctors to prescribe long-term antibiotic therapy for the treatment of Lyme disease

5. The Commission recommends that the MDPH take a more proactive role in communicating the limitations of laboratory testing to healthcare providers in Massachusetts, including the CDC's statement that negative screening tests should not replace clinical judgment. As is true with all antibody-based tests, these may be negative early in the infection, and immune responses may be blunted due to early administration of antibiotics or other medical conditions.
6. The MDPH should regularly review its educational materials, both printed and online (e.g. *Tickborne Diseases in Massachusetts* – a physician's reference manual), and update as needed to include clinically diagnosed Lyme disease and supplemental information that physicians would find useful regarding treatment as well as any additional information about prevention, diagnosis and treatment as it becomes available.

### ***Co-infections***

Adding to medical complications is the growing incidence of co-infections, those tick-borne diseases sometimes carried concurrently by the same tick (*Ixodes*). Lyme disease (*Borrelia burgdorferi*) is the predominant illness. The other two most commonly found diseases are Anaplasmosis (formerly Ehrlichiosis) and Babesiosis, both of which have dramatically increased in Massachusetts during the past three years. To make matters worse, *Babesia* (a malaria-like protozoan) has been found to be tainting blood-bank supplies. It has also been found capable of passing from mother to unborn child. Not yet confirmed as a tick-transmitted co-infection in humans, *Bartonella* is another bacterium under study (transmission has been demonstrated to occur in other mammals). It should also be noted that the 'dog tick' (*Dermacentor*), although far less of a threat than *Ixodes*, can transmit Rocky Mountain Spotted Fever and/or Tularemia. This list is not intended to be all-inclusive.

### ***Critical Need for More Research***

Two important medical organizations have published guidelines for diagnosis and treatment of Lyme disease, the Infectious Disease Society of America (IDSA, [www.idsociety.org](http://www.idsociety.org))<sup>18</sup> and the International Lyme and Associated Diseases Society (ILADS, [www.ilads.org](http://www.ilads.org))<sup>19</sup>

“The medical community; ranging from physicians to medical research institutes, have varied perceptions of Lyme disease and appropriate treatment methods. While some physicians treat for acute as well as chronic Lyme disease, there are others who feel as though the research that currently backs the IDSA's recommendation on twenty-eight days of antibiotic treatment for all Lyme disease patients is the most accurate and therefore continue to follow their guidelines. ILADS has released their own research regarding Lyme disease which is contrary to the IDSA's in that their recommendation for the duration of therapy is guided by clinical response, rather than by a specific timeline” (*Lyme Disease in Massachusetts: A Public Health Crisis*, April 2011, pg. 16).

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<sup>18</sup> represents physicians, scientists and other health care professionals who specialize in infectious diseases

<sup>19</sup> is a nonprofit, international, multi-disciplinary medical society, dedicated to the diagnosis and appropriate treatment of Lyme and its associated diseases. ILADS promotes understanding of Lyme and its associated diseases through research and education and strongly supports physicians and other health care professionals dedicated to advancing the standard of care for Lyme and its associated diseases

Although there is general agreement that published guidelines have never been intended to replace clinical judgment, these two different approaches to treatment have led to a continuing controversy that has significantly impacted the delivery of care for Lyme patients in Massachusetts. This conflict underscores the compelling need for a serious national investment in scientific research directed to clarify diagnosis and treatment options:

1. Better Lyme diagnostics, testing that is not dependent upon the production of antibodies
2. More clinical research relative to treatment protocols.

Including members from top Lyme organizations, ILADS, Lyme Disease Association, Inc., and IDSA to discuss what funding is necessary and how to best address the needs of Lyme patients would be a way to include parties with diverse viewpoints and concerns. In its 2011 report cited earlier, the Institute of Medicine (IOM), National Academy of Sciences, stressed the necessity for a collaborative working relationship, urging an effort toward “creating a new environment of trust and a better environment for more constructive dialogue to help focus research needs and achieve better outcomes.”

The Commission urges our state legislators to press our congressional delegation for support of federal legislation (e.g. HR 2557-Smith, S 1381-Blumenthal) including federal funding for this research. Much remains to be learned about Lyme and the other tick-borne diseases, their diagnoses and treatment. It is a national problem and without strong support for twenty-first century research, we will not make progress towards curing this disease.

### ***Partnerships***

Members of the Commission have identified opportunities for partnerships to facilitate the dissemination of educational information, including local boards of health, town and city libraries, school libraries, community hospitals to help in hosting regional programs with CME accreditation, business sponsors for public-service announcements and other activities.

### ***Implementation Advisory Committee***

It is recommended that an ‘Implementation Advisory Committee’ be appointed by the Governor to function after the work of this commission is completed. With a membership of diverse interests represented, its charge would be to identify funding opportunities and venues by which Commission recommendations can be implemented and to encourage follow through.

### ***True Costs of Lyme Disease in Massachusetts***

Given austere economic times, we must evaluate the cost-benefit ratio of mounting an effective and comprehensive public awareness campaign regarding Lyme and other tick-borne diseases.

In his letter to the residents of the Commonwealth, preface to *Lyme Disease in Massachusetts: A Public Health Crisis*, Chairman David P. Linsky of the House Post Audit and Oversight Committee pointed out that “millions of dollars are lost in employee absences due to Lyme disease. Each year hundreds of school children miss school. Millions of dollars are spent in medical care.” Although we do not have precise figures, it seems reasonable to declare that the costs are indeed in the millions, a staggering burden for families and the Commonwealth. In Massachusetts, the number of reported cases in 2008 was 3,960, but according to the CDC, reported cases of Lyme disease underestimate its true prevalence by a factor of ten. This means

that the actual number of cases of Lyme disease may have been approximately 39,600; the great majority of which went undetected and untreated.

