Presentation to DR. Leah Devlin

21 April 08

Lyme disease: A Patients Perspective of Lyme disease/ Lyme related illnesses and being diagnosed in NC

Attendees:

Dr. Leah Devlin – State Health Director

Dr. Jeffery Engel – Chief, Epidemiology Section

Dr. Marcia Herman-Giddens – President, Tick-borne Infections Council of North Carolina, Inc

LtCOL Dave XXXXXX (USMC - RET) – Resident of NC

This presentation is from an educated patient's perspective on the current medical view of Lyme disease and associated Lyme related illnesses in our state. My goal is to present the facts, as they apply to the residents of this state, by showing a closer representation of the actual number of residents being treated for Lyme and Lyme related illnesses and the difficulties residents face in the diagnosis and treatment for Lyme and these illnesses. These data are based on information gathered during the past two months through research conducted by myself and with the help of other Lyme patients.

Since this meeting is specific for Dr. Devlin and time may be an issue to complete the presentation, please hold comments to the end of this presentation.

How Many Residents Are Really Treated For Lyme and Lyme Like Illnesses Each Year?

Before we can address the main issue of today's meeting, we must first establish the approximate number of NC residents treated for Lyme and Lyme related illnesses each year. Although state documentation says that Lyme disease is "scarce" this is not true from my perspective and the following information is used to demonstrate this fact (Ref NC ID notes).

Fact: The CDC reportable case statistics for the state has little relation to the actual number of residents being treated for Lyme and Lyme Like Illnesses.

The best mathematical model to illustrate this point is to use total of the state's CDC reported Surveillance cases of Lyme disease and divide this number by the total years involved. Since there were 1234 cases reported from 1992 to 2006, the overall average for each year in our state is 76 cases. The CDC acknowledges that the magnitude of underreporting is somewhere between 6-12 times the number of reportable cases for Lyme disease (Ref MMWR of May 2004). On a conservative side, I used the number 8. This reasoning is based on the following facts.

Doctors do not report a case for fear of highlighting themselves to the State Medical Board, their peers, insurance companies or it's just not done. Obviously, if the doctor does not report, then the state is never aware of the possible CDC case. Some of the reasons the case reports are low and the actual number of treated residents are many times greater:

1. Doctors are "running scared" as quoted by Dr. Pittman in the N&O article. Dr. Jemsek's medical board hearing has some NC

doctors afraid to report those patients they treat for fear of bringing attention to themselves. Just look at the dramatic drop in case reports the past 2 years (Ref). My Federal Aviation Association medical doctor, when asked what his response would be to a positive Lyme blood test on a patient in NC said "a positive blood test in this state would be a **false positive"** as stated by the CDC (CDC's policy statement for a non-endemic county) What this means is that a patient can test positive for Lyme Disease but since the CDC says its most likely a false positive in a non endemic county, the doctor will not diagnose Lyme without the EM rash (only 30 – 50 % of patients may get the rash).

2 Doctors are treating Patients **but using different diagnosis** codes in order to allow longer term antibiotic treatment. Meaning these doctors are not reporting to the state (ref from support group leader). Doctors are taught in medical school "to treat the patient" and some are, but through non-Lyme diagnosis codes that allow longer term antibiotics without drawing attention to their practice.

3 Residents are forced to seek out-of-state medical care to be diagnosed and treated. These cases are likely to go unreported to the state. Many patients have reported that they seek medical treatment out-of-state in order to get diagnosed and treated. (Example: the state Medical Board told Mrs. XXXXXX to take her daughter to another state for IV treatment as NC would not authorize longer treatment, even though her daughter was rapidly going blind from Lyme disease).

