

**Connecticut General Assembly
Public Health Committee Public Hearing
Friday, March 8, 2013
Wesleyan University**

Public Testimony Submitted and Support

Proposed Bills:

❖ **HB – 5140** *AN ACT ESTABLISHING A TASK FORCE TO
STUDY LYME DISEASE TESTING*

❖ **SB – 0368** *AN ACT REQUIRING THE DEPARTMENT OF
PUBLIC HEALTH TO REPORT ON LYME DISEASE AND OTHER
TICK-BORNE ILLNESSES*

Marie Benedetto, CPA, MST

mbenelyme@gmail.com

Marie L. Benedetto
329 Cherry Hill Rd.
Middlefield, CT 06455

Connecticut General Assembly
Public Health Committee
Room 3000 – Legislative Office Bldg.
Hartford, CT 06106

March 10, 2013

Distinguished Members of the Public Health Committee;

I would like to thank you for the opportunity to speak before you on March 8, 2013 at Wesleyan University on matters involving **Lyme and Tick-Borne Diseases** in Connecticut. As you heard from many constituents, Lyme and Tick-Borne Diseases is truly a public health threat to the citizens of Connecticut.

As I promised at the public hearing, I have gathered information for you to use when you discern on the **proposed bills HB-5104 and SB-0368** both relating to Lyme and Tick-Borne Diseases. Support for my testimony and as well as for the many questions asked by the Committee can be found in the “Public Testimony Submitted and Support” booklet included herein.

Many testimonies (those you heard on March 8 and those submitted in writing) reveal the true experiences of those who have had the misfortune to navigate through this complex disease, not only medically, but professionally, politically, psychologically and financially. Due to the complexities, **a well-balanced, scientifically diverse Advisory Committee is truly warranted** to take the time to assess the many challenges that face those who have the disease and those who are at risk (all of our citizens in CT).

Please take the time necessary to read the information and the testimonies of those submitted. I can assure you that these are just the mere few of those currently afflicted with this disease in our state. To help you understand the impact of the citizens around you, I encourage you all to spend a few minutes (where ever you go) asking the question to our citizens, “What do you know about Lyme and Tick-Borne Diseases in Connecticut?” “Have you or anyone you know been effected by this disease?” You will quickly find people all around you who know someone (or many) who have been devastated by this disease. The next time you stop for a cup of coffee, just ask... The next time you are in line at the grocery store, just ask... Please, ask the question to your friends, family, peers, public... understand the need for change in the face of this terrible disease. The health of the Connecticut citizens you represent depend on it.

Respectfully yours,



Marie L. Benedetto mbenelyme@gmail.com or 860-324-4237

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***“Knowing is not enough; we must apply.
Willing is not enough; we must do.”***

Johann Wolfgang von Goethe –
Scientifically and politically minded literary artist (1800s)

***“Just because you cannot SEE the pain;
Doesn't mean it is not there....”***

Mattina Benedetto –
*13 year-old Lyme Disease patient for 8 years...
A message to doctors...*

On March 8, 2013, my daughter, Mattina Benedetto, spoke before the Public Health Committee articulating her eight-year battle with Lyme and other Tick-Borne Diseases.

Let the **wisdom, courage and perseverance** she has put forth in facing this Disease and speaking with you, **set the example** you will need to **move forward with the change so desperately needed** for the citizens of Connecticut in the face of Lyme and Tick-Borne Diseases.

March 6, 2013 – Senate Bill 0368/HB 5104 – Public Testimony

To Connecticut Public Health Committee:

Summary: My personal experience with Lyme and other Tick-Borne Diseases can be found at the bottom of this testimony. As you will note, my family’s experience is not all that different than the many others who have had the unfortunate experience to face this disease and navigate the difficult process of obtaining adequate information and prompt, appropriate diagnosis and care.

Awareness (prevention), Prompt, Appropriate Diagnosis and Care... Sounds like something simple to obtain after a disease well-known to Connecticut for over thirty years.

Ironically that is not the case...

The number of Lyme disease cases in the United States has doubled since 1991. The Centers for Disease Control and Prevention estimate that there are nearly 325,000 new cases each year—**making Lyme disease an epidemic larger than AIDS, West Nile Virus, and Avian Flu combined.** Yet, only a fraction of these cases are being treated, due to inaccurate tests and underreporting. Each year, hundreds of thousands go undiagnosed or misdiagnosed, often told that their symptoms are all in their head.

**Centers for Disease Control (CDC), Infectious Disease Society (IDSA), International Lyme and Associated Disease Society (ILADS), CT Dept. of Public Health, Lyme Organizations (See Agreement Chart)

All Sources Agree (per sourced information**)	Experience/Challenges (faced by the general public, patient/physician)
Causes of Lyme and Tick Borne Diseases:	Causes of Lyme Disease Misunderstood:
Lyme disease is caused by bacterium – <i>Borrelia burgdoferi</i>	The white-footed mouse lives in all kinds of areas, particularly in people’s yards/barns/garages/stonewalls, edges of forest.
90% Reservoir of this bacteria resides in a white-footed mouse - which infects ticks that feed on them	Many people are under the impression that care is only needed if you go for a walk in the woods. Squirrels, foxes and other animals also carry ticks, not just deer.
Transmitted to humans by bite of infected black-legged ticks	Questions arise on how long the tick needs to feed to increase risk of infection
Ticks that transmit Lyme disease also transmit other tick-borne diseases	Co-infections are not commonly known by physicians/public, so symptoms may be missed
Prevalence:	What really is the prevalence in CT?
Prevalent across the United States and throughout the World	CT has been the epicenter for Lyme for years... CDC acknowledges 10% underreporting
Most common disease carried by ticks in the United States, and the number of those afflicted is growing steadily—from 10,000** (100,000) reported cases in 1992 to 30,000 in 2009** Underreported 10% - 300,000 cases	CT IS an ENDEMIC area – but how many ticks are infected? With what bacteria or other tick-borne diseases are they infected with that pose a risk to human? Veterinarian reports ¼ dogs are tested positive with Lyme bacteria in Middlesex County
95% of all cases occur in the Northeast/Upper Midwest	Surveillance criteria has changed over time skewing comparison data

All Sources Agree (per sourced information**)	Experience/Challenges (faced by the general public, patient/physician)
CT – 2011 reported 30,380 (based upon underreported 10% and reported 3,380 cases)	Changes in case definition for laboratory and physician reporting has changed over time skewing comparison data
25% of reported cases are children ages 5-19	Local Tick Tests have not been widely performed
Prevention/Awareness:	How can the Unaware become Aware?
Most humans are infected through bites of immature ticks called nymphs (size of a poppy seed)	Bites go undetected very often – so the only thing one may be aware of is onset of symptoms
Ticks can attach to any part of the body, but are often attach in hard-to-see areas; groin, armpits, and scalp.	No funding has been made available to do community-based awareness programs
A single tick bite can have debilitating consequences	An infrastructure is in place (local health departments) who are also unaware of this disease and the prevalence of symptoms
Best treatment is prevention/reducing exposure to ticks	Prevention measures (tick checks, showering, covered skin, etc) is fantastic, but not always practical. Young children run in and out all day and will not wear pants/long-sleeve shirts in the summer
Prompt Diagnosis and Treatment	The average patient sees 5 doctors in 2 years before being diagnosed with Lyme and other Tick-Borne Diseases (Ida.org)
EARLY treatment is KEY to prevent severe illness	If tick bites go undetected, wait until symptoms appear before going to physician
If left untreated, infection can spread to joints, heart and nervous system	Physician doesn't ask about potential exposure to ticks (even though we are in an endemic area) or if the patient remembers a tick attached
Clinical manifestations most often involve; skin, joints, nervous system and heart	General practice, if symptoms are vague – is to wait and see Available information is out-dated – in need of revision
Lyme Disease is diagnosed based on symptoms, physical findings and possibility of exposure to infected ticks	If Practioner suspects Lyme, a test will be ordered Reliability of the tests are in question
Lyme Disease is a CLINICAL diagnosis	Practioner will often use Laboratory tests to DIAGNOSE or RULE OUT the disease
Laboratory testing may be helpful if used and interpreted properly	Laboratory tests are NOT all the same – case definition of positive results are reported based on surveillance guidelines
Healthcare Practitioners in endemic areas should become familiar with the clinical manifestations and recommended practices for diagnosing and treating Lyme and other Tick-Borne Diseases	Many physicians are not aware of any Lyme or other co-infection symptoms other than “achy joints” and “bulls-eye” rash. Neuro symptoms are often missed during this phase. If caught – often standard protocol of antibiotic treatment is not enough (40% often end up with life-time effects of the untreated disease)(Ida.org)

***“Knowing is not enough; we must apply.
 Willing is not enough; we must do.”***

Johann Wolfgang von Goethe –

Scientifically and politically minded literary artist

2013 Legislative Proposal: - Senate Bill 0368 and combine House Bill 5104

1. Scientifically Diverse Lyme and Tick-Borne Disease Advisory Committee
(The language in the bill MUST ensure broad spectrum AND MUST include patient representatives)
2. Review Major Gaps in Understanding the Tick-Borne Diseases
3. Identify Opportunities for:
 - a. Coordination of Efforts between agencies/communities and organizations
 - b. Additional Funding for Community-Based Programs for Awareness, Physician Awareness, Research and Prevalence testing
4. Report on Findings and Make Recommendations based upon those findings (see VA Lyme Disease Task Force Final Report)
5. Reporting from CT DPH – incorporating two standards of care throughout...
 - a. Annual Public Reporting of grants/funding dedicated to Lyme and Tick-Borne Diseases (including community-based awareness programs)
 - b. Annual Statistical Reporting
 - c. Consistent and updated information on Website regarding disease and associated risks (easily accessible for the unaware)
 - d. Coordinated Awareness – State Parks, Schools, Local Communities, etc.

Respectfully Submitted; March 7, 2013

Marie Benedetto, CPA, MST

mbenelyme@gmail.com

Personal Experience – Myself (symptoms started 3/2012 – currently being treated 3/2013)

Infected after playing ball with my children in our front yard in Middlefield. Aching/crackling neck, progressing to shoulders, upper arms, back, hip and right thigh. Muscle twitches/pulses and atrophy, delayed motor skills, slowed speech, slurred speech, muscle weakness, cognitive barriers, double vision (images overlaid), decrease in hearing, ringing in ears, sensitivity to noise, increased irritability, decrease cognitive stamina, not able to spell or speak the right words, unmotivated, migraine headaches, began falling, unable to do anything quickly or concentrate for any extended period of time, right knee/leg felt swollen(big), SPECT scan revealed decrease in blood flow in areas of brain.

Initial visit to general Practitioner; tested for Lyme, arthritis and MRI (m.s.)... Per physician, Lyme titer was “negative”, recommended a neurologist. In meantime, went to Naturopath, felt symptoms were consistent with Lyme and tested again. The test then came back positive with two I’m (even according to CDC). Called Physician and faxed new results, 4 weeks Doxycycline ordered. Neurologist confirmed that infection spread through spinal cord based upon symptoms, but was certain that 4 weeks Doxycycline would be sufficient. I didn’t start Doxycycline until about 8 weeks after initial infection.

By the 4th week, I was symptom free on the Doxycycline. I knew I couldn’t get any more antibiotics from my physician, but also knew-based upon my daughter’s experience, that this might not be enough. Sure enough – two weeks after going off the Doxycycline, all symptoms returned, although not as intense at first, but more severe and systematic overall.