Consider a recent large national survey that reported on 2,424 respondents whose clinical diagnosis of Lyme disease was supported by positive blood tests. Findings indicated that most of these patients had difficulty obtaining a diagnosis and treatment for their illness, had to travel great distances (100 miles or more) to obtain treatment, and were denied coverage for their illness by their health insurance. 95% of the respondents reported that they had had Lyme for two years or more (many for more than 20 years), 65% had to cut back or quit work or school at some point during their illness, and 25% were on disability at some point. For this latter group, 75% were on disability for longer than one year ( Johnson, L., Aylward, A., Stricker R., Healthcare access and burden of care for patients with Lyme disease: A large United States survey, 2011 Health Policy Vol. 102 (1):64-71).

Consider also the fact that chronic illness accounts for 84% of Lyme healthcare costs. Notably, only 21% of this figure is due to the cost of treatment, while 79% is due to lost economic output, or productivity loss (Johnson, Lorraine, "Financial Burden of Lyme Disease", Presentation at the Gibson Forum in Saratoga, New York at Skidmore College May 21, 2012). Clearly, the costs to Massachusetts of undiagnosed and untreated Lyme disease are enormous, both on an economic level as well as in terms of the pain and suffering of its victims. This situation demands a vigorous and extensive awareness campaign aimed both at our residents and the professionals charged with their care.

### **Insurance and Liability**

While some patients who contract Lyme disease in Massachusetts are treated effectively; numerous other patients encounter issues surrounding receiving adequate treatment while others encounter difficulty accessing their prescribed treatment often due to denials from insurance companies and the high costs associated with treatment. In some instances insurance companies have denied patients coverage and in some cases approved medications only to later repeal coverage and demand re-payment from the patient. This is happening to many of our Massachusetts families, and has been noted by at least two treating physicians and one home-infusion company. Note that at least one health insurer has the following policy posted on its website: "prior authorization is not a guarantee of coverage."

1. While the Physician Protection Act protects physicians from liability, it is not a guarantee of treatment. We believe however that the Physician Protection Act was intended not only to protect physicians from medical board charges, but also to permit informed consent and to protect the patient's right to receive treatment. Viewed in this way, it would seem that restrictive Lyme disease insurance guidelines essentially sabotage the intent of the Physician Protection Act, and interfere with patients' rights to receive treatment. It is for this reason that the Commission recommends that mandatory Lyme disease insurance coverage be enacted in Massachusetts.
  - a. Rhode Island has passed such a law, and provides us with an effective precedent and model. It may be viewed at:

[http://www.lymediseaseassociation.org/index.php?option=com\\_content&view=category&layout=blog&id=148&Itemid=535](http://www.lymediseaseassociation.org/index.php?option=com_content&view=category&layout=blog&id=148&Itemid=535)

“Every...insurance policy...shall provide for coverage for diagnostic testing and long-term antibiotic treatment of chronic Lyme disease when determined to be medically necessary and ordered by a physician acting in accordance with (RI’s physician protection bill) after making a thorough evaluation of the patient’s symptoms, diagnostic test results and response to treatment. **Treatment otherwise eligible for benefits pursuant to this section shall not be denied solely because such treatment may be characterized as unproven, experimental, or investigational in nature...**”.

The section in bold above is particularly relevant for Massachusetts, given that some of our major health insurers have developed extensive, highly restrictive guidelines which rely heavily on laboratory testing, and do indeed characterize such treatment in those terms. Blue Cross/Blue Shield, for example, has developed an eight page set of guidelines regarding its coverage of IV antibiotic treatment which relies heavily on results of laboratory testing. Similarly, Harvard Pilgrim has developed guidelines both for oral and antibiotic treatment of Lyme, which also rely heavily on lab testing - despite their noting in these guidelines that “Diagnosis of Lyme disease is difficult as currently available serologic<sup>20</sup> tests may be unreliable”.

There is currently no existing means to determine if the infection caused by the Lyme disease bacteria is still present or absent in a given individual, or that a particular length of treatment is ideal. There is however ample observational evidence, published and otherwise, that effective treatments do exist. Until such time comes that those treatments are evaluated in controlled trials, physicians need to be able to use their best clinical judgment when treating patients with persisting/chronic symptoms.

- b. Massachusetts State Representative Theodore C. Speliotis - (D – Danvers) has filed a bill that would provide mandatory insurance coverage for Lyme disease in Massachusetts. This bill is closely patterned after the Rhode Island law, but needs to be updated to reflect the passage of the Physician Protection Act in Massachusetts, similar to how this was done in Rhode Island.
2. It is also recommended that a mechanism be devised to oversee potential violations of the insurance mandate, should it be adopted by the Commonwealth, as well as to investigate reports of potential discrimination against patients with Lyme disease, particularly those who may have received a diagnosis based on clinical criteria. The Division of Insurance and the office of the Attorney General could possibly provide assistance with this oversight.

Below are lists of patients who self-reported their experiences relative to insurance concerns. Their names and city and towns have been abbreviated and grouped by county in order to protect

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<sup>20</sup> the study that deals with the properties and reaction of serums especially blood serum

the patients' rights. **It is important to note that while their experiences have been included here in order to highlight the considerable difficulties some patients with Lyme disease are experiencing, this information is not statistically significant and is in no way meant to provide a comprehensive representation of all Lyme patients.** Many patients with Lyme disease report positive outcomes with no complications or ill effects.