4 I made contact with 30 of our county health departments for their numbers of tick-borne disease, what they reported to the state, and what each County Health Director's own personal view was on tick related diseases. In some cases the state's reported numbers are lower than what the county reported. This fact may be "normal business" with the state reviewing cases and disallowing some of them but Dr. Engel also stated he does not accept reports from labs which do not use commercial testing assays (FDA approved assays). While each individual state may set their own standards for case reporting, NC's position discounts some of the most accurate and noted testing facilities in the country (Irene is one). **Since other states accept all CLIA certified labs results, but not NC, the state can't make comparisons of NC's low case numbers to states which allow case reports verified by all certified labs**. My research shows that Irene scored higher than any other lab in accuracy of Western Blot testing (ref). If the lab is CLIA certified and meets every standard of testing by government certified credential testing measures, then the state should allow all the results of every certified lab in order to get a more accurate count of Lyme related Illnesses in the state.

5 Lyme disease is a Clinical Diagnosis by the treating physician, as stated by the CDC. Clinical diagnoses of patients with later stage infection do not always meet the CDC definitions of surveillance criteria. The CDC's surveillance criteria were first established in 1995 and have changed little since. It has been documented that patients with longer term infection present various symptoms and have weaker immune systems. Also, Late Stage Lyme can produce weaker infection bands from laboratory testing of Western Blot tests and may not meet CDC reportable criteria however any positive Bb band detected can be diagnostic for the clinical diagnosis of the patient.

6 Some Infectious Disease doctors do not perform the ELISA test and go straight to the Western Blot because of greater reliability (Ref). They are attempting to diagnosis the patient and not trying to achieve CDC surveillance criteria. Without the ELISA, the case will not meet CDC reportable criteria for the state, although the patient is still diagnosed and treated for the disease.

7 Military Reporting for the state of North Carolina shows an 8 to 1 treatment -to-reportable-cases for the last 5 years.

The following chart is of reportable military cases of Lyme disease in NC since 1998

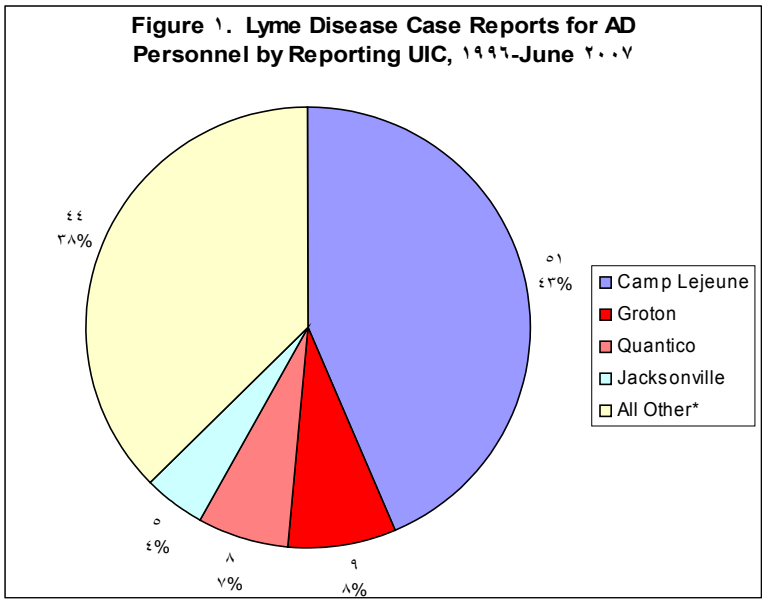
	1998	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**Total**
Bragg	2	2	1	0	0	0	0	0	1	**6**
Lejeune	0	0	0	0	6	1	1	1	2	**11**
Cherry Point	0	0	0	1	1	1	1	0	0	**4**
New River	0	0	0	1	0	0	0	1	0	**2**
Pope	0	0	0	0	0	0	0	0	0	**0**
Seymour Johnson	0	0	1	0	0	0	0	0	0	**1**
Other	0	0	0	0	0	0	1	0	0	**1**
Total	**2**	**2**	**2**	**2**	**7**	**2**	**3**	**2**	**3**	**25**