After Lyme Literate Doctor Visit, put on oral antibiotics, but progress slow and worried about decrease blood flow in brain (per SPECT Scan) and consistent cognitive dysfunction. IV therapy ordered – I am nearly symptom free currently (after 10 weeks) while on IV and feel much better. Able to maintain cognitive stamina and seamlessly do the things that became very difficult (e.g. like making a bed, speaking intelligently, spelling).

I KNEW about Lyme disease and KNEW who to go to, and STILL couldn’t get treated quickly enough. It is about one year since my symptoms began. I hope that I will be able to recover fully from this ordeal so that I can better take care of my family and balance my work/social life.

Marie L. Benedetto
329 Cherry Hill Rd.
Middlefield, CT 06455
mbenelyme@gmail.com

Personal Experience; Marie L. Benedetto – daughter infected

Lyme/co-infected daughter, undiagnosed for 6 years (Age 5 to current age 13)

Symptoms: Chronic fatigue/stamina issues, night sweats, vision, hearing issues, cognitive/fogginess issues, lower body temperature, sleep issues, continued illness, walking/balance issues, food sensitivities, compromised immune system, fevers, neurological dysfunction/weakness on right side of body, excruciating burning shooting pains, paralysis of leg, arm, face, feet, temporary blindness, numbness, memory loss, at times unable to walk or talk, unable to attend her entire fourth-grade year at school, misconception about her academic abilities, etc. etc. A LOT of issues for a young girl that may have been avoided...Reinfection in November 2012, caused tremors, numbness in left hand, feet, legs... in addition, anxiety and social withdrawal from friends.

Treatment from medical community – passive, not knowledgeable, unwilling to link symptoms holistically, general disregard, implied mental illness, even with knowledge of tick bite and risk factors, when diagnosed with Lyme Disease – many medical professionals wouldn't even use the word or acknowledge you. They wouldn't even write it in the medical records even after you told them the history...even after you gave a positive lab report (even according to CDC positive)...

Our actual detailed story of our challenges with the local medical community would send shivers down most parents' spines.. and they would **never** again go to a doctor without using their own sense of self-advocacy armed with knowledge and maintain their own medical history.

Costs Associated: We have spent tens of thousands of dollars (I have actual numbers for submission if you wish) of our own money as insurance companies do not always cover the medical specialty of which is needed to fight this disease. The insurance company has also paid a great portion of various bills adding to the surmounting cost of this disease to our family. If the information was generally accepted and available at the time my daughter became ill, a pediatricians' question "Has she been bit by a tick in the recent past" may have been asked and all of this could have been prevented with a \$25.00 bottle of antibiotics. There is no measurable cost to the pain and suffering my daughter (and our family) has endured for the past eight years.

Final Treatment – We needed to go out of state (**New York City**) – it appears if anywhere from New Haven County and North in CT (at the time)– absolutely NO acknowledgement whatsoever that there is even the remote possibility you can contract LYME disease/co-infections.

Received treatment with antibiotics (oral and IV) (3 yrs of treatment) and holistically treated to support immune, endocrine, and nervous system. **Co-infections are significant in her diagnosis and treatment.** She is currently doing well in school, has more stamina, better concentration, stronger immune system. Unfortunately due to the **prolonged disease**, some **permanent damage** may have been done (thyroid and nerve damage) and will continue to have to be monitored for relapses (due to how the bacteria can hide and wait for an opportunity) and then will be treated. She is left with memories of her childhood being ill, in pain/incapacitated at times. Now our fears lie ahead of relapse and will she pass this on in utero should she have a child in her future...it is a possibility that we don't want to face...

Next Steps: Now that my daughter is on a seemingly positive healthy path – I have more time to dedicate my energies to improving the process, awareness and overall good health of the citizens of Connecticut. I want to help the individuals and families avoid the challenges and hurdles we faced in finding the appropriate medical care needed for our daughter. It is devastating to the families and not to mention the victim herself. No child or citizen in the State of Connecticut or anywhere for that matter should have to undergo the scrutiny and general disregard of the medical community that we had to face.

People have sought me out with their own challenges facing them with similar symptoms, stories... I can name over 30 individuals alone who have sought me out in the past year (even perfect strangers) that have the same story...A most powerful realization that came to me in 2009 when my daughter was first diagnosed when I attended a local symposium in Glastonbury to learn more about Lyme Disease. Over 300 people attended this local event, all strangers in the room, yet linked together with the same story...we all experienced similar symptoms, similar medical community pushback and disregard... How can we all be CRAZY? These were just 300+ local people who happened to hear of the event, and happened to be able to make it to the event...all with similar symptoms and stories... That is statistically significant to me.

My hope is that we can come together and provide the awareness necessary to protect the health of our citizens.

Bill Number: S0368

Lyme and Tick-Borne Diseases testimony

Submitted by: Paul Benedetto, Middlefield, CT paulbenedetto@yahoo.com

March 8, 2013

Lyme Disease is a bacterial infection transmitted to humans by the bite of a tick. According to the CT Dept of Public Health, there are more confirmed cases of Lyme Disease in CT in 2011 than any other reported disease except for Chlamydia and Gonorrhea.

I have been a Lyme Disease patient. At present, my wife and daughter are Lyme patients.

As is common amongst those with Lyme Disease, I had persistent symptoms for a number of years that were always unexplainable by each doctor I had visited. I saw general practitioners and specialists, some offering ideas about the cause of my symptoms, some not. However, the symptoms never quite fit the suspected causes. After many years, one doctor suspected Lyme Disease, I was finally diagnosed and was able to be treated.

The difficulties with Lyme disease are too complex and too voluminous to discuss in the three minutes I am permitted to speak at this hearing, so I will note two of them, related to diagnosis.

First, Symptom Variety and Inconsistency.

There is no definitive symptom or set of symptoms that consistently determines a Lyme infection. There can be a wide range of symptoms, many of which can be inconsistent from patient to patient. The variety and inconsistency make it difficult for doctors to make a clinical diagnosis. Imagine how confusing, time-consuming and expensive it is for the patient. Each doctor may be using a different source of information on symptoms and diagnosis. Some doctors will use CDC surveillance criteria as a diagnosis guideline, despite documentation to the contrary.

Second, Blood Testing.

There is no single, definitive test that can determine whether or not a person has a Lyme infection. The blood testing primarily used today does not enjoy universal agreement on what defines a positive result. Different labs will report different sets of data. There are false positives and false negatives. The test is known to be of low accuracy. Despite these shortcomings, many doctors will not perform a clinical diagnosis, but will rule out Lyme disease if they interpret a blood test as negative.

As long as there are difficulties with diagnosis as I have outlined, patients will continue to suffer without adequate treatment.

My name is Mattina Benedetto. I am thirteen years old and live in the town of Middlefield with my parents and brother. I am writing to you about my horrible experience with an awful disease. Lyme Disease. I have been battling Lyme Disease ever since I was the young age of five, but wasn't diagnosed and treated until the age of 10. Since then my life has been drastically changed over long difficult years. My life has not only been changed but dreadfully painful.

Some of my symptoms were (and some still are):

Nerve pain - stabbing shooting pains in arms and legs
Skin pain - like sunburn pain - clothes on my skin would hurt
Aching neck, wrists and knees
Muscle weakness
Intermittent tremors
Soles of my feet would hurt
Always getting sick with fevers/colds/flu's
Intestinal issues
Complete memory loss - didn't even recognize my mother on one severe occasion
Short-Term Memory issues
Fatigue - not able to get out of bed
Paralysis of jaw/tongue, arm, leg
Loss of vision in right eye
Double vision/flashing lights
Feelings of passing out
Numbness in my hands, feet and legs
Chest pains

School

I missed my whole fourth grade year
I felt lonely, helpless and I was annoyed that there was nothing I could do about it.
I missed my friends and wanted to be at school
It was extremely hard to keep up with school work while at home
I would try so hard to do well, but just couldn't do well at school
It is often difficult to find my words - sometimes I just give up speaking

Treatment at Doctors Office

They didn't seem to believe me and it would make me feel horrible. I felt ignored and disrespected.

Treatment:

Finally (after 5 1/2 years) we found a doctor who believed me... and I started the painful process of treatment..
Past three years: pills, supplements and more pills - sometimes up to 7 times a day
IV through port in my chest
Painful weekly shots

**Lyme Tick-Borne Diseases
Sources of Information
Agreement Chart**

	<u>CDC</u>	<u>IDSA</u>	<u>ILADS</u>	<u>CT DPH</u>	<u>LDA</u>	<u>LD.org</u>	<u>NIH</u>
Causes of Lyme and Tick-Borne Diseases							
<i>Lyme disease is caused by the bacterium Borrelia burgdorferi and is transmitted to humans through the bite of infected blacklegged ticks.</i>	X	✓	✓	✓	✓	✓	
<i>The ticks that transmit Lyme disease can transmit other tickborne diseases as well.</i>	X	✓	✓	✓	✓	✓	
Prevalance of Lyme and Tick-Borne Diseases							
<i>Prevalant across the United States and throughout the world</i>		✓	X		✓	✓	
<i>Lyme disease is the most common disease carried by ticks in the United States, and the number of those afflicted is growing steadily—from 10,000 reported cases in 1992 to 30,000 in 2009. Underreported 10% - 300,000</i>	X	✓	✓	✓	✓	✓	
<i>Approximately 95 percent of all cases of Lyme disease occur in the Northeast and the Upper Midwest.</i>		X	✓	✓	✓	✓	
<i>Connecticut 2011 - 3038 Lyme Disease (underreported - 10%) +30,000</i>	X	✓	✓	X	✓	✓	
Awareness/Prevention							
<i>Ticks can attach to any part of the human body but are often found in hard-to-see areas such as the groin, armpits, and scalp.</i>	X	✓	✓	✓	✓	✓	
<i>Most humans are infected through the bites of immature ticks called nymphs. Nymphs are tiny (less than 2 mm) and difficult to see;</i>	X	✓	✓	✓	✓	✓	
<i>A single tick bite can have debilitating consequences.</i>	X	✓	✓	✓	✓	✓	<u>Critical Needs Gap</u>
<i>The best treatment for Lyme disease is prevention/reducing exposure to ticks</i>	X	X	✓	✓	✓	✓	
Prompt Diagnosis and Treatment							
<i>Early treatment is the key to prevent severe illness</i>		✓	✓	X	✓	✓	
<i>If left untreated, infection can spread to joints, the heart, and the nervous system.</i>	X	✓	✓	✓	✓	✓	X
<i>Clinical manifestations most often involve the skin, joints, nervous system, and heart</i>		✓	✓	✓	✓	✓	
<i>Lyme disease is diagnosed based on symptoms, physical findings (e.g., rash), and the possibility of exposure to infected ticks; laboratory testing is helpful if used correctly and performed with validated methods.</i>	X	✓	✓	✓	✓	✓	
<i>Lyme and Tick-Borne Diseases is a CLINICAL diagnosis</i>	✓	✓	X	✓	✓	✓	
<i>Health care practitioners, particularly those in areas of endemicity, should become familiar with the clinical manifestations and recommended practices for diagnosing and treating Lyme disease, HGA, and babesiosis (A-III)</i>		X	✓	✓	✓	✓	

X sourced information
✓ agree with sourced information

Centers for Disease Control (CDC), Infectious Disease Society (IDSA), International Lyme and Associated Diseases Society (ILADS), CT Department of Public Health (DPH), Lyme Disease Association (LDA), Lymedisease.Org (LD.org), National Institute of Health (NIH)

TABLE B-1 Annual Funding of Tick-Borne Disease Studies by Agency/Organization, 2006–2010

Agency/Org (#)	2006	2007	2008	2009	2010	Average
NIH-NIAID (404)	\$91,765,324	\$83,686,260	\$63,747,787	\$73,563,255	—	\$62,552,525
CDC (19)	\$5,706,765	\$5,631,765	\$5,614,765	\$1,226,765	\$9,685,126	\$5,573,037
NIH-NIAMS (15)	\$2,051,376	\$2,579,209	\$2,758,608	\$3,231,214	—	\$2,655,102
US-EPA (6)	—	—	—	—	\$1,509,759	\$1,509,759
USDA-ARS (5)	\$1,424,000	\$1,428,000	\$1,447,000	\$1,376,000	\$1,506,000	\$1,436,200
NSF (5)	\$390,196	\$1,093,733	\$1,436,180	\$2,990,954	\$376,133	\$1,256,439
NIH-NINDS (4)	\$662,366	\$458,834	\$654,163	\$220,625	\$597,877	\$518,776
US Army PHC (1)	\$237,750	\$237,750	\$243,500	\$232,000	\$237,750	\$237,750
USDA-NWRC (2)	—	—	—	—	\$318,000	\$318,000
YEARLY TOTAL	\$102,000,027	\$94,877,801	\$75,902,003	\$82,840,813	\$12,483,136	\$73,620,756

Handwritten note: A circle around the total value \$73,620,756 with an arrow pointing to it.

