

# Addressing the Gaps in Scientific Research on Lyme and Other Tick-Borne Diseases

## The Patient Perspective

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Definitional Term:

“Lyme” is used to signify the complex of Lyme & co-infections

# Burden of Disease

- ▶ Lyme is finally identified as a national epidemic
  - We are just beginning to acknowledge the degree of this growing complex disease burden
    - Recognition of persistent Lyme infection is crucial
    - From several presentations, encouraged recognition of persistent infection appears to be coming
    - The science of mice is interesting, but where are the studies of the primates?
    - Until we have the answers: MUST KEEP THE FOCUS ON THE PATIENT
    - Support the art of practicing medicine

*Treat the patient not the test (Olano)*

# Burden of Disease

- Livelihood
- Career
- Family
- Life Savings
- Burden on Society

**Krause: Complications of Babesiosis include acute respiratory failure, congestive heart failure and death!**

- Children—loss of childhood
- Children are not “little adults”

*[For a child] long term effects last 50–70 years (Jacobs)*

# Diagnostics

- ▶ This is a very complex disorder for which we need better diagnostic tools.
  - to allow us to better characterize both acute and persistent manifestations of Lyme and associated co-infections
- ▶ Recognize AND STUDY persistence



*Everyone is studying the early stage of this infection, no one is studying the persistent phase of the infection (Barthold)*

*The hardest thing to say to a parent is "I don't know"  
(Jacobs)*

# Case Definition

- ▶ The CDC surveillance criteria is inappropriate for treatment
  - Used to deny insurance coverage
  - Discourages physician treatment
  - Much misunderstood in the general medical community
  - Behind medical board investigative decisions
- ▶ Expand the case definition to include the emerging spectrum of disease
- ▶ Recognize different treatment regimens are appropriate and give the clinician the breadth to practice the art of medicine

***You do not require an antibody response to develop the disease - Weis***

***How a disease is defined often defines the winners and the losers - Aronowitz***

# Surveillance/Reporting

- ▶ Redefine criteria for surveillance
  - Current criteria misleads clinicians in reporting and diagnosing
  - Case definition is dated/restrictive and doesn't identify most patients
  - Must expand the conditions/symptoms in the definition
- ▶ Remove regional biases
- ▶ Include all the tick-borne diseases
- ▶ Specifically
  - Develop an automated, standardized report or technique to assist in reporting compliance
  - Consistent reporting criteria for all states (as noted in Hadler's Commissioned paper)
  - Broaden the case definition for surveillance to include advanced late-manifestations of Lyme disease and co-infections

*“... the poor understanding of the true incidence and geographical distribution ... I don't think we have a clue” (Jacobs)*

# A New Approach

- Several presenters highlighted significance of co-infections & their immune suppressing properties
  - BUT: Most science dealt with ACUTE; no one studying CHRONIC
- Chronic Lyme needs to be included in the differential diagnosis
- Symptoms dismissed as “subjective” need to be quantified and given clinical weight
  - We heard broad agreement on list of ongoing symptoms
- Acute Lyme presents year round as flu like symptoms with or without a rash
- Chronic Lyme can be an active persistent infection, immune response and/or a chronic mechanism perpetuating ongoing symptoms
- Banish the term of *Post Lyme Disease syndrome*
  - Suggests absence of infection
  - For which there is no proof in chronic patients

*“How can you say, ‘I’ve treated you for 4 weeks and therefore you no longer have Lyme disease.’ The fact is, we don’t know! (Donta)*

# Critical Research for the 21<sup>st</sup> Century

- ▶ Dr Luft's research on the characterization of borrelia genotypes
- ▶ Informatics to create national databases that capture every aspect of the disease in the ecosystem, the vectors and the patients
- ▶ A “Manhattan-like project” to address the tick borne disease burden – Liegner
  - Not hyperbole

*We need direct antigen detection,  
I'm not keen on antibody tests (Donta)*



# Research Focus

- ▶ The **ADNI Model**
  - The Alzheimer's Disease Neuro-imaging Initiative (ADNI) model
- ▶ Recently announced discovery of significant NEW BIOMARKERS for Alzheimer's
- ▶ Dr. John Trojanowski, Univ. of Pennsylvania

3-point program:

- Agree to share all data
- Every finding immediately public
- Renounce ownership and patent rights.

**“.. we all realized that we would never get biomarkers unless all of us parked our egos and intellectual-property noses outside the door”**

Dr. John Trojanowski, a researcher at the University of Pennsylvania

# Research Focus

- ▶ Construct research that addresses the complexity of the disease:
  - Multiple pathogens
  - Role of mutation
  - Immune system evasion and suppression
  - Subspecies and strain variation
  - Multiple mechanisms for persistence
  - Patient population heterogeneity
- ▶ Focus Funding:
  - New proposals : Focus on persistent, post treatment illness
  - Fresh blood: (and I don't mean samples on glass slides)
  - Creative ideas to address persistence
- ▶ Replace the CDC surveillance criteria for study design
  - As an entry criteria it eliminates a vast majority of Lyme patients
  - Too small a sample size

***Underpowered studies which purport to demonstrate universal efficacy need to be viewed with circumspection (Luft)***

# Collaboration is Key

- Unfortunately, It took a congressional mandate to bring the medical, scientific and patient community together
- We need an NIH funded committee such as the Chronic Fatigue Committee
  - We can learn from each other
- We can no longer impede medical progress with polarizing controversy
- We need to continue this dialogue
  - Encourage mutually respectful collaboration between researchers and clinicians
  - Include patient participation
  - Reach out for diverse views of clinical treating doctors

***All that shouting drowns out all the complexity and the nuance and the work that needs to be done (Pam Weintraub)***

# While we wait??

- We asked state advocacy and support leaders across the country where they felt further research in their state was needed:
  - Doctors are not updated on the existence of Lyme in their state or the expanded list of symptoms
  - If doctors pursue testing they rely solely on the ELISA test
  - Lack of physician knowledge and poor testing result in faulty surveillance data
  - Let the doctors practice their art as well as the craft

*Lyme disease is a clinical diagnosis*

# Critical Next Step

- ▶ IOM Workshop II
  - Include treatment in its scope
  - Focus on Persistent Disease
  - Establish and validate the complex, chronic presentations that represent the burden of the disease

*Science is not belief;  
but the will to find out! (Luft)*



# Guiding Principle

## It's About the Patient