**Below are three testimonies of the seven patients who reported denials of insurance coverage**

1. S.H. - "Denied coverage for IV abx by Blue Cross Blue Shield-Anthem. I saw my most progress during my 3 month treatment but had to come off of it because of denial and now cannot afford it on my own. I appealed my denial 3 times and my final letter from them came from a nurse that said in print, I did not have Lyme disease even though my doctor was within their network! (I know I'm not alone!)"
2. L. F. - "insurance doesn't cover office visits and I paid for my IV abx for over a year that insurance wouldn't pay we spent over \$10,000 last year. Now my husband may need IV abx and to be out of work for a month or two." Currently 5 family members in treatment.
3. D.S. - "insurance has not paid for testing or Lyme doctor appointments"

**The following describes seven patient's experiences out of the one hundred and twenty-two that stated that they have not been helped by the current standard of treatment, or experienced significant treatment delays (many of the one hundred and twenty-two also indicated that insurance coverage for treatment had been denied)**

1. L.F. – Worcester County, MA - "has spent over \$10K in the past year on antibiotics and currently 5 family members are infected".
2. C.K. – Berkshire County, MA – "I was treated with 3 weeks of Doxy and told my Lyme would be eradicated, that even 4 wks wasn't necessary. I went on to see 5 more Dr's and a trip to the ER- My symptoms worsened and I suffered greatly for the following 5 months until I was able to find a Dr. 4 1/2 hrs away who put me on medication (currently on) for the last 8 months that has saved me".
3. E.R. – Bristol County, MA (daughter misdiagnosed for over a year due to inaccurate testing and lack of knowledge of 5 specialists. She was eventually effectively treated in CT with abx but required treatment considerably beyond recommended IDSA guidelines).
4. A.P. – Essex County, MA [Became ill at age 11 misdiagnosed for over 2 years due to poor testing and lack of knowledge by many specialists for over 2 years, multi-systemic involvement by that time, treated in CT well beyond IDSA guidelines. Insurance covered oral antibiotics and some testing, but we had to pay everything else out-of-pocket, even though there was no covered option for her. Delay in diagnosis caused many health problems (and continued visits to specialists in many fields, which have been covered by Blue Cross) and she is just now healthy enough to resume a 'normal' life at age 20].
5. S.F.P. – Essex County, MA (Delay in treatment due to inaccurate testing. Difficulty finding a local doctor to treat me, even with a CDC positive Western blot and all sorts of neuro symptoms including major brain fog and memory loss. Three weeks of doxy did nothing. Required lengthy treatment (eventually in CT) with combinations of antibiotics to reclaim my brain. Insurance wouldn't cover doctor in CT, but did cover oral antibiotics).
6. L.L. – Essex County, MA - "When I got the initial flu-like symptoms I called my doctor. They sent me straight to the Beverly Hospital for a test and told me to wait. It came back with one fewer band than needed for diagnosis so they didn't treat it. Soon after, I had ER rashes all over my body and was so sick that I couldn't tell what day it was or walk straight. They gave me 3 weeks of antibiotics. It wasn't nearly enough and didn't make my symptoms go away. I went to another doctor in MA who treats Lyme and got more antibiotics. When I told my PC doc, he said that I could no longer be his patient because I had taken more than the antibiotics he prescribed me. Just the beginning of a long and gory story".
7. L.C. – Middlesex County, MA - "I personally battled a myriad of physicians, including Pediatricians, Neurologists, Cardiologists at Children's Hospital in Boston, Psychiatrists and Psychologists at McLean Hospital when I was trying to advocate for my 16 year old daughter for a proper diagnosis and treatment plan. It was like trying to break down the Great Wall of China, extremely difficult, frustrating and emotionally exhausting. Unfortunately, due to this unappreciable controversy in the medical world in

regards to Lyme disease, we were forced to seek treatment with an ILAD's supported physician in NYC, paying out of pocket expenses that were high and not covered by our insurance plan. This is disgraceful and unnecessary! It needs immediate attention and desperately needs to change ASAP. Please support the efforts of those involved who are trying to make a difference in the lives of innocent and helpless patients and their families who are suffering with Lyme disease”.

**Here are several more informal examples from other sources:**

- a. A family with several sick members sought treatment for Lyme disease from a practitioner outside of their insurance network, because they had been unable to find someone inside their network who would treat them. They had to drive over two hours for this care, pay for it out-of-pocket, and wound up taking out a second mortgage to cover it. They believe that the treatment was effective and has restored them to better health and functioning. Prior to getting treated, the mother in particular had been so sick that she had been unable to get out of bed.
- b. A young woman of 24 was misdiagnosed with ALS and given two years to live. Her mother, refusing to accept this prognosis, searched for better answers and found a neurologist who suspected Lyme disease. Their insurance denied the physician's prescription to treat her with IV Rocephin (i.e., intravenous treatment for neurological Lyme disease). She appealed the decision and hired an attorney. The insurance company eventually agreed to the treatment, but the battle caused a significant delay in getting it started. Now, several years later, the patient is much improved, but suffered severe muscle wasting and other residual effects, for which she has been awarded social security disability coverage.
- c. A very ill professional went to several medical providers searching for an answer for her tendon and joint pain, severe headaches, cognitive decline, weight loss and more. She suffered a significant delay in her diagnosis and treatment, despite an abnormal brain MRI, and has been unable to work for several months. Finally, two physicians, one of them a neurologist, diagnosed her with Lyme disease and prescribed intravenous (IV) Rocephin. Her Blue Cross/Blue Shield Plan would cover only one month of treatment, per their strict regulations for intravenous antibiotic treatment for Lyme disease. This caused a hiatus of over a week in her treatment. She and her husband have decided to pay for it out-of-pocket, causing them even greater financial hardship.
- d. An infusion company reported that an insurance company gave prior authorization for four patients to receive intravenous antibiotic treatment for Lyme disease. The insurer later rescinded the approval and demanded repayment of several thousands of dollars. When the infusion company pointed out that they had received prior authorization for the services for each patient, the insurer stated that “prior authorization is not a guarantee of coverage.” The infusion company was able to avert this disaster on behalf of these patients by finding a loophole: the insurer's website had not yet been updated to reflect its newer, more restrictive intravenous