From: B, Federal Funding of Tick-Borne Diseases



Handwritten note: How much does it get annually? We don't really know (not easily accessible.)

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.

Institute of Medicine (US) Committee on Lyme Disease and Other Tick-Borne Diseases: The State of the Science.

Washington (DC): National Academies Press (US); 2011.

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LYME VS. WEST NILE DISPARITY

Table 2: Human Cases of WNV Infection - Connecticut, 2000-2011

Total Cases	89
Age range (median)	6-89 (57)
Gender	
Female	42 (47%)
Male	47 (53%)
Syndrome	
Meningitis/Encephalitis	64 (72%)
WNV Fever	24 (27%)
Other Clinical Unspecified	1 (1%)
Fatalities	3 (4%)
Hospitalized	60 (67%)

2000-2011
LYME
 35,566*
 * 355,660

Same period 2000-2011 WNV = 89
 LYME DISEASE = 355,660

-how is this possible?

Table 3: Fatal Human Cases of WNV Infection - Connecticut, 2000-2011

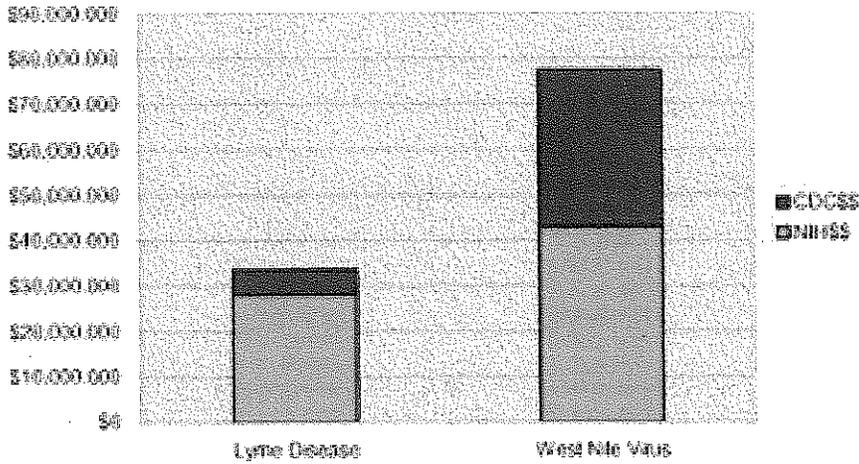
Total Cases	3 deaths
Age range (median)	81-89 (83)
Gender	
Female	2
Male	1
County	
Hartford	1
New Haven	2
Town	
East Haven	1
New Britain	1
New Haven	1
Syndrome	
Meningitis/Encephalitis	3
WNV Fever	0
Other/Clinical Unspecified	0

est:
 LYME - 40%
 LT illness
 125,000 +

Disparity in Funding: Lyme vs. West Nile

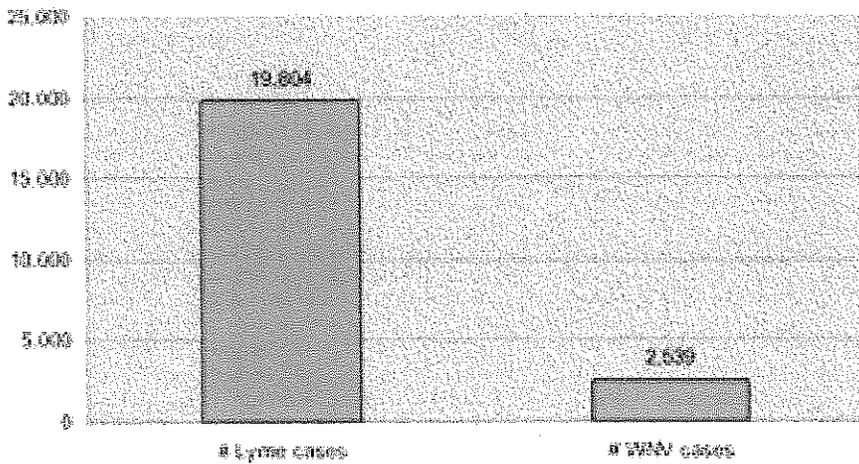
FED FUNDING DISPARITY

Federal Funding for Vector-Borne Diseases 2004



CT FUNDING - ?
 not available
 (or easily accessible)

Reported Cases of Lyme Disease vs. West Nile Virus 2004



Lyme disease is almost eight times more commonly reported than West Nile Virus in the U.S., yet the government spends 18 times more money on each case of WNV.

California Lyme Disease Association 2004

Connecticut Department of Public Health
 Reported Cases of Disease by County - 2011

DISEASE	Fairfield	Hartford	Litchfield	Middlesex	New Haven	New London	Tolland	Windham	Unknown	Total
Malaria	3	6	0	0	6	4	0	0	0	19
Measles	0	0	0	0	1	0	0	0	0	1
Menigitis	1	0	0	0	2	0	0	0	0	3
Neonatal sepsis	7	5	0	0	11	0	1	0	0	24
Pertussis	26	10	4	4	13	8	1	2	0	68
Plague	0	0	0	0	0	0	0	0	0	0
Pneumococcal disease, invasive	67	115	17	19	89	22	18	11	0	358
Poliovirus	NR	NR	NR	NR	NR	NR	NR	NR	NR	0
Psittacosis	0	0	0	0	0	0	0	0	0	0
Q Fever	0	0	0	0	0	0	0	0	0	0
Rabies (Human)	0	0	0	0	0	0	0	0	0	0
Rabies (Animal)	43	42	18	12	36	19	19	5	1	195
Reye Syndrome	0	0	0	0	0	0	0	0	0	0
Rheumatic Fever	0	0	0	0	0	0	0	0	0	0
Rocky Mountain Spotted Fever	49	7	5	0	24	9	0	0	0	94
Rotavirus	0	0	0	0	0	0	0	0	0	0
Rubella	144	98	14	16	106	51	15	26	0	470
Salmonellosis	NA	NA	NA	NA	NA	NA	NA	NA	NA	0
Sexually Transmitted Diseases	2,744	4,223	259	347	4,123	654	267	303	744	13,664
Chancroid	436	934	21	71	748	95	31	22	91	2,449
Chlamydia	0	0	0	0	0	0	0	0	0	0
Gonorrhea	34	26	2	4	43	4	3	6	1	123
Neonatal Herpes	18	11	1	0	8	1	0	2	0	41
Syphilis (<1 year or early syphilis)	153	264	54	25	326	51	28	24	0	925
Shigellosis	0	0	0	0	0	0	0	0	0	0
Staphylococcus Aureus, Methicillin-resistant, invasive	0	0	0	0	0	0	0	0	0	0
Tetanus	0	0	0	0	0	0	0	0	0	0
Trichinosis	33	17	2	4	19	7	0	1	0	83
Tuberculosis	2	3	0	0	0	0	0	0	0	5
Typhoid Fever	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Typhus	62	71	36	18	59	28	17	13	0	304
Varicella (confirmed & probable)	10	3	0	0	7	4	1	2	0	27
Vibrio infections	0	0	0	0	0	0	0	0	0	0
Yellow Fever	2	1	3	0	1	0	0	0	0	7
Yersiniosis	6	1	0	0	2	0	0	0	0	9
West Nile Virus (fever & invasive)	0	1	0	0	0	0	0	0	0	1

NA = Not Available
 NR = Not Reportable

Proposal for CT Bill – Lyme and Tick-Borne Disease Prevention, Education and Research Act

Marie Benedetto – mbenelyme@gmail.com

Caye Helsley - caye@helsley.com

Public Health Committee Public Hearing – March 8, 2013

Purpose: Establish a Tick-Borne Disease Advisory Committee (“**TBDA Committee**”) under Proposed Bill: “Lyme and Tick-Borne Disease Prevention Education and Research Act of 2013”

I. Duties of TBDA Committee: Ultimate Goal – *Advise and give recommendations to CT Department of Public Health (and related agencies/organizations) within one year of commencement of TBDA Committee, subsequent year/s ensure recommendations are implemented timely:*

1. **Review Published public/private** treatment guidelines, scientific information, and evaluate such strategies for effective representation of wide diversity of views
2. **Identify Opportunities** to coordinate efforts with Fed/CT/other State agencies and private organizations
3. **Ensure broad spectrum** of scientific viewpoints represented in public health policy decisions and that the information disseminated to public and physicians is balanced
4. **Identify need for funding** for research, physician education, and general public awareness
5. **Make appropriate recommendations** to CT Department of Public Health/Other applicable State Agencies (and/or Governor) on such as **but not limited to:**
 - **Disease Prevention**
 - **Opportunities for cooperative communication** and posting of information between agencies and organizations
 - **Current Testing Methods and Guidelines**
 - **Education (Physician and General Public)**
 - **Research Findings/Funding**
 - **Surveillance**
 - **Other Current Concerns**
 - Animal/Vector Transmission
 - Pregnancy and Sexual Transmission
 - Blood and Organ Donors
 - Children and Effect on Learning in Our Schools (at risk group ages 5-14 *cdc)
 - Other

Proposal for CT Bill – Lyme and Tick-Borne Disease Prevention, Education and Research Act

Marie Benedetto – mbenelyme@gmail.com

Caye Helsley - caye@helsley.com

Public Health Committee Public Hearing – March 8, 2013

Second Section Proposed:

Proposed Bill Key Points: SB 00368:

Currently Reads: ***AN ACT REQUIRING THE DEPARTMENT OF PUBLIC HEALTH TO REPORT ON LYME DISEASE AND OTHER TICK-BORNE ILLNESSES.*** (change title name: ***Lyme and Tick-Borne Disease Prevention, Education and Research Act***)

Be it enacted by the Senate and House of Representatives in General Assembly convened:

That chapter 368a of the general statutes be amended to require the Department of Public Health, in consultation with an advisory board established to study Lyme disease, to, not later than September 1, 2013, (1) report to the joint standing committee of the General Assembly having cognizance of matters relating to public health concerning recommendations for best practices to prevent, diagnose and treat Lyme disease and other tick-borne illnesses, and (2) disseminate information to the public and health care providers concerning the prevention and treatment of Lyme disease.

Statement of Purpose:

To ensure the state identifies, reports and implements best practices of incorporating diversified scientific viewpoints with regard to Lyme disease and other tick-borne illnesses.