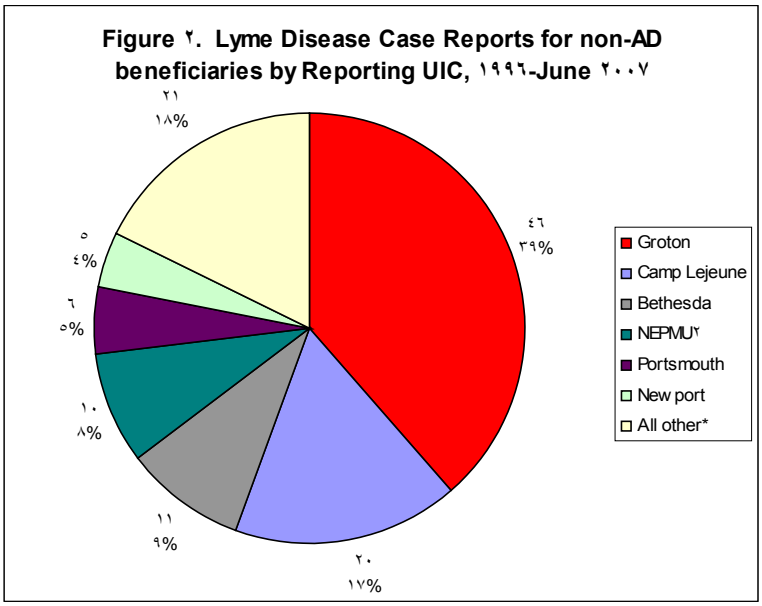
Ambulatory visits (first occurrences)

	1998	1999	2000	2001	2002	2003	2004	2005	2006	Total
Bragg	4	7	10	11	10	1	3	4	10	**60**
Lejeune	7	7	10	4	22	13	9	10	4	**86**
Cherry Point	4	4	2	3	3	1	3	1	1	**22**
New River	0	0	1	4	0	0	4	1	2	**12**
Pope	2	0	0	2	2	0	0	1	0	**7**
Seymour Johnson	0	1	1	1	0	0	1	2	0	**6**
Other	1	0	1	0	2	1	1	0	0	**6**
Total	**18**	**19**	**25**	**25**	**39**	**16**	**21**	**19**	**17**	**199**

DMED query 7 March 2008

The military has designated both Ft. Bragg and Camp Lejuene as "high risk" areas from previous risk assessments done by the military. Also, the following reference by the Naval Environmental Health Center (June 2007) cites NC as the highest state for numbers and percentage of Naval military members confirmed for Lyme disease (even higher than CT, a Lyme endemic region) using both active and off- duty military statistics.





*All other includes UICs that reported 5 or fewer cases

71 cases of confirmed Lyme disease between active and off-duty personnel from 1996 to 2007 at Camp Lejuene.

Other points supporting Lyme disease and related illnesses:

1 The majority of migrating new residents to this state are from known Lyme Endemic states. These new residents also bring their pets (and any acquired infection to NC) but may not present serious symptoms until having to see NC doctors. (**The resident does not have to be infected here to face the difficulty of being diagnosed here**). These residents may have either a late or "chronic" stage of Lyme related illness and typical tests results are usually CDC negative due to immune system suppression from many years of infection. Infection rates as high as 18% of Connecticut dogs tested positive for Bb in one veterinarian study. Look at the following two slides.

2 The number of animals infected and treated for Lyme disease is steadily increasing, especially canines. Last year the NC State Vet School verified 2 dogs with Bb who never left the state. Infected pets can be used as a marker for tracking which counties are most affected and this can translate to percentages for human exposure and infection rates. Based on data from Idexx laboratories, there were 379 positive cases of Lyme disease in canines from 2000-2007 in NC. Additionally, there were 558 canine cases of Ehrlichia during the same years. **Wake, Onslow and Mecklenburg counties were the highest reporting - the same as with human Lyme disease.**

3 The White Tail deer population in NC is increasing and is presently at its highest levels. This deer is a host for the black-legged tick as well as the Lone Star Tick.

4 It's not just Lyme related or Lyme-like disease, it can be STARI! The state only tracks one of many co-infections associated with Lyme – Ehrlichiosis but Babesiosis, Bartonella, tularemia or other co-infections are possible. If residents have one of these illnesses, then it's still a Lyme-like illness and is treatable with proper antibiotics.