antibiotic coverage. However, this will not help future patients who seek this type of coverage.

3. There have been reports from physicians that they are having difficulty getting their prescriptions and other prescribed treatments covered for their patients.
  - a. One physician reported experiencing problems and refusals over the past few years, and more so recently, with having his prescriptions for more than 30 days of antibiotics being filled or honored by insurers and prescription companies. He stated that this has been especially the case with MedCo, a national prescription company utilized by several third party carriers (e.g. BC/BS), and relates to both oral and IV antibiotics for greater than 30 days. Recently, one insurer refused to provide 30 days of IV treatment for even early Lyme disease, instead authorizing only the 28 days authorized by the company's guidelines. This case demonstrates the rigidity of the company's guidelines. He notes that, by restricting the types and length of antibiotic treatment that can be used to treat persistent or relapsing Lyme disease, or what some may call post-Lyme disease, physicians caring for such patients are being denied the right (established by the passage of the Physician Protection Act) to use their clinical judgment in caring for them.
  - b. Another physician's office reported that they have had much more difficulty getting insurance authorization for the treatments ordered for their patients. They relate this to the passage of the Physician Protection Act in Massachusetts last year: it is their impression that insurers have created more restrictive guidelines which are making it harder for patients to get coverage. In other words, even if they are able to find a physician willing to diagnose and treat them for Lyme, many patients are unable to afford the associated costs. Hours and hours of staff time are being taken up in the effort to obtain prior authorizations, and/or to appeal denials.

**Below is a list of patients who report that they were denied treatment for Lyme disease by various medical facilities in Massachusetts**

1. J.K. and D.K. of Worcester County, MA – four of their five children have or have had Lyme. Denied by insurance company after Head of ID at MGH writes script for simple IV antibiotics for their daughter. Told by doctors they couldn't treat their eldest daughter properly because their licenses would be jeopardized by doing so. Family continues to pay out of pocket for treatment costs.
2. B.R. of Hampden County, MA - Denied care at Baystate Medical after showing positive IGENEX for Lyme disease and positive test work for co-infections. Denied treatment. She has had to mortgage her home to pay for her doctor visits and medications. Now can work only part time and cannot repay loans.
3. J.S. of Middlesex County MA – Denied further coverage for ongoing medications prescribed by a Neurologist because treatment went past 28 days.
4. E.H. of Bristol County, MA – Her Primary Care Physician denied treatment because tick was not attached for more than 24 hours despite EM Rash. Patient sent tick to be tested on her own and it tested positive for Lyme disease. PCP offered one doxy pill. Now testing CDC positive on Western Blot and physician says its false positive and symptoms are “all in your head” while offering a sleeping pill.

5. B.D. of Suffolk County, MA – Denied treatment by a Neurologist and Infectious Disease Specialist at MGH after a positive Lyme test and being ill for several months. Also denied treatment at Harvard Vanguard Medical Center following one positive Lyme test and three weeks of antibiotics. Still very ill two physicians told her the test was a false positive and patient was probably just stressed and anxious.
6. M.H. of Norfolk County, MA – Son was denied treatment by two doctors at Dedham Medical Assoc. despite being CDC positive and symptomatic. She has also been denied treatment because testing was negative despite ongoing symptoms of Lyme disease.

There are currently no means to determine if the infection caused by the Lyme disease bacteria is still present or absent in a given individual, so there can be no definitive statements made that only a certain number of days or only certain antibiotics can be used to treat persistent or relapsing Lyme disease, or what some may call post or chronic Lyme disease, and that physicians caring for such patients may use their clinical judgment in prescribing treatments for longer than 30 days. The only clinical treatment trial that showed that one month of IV treatment (i.e. ceftriaxone) followed by two months of oral treatment (doxycycline) did not result in resolution of the symptoms cannot and should not be used to deny treatment for longer periods of time with other antibiotic regimens.

There is ample observational evidence, published and otherwise, that there are other effective treatments, and until such time comes that those treatments are evaluated in controlled trials, physicians need to be able to use their best clinical judgment when treating patients with persisting/chronic symptoms.

## **Prevention**

The following outlines the best practices available for the prevention of Lyme disease and other tick borne illnesses prevalent in Massachusetts. It is believed that through these practices the incidence of Lyme disease could be greatly reduced in order to prevent and later stages of the disease that have now infected so many Massachusetts residents.

The focus of the prevention efforts are on vaccination, environmental modes of intervention, deer management, and education on personal protection. An integrated strategy comprising short and long term approaches is required for its success.