Reporting from DPH – Statistical/Fiscal and Policy

- 1) Annual Public Reporting of grants and funding received by DPH designated for Lyme Disease and other tick borne illness (retroactive to 1996 – and continuing annually, designating benefitting communities, and with outcome data/resulting actions)
- 2) Annual DPH Grants/appropriations for prevention/awareness programs retroactive to 1996 – and continuing annually, designating benefitting communities, and with outcome data/resulting actions)
- 3) How is DPH utilizing Local Communities and Town/District DPH for public awareness regarding tick-borne diseases?
- 4) Policy for reviewing website updates/consistencies and diversified scientific viewpoints reported to the public.

Proposal for CT Bill – Lyme and Tick-Borne Disease Prevention, Education and Research Act

Marie Benedetto – mbenelyme@gmail.com

Caye Helsley - caye@helsley.com

Public Health Committee Public Hearing – March 8, 2013

Some proposed changes to website:

- Flash Dashboard on **front page of website**: 5 most common reportable diseases in CT (ongoing)
- Featured Links: **Lyme and Tick-Borne Diseases (most commonly reported disease in CT/Nation – absolutely should be a featured Link at all times)**
- **Statistics and Research** – (left side of webpage) No mention of Lyme here at all? (lead, west Nile, aids, food borne illness) yet compare stats?
- **Defined User/Focus Group to assist in proposed changes to website**
- **Access to website for “awareness purposes” – should include direct access without having to “know” the word Lyme/Tick-Borne Diseases**

Legislative Guidance:

Virginia: Commonwealth of Virginia The Governor’s Task Force on Lyme Disease
FINAL REPORT Adopted Unanimously on June 30, 2011 (See page 29 of Source Book)

Federal Senate Bill: S1381 (2012) (See page 35 of Source Book)

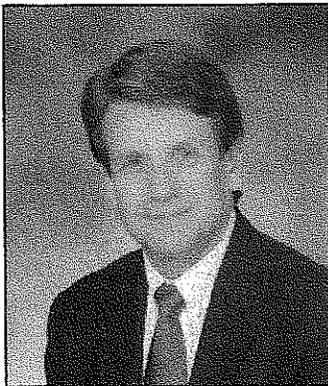
Other Legislative Proposed/Bills Passed: (see page 24 of Source Book)

VA-

Waking Up the Nation,
One Reader at a Time...

PUBLIC HEALTH ALERT

The Virginia Governor's Task Force on Lyme Disease Final Report Adopted Unanimously



Michael Farris, Chairman of
Governors Task Force

Introduction

In response to reports of the growing number of cases of Lyme disease and other tick-borne illnesses and out of a sense of concern for the significant number of Virginians infected with these diseases, Governor Bob McDonnell and Secretary William Hazel convened this task force to study and make recommendations in the following areas:

Add Surveillance

- ❖ Diagnosis
- ❖ Treatment
- ❖ Prevention
- ❖ Impact on Children
- ❖ Public Education

Add - Physician Education

The Governor and the Secretary appointed the following persons to serve on

the Virginia Task Force on Lyme Disease:

Michael Farris, Chairman, The Governor's Task Force on Lyme Disease; Chancellor, Patrick Henry College

Heather Applegate, Ph.D., child psychologist. Supervisor, Diagnostic and Prevention Services, Loudoun County Public Schools and private clinician

Dianne L. Reynolds-Cane, MD, Director, Virginia Department of Health Professions

Douglas W. Domenech, Secretary of Natural Resources, Commonwealth of Virginia

Bob Duncan, Executive Director, Virginia Department of Game and Inland Fisheries, Commonwealth of Virginia

Keri Hall, MD, MS, State Epidemiologist, Virginia Department of Health

William A. Hazel, Jr., MD, Secretary of Health and Human Resources, Commonwealth of Virginia

Kathy Meyer, co-organizer of Parents of Children with Lyme Support Network, Northern Virginia

Samuel Shor, MD, FACP, Associate Clinical Professor George Washington University Health Care Sciences and private practice, Internal Medicine, Reston, VA

Monte Skall, Executive

Director, National Capital Lyme and Tick-Borne Disease Association, Mclean, VA
Lisa Strucko, Pharm.D. Clinical Pharmacist, Leesburg Pharmacy, Leesburg, VA
Rand Wachsstock, DVM, veterinarian, Springfield, VA and former instructor in biochemistry at Yale University.

The Task Force held eight separate hearings with two distinct hearing categories. There were five separate hearings devoted to citizens of Virginia who had been impacted by Lyme and other tick-borne illnesses. These hearings were held in:

- ❖ Virginia Beach
- ❖ Richmond
- ❖ Roanoke
- ❖ Springfield
- ❖ Harrisonburg

Over 100 citizens testified at these hearings. We were profoundly impacted by this testimony and thank the citizens for their sacrificial efforts to testify.

A second set of hearings were held devoted to particular topics. At these topical hearings, the bulk of the testimony was from subject matter experts, supplemented by testimonies from citizens that had been asked to focus on

the particular issue at hand. The following expert witnesses appeared before our Task Force in these hearings:

Diagnosis & Treatment

Marty Schriefer, MD, Chief of Diagnostic and Reference Laboratory, Centers for Disease Control and Prevention

Daniel Cameron, MD, Past President of International Lyme and Associated Diseases Society, epidemiologist and private practice, Internal Medicine, Mt. Kisco, NY.

Elizabeth L. Maloney, MD, Lyme disease educator and Family Practice physician, Wyoming, MN

Paul G. Auwaerter, MD, representative, Infectious Diseases Society of America Prevention

Charles S. Apperson, Ph.D., Dept. of Entomology, North Carolina State University
Kerry Clark, MPH, Ph.D. Associate Professor, Epidemiology & Environmental Health,

Department of Public Health, University of North Florida
David N. Gaines, Ph.D., Public Health Entomologist, VA Department of Health, Office of Epidemiology

J. Mathews (Mat) Pound, Ph.D., Research Entomologist,

UVA Public Health Committee Hearing - March 8, 2013

PUBLIC HEALTH ALERT

and prevention activities have become increasingly labor and resource intensive. A strategic public health investment is necessary to enhance VDH's ability to prevent and control the spread of tick-borne diseases.

Specific Findings and Recommendations

In addition to these general observations, we make the following specific findings and recommendations based on the testimony that we received from our hearings:

Diagnosis

1. As acknowledged by the CDC, Lyme disease and many related tick-borne illnesses cannot be adequately diagnosed by serology alone in many cases.
2. There is no serological test that can "rule out" Lyme disease.
3. Clinical diagnosis that may be supported by serology remains the proper method for the diagnosis of Lyme and related illnesses.
4. Clinical diagnosis is not limited to the observation of an EM rash. A significant proportion of patients with Lyme disease may never develop or observe such a rash. Moreover, the EM rash can manifest in non-traditional patterns. The medical community needs a more comprehensive set of visual illustrations so that non-traditional patterns may be properly recognized.
5. Many lay witnesses testified that members of Virginia's

medical community inaccurately believed that serology alone can "rule out" Lyme disease.

6. According to lay testimony, there are some members of the Virginia medical community who have refused to consider a diagnosis of Lyme and related illnesses on the ground that "we do not have Lyme in Virginia" or in this "part of Virginia." Lyme disease is present in all parts of Virginia, endemic in most parts of the state, and emerging throughout the Commonwealth.

7. The testimony that came before the Task Force relayed the highly questionable nature of the ELISA test for early localized disease. We encourage the use of clinical judgment at all stages due to the significant limitations of current serology.

8. We recommend that the VDH reporting form include the disclaimer "The CDC case definition is designed for surveillance purposes only. Clinical judgment should be exercised in assessing patients for Lyme disease as meeting the surveillance case definition is not required for the diagnosis of Lyme disease."

9. Since ticks often carry multiple pathogens and we received testimony that many Virginians have multiple tick-borne illnesses that may require comprehensive analysis and treatment, the medical community should be educated on the presence of coinfections.

10. Great caution should be taken whenever a blacklegged tick is attached and especially

reports about the length of time of attachment can be unreliable as some patients may not have observed the exact moment of attachment. Medical providers should be at their liberty to treat Lyme disease prophylactically in such cases because of the high risk of disease. (Note that single-dose prophylaxis may lower the sensitivity of subsequent serology, as stated by the CDC.) Moreover, it is clear that early treatment is very important to prevent many serious complications of Lyme disease.

11. The Task Force encourages increased financial support for Internal Review Board-approved, peer-reviewed clinical studies associated with Lyme disease diagnosis and treatment. The Task Force encourages financial support for Virginia's college and university researchers who undertake research on Lyme or tick-borne disease. This should include all scientific realms. We commend Old Dominion University for undertaking vital research in the Tidewater region. (Rationale: Additional research that investigates the validity and reliability of diagnostic and preventative tools and provides guidance for appropriate treatment will support quality of care and patient outcomes.)

12. The Task Force encourages institutions offering graduate-level medical degrees to offer comprehensive instruction about Lyme and other tick-borne diseases. Due to the rapidly evolving nature of the scientific research and literature on tick-borne disease, medical educators should use due diligence to teach comprehensive and up-to-date information in all aspects of

tick-borne disease. (Rationale: Student clinicians (medical, nurse practitioner and physician's assistant students) are the clinicians of the future and should be aware of Lyme and other tick-borne diseases as medical conditions in Virginia.)

13. VDH should continue to provide information to clinicians practicing in the Commonwealth concerning the epidemiology of Lyme disease in Virginia, a physician's responsibility to report Lyme disease, the information VDH requires to classify a case, the purpose of the surveillance case definition, Lyme disease prevention measures and tick identification. VDH should also continue to provide information to clinicians practicing in the Commonwealth about other tick-borne diseases in Virginia. (Rationale: This recommendation articulates VDH's current practice and speaks to its commitment to continue these informational efforts in regard to tick-borne disease, with a particular focus on Lyme disease as it is the most commonly reported tick-borne disease and is present in all parts of Virginia, endemic in most parts of the state and emerging throughout the Commonwealth.)

VDH should emphasize that due to the rapidly evolving nature of the scientific research and literature on Lyme and tick-borne disease, medical professionals should use due diligence to stay abreast of information in all aspects of tick-borne disease to educate their ability to clinically assess patients.

Treatment

1. There is no serological test that can tell a medical provider when a patient has been cured of Lyme disease.

PUBLIC HEALTH ALERT

attempt deer and/or tick population control. The Governor should include funding in the 2012 Budget Bill that is sufficient to adequately support this initiative. (Rationale: Developing guidance in this manner will allow for the development of control strategies that are more comprehensive than either Secretariat currently offers in regard to Lyme and other tick-borne diseases.)

8. Public education programs on Lyme prevention should continue to emphasize these (and other) important practices:

Land-use practices for preventing tick exposure:

❖ Animal exclusion and landscaping

Homeowners should consider fencing and landscaping choices that tend to exclude deer (the primary adult tick host) and mice (the Lyme bacterium reservoir). Do not plant vegetation that attracts deer, remove food and cover that attracts mice (e.g. wood piles trash), and reduce tick breeding grounds (e.g. clear trees and brush and regularly mow grass). Homeowner associations and other real estate contracts should avoid clauses that restrict the ability of homeowners to effectively exclude deer from their property or control deer populations in their neighborhoods.

❖ Tick control

Local, state, and federal agencies should continue to evaluate the utility of host-specific application of acaricides (e.g., USDA 4-poster devices) to combat Lyme disease in this Commonwealth.

their use is warranted, the Virginia Department of Game and Inland Fisheries (DGIF) should put in place an orderly and responsible permitting process. DGIF is working with localities to investigate if this tool is a practical solution for managing tick populations. Currently, DGIF is working with Fairfax County on such a study and will develop potential permit conditions that will safeguard wildlife populations and habitats while not inhibiting the use of the 4-poster system. Current regulations and codes exist to allow for the supervised use of these devices. DGIF should work with VDH and local governments to make sure that proper safeguards are put in place and necessary data is collected on the use of these devices. Budget for tick testing should be considered by the General Assembly.