5 **Lyme and Lyme related illness is a clinical diagnosis**. But most every Primary Care Physician (PCP) will rule out Lyme if the patient produces a negative blood test. The CDC clearly states that a negative test does not rule out Lyme disease. This lack of knowledge concerning the proper diagnosis of Lyme by the average PCP, then leads to the patient being misdiagnosed with some other disease. *To demonstrate this point, I asked every doctor I came into contact with the past 3 months and every one of them said they would discount Lyme with a negative test result*. Up to 50 percent of Lyme Disease suffers may test negative, depending on the lab, the length of time infected, their immune system, lab reliability - since the Lyme test depends on the patient's *immune system recognizing the bacteria* (both the ELISA and Western Blot do not detect actual Bb but detect antigens produced by the patient's immune system in response to the bacteria).

6 Point-Counter-Point –Dr. Engel responded to my letter concerning Lyme disease in NC. 1) "IgM antibody tests are notoriously inaccurate, fraught with an unacceptably high false positive rate, and are not indicated or accepted for the diagnosis of Lyme disease" – **for reporting maybe but not for confirmation or to aid in the clinical diagnosis of the patient**. 2) "DHP officials have looked hard for evidence of Lyme Disease in NC, but found only uncommon and sporadic detection of Bb in

the state." **But Dr. Apperson's study, the coastal region study and hundreds of patients** being treated each year confirms that Lyme and Lyme related disease is real in NC and at higher numbers than the state acknowledges. When was the last time a creditable study was done in this state looking for black- legged ticks, Bb and how much has changed in demographics and population expansion since then? 3) **"It's STARI not Lyme" – this does not matter as it's still a Lyme-like illness**. STARI is very serious and you can't use the "it's not Lyme" theme forever. This disease needs proper attention now and this has not been shown be occurring. 4) **"NC College of Veterinary Medicine rarely detects Bb in NC dogs"** – 371 treated dogs is not rare.

Lack of funding has produced no new studies of the current black- legged tick and Bb in the state. The only issue really important to the residents of this state **is that adequate medical treatment can be provided to them**, not where or how the infection was acquired.

The state's literature says that true Lyme disease is scarce but from a patient's perspective, it is very real and on an increase from what the surveillance case numbers have shown the past two years.

Summary: Using the 8 x 76 formula we have a projected number of 600+ residents being treated each year from Lyme and Lyme Like Illness. (Note: this number does not count the fact that NC leads the nation in RMSF every year).

Dr. Engel, how many cases of RMSF and Lyme disease where reported last year?

For whatever reason, it appears the state down plays the significance of Lyme and its related illnesses. This attitude severely affects the medical community's opinion of this disease, adversely

affecting the ability of residents to be properly diagnosed and treated by the state of NC.

The current NC medical "climate" and attitude towards Lyme related illness leads to denial of adequate and reasonable medical diagnosis and treatment for state residents.

Dr. Engel stated in his letter to me, "Thus I support the vast majority of NC physicians who, like me, base their practice on scientific evidence. Until we have such evidence, physicians are correct to be skeptical of Lyme disease acquired in NC"

This view is flawed in that treating doctors should not care where the disease was acquired but only care about the correct and adequate treatment of the patient.

1. The average, primary care doctor looks to the state for guidance in diagnosing diseases, such as Lyme, which can present with so many different symptoms. This guidance is found in the State's Infectious Disease Manual. The state says Lyme disease is scarce, we don't have the high numbers like Connecticut, "It's not Lyme its STARI", Bb does not have adequate hosts to survive in this state. Then the state goes on to say it's up to the medical community to convey this message to the residents and clear up the misunderstanding and pass along the "truth" about Lyme disease.

Let's talk about misinformation. Chronic Lyme, CT's numbers, STARI, Ref 2, is there a test for Lyme disease?