It is critical to make the distinction between short and long term approaches because the kinds of resources needed are very different, and the expectations of results are very different. With short term methods, there may be relatively immediate but not necessarily sustained reduction in disease incidence. With long term methods, the goal is to reduce incidence significantly over ten years. It would be premature at this point, however, to set a defined goal for Lyme disease risk reduction. Setting such a goal is dependent on defining the modes of intervention, promoting stakeholder commitment, and securing resources and funding.

Short term methods can be immediately implementable, have a focus on individuals or small groups of individuals, take place on a daily to yearly basis and require a substantive attention level and degree of commitment to keep doing them and to continue ongoing funding.

Long term has the ultimate goal of returning Massachusetts to the tick bite frequency and Lyme disease incidence of 30-50 years ago when Lyme disease was not a problem; or, to have in place an infrastructure that maintains a lower incidence. The approaches are slow and steady, needing to establish solid frameworks conceptually via education and by promoting environmental management. After initial outlay of funds, resources, and effort (ramp-up phase) only minor input is required to maintain “control.”

Examples of short term methods are: repellent use and regular tick checks, yard spraying or yard cleanup, trail brush management.

Long term methods include deer reduction, habitat modification, education to promote tick-bite protection behaviors and practices such as being “TickSmart” or knowing to see a healthcare provider if one has a rash or an unexplained fever during the summer.

Ideally, a menu of vetted options should be presented to communities and such options may be selected depending on local resources and commitment. While long term management approaches are undertaken, short term approaches such as personal protection must be undertaken. It should be noted that the emergence of Lyme disease required 50 years and thus it may not be reasonable to have expectations that any effort can immediately impact risk.

The four primary areas of focus needed to implement an integrated risk management system are vaccination, education, environmental controls and funding.

### ***Vaccination***

1. The Commission believes a vaccine to prevent Lyme and other tick-borne diseases is necessary and recommends research for the development of a vaccine that targets multiple strains of Lyme and other tick-borne illnesses which are becoming more prevalent in our state.
2. Legislation should be drafted to specify compelling tax incentives for Massachusetts-based companies to promote advanced preclinical development of immunogens with peer reviewed evidence of efficacy in animal models and for sponsoring of the clinical trials needed for FDA approval.

### ***Environmental Interventions***

Lyme disease emerged as a result of three main factors: (1) reforestation after the abandonment of pastures and farms, (2) increased development (suburbanization) and recreational use of habitat, and (3) expansion in the density and distribution of white tailed deer, the main reproductive host of the deer tick. Along with these factors, the increased density of human population in the modified environment put and puts more people at risk. Returning the Massachusetts landscape to a time 50 years ago would be the ultimate long term intervention, one that would ensure that our children's children would not have to face the risk of infection as we do today. Of these, development and habitat use cannot be manipulated. Habitat may be

managed to a certain extent. Deer density is the only one of the factors over which we have any possible control.

1. The Pesticide Bureau should add specific tick-relevant training through the pesticide licensing exam materials.
  - Application of insecticides (spraying, particularly of granular pyrethroids or organophosphates as acaricides<sup>21</sup>) does indeed work to will reduce the density of ticks in the environment (Stafford 2007). This is supported by numerous peer reviewed scientific publications.
  - Controlling ticks by application of insecticide is underutilized, perhaps reflecting a lack of public awareness of this option as well as largely unfounded fears of pesticides in general. It should be noted that organic alternatives to the synthetic pyrethroids and organophosphates are available, such as pyrethrin; insecticidal soap, diatomaceous earth, garlic oil, and entomopathogenic nematodes also show some degree of efficacy in reducing ticks around yards, although not as effectively or economically as with the synthetic products. Spraying may currently be done by the individual homeowner or by commercial licensed pesticide applicators. However, the actual efficacy of professional pesticide applicators in controlling ticks is not known. There is no recognized standard of training to deal specifically with ticks. All pesticide applicators are required to take an exam and maintain an applicators' license through the Pesticide Bureau but such training does not include specific instruction on ticks.
  - The commission might explore the mechanism to add specific training through the pesticide training programs and examinations.
  - Host targeted acaricides (e.g., tick tubes or 4 posters) can be useful. In sites where chipmunks are not present, tick tubes (which contain cotton nesting material treated with permethrin) effectively reduce the density of infected ticks (Mather et al. 1987). 4 posters will reduce local host seeking deer tick density by 70-80% (Pound et al. 2009). Both of these interventions are expensive and must be undertaken every year. The 4 poster is considered experimental in Massachusetts and currently requires a scientific research permit issued by MassWildlife; there are concerns about exposure of hunters to chemicals (by eating venison from sites where 4 posters are deployed) as well as preventing the "baiting" of deer during hunting season. Although 4 posters have been found to be effective, and could be considered for local integrated tick management programs, the expense is likely to be prohibitive. It is estimated that Nantucket would require an expenditure of \$300,000-400,000 each year for an indeterminate number of years to deploy and maintain island-wide coverage that might effectively reduce tick density. Such intensified application would likely select for pesticide resistance in that deer tick population. Nonetheless, host targeted acaricides must be considered in any integrated tick management program, and accordingly education on prevention should include such information. In particular, 4 posters should be considered where intensified deer management is not possible.

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<sup>21</sup> pesticides that kill mites and ticks

The expense for deploying host targeted acaricides would be borne by communities or by individual property owners.

2. Spraying to control ticks should be promoted by public education. Precise recommendations for active ingredients, formulations, modes of application, and timing of applications (Stafford 2007) need to be made widely available.