❖ Deer Control

DGIF is to be commended for its appropriate expansion of hunting seasons and limits for deer. Further expansions should be considered. Public information campaigns should be conducted to encourage all willing Virginians to participate in an effort to achieve appropriate deer populations for the sake of public health.

❖ Acaricides

Public information about the safe and appropriate use of acaricides should be a component of public education efforts.

Human practices to limit exposure to ticks:

❖ Avoiding tick habitat

The public needs to

be informed about the nature of tick habitat and the danger of entering into such habitat unprepared.

❖ Appropriate dress and/or repellants (especially in tick habitats)

When entering such habitat is necessary, the public needs to be informed about best practices to avoid tick exposure (proper dress, repellants, tick checks, etc.)

❖ Showering after being outdoors

The public needs to be informed of the value of a thorough shower within a short time after concluding outdoor activities where tick exposure has been possible.

❖ Evening tick check

The public should be informed of the necessity of a once-a-day thorough tick check after being outdoors (especially in tick habitat). Children especially should be checked daily.

❖ Proper pet practices

Vaccination and repellants for pets should be strongly encouraged. The public should be aware that even though pets have been properly treated, they can still bring ticks into the home that leave the pet and bite a human. Accordingly, indoor pets should be controlled to avoid entry into tick habitat.

Children

1. One expert testified concerning a potential for in utero transmission of Lyme disease. The CDC has proclaimed on its website, "Untreated, Lyme disease can be dangerous to your unborn child."¹ VDH should include information for preg-

nant women in the educational materials that it provides to the general public and to healthcare providers who care for pregnant women.

2. VDH should inform the public of the fact that children are a high-risk group for contracting Lyme disease. Parents need to be alert to the possibility of Lyme-especially when a child presents with symptoms that are not easily categorized as some other illness with an identified etiology.

3. VDH needs to undertake focused campaigns to help educate pediatricians, family practitioners, urgent care clinicians, and other clinicians about the importance of early recognition of Lyme disease.

4. VDH, the Virginia Department of Education, other agencies, and subject matter experts as appropriate should collaborate to create a best practices document focused on children with Lyme and related illnesses. Topics that should be considered include:

❖ Proper construction of school grounds to promote deer exclusion and avoid unnecessary exposure to ticks

❖ Before taking students outdoors for instructional field investigations, consideration of the site's likelihood for ticks and then, in cooperation with parents, preparation of the students, parents, and teachers accordingly with the following simple guidelines: wear appropriate clothing, use repellents and perform thorough tick checks. (The benefits of outdoor recreation and education is very important for our children's develop-

- Balanced (Scientifically Diverse)
- Membership Guidelines
- Accountability
- Patient Representative
- Physician Awareness

112TH CONGRESS
1ST SESSION

2012-Bill - (a 2013 bill now exists)

This bill is special in that it comprehensively + thoughtfully articulates an advisory committee that is balanced.

S. 1381 See "MEMBERSHIP" page 38

To provide for the expansion of Federal efforts concerning the prevention, education, treatment, and research activities related to Lyme and other tick-borne diseases, including the establishment of a Tick-Borne Diseases Advisory Committee.

IN THE SENATE OF THE UNITED STATES

JULY 18, 2011

Mr. BLUMENTHAL (for himself, Mr. REED, Mrs. GILLIBRAND, Mr. WHITEHOUSE, Mr. LIEBERMAN, and Mr. FRANKEN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To provide for the expansion of Federal efforts concerning the prevention, education, treatment, and research activities related to Lyme and other tick-borne diseases, including the establishment of a Tick-Borne Diseases Advisory Committee.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the "Lyme and Tick-Borne
5 Disease Prevention, Education, and Research Act of
6 2011".

1 rash illness (STARI). Multiple diseases in 1 patient
2 make diagnosis and treatment more difficult.

3 (6) The Centers for Disease Control and Pre-
4 vention reported more than 38,000 confirmed and
5 probable Lyme disease cases in 2009. Over the past
6 decade, the incidence of Lyme disease has increased
7 by 84 percent.

8 (7) According to the Centers for Disease Con-
9 trol and Prevention, from 1992 to 2006, the inci-
10 dence of Lyme disease was highest among children
11 aged 5 to 14 years of age.

12 (8) Persistence of symptomatology in many pa-
13 tients without reliable testing makes diagnosis and
14 treatment of patients more difficult.

15 **SEC. 3. ESTABLISHMENT OF A TICK-BORNE DISEASES ADVI-**
16 **SORY COMMITTEE.**

17 (a) ESTABLISHMENT.—Not later than 180 days after
18 the date of the enactment of this Act, the Secretary of
19 Health and Human Services (referred to in this Act as
20 the “Secretary”) shall establish within the Office of the
21 Secretary an advisory committee to be known as the Tick-
22 Borne Diseases Advisory Committee (referred to in this
23 section as the “Committee”).

24 (b) DUTIES.—The Committee shall—

1 (1) APPOINTED MEMBERS.—

2 (A) IN GENERAL.—From among individ-
3 uals who are not officers or employees of the
4 Federal Government, the Secretary shall ap-
5 point to the Committee, as voting members, the
6 following:

7 (i) Not less than 4 members from the
8 scientific community representing the
9 broad spectrum of viewpoints held within
10 the scientific community related to Lyme
11 and other tick-borne diseases.

12 (ii) Not less than 2 representatives of
13 tick-borne disease voluntary organizations.

14 (iii) Not less than 2 health care pro-
15 viders, including not less than 1 full-time
16 practicing physician, with relevant experi-
17 ence providing care for individuals with a
18 broad range of acute and chronic tick-
19 borne diseases.

20 (iv) Not less than 2 patient represent-
21 atives who are individuals who have been
22 diagnosed with a tick-borne disease or who
23 have had an immediate family member di-
24 agnosed with such a disease.

① *lymediseaseassociation.org*
② *lymedisease.org*

Need criteria for years treating patients - short term + long-term

patient representation is absolutely key.

1 (3) CO-CHAIRPERSONS.—The Secretary shall
2 designate the Assistant Secretary of Health as the
3 co-chairperson of the Committee. The appointed
4 members of the Committee shall also elect a public
5 co-chairperson. The public co-chairperson shall serve
6 a 2-year term.

7 (4) TERM OF APPOINTMENT.—The term of
8 service for each member of the Committee appointed
9 under paragraph (1) shall be 4 years.

10 (5) VACANCY.—A vacancy in the membership of
11 the Committee shall be filled in the same manner as
12 the original appointment. Any member appointed to
13 fill a vacancy for an unexpired term shall be ap-
14 pointed for the remainder of that term. Members
15 may serve after the expiration of their terms until
16 their successors have taken office.

17 (d) MEETINGS.—The Committee shall hold public
18 meetings, except as otherwise determined by the Sec-
19 retary, after providing notice to the public of such meet-
20 ings, and shall meet at least twice a year with additional
21 meetings subject to the call of the co-chairpersons. Agenda
22 items with respect to such meetings may be added at the
23 request of the members of the Committee, including the
24 co-chairpersons. Meetings shall be conducted, and records

1 member of the Committee shall be a permanent salaried
2 employee.

3 **SEC. 4. FEDERAL ACTIVITIES RELATED TO THE DIAGNOSIS,**
4 **SURVEILLANCE, PREVENTION, AND RE-**
5 **SEARCH OF LYME AND OTHER TICK-BORNE**
6 **DISEASES.**

7 (a) IN GENERAL.—The Secretary, acting as appro-
8 priate through the Director of the Centers for Disease
9 Control and Prevention, the Director of the National Insti-
10 tutes of Health, the Commissioner of Food and Drugs,
11 and the Director of the Agency for Healthcare Research
12 and Quality, as well as additional Federal agencies as the
13 Secretary determines to be appropriate, and in consulta-
14 tion with the Tick-Borne Diseases Advisory Committee,
15 shall provide for—

16 (1) the conduct or support of the activities de-
17 scribed in subsection (b); and

18 (2) the coordination of all Federal programs
19 and activities related to Lyme disease and other
20 tick-borne diseases.

21 (b) ACTIVITIES.—²The activities described in this sub-
22 section are the following:

23 (1) DEVELOPMENT OF DIAGNOSTIC TESTS.—

24 Such activities include—

1 (C) to evaluate the feasibility of creating a
2 national uniform reporting system including re-
3 quired reporting by laboratories in each State.

4 (3) PREVENTION.—Such activities include—

5 (A) the provision and promotion of access
6 to a comprehensive, up-to-date clearinghouse of
7 peer-reviewed information on Lyme and other
8 tick-borne diseases;

9 (B) increased public education related to
10 Lyme and other tick-borne diseases through the
11 expansion of the Community Based Education
12 Programs of the Centers for Disease Control
13 and Prevention to include expansion of informa-
14 tion access points to the public;

15 (C) the creation of a physician education
16 program that includes the full spectrum of sci-
17 entific research related to Lyme and other tick-
18 borne diseases, and, in coordination with the
19 Advisory Committee established under section
20 3, the publication of an annual report that eval-
21 uates published guidelines and current research
22 available on Lyme disease, in order to best edu-
23 cate health professionals on the latest research
24 and diversity of treatment options for Lyme
25 disease; and



This is an absolute must - our CT physicians are so unaware - They need support from CTDPH in expanding their knowledge + protecting them

1 to any other authorization of appropriations avail-
2 able for the purposes described in paragraph (1).

3 **SEC. 5. REPORTS ON LYME AND OTHER TICK-BORNE DIS-**
4 **EASES.**

5 (a) IN GENERAL.—Not later than 18 months after
6 the date of enactment of this Act, and annually thereafter,
7 the Secretary shall submit to Congress a report on the
8 activities carried out under this Act.

9 (b) CONTENT.—Reports under subsection (a) shall
10 contain—

11 (1) significant activities or developments related
12 to the surveillance, diagnosis, treatment, education,
13 or prevention of Lyme or other tick-borne diseases,
14 including suggestions for further research and edu-
15 cation;

16 (2) a scientifically qualified assessment of Lyme
17 and other tick-borne diseases, including both acute
18 and chronic instances, related to the broad spectrum
19 of empirical evidence of treating physicians, as well
20 as published peer reviewed data, that shall include
21 recommendations for addressing research gaps in di-
22 agnosis and treatment of Lyme and other tick-borne
23 diseases and an evaluation of treatment guidelines
24 and their utilization;



General
Assembly

**Proposed Bill No.
368**

January Session,
2013

LCO No. 1904

Referred to Committee on PUBLIC HEALTH

Introduced by:

SEN. BARTOLOMEO, 13th
Dist.

REP. FAWCETT, 133rd Dist.

SEN. DOYLE, 9th Dist.

REP. FRITZ, 90th Dist.

SEN. GERRATANA, 6th Dist.

REP. LESSER, 100th Dist.

REP. ABERCROMBIE, 83rd
Dist.

*The language in
this bill must be
carefully designed -
Please refer to
my proposed bill &
prior year Federal
Senate Bill 51381*

**AN ACT REQUIRING THE DEPARTMENT OF PUBLIC HEALTH TO REPORT ON
LYME DISEASE AND OTHER TICK-BORNE ILLNESSES.**

Be it enacted by the Senate and House of Representatives in General Assembly
convened:

That chapter 368a of the general statutes be amended to require the Department of
Public Health, in consultation with an advisory board established to study Lyme



Lets combine efforts on bills

General Assembly

Committee Bill No. 5104

January Session, 2013

LCO No. 2984



Referred to Committee on PUBLIC HEALTH

Introduced by:
(PH)

Testing is too narrow & focus -
all things are interrelated -
This bill will actually hurt
patients - I know that is
not what is intended -
Please consider changing
the language in
this bill.