2 There are NC medical institutions and doctors who will not see a patient if they mention Lyme disease or related illness. All of the negative press, insurance issues and medical scrutiny over Lyme disease have caused NC doctors to deny medical services to those suffering from these diseases because of political views and possible doctor scrutiny. For example, if you try to make an appointment at Duke Hospital for Lyme disease they will tell you that they do not see patients for Lyme and for you to see your PCP.

3 I've reviewed the past 1 ½ years of the state's EPINOTES and Health Department Press Releases. Until the Press Release last week, not one mention of Tick Related news except the one death from RMSF last year. Where is the Pro-Active communication to our residents and medical community educating them on tick related diseases as stated by Dr. Engel during the meeting with Lane Huggins in 2005? **North Carolina's Tick Awareness Week** is coming up next month but no mention of this event in last week's Press Release dealing with tick season. Was this an oversight? Furthermore, the numbers of RMSF, Lyme and Ehrlichiosis, stated in the press release, were much less than the state officially reported for 2007.

4 Wake County has repeatedly met the CDC's criteria for endemic status and last year Wake and Onslow both met this criteria. Why has the state Health Department not made this designation? Once a county is known to have a higher incidence of Lyme disease, different rules apply and doctors are able better able to diagnose possible Lyme related illnesses. This action will greatly benefit patients in the diagnosis of Lyme and related illnesses.

5 The Jemsek case and Pittman's comment of "doctors being scared" typifies the current medical attitude of doctors. Combine

this with the state's comments that Lyme is "scarce" and it's not really Lyme, "its STARI" further complicates residents receiving adequate and comprehensive medical care. Doctors are afraid, will not treat or can't adequately treat for Lyme disease. Residents have been told there is no Lyme here" or misdiagnosed with other chronic diseases so many times that many have given up hope and now permanently suffer from this action. Additionally, any delay in adequately diagnosing and treating Lyme illnesses causes the patient to endure more permanent damage to their bodies and additional suffering, expense and longer treatment protocols.

Some NC residents have Late – Stage or Chronic Lyme and have had the disease for a long time. NC does not have the talent base of Primary Care Doctors who are able to clinically diagnosis Lyme disease in this stage or the support of the medical board for long term treatment of Lyme. This is why so many residents spend huge amounts of money to travel out of state to seek medical assistance. This fact needs to be addressed by our Health officials and the clinical aspect of Lyme diagnosis emphasized to our doctors.

Another tick study is not what the suffering patients needs but insurance from their Heath Department that the state is doing all it can to help them "NOW" not years down the road. Tick surveys and studies are required from a scientific standpoint and are valuable from that aspect, but offer no immediate assistance to patients suffering today. Doctors know, "you treat the patient" and measure success by how they respond to this treatment. Our doctors need positive guidance from the state in order to support aggressive and adequate treatment, not fear of reprisal by the state Medical Board. The state's view on Lyme disease must change.

Recommendations

1) The Health Department removes the wording that Lyme disease is "scarce or rare" in North Carolina from all publications and rewrites ID notes and use information similar to our surrounding state's information. The Rare/scarce statement misleads the medical profession in not suspecting a Lyme related illness for initial diagnosis.

2) That Wake and Onslow counties be designated endemic counties in accordance with CDC criteria as establish in the 2008 Case Definition Criteria. This will lead to better diagnosis and treatment of patients.

3) The Health Department becomes more active in promoting Lyme disease and Lyme related illnesses prevention/treatment within North Carolina. Information is presented to both the medical community and residents as to prevention, diagnosis and adequate treatment. Additionally, the medical profession needs to feel safe and become more knowledgeable in recognizing the clinical diagnostic criteria and in the aggressive medical treatment of this disease.

4) Comply with the CDC's request for patients who may have STARI by making this study's request for information know to all NC doctors. This is the only way you will know if it's Lyme disease or some other version of the illness. If it meets the case definition for Lyme disease, then it's Lyme unless proven otherwise. Study the patient, not the tick for the fastest collection of information and overall determination of what illnesses are truly affecting residents of NC.