All applications must be performed as directed by the product label (the label is the law) but there are nuances to the application that are unappreciated. For example, entire yards including lawns need not be treated; solely the perimeter and abutting tick habitat need attention. Thus, both homeowners and professional applicators require education on how to use insecticides to reduce tick density.

3. A study of costs should be conducted the State Reclamation Board to determine what extra funds would be needed for each mosquito control district to expand the scope of their work to include tick control measures. Such a study would be facilitated by the development of a “best management practices” (BMP) that might be implementable by mosquito control projects. Thus, prior to studying the costs of incorporating tick control into the mission of mosquito control projects, the State Reclamation and Mosquito Control Board should explore a specific tick control BMP.

- As a consequence, Massachusetts State Representative Carolyn C. Dykema (D – Holliston) filed *An Act relative to the control of tick-borne illness* which could be amended and filed to allow changing the legislative basis for mosquito control to include the option to offer tick control measures.
- Representative Dykema has previously introduced this bill to incorporate tick control activities under the nine mosquito control districts overseen by the Department of Agriculture Resources (DAR) through the State Reclamation Board. This bill was not reported out of the Joint Committee on Environment, Natural Resources and Agriculture last year. Mosquito control projects raise the following issues: a study needs to be done to estimate the extra costs associated with adding extra responsibilities; additional appropriations to mosquito control budgets via the cherry sheet to enable extra responsibilities may jeopardize current town memberships and have a net negative effect on an important public health function (mosquito control); no best management practices exist for tick control at the level of a state agency, such a document would be required to realistically estimate costs. It is likely that adding tick control would be more labor intensive because of the need for evaluating and treating individual properties as opposed to most mosquito intervention, which targets neighborhoods or larger areas. Thus, legislation at this point to force mosquito control projects to incorporate tick control may be premature and possibly counterproductive.

4. Department of Conservation and Recreation (DCR) and other stakeholders overseeing property that is open to public recreational use in the Commonwealth should examine options for reducing tick habitat, including the use of controlled burns and vegetation

removal. Costs for such options need to be defined and DCR appropriations should be modified as necessary and possible to allow for implementation of any new management efforts.

- Trail signs should be recommended to all Massachusetts state parks through a letter to the DCR attached to a copy of this commission's report citing the current need to begin to implement prevention and awareness methods currently available. Signs can be obtained through the CDC.gov website free of charge.
  - This environmental discussion has heretofore focused on short term approaches (those that require continuous expenditure of resources and time). Long term approaches – restoring the environment to what it was before deer ticks were a problem – need to be considered. Forest management practices need to be examined to determine whether there are ways to reduce habitat favoring deer ticks. The current practice of fighting forest fires allows brush and leaf litter to accumulate, thereby promoting dense habitat for ticks and mice. Controlled burns and brush clearing should be explored as means of reducing habitat. Such a strategy could also alleviate the extreme uncontrolled wildfire hazard in many sites.
5. A study should be performed to determine how to ensure compliance for tick control on school properties, particularly to identify the resources needed and the means of enforcement. A goal should be set such as “100% of school grounds to be tick free by 2015”.
- Two facets of acaricide use need further discussion. One, prioritizing the treatment of school properties would seem to be noncontroversial but there are substantive regulatory requirements (pursuant to The Children and Families Protection Act Chapter 85 of the Acts of 2000; part of the Massachusetts Pesticide Control Act). These include the requirement that each school must have a written updated Integrated Pest Management (IPM) plan, and any application requires written advance notification to all stakeholders. Certain pesticides effective against ticks (such as permethrin and resmethrin) are banned from use on school properties.
  - Secondly, if a school IPM plan cannot include an effective spray against ticks, an alternative must be implemented excluding the use of pesticides/acaricides. Perimeter treatments such as brush clearing and mulch or gravel barriers which would reduce the interface between school activities and the environment that harbors tick infestations. Helping our schools to become Lyme literate is a key element in prevention.
6. MassWildlife should study the costs and benefits of expanded access to crossbow hunting which includes any hunter who becomes certified through a crossbow safety and proficiency training program. Legislation should be filed to implement such access for deer hunters, and MassWildlife should develop or modify regulations to accommodate the expanded use of crossbows for hunting deer.