AN ACT ESTABLISHING A TASK FORCE TO STUDY LYME DISEASE TESTING.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

- 1 Section 1. (Effective from passage) (a) There is established a task force
- 2 to study Lyme disease testing. The task force shall review policies for
- 3 Lyme disease testing in this state and in other states.
- 4 (b) The task force shall consist of the following members:
- 5 (1) Two persons experienced in the study of infectious disease, one
- 6 each appointed by the president pro tempore of the Senate and the
- 7 speaker of the House of Representatives;
- 8 (2) Two physicians experienced in treating Lyme disease, one each
- 9 appointed by the majority leader and the minority leader of the Senate;
- 10 (3) Two persons experienced in the clinical laboratory evaluation of
- 11 Lyme disease, one each appointed by the majority leader and the
- 12 minority leader of the House of Representatives;
- 13 (4) The Commissioner of Public Health, or the commissioner's

This must be scientifically diverse group (see my proposal)

last 5 cases last 7 yrs

more from varying specialties

Dr. Sin Heng Lee
pathologist
Dr. Eva Sapi -
University of
New Haven

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Lyme Disease

Lyme disease was first recognized in the United States in the "Lyme", Connecticut area when in 1975 a cluster of children and adults experienced common arthritic symptoms. The disease became a physician reportable in Connecticut in 1979. Since then, it has become the most commonly reported tick-borne disease. Although the disease is named after the small town of Lyme, CT, it was recently determined that the disease is thousands of years old. In 2012, researchers announced that the "Ice Man" who was found melting out of an Alpine glacier in 1991 had Lyme disease.

Lyme disease is caused by bacteria called *Burgdorferi*. These bacteria are transmitted through the bite of an infected tick, *Ixodes scapularis*, also known as the black-legged or deer tick. There is a blood test for Lyme disease but it isn't always conclusive.

Symptoms often begin with an expanding red rash around the area of the bite and flu-like symptoms that include muscle aches, fatigue, and fever. These symptoms generally appear 3-32 days after the bite. The early signs of the disease can be overlooked or misdiagnosed. In addition, some people bitten by an infected deer tick do not develop the early symptoms of Lyme disease. If it is not diagnosed and treated promptly, symptoms of Lyme disease may appear weeks to months later, causing serious complications of the joints, nervous system, and heart. Lyme disease is treated with antibiotics.



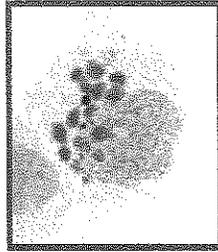
Photo credit: CDC

Anaplasmosis

Anaplasmosis (HGA), formerly known as human granulocytic ehrlichiosis (HGE), is caused by a bacteria called *Anaplasma phagocytophila*. These bacteria infect white blood cells and are transmitted through the bite of the same tick that causes Lyme disease.

Symptoms of HGA generally include sudden onset of fever, headache, muscle aches, and/or

fatigue. Nausea, vomiting, or rash may be present in some patients, although many people infected will not become sick. Illness can range from mild to potentially life threatening. Symptoms occur 7-21 days after the tick bite. Laboratory findings may include thrombocytopenia (decreased number of blood platelets), leukopenia (a decreased number of white blood cells), and/or elevated liver enzymes in the blood. Anaplasmosis may be confused clinically with Rocky Mountain spotted fever (RMSF); however, absence of a prominent rash is a good indicator it is not RMSF. As with Lyme disease, this disease is also treated with antibiotics.



The bacteria that cause human granulocytic anaplasmosis (HGA). CDC

Babesiosis

Babesiosis is caused by a one-cell parasite that infects red blood cells. The parasite, called *Babesia microti*, can be seen within red blood cells when viewed under a microscope. Babesia are most frequently transmitted by the bite of an infected deer tick, and rarely by blood transfusion from an infected donor.

Symptoms of babesiosis may include fever, chills, muscle aches, fatigue and jaundice secondary to hemolytic anemia (destruction of red blood cells). These symptoms may appear 1-4 weeks after the bite. While most people will not become ill, babesiosis can be a potentially severe and sometimes fatal disease. Babesiosis is treated with a combination of medications which usually include quinine and/or clindamycin.

Co-infections

Co-infections are possible through the bite of a single infected deer tick. This means, you can become infected with the microorganisms that cause Lyme disease, anaplasmosis, and babesiosis with a single bite from an infected deer tick. Symptoms from different diseases makes it more difficult for a diagnosis and treatment.

The only way to prevent these diseases is to prevent tick bites.

Rocky Mountain Spotted Fever

Rocky Mountain spotted fever (RMSF) is the most severe and most frequently reported illness caused by rickettsia bacteria, which also cause typhus, in the United States. In Connecticut, RMSF has been reportable since 1980 making it the longest reported tick-borne disease. It is also the least reported tick-borne illness in Connecticut with an average of only 3 cases reported annually.

Rocky Mountain spotted fever is caused by *Rickettsia rickettsii*. Unlike the previously mentioned tick-borne diseases in Connecticut, RMSF is transmitted through the bite of infected *Dermacentor variabilis*, the American dog tick.

Symptoms of RMSF include sudden onset of fever, headache, and muscle pain, followed by a rash. These symptoms may appear 3-14 days after the bite of an infected dog tick. As with other tick-borne diseases, RMSF can be difficult to diagnose in the early stages, and without prompt treatment can cause serious and sometimes fatal illness. This disease is treated with antibiotics.

Treatment

Treatment of tick-borne diseases should begin as soon after infection as possible. Treatment is generally very effective. If you are bitten by a tick, remove the tick as soon as possible. Write on the calendar the date you removed the tick and the part of the body from which it was removed. If you experience any of the symptoms previously mentioned for any of the tick-borne diseases, contact your physician. It will be important for your physician to have a complete history of your exposure to ticks. If you experience an expanding red rash and can not see your physician right away, take a picture of the rash and bring that picture with you at the time of your doctor appointment. Anaplasmosis, Lyme disease, and Rocky Mountain spotted fever are treated with some of the same antibiotics.

Early treatment is the key to prevent severe illness.

the treatment options are covered by health insurance).[19] For example, patients with prostate cancer (where significant uncertainty exists regarding long-term treatment outcomes) must elect between watchful waiting, radiation and surgery. The legal doctrine of informed consent also requires that patients be advised of material treatment options. Treatment choices involve trade-offs between the risks and benefits of treatment options that only patients—who know the kinds of risks they are willing to run and the types of quality of life outcomes that matter to them—are uniquely suited to make. [20]

Respect for the basic autonomy of the patient is a fundamental principle of medical ethics. Without adequate information about treatment options, their probable outcomes, and the risks and benefits associated with each, patients cannot act autonomously. Today, however, many patients are either denied treatment by their HMO physicians who follow actuarial treatment protocols generated to keep treatment costs down, or they must find an independent physician to treat them, with the all but foregone conclusion that coverage for this treatment will be denied by their insurer based on cherry-picked (economically favorable) guidelines. Moreover, HMO physicians generally do not advise their patients that treatment alternatives exist.

Scientific uncertainty about Lyme disease has resulted in more than one treatment approach (like prostate cancer). We agree with the AMA, ACP and other professional medical organizations interested in promoting informed patient consent and want to make sure that:

- Physicians, insurers, patients and governmental agencies are educated that two treatment approaches exist;
- Physicians give patients sufficient information about treatment options to enable patients to make a meaningfully informed choice and respect the autonomy of that choice;
- Insurance reimbursement be provided for treatment rendered in accordance with either standard of care; and
- Government agencies provide unbiased information and remain neutral regarding both standards of care and treatment approaches.

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TESTING
CALDA CDC Survey Results
 (182 Respondents)

by Lorraine Johnson, JD, MBA and Theresa Denham

Misuse of the Centers for Disease Control and Prevention (CDC) surveillance criteria for diagnostic purposes is a significant problem for patients with Lyme disease, causing misdiagnosis and treatment delays that may permit the disease to advance from the more easily treated acute infection to a chronic treatment resistant infection. As part of an informal study, a survey questionnaire was distributed to patients with persistent Lyme disease through the Lyme Times publication nationally and through selected doctors' offices throughout the nation during the last quarter of 2003 and throughout 2004. The study was completed in January 2005. Preliminary results suggest widespread misuse of the CDC surveillance criteria for diagnostic purposes resulting in significant diagnostic delays. Respondents were asked to provide a unique patient identifier to ensure that no duplication of results occurred. This article reflects the responses of the 182 respondents that were diagnosed with Lyme disease.

ELISA Misdiagnoses (1)

Seventy-three percent (73%) of respondents were denied a diagnosis for Lyme at least once due to a negative ELISA by CDC criteria. Of these, 31% were denied access to a Western blot (WB) by their physicians due to a negative ELISA.

Western Blot Misdiagnosis (2)

Sixty-one percent (61%) of respondents were denied a diagnosis for Lyme at least once due to a negative WB blot by CDC surveillance band criteria.

ELISA and Western Blot: Misuse of CDC Surveillance Criteria for Diagnostic Purposes			
	ELISA	Western blot (CDC surveillance criteria)	Total (non-duplicated)
Misdiagnosis basis	73%	61%	81%
Doctor refused to do Western blot	31%		
Medical Reimbursement Denials	16%	19%	

Method of Diagnosis

Of the diagnostic methods surveyed, only 13% of those responding were diagnosed by ELISA. The WB supported 67% of the Lyme disease cases, with significant bands present and not necessarily falling into the CDC surveillance criteria. Diagnosis by Polymerase Chain Reaction (PCR) and spinal tap were 12 and 3%, respectively. Clinical diagnosis, without supporting lab tests, accounted for 24%.

Diagnosis and Treatment Delays

The misapplication of CDC surveillance criteria (either ELISA or WB) for diagnostic purposes resulted in a delay in diagnosis of one year or more for 49% of responding patients. The average period of delay in diagnosis was almost 4-½ years. A full 81% of patients had physicians fail to diagnose their Lyme disease because of misapplication of the CDC surveillance criteria for diagnosis. Many of these patients incurred treatment delays as well. Delayed diagnoses in Lyme disease can allow the disease to progress from one that is generally treatable to one that is more resistant or unresponsive to treatment, with devastating consequences to the patient.

TESTING

Understanding the Western Blot

By Carl Brenner

Revised: September, 1996

Inquiries about various issues relating to Western blot (WB) testing are frequently posted to the Lyme disease discussion groups on the Internet. Among the most commonly asked questions are: What laboratory techniques are used to carry out the assay? What exactly is being measured? What is a "band"? How are the results interpreted? What are the CDC criteria for a "positive" test? Although some of the medical jargon associated with immunology can be a little overwhelming, the scientific principles behind these tests are not difficult to grasp. The following article is offered as a primer in the techniques and interpretation of Western blotting, and should help most patients navigate their way through some of the medical and scientific terminology associated with the assay.

First of all, it should be noted that the Western blot is usually performed as a follow-up to an ELISA test, which is the most commonly employed initial test for Lyme disease. "ELISA" is an acronym for "enzyme-linked immunosorbent assay." There are ELISA tests and Western blots for many infectious agents; for example, the usual testing regime for HIV is also an initial ELISA followed by a confirmatory Western blot.