- Enhanced deer management needs to be implemented aggressively given the central role of deer in the life cycle of the deer tick, as summarized in numerous peer reviewed publications (Telford 2002; eds. Aguirre et al. Conservation Medicine). Each female deer tick that obtains a blood meal will lay 2000 eggs. Female deer ticks will feed only on larger animals such as dogs, deer, moose or bear. There is much misunderstanding of the deer tick life cycle with assertions that mice are more influential hosts; mice and other small animals (many passerine birds, shrews, squirrels and chipmunks) do feed immature ticks (larvae and nymphs) but never feed adult ticks, which are the only reproductive stage. Targeting the hosts of immature ticks to prevent the feeding of 2000 larvae or 200 nymphs could easily be compensated for by the successfully feeding of one female tick. Deer ticks, however, emerge from eggs largely uninfected and thus acquire infection from such small hosts. Two things are thus needed for ecologic risk: production of new ticks (deer bloodmeal) and infection of new ticks (mice and birds).
  - Deer proof fencing, deer reduction, and pesticide application to deer via “4-posters” (Telford 2001; Pound et al. 2009) have all been demonstrated to reduce the local density of deer ticks. Sustained low densities of deer (to about 8 per square mile; many Lyme endemic communities have deer densities of 30-50 per square mile) will greatly reduce the overall contamination of the environment by ticks but not totally eliminate risk (Telford 1993). It is likely, however, that there are many sites, such as those that are heavily residential, where deer targeted strategies may be too late. Identifying areas where deer density is not currently enough to promote pest densities of deer ticks and ensuring that deer herds do not increase there should be a priority. Deer can, however, be safely managed in suburban sites with controlled hunts (Kilpatrick et al. 2007). Archery should be promoted and expanded; the use of crossbows in particular. Currently, crossbows are allowed only for individuals who cannot physically use a compound bow and present a letter of application to MassWildlife from his or her healthcare provider.
7. It is recommended that the Massachusetts Division of Fish and Wildlife explore the costs and benefits of changing to the archery safety zone to 150 feet of an inhabited dwelling to allow greater access to sites for deer management. Legislation should be filed to implement this recommendation with MassWildlife’s approval.
- A major factor in the expansion of dense deer herds is the safety zone which prevents hunting within 500 feet of an inhabited house without written permission. The majority of land in eastern Massachusetts is thereby rendered inaccessible to hunters (O’Shea, 2010. MassWildlife Magazine). New Jersey has recognized this obstacle to effective deer management in heavily suburbanized habitats and in 2010 changed their archery safety zone from 450 feet of a habitation to 150 feet (New Jersey Department of Environmental Protection, “Bowhunting Safety Zone Perimeter Bill Signed by Governor”). There has been no increase in hunting-related accidents.

## *Education*

There is overwhelming support for enhancing tick awareness and tick-bite protection education for tick-borne disease (TBD) prevention at all levels from preschool to homeowners.

- Personal protection, in particular, is a tool that can have immediate results in reducing risk
- Knowing that nymphal deer ticks are the principle Lyme disease vectors would likely promote enhanced personal protection measures when this stage is most active
- Understanding the deer tick life cycle potentially would promote support and implementation of other Lyme disease prevention interventions such as deer reduction or proper pesticide application
- Knowing where you are and are not at greatest risk for infection with TBDs is a critical decision support tool for helping to engage people in adapting preventive behaviors

The following outlines strategies for effective dissemination of tick-bite protection messages, and suggested topics to help all Massachusetts residents and visitors become “tick literate” for TBD prevention.

Currently, in Massachusetts as in most states, information for tick-bite protection and TBD prevention is disseminated to the public in various formats and structures. There is little coordination or consistency in message selection or source, delivery emphasis, or sensitivity to seasonal dynamics of tick encounter risk. Moreover, few programs use concepts promoting behavior change in a consistent or effective way. Various health promotion models are available to help people at all levels (some work better for adults than for children) engage in behaviors that will prevent a negative health outcome (i.e. contract a TBD). For example, one widely-used construct, the Health Belief Model, emphasizes that people must: (1) believe that they are susceptible and likely to fall victim to the disease, (2) believe that the disease has potentially significant adverse consequences for their well-being, (3) believe that preventive behavior is effective, and (4) believe that they have the ability to engage in the preventive behaviors. Additionally, people need to constantly be reminded of the what, when and how to of performing the behaviors. The goal of any health promotion effort should be focused on increasing knowledge leading to the desired behavior/attitude change.

Simple messages can easily be understood by most people when disseminated through audio and visual media while complex messages are best understood when read. To effectively reach the target audience for TBD prevention, simple messages (“Got Ticks? Get Information!”) can be used as “teasers” to raise awareness and direct people to user-friendly resources that provide preventive “calls to action” coupled with engaging decision support tools and applications. The user-friendly resource should include, at least, all of the following:

- Provide for a distinctive Massachusetts brand (for example Massachusetts could modify other existing programs such as “TickSmart” in Rhode Island) for our own population which contains core call-to-action messages
- Use strategies for removing implementation barriers



- Use stakeholder-appropriate messaging (school-age children, adults working with school-age children, outdoor workers, homeowners, pet owners, people engaging in higher tick risk recreational activities, etc.)
  - Take a theory-based approach (eg. Health Belief Model or others)
1. Short videos, especially those portraying members of the target audience, can be helpful in providing more specific “how to” decision support, and can readily be downloaded from media sites like YouTube. In general, campaigns utilizing multiple media channels that effectively integrate simple, easily understood messages directing people to more content-rich websites or other readily available resources are more likely to result in adoption of preventive best practices.

With Lyme disease, there is ample evidence (Gould et al. 2008; Malouin et al. 2003) suggesting that people living in Lyme disease endemic areas already are well-aware of the problem and believe that they are familiar with many of the recommended preventive best practices. Based on these studies, increasing knowledge alone does not appear to be effective in getting people to consistently engage in Lyme disease prevention behaviors. Prior to making a final decision regarding campaign content, it may be necessary to identify particular “barriers” to implementation. This may best be achieved through the use of focus group surveys with key stakeholder groups (parents, school nurse educators, etc.). Nevertheless, a social marketing approach using more targeted, audience-focused strategies is likely to produce the best results.

2. Community partnerships and buy-in are likely to be critical to the success of a statewide social marketing campaign to implement effective tick bite protection for preventing TBDs. One goal of the campaign should be to align as many stakeholder groups and interests (town Boards of Health, school nurse educators, camp directors, state and local parks and recreation departments, Lyme support groups, local business owners, healthcare providers, etc.) into a cohesive group under the guidance of a single initiative. Critical elements include highly credible sources of evidence-based information used in developing campaign messages, and a readily identifiable “branding” for all components of the campaign. Forming strategic alliances and brand penetration will promote sustainability and maximize success of the campaign.
3. Develop and or fund a health promotion theory-based, engaging, public information and educational health promotion campaign to run annually with seasonally appropriate prevention messages. This campaign should have a Massachusetts “brand” and a consistent message available 24/7 through a variety of channels (internet, mass media, local media, public health, etc.). In addition Healthcare providers need continuing medical education to provide prevention messages for tick borne diseases.

There are several important messages that need to be disseminated to the public related to tick bite protection and TBD prevention. Active learning strategies (questions, quizzes, etc.) are likely to be more effective than passive learning for message retention and understanding. Important content topics might include tick reduction/avoidance strategies, vector control strategies, tick-bite management strategies, tick identification resources, decision support for

taking prevention action. Ideally, the campaign would help all Massachusetts residents and visitors know:

- Where they are at risk and the likelihood of tick encounters
- The habitats and activity seasons of vector ticks
- Disease associations with different types of ticks
- How to conduct daily tick checks
- How to safely remove a tick
- How to most effectively repel ticks
- How to effectively reduce tick encounter risk in the home environment
- How to protect pets from ticks and how to keep pets from carrying ticks to people
- What the role of various wildlife is in propagating ticks and disseminating disease agents

It is recognized that the costs and benefits of individual modes of intervention remain to be fully understood. The actual efficacy of many measures recommended by tick biologists have been poorly studied due to lack of research funding. Nonetheless, this does not mean that action should not be taken until efficacy is fully “proven”.

The Massachusetts Medical Society should be encouraged to develop a user-friendly resource (Physician TBD Prevention Primer) and CME programs to promote provider involvement in prevention. Veterinary health care providers should also be included in the prevention effort. Each year during the month of May TBD prevention information could be displayed in offices and clinics of veterinary and human health care providers. Another method to effectively and economically disseminate information on prevention is to involve health care insurers who frequently send messages on health promotion and disease prevention.

Finally, we have little understanding as to the baseline level of knowledge in our target populations. Few KAP surveys have been done. In coastal Connecticut, the surprising conclusion that households would not spend more than \$100 a year to mitigate tick borne infection risk (surprising because Fairfield County comprises one of the nation’s top 5 per capita incomes) was published in Gould et al. (Vector Borne Zoonotic Diseases 2008). A pilot deployment of the CDC questionnaire used in the Gould et al. paper will be done on Martha’s Vineyard this summer. It is possible that this validated survey instrument could be useful in measuring the current level of awareness and provide a means of documenting the efficacy of any future effort to promote awareness. CDC has provided permission to freely use this survey instrument.

#### **FUNDING:**

1. The state should provide funding dedicated to the education of the general public as well as the medical community in order to provide them with the most up-to-date materials regarding prevention, as well as diagnostic tools and treatment practices
  - a. State funds should be allocated as an annual line item for MDPH to employ a full time professional health educator focused on the prevention of Tick borne diseases in the Commonwealth.
    - i. CDC did provide MDPH with 5 years of funding to enhance surveillance during the late 1990s and early 2000s. These funds were utilized to

implement a standardized reporting system and co-opted to develop/provide educational materials to Boards of Health as well as to the citizens of the Commonwealth (e.g., a Memorial Day media educational blitz). Subsequently, a State appropriation administered by MDPH was provided to the Barnstable County Department of Health and Environment to enhance education on Cape Cod. Cape Cod now has perhaps the most aware residents of the Commonwealth, and has not had the same increases in reported cases of Lyme disease as other parts of the state. This appropriation was recently discontinued and the future of the Cape effort is unclear.

- ii. These efforts demonstrate what a relatively small amount of funds (\$100,000-300,000 per year) can do to better the public health of Commonwealth residents. There is strong subcommittee support for advocating on behalf of MDPH as a priority recipient for any available future state funding. A full time MDPH health care educator and a modest budget for supplies and assistance could greatly enhance education related to prevention.
    - b. Funding for lectures in order to educate Health Care Providers about information on improving diagnosis and treatment of Tick borne illness and discussion of chronic Lyme disease and post-Lyme syndrome. The lectures would be approved by the American Medical Association (AMA) and provide incentives to medical providers via continuing education credits (CME).
    - c. Funding for MDPH and CDC updates, town websites and public service announcements.
    - d. State provided funding for engaging educational health promotion campaign, tick bite prevention, and knowledge, attitudes and practices (KAP) survey
2. Support of State and Federal funding for tick-borne disease research is strongly recommended. Research should include improved testing and treatment options, as well as research to understand the pathways of human transmission. Including the members from top Lyme organizations, ILADS(International Lyme and Associated Diseases Society), Lyme Disease Association, Inc., and IDSA (Infectious Disease Society of America) to discuss what funding is necessary and how to best address the needs of Lyme patients would be a way to include parties with diverse viewpoints and concerns.
- a. Funding to establish reliable and valid testing for stages of Lyme disease such as acute, post-acute, chronic and recurrent
  - b. \$42,000 for 5 additional questions to be added on the DPH reporting form

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International Lyme and Associated Diseases Society - [www.ILADS.org](http://www.ILADS.org)

California Lyme Disease Association - [www.Lymedisease.org](http://www.Lymedisease.org)

B.L.A.S.T. program - [www.ridgefieldct.org](http://www.ridgefieldct.org)

TickEncounter Resource Center at University of Rhode Island: [www.tickencounter.org](http://www.tickencounter.org)