Both the ELISA and the Western blot are "indirect" tests -- that is, they measure the immune system's response to an infectious agent rather than looking for components of the agent itself. In a Lyme disease ELISA, antigens (proteins that evoke an immune response in humans) from *Borrelia burgdorferi* (Bb) are fixed to a solid-phase medium and incubated with diluted preparations of the patient's serum. If antibodies to the organism are present in the patient's blood, they will bind to the antigen. These bound antibodies can then be detected when a second solution, which contains antibodies to human antibodies, is added to the preparation. Linked to these second antibodies is an enzyme which changes color when a certain chemical is added to the mix. Although the methodology is somewhat complicated, the basic principle is simple: the test looks for antibodies in the patient's serum that react to the antigens present in *Borrelia burgdorferi*. If such antibodies exist in the patient's blood, that is an indication that the patient has been previously exposed to *B. burgdorferi*.

Cross-reacting antibodies

However, many different species of bacteria can share common proteins. Most Lyme disease ELISAs use sonicated whole *Borrelia burgdorferi* -- that is, they take a bunch of *B. burgdorferi* cells and break them down with high frequency sound waves, then use the resulting smear as the antigen in the test. It is possible that a given patient serum can react with the *B. burgdorferi* preparation even if the patient hasn't been exposed to Bb, perhaps because Bb shares proteins with another infectious agent that the patient's immune system *has* encountered. For example, some patients with periodontal disease, which is sometimes associated with an oral spirochete, might test positive on a Lyme ELISA, because their sera will react to components of Bb (like the flagellar protein, which is shared by many spirochetes) even

should take into account both the vagaries of the human immune response and the possibility that strain variations in Bb might produce unusual banding patterns.

Official criteria

The CDC criteria for a positive WB are as follows:

* For IgM, 2 of the following three bands: OspC (21-25), 39 and 41. * For IgG, 5 of the following ten bands: 18, OspC (21-25), 28, 30, 39, 41, 45, 58, 66 and 93.

How were these recommendations arrived at? The IgG criteria were taken pretty much unchanged from a 1993 paper by Dressler, Whalen, Reinhardt and Steere [2]. In this study, the authors performed immunoblots on several dozen patients with well characterized Lyme disease and a strong antibody response and looked at the resulting blot patterns. By doing some fairly involved statistical analysis, they could determine which bands showed up most often and which best distinguished LD patients from control subjects who did not have LD. They found that by requiring 5 of the 10 bands listed, they could make the results the most specific, in their view, without sacrificing too much sensitivity. ("Sensitivity" means the ability of the test to detect patients who have the disease, "specificity" means the ability of the test to exclude those who don't. Usually, an increase in one of these measures means a decrease in the other.)

1993 into
STILL in place

The IgM criteria were determined in much the same fashion (by different authors in different papers). Fewer bands are required here because the immune response is less mature at this point. Several studies have shown that the first band to show up on a Lyme disease patient's IgM blot is usually the one at 41 kDa, followed by the OspC band and/or the one at 39. The OspC and 39 kDa band are highly specific for Bb, while the 41 kDa band isn't. That's why the 41 by itself isn't considered adequate. Here's the rub, though: the CDC doesn't want the IgM criteria being used for any patient that has been sick for more than a month or two. The thinking here is that by this time an IgG response should have kicked in and the IgM criteria, because they require fewer bands, are not appropriate for patients with later disease.

Criticism of CDC criteria

A number of criticisms have been offered of the CDC criteria since their adoption in 1994. The first is centered on the CDC's failure to make any qualitative distinction among the various bands that can show up on a patient's Western blot. A number of Lyme disease researchers feel that different bands on a WB have different relative importance -- that "all bands are not created equal." For example, many patients with Lyme disease will show reactive bands at, say, 60 and/or 66 kDa. However, these correspond to common proteins in many bacteria, not just *Borrelia burgdorferi*, and so are of limited diagnostic usefulness, especially in the absence of other, more species-specific bands. The band at 41 kDa corresponds to Bb's flagella (the whip like organelles used for locomotion -- Bb has several) and is one of the earliest to show up on the Western blots of Lyme disease patients. But for some reason it is also the most commonly appearing band in control subjects. This may be due to the fact that many people are exposed to spirochetes at some time in their lives and so their sera might cross react with this protein.

On the other hand, certain other bands are considered highly specific for Bb -- the aforementioned 31 kDa band, for example, or 34 (OspB) or 39 or OspC (anywhere between

seropositive patients, which tends to reinforce the circular and erroneous notion that virtually all patients with late Lyme disease are seropositive.

It should also be noted that a positive Western blot is not necessarily an indication of active Lyme disease. A patient's immune response to *B. burgdorferi* can remain intact long after curative treatment for a Lyme infection; therefore, the results of a Western blot assay should always be interpreted in the context of the total clinical picture.

Carl Brenner is a scientist, a member of the Scientific Review Board of the National Research Foundation for Tick Borne Diseases, and former patient representative on the NIH Lyme Disease Advisory Panel.

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* Note - On current lab reports - CDC surveillance criteria is written on the report as "what is positive for CDC purposes". The physician often reads that to denote "diagnostic positive/negative" - misleading the physician. Typically further down on the lab report, a note may appear that an "INO" ~~indertinent amount~~ (indertinent amount) may be clinically significant - but generally physicians do not get that far in reading the report...

SHORT REPORT

Open Access

Early Lyme disease with spirochetemia - diagnosed by DNA sequencing

Sin Hang Lee^{1*}, Veronica S Vigliotti^{1†}, Jessica S Vigliotti^{1†}, William Jones^{1†}, Jessie Williams^{2†}, Jay Walshon^{2†}

Abstract

Background: A sensitive and analytically specific nucleic acid amplification test (NAAT) is valuable in confirming the diagnosis of early Lyme disease at the stage of spirochetemia.

Findings: Venous blood drawn from patients with clinical presentations of Lyme disease was tested for the standard 2-tier screen and Western Blot serology assay for Lyme disease, and also by a nested polymerase chain reaction (PCR) for *B. burgdorferi* sensu lato 16S ribosomal DNA. The PCR amplicon was sequenced for *B. burgdorferi* genomic DNA validation. A total of 130 patients visiting emergency room (ER) or Walk-in clinic (WALKIN), and 333 patients referred through the private physicians' offices were studied. While 5.4% of the ER/WALKIN patients showed DNA evidence of spirochetemia, none (0%) of the patients referred from private physicians' offices were DNA-positive. In contrast, while 8.4% of the patients referred from private physicians' offices were positive for the 2-tier Lyme serology assay, only 1.5% of the ER/WALKIN patients were positive for this antibody test. The 2-tier serology assay missed 85.7% of the cases of early Lyme disease with spirochetemia. The latter diagnosis was confirmed by DNA sequencing.

Conclusion: Nested PCR followed by automated DNA sequencing is a valuable supplement to the standard 2-tier antibody assay in the diagnosis of early Lyme disease with spirochetemia. The best time to test for Lyme spirochetemia is when the patients living in the Lyme disease endemic areas develop unexplained symptoms or clinical manifestations that are consistent with Lyme disease early in the course of their illness.

Background

Lyme disease is a tick-borne human infection which is an imperative differential diagnosis for internal medicine physicians offering primary care to ambulatory patients in the endemic counties of the United States. Hematogenous dissemination of the *Borrelia burgdorferi* spirochetes from the initial skin site of a tick bite is believed to cause secondary skin lesions and extracutaneous manifestations in Lyme disease [1]. *Borrelia* spirochetemia, when validated, provides reliable objective evidence for the diagnosis of early Lyme disease, based on which timely appropriate treatment is instituted to avoid tissue damage and to prevent the infection from going into chronic phase. However, *B. burgdorferi* spirochetemia is transient, and the culture techniques which require at

least 9 mL of plasma sample and may take several weeks to recover [2] are not practical as a routine diagnostic tool. Pathogenic *Borrelia burgdorferi* cells are known to exist in non-dividing or slowly dividing forms which may not generate a visible positive growth in artificial media at all [3]. The diagnosis of early Lyme disease has been a challenging task for the primary contact physicians practicing in the endemic areas [4].

The polymerase chain reaction (PCR) technologies for the study of the most conserved genospecies-specific *Borrelia burgdorferi* sensu lato 16S ribosomal RNA gene, or 16S rDNA, have been used in epidemiology research [5,6]. Using a pair of specific TEC1 and LD2 primers for PCR, the chances of non-specific amplification of 16S rDNA derived from spirochetes unrelated to Lyme disease are minimized [7]. However, little attempt has been made to transfer this procedure into clinical laboratory practice because the method is not robust enough for routine diagnostic applications. We have recently refined this research tool with a nested PCR technology for DNA

* Correspondence: sinhang.lee@milfordhospital.org

† Contributed equally

¹Department of Pathology, Milford Hospital, 300 Seaside Avenue, Milford, 06460, USA

Full list of author information is available at the end of the article

approved by the Milford Hospital Institutional Review Board.

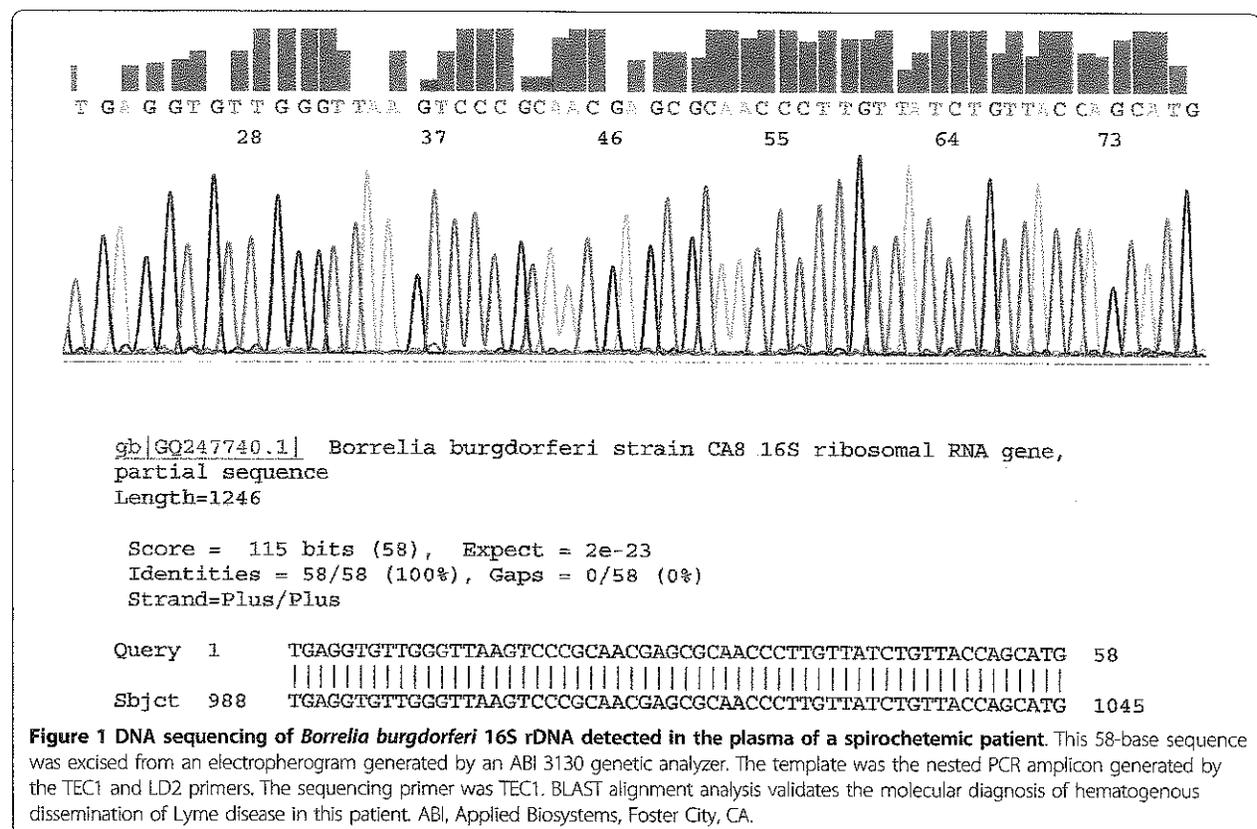
Results

As previously reported, nested PCR amplification of the conserved segment of *B. burgdorferi* sensu lato 16S rDNA for signature sequence analysis generated a 293 base-pair (bp) amplicon with the TEC1 and LD2 primers. After confirming a 100% identities match with a unique specific DNA sequence for *B. burgdorferi* sensu lato 16S rDNA stored in the GenBank database using the online Basic Local Alignment Search Tool (BLAST), the molecular identification of the nested PCR product as a genomic DNA of *B. burgdorferi* was established beyond a reasonable doubt. BLAST analysis of a 50-60 bp sequence downstream of the LD2 primer-binding site was more than adequate to achieve a very low E-value, which indicates that the chance of molecular mis-identification is infinitesimal. A segment of the electropherogram containing the signature nucleotide sequence (Figure 1) was incorporated in the laboratory report for completion of an evidence-based molecular diagnosis of Lyme borrelia spirochetemia.

Our experience confirmed that PCR is not a specific tool for DNA identification, especially for the diagnosis

of Lyme disease. From this series of 436 patients, 3 plasma samples were found to contain non-target DNA which led to generation of PCR products of a molecular size similar, but not identical, to that of the *B. burgdorferi* 16S rDNA. These non-Lyme disease DNA molecules were amplified by the PCR primer pair designed for *B. burgdorferi* DNA replication. However, in the absence of a fully matched *B. burgdorferi* target DNA template, these unintended and non-target DNA molecules were amplified by the partially matched primers during the highly sensitive nested PCR process. One of such non-target PCR amplicons was only 6-bp shorter than the expected 293-bp *B. burgdorferi* 16S rDNA fragment, as observed on gel electrophoresis (Figure 2). Only DNA sequencing could confirm that it was really a 287-bp 16S rDNA fragment of an environmental bacterium (Figure 3). As indicated in the GenBank database, the primer binding sites selected for PCR amplification of the most conserved 16S ribosomal RNA gene of the genospecies of *Borrelia burgdorferi* sensu lato also bear great similarities in DNA sequence with the 16S ribosomal RNA genes of other bacterial species (Figure 4).

There was an obvious difference in the test results between the 333 blood sample pairs from the patients referred to the laboratory by the individual private



Alignment of the DNA sequences of the two PCR primer binding sites with 10 adjoining bases of *B. burgdorferi* sensu lato 16S rDNA (a) against those of an environmental bacterium (b) (see Figure 3)

(a) ctggggagtgatgctcgcaagagtgaaactcaX-----gggactcagataagactgccggtgataagtc
 (b) ctggggagta**acgg**tcgcaagattaaaactcaX000000ggcactcta**atg**agactgccggtgacaaaacc

Figure 4 Two partial DNA sequences retrieved from the National Center for Biotechnology Information database. (a) GenBank Locus GQ247740, a 293-base long signature sequence for *B. burgdorferi* 16S rDNA. TEC1 (left) and LD2 (right) PCR primer sites underlined. (b) GenBank Locus FJ948170, a 287-base long sequence of 16S rDNA for numerous environmental bacteria. TEC1 and LD2 primer sites underlined. Note 6 mismatched bases printed in red bold face. X----- = 231 bases in a sequence specific and unique for *B. burgdorferi* 16S rDNA. X = 225 bases in a sequence nonspecific for environmental bacterial 16S rDNA. 000000 = 6 slots with no nucleotide bases. In the absence of a fully matched *B. burgdorferi* DNA, the PCR primers may bind to a partially matched non-target bacterial DNA templates which are not infrequently present in normal human blood. Only DNA sequencing can distinguish the 287 base-pair PCR amplicon of a common environmental bacterial 16S rDNA from a 293-base *B. burgdorferi* 16S rDNA.

skin rash. At the time of the initial visit, none of the spirochetemic patients registered a fever. On 4 patients for whom a CBC was ordered, 3 (3/4) showed slight leukocytosis with an increased percentage of neutrophils. One patient who had a concomitant chronic liver disease showed evidence of leukopenia. None of the 7 spirochetemic patients recalled a history of recent tick bites. As stated above, only one of the 7 spirochetemic patients (1/7) was found to be positive for the 2-tier serology test at the time of the initial visit. Follow-up information obtained from the primary care physicians of the patients confirmed that all presenting clinical symptoms and signs ascribed to Lyme borreliosis resolved completely after treatment with oral doxycycline, without recurrences in the ensuing 6-11 months. Only one of the 6 spirochetemic patients who were serologically negative at the initial visit was re-tested for possible rising antibody titers of Lyme disease, and the serology re-testing result was also negative. The

major relevant clinical findings of the 7 spirochetemic patients were summarized in Table 3.

Discussion

Accurate diagnosis of early Lyme disease plays a pivotal role in “curing” the infection with appropriate antibiotic treatment, and in preventing the infection from going into chronic phase which may cause debilitating tissue damage. However, the clinical manifestations of early Lyme disease are highly variable and often not easily distinguished from those caused by other illnesses. The commonly used 2-tier serology laboratory test which usually only turns positive during convalescence of the infection is reported to be negative or non-diagnostic in 75% of the “clinically confirmed” cases of early Lyme disease [4]. Testing for *B. burgdorferi* spirochetemia has been suggested to be the laboratory approach to diagnose early Lyme disease at the stage of hematogenous dissemination of the bacteria, which is believed to

Table 1 Comparison of nested PCR and 2-tier serology in detection of Lyme disease among 333 patients referred by private practitioners from offices

	Two-tier Serology		Total
	+	-	
Nested PCR +	0	0	0
Nested PCR -	28	305	333
Total	28	305	333

+ = positive.
 - = negative.

Laboratory detection of Lyme disease among 333 patients referred from private offices:

Confirmed case prevalence = 28/333 = 8.4% (2-tier serology only).

Sensitivity of nested PCR = 0% (0/28).

Sensitivity of 2-tier seropositivity = 100% (28/28).

Table 2 Comparison of nested PCR and 2-tier serology in detection of Lyme disease among 130 patients visiting emergency room and walk-in clinic

	Two-tier Serology		Total
	+	-	
Nested PCR +	1	6	7
Nested PCR -	1	122	123
Total	2	128	130

+ = positive.
 - = negative.

Laboratory detection of Lyme disease among 130 ER/walkin patients:

Confirmed case prevalence = (7+1)/130 = 8/130 = 6.2% (DNA sequencing or 2-tier serology).

Sensitivity of nested PCR = 87.5% (7/8).

Sensitivity of 2-tier seropositivity = 25% (2/8).

precede the appearance of the diagnostic antibodies [1,2,4]. However, the traditional microbiology blood culture techniques are not practical for the diagnosis of Lyme disease because it takes several weeks to recover a positive growth of the Lyme spirochetes in the liquid media. Attempts to culture *B. burgdorferi* spirochetes from patients' blood as a diagnostic tool have largely resulted in disappointments [11]. Non-dividing or slowly dividing *Borrelia burgdorferi* cells which do not generate a discernible positive culture in artificial liquid media are known to cause infections in animals [3]. The other alternative to detect this fastidious infectious agent in a patient's blood is to test for its genetic fingerprint materials, namely by a NAAT.

Several PCR-based nucleic acid amplification tests have been used for the detection of *B. burgdorferi* DNA in the blood samples of patients suffering from Lyme disease. However, their sensitivity is generally too low to be useful for clinical application [12-15] in part due to a lack of consistency of the *Borrelia burgdorferi* genetic materials targeted for PCR amplification by these methods. The lack of rigorous validation of the PCR products has also caused false positive results which can lead to inappropriate treatment with potentially serious complications [16,17]. Adoption of a NAAT procedure for the diagnosis of Lyme disease must proceed with caution.

Since all bacteria contain a 16S ribosomal RNA gene, or 16S rDNA, which differs from one another in their respective unique hypervariable regions, three oligonucleotide PCR primers, known as LD1, LD2 [5,6], and TEC1 [7], have been introduced to amplify a highly conserved region of the *B. burgdorferi* sensu lato 16S rDNA for its molecular fingerprint identification. In combination with the nested PCR and direct automated DNA sequencing technologies, these genospecies-specific PCR primers are useful in generating reliable materials for sequence alignment analysis using the online GenBank database as the standard for validation of the *B. burgdorferi* sensu lato 16S rDNA [8]. The potential value of their clinical application in confirmation of early Lyme disease spirochetemia has been demonstrated by the results presented in this report.

One potential pitfall in targeting a highly conserved bacterial 16S rDNA of the genospecies of *B. burgdorferi* sensu lato for molecular diagnosis of Lyme borrelia spirochetemia is that some environmental bacterial 16S rDNA fragments, which may be present in normal human blood samples [18,19], can be amplified by the chosen PCR primers, especially when the nested PCR technology is employed to increase the detection sensitivity (Figures 2, 3, 4). This kind of potential false positive result generated by a non-specific PCR can be eliminated by routine direct DNA sequencing of all

putative PCR-positive materials with their signature sequences validated through online GenBank sequence alignment algorithms (Figure 1).

In one residential suburb where Lyme disease is endemic, we found that 5.4% of the ER/WALKIN patients presenting with Lyme disease-like clinical manifestations were shown to have *B. burgdorferi* spirochetemia while none (0%) of the patients referred to the laboratory from their private doctors' offices with the same differential diagnosis had evidence of spirochetemia when tested by the same procedure. In comparison, only 1.5% of the ER/WALKIN patients in the same group were positive for the 2-tier antibody serology test for Lyme disease while 8.4% of the patients referred from the private doctors' offices were positive for the 2-tier serology test. These findings seem to indicate that the best time for detecting spirochetemia in early Lyme disease is when the onset of the clinical manifestations is noticed by the patient. Such immediate medical attention is probably only available at the ER or WALKIN in most endemic regions. Waiting for a scheduled appointment to the regular private doctor's office may miss the window of opportunity in DNA detection at the time when the Lyme disease bacteria are circulating in the blood, but only briefly.

In our series, 6 of the 7 (85.7%) PCR-detected, DNA sequencing-confirmed Lyme spirochetemic patients did not develop the 2-tier Lyme disease antibodies at the time of initial laboratory testing. Since these patients were all suspected of suffering from Lyme borreliosis based on clinical manifestations alone, they were prescribed a short course of preventive doxycycline while waiting for the laboratory test results. The antibiotics would be discontinued when the 2-tier serology screen test and the PCR test results were both found to be negative. All ER/WALKIN patients were referred back to their regular primary care physicians for follow up, and most private healthcare practitioners did not order additional serology tests for these patients. Therefore, it is not known if these 6 sero-negative, proven spirochetemic patients would turn sero-positive for the 2-tier serology test during their long-term convalescence. If no further follow-up serology tests were ordered, or if the subsequent 2-tier antibody tests turned out to be negative as a result of the initial partial treatment [20,21], these 6 Lyme disease patients would have been classified as having "no evidence of Lyme disease", except for the DNA evidence of Lyme spirochetemia. These clinical observations emphasize the importance of public education in the diagnosis of Lyme borrelial spirochetemia. Early Lyme disease is essentially a patient-initiated laboratory diagnosis under the guidance of an alert physician. The patients generally control the window of