

Research for Lyme Infection-Associated Chronic Illnesses Treatment: Broadening the Lens – Committee Meeting 2

WORKSHOP AGENDA

Committee on the Evidence Base for Lyme Infection-Associated Chronic Illnesses Treatment

Thursday, July 11, 2024

Workshop Objectives:

- Describe the current state of Lyme IACI research for treatments and diagnostics to clarify barriers in development of new, effective therapeutic interventions;
- Explore recent advancements from other biomedical research fields with the potential to address these barriers by catalyzing scientific breakthroughs or translation of discoveries to treatments;
- Understand patient-defined priorities for research and discuss potential opportunities for engaging this perspective in developing a biomedical research agenda; and
- Discuss research strategies and infrastructure that could facilitate the application of innovations from other fields into the Lyme IACI research context.

DAY 1 – THURSDAY, JULY 11, 2024

CLOSED SESSION

9:00 AM

Committee meets in closed session

OPEN SESSION

9:30 AM

Welcome
KENT KESTER, *Committee Chair*
Former Vice President, Translational Medicine
IAVI

Opening Session: An Overview of Challenges in Lyme IACI Research

Objectives

- Understand Lyme IACI disease impact; and
- Present overview of current status of ongoing research for Lyme IACI.

Framing Questions

- What is the impact of Lyme IACI in the US and globally?
- What is the current evidence base toward understanding and developing treatments for Lyme IACI?
- What are key scientific or technical barriers in addressing challenges to develop new treatments?
- How are patient perspectives and input incorporated into prospective research studies?

9:35 AM	Patient Perspective: Impact of Lyme IACI RHISA PARERA Patient Writer, Director, Producer <i>Your Labs Are Normal</i>
9:45 AM	Overview: Current Status and Challenges in Research for Lyme IACI Treatment JOHN AUCOTT Director, Johns Hopkins Lyme Disease Clinical Research Center Associate Professor of Medicine Johns Hopkins University
10:05 AM	Building on Current Progress: Reflections from the HHS Tick-borne Diseases Working Group C. BENJAMIN BEARD Deputy Division Director, Division of Vector-Borne Diseases Centers for Disease Control and Prevention
10:15 AM	Q&A
10:45 AM	BREAK

SESSION 1: Potential Commonalities Across Other Fields and Implications for Lyme IACI

Objectives

- Examine the commonalities between Lyme IACI and other diseases and potential shared mechanisms of pathology; and
- Evaluate the relative strength of evidence for the potential mechanisms of Lyme IACI pathology
- Discuss implications and unique considerations for Lyme IACI.

Framing Questions

- What similarities or differences exist between Lyme IACI and other IACI with neurologic, cognitive, or psychiatric symptoms?

- What does the current evidence suggest about the biological plausibility of the neurologic, cognitive, and psychiatric symptoms of Lyme IACI being caused by different mechanisms of pathology?
- What factors should be considered in prospective studies that seek to identify whether there are inflammatory and/or autoimmune biomarkers associated with Lyme IACI?
- Is research on pathogen persistence from other IACI translatable to developing potential treatment for Lyme IACI?

11:00 PM	<p>Autoimmune mechanisms of IACI WILLIAM ROBINSON James W. Raitt, M.D. Professor of Medicine Stanford University</p>
11:10 PM	<p>Inflammatory responses in IACI DANIEL CLAUW Professor of Anesthesiology; Internal Medicine (Rheumatology); and Psychiatry Director, Chronic Pain and Fatigue Research Center University of Michigan</p>
11:20 PM	<p>Mechanisms of colonization and pathogenesis JOHN LEONG Edith Rivera and Hyman S. Trilling Professor and Chair of Molecular Biology and Microbiology Tufts University</p>
11:30 PM	<p>Elucidating pathophysiology: lessons from ME/CFS AVINDRA NATH Senior Investigator and Clinical Director, Division of Neuroimmunology & Neurovirology National Institute of Neurological Disorders and Stroke, NIH</p>
11:40 PM	<p>Discussion and Q&A</p>
12:15 PM	<p>LUNCH</p>

SESSION 2: Advances in Diagnostics Research

Objectives

- Explain the relationships between diagnostics research and research on Lyme IACI etiology and treatment;
- Provide an overview of current approaches to diagnostics that may hold promise for Lyme IACI diagnosis;
- Identify current challenges in advancing diagnostics to support development of Lyme IACI treatment and emerging technologies that may mitigate these challenges; and
- Discuss opportunities for implementation of these emerging technologies and other mitigating factors.

Framing Questions

- What are challenges in developing diagnostics for Lyme IACI?
- How do these challenges impact development of treatments?
- What scientific advances exist that may address these challenges?
- What are barriers (technical and/or market forces) to implementing these technologies for Lyme IACI?

1:00 PM	<p>Current diagnostic approaches and emerging technologies CHARLES CHIU Professor of Laboratory Medicine and Medicine University of California, San Francisco</p>
1:10 PM	<p>Challenges in diagnostics research NANCY KLIMAS Director, Institute for Neuro-Immune Medicine Professor of Medicine Nova Southeastern University</p>
1:20 PM	<p>Challenges in advancing new diagnostics development RAYMOND DATTWYLER Professor of Pathology, Microbiology and Immunology, Medicine, and Pediatrics New York Medical College</p>
1:30 PM	<p>Challenges in regulatory considerations of new diagnostics ELLIOT COWAN Founder & Principal Partners in Diagnostics</p>
1:40 PM	<p>Discussion and Q&A</p>

SESSION 3: Strategies to Improve the Applicability of Research

Objectives

- Explore elements of study designs that enable collection of data from more inclusive patient samples;
- Discuss strategies to standardize research questions and outcome measures; and
- Assess the feasibility of implementing data sharing practices across Lyme IACI research studies;

Framing Questions

- What are key factors to model or consider in large or in-depth prospective studies designed to interrogate potential pathways to developing treatments for Lyme IACI?
- What challenges may have been encountered or can be anticipated in collecting and sharing data across different studies?

2:10 PM	<p>Patient generated data BETH JAWORSKI Director of Participant Platforms All of Us Research Program, National Institutes of Health</p>
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2:20 PM	<p>Patient registries and biobanks for Lyme IACI LIZ HORN Principal Investigator Lyme Disease Biobank</p>
2:30 PM	<p>Platform trial designs toward standardization and quality across studies ROGER LEWIS Investigator, The Lundquist Institute Professor of Medicine University of California, Los Angeles</p>
2:40 PM	<p>Research trials network and data sharing RACHELE HENDRICKS-STURRUP Director, Real-World Evidence Duke-Margolis Institute for Health Policy</p>
2:50 PM	<p>Discussion and Q&A</p>
3:20 PM	<p>BREAK</p>

SESSION 4: Bridging Opportunities and Action

Session Objectives

- Identify additional barriers that restrict progress on Lyme IACI research;
- Consider how patient-defined research priorities and patient-reported outcomes can inform future research; and
- Discuss opportunities to advance translation of Lyme IACI research into development.

Framing Questions

- What mechanisms or processes are need to incorporate patient priorities into the research agenda in a more systematic way?
- How can barriers to the conduct of Lyme IACI research be overcome? Who needs to be involved in developing solutions to address those barriers?
- What opportunities already exist to advance Lyme IACI research toward the development of treatments and diagnostics, and how can those opportunities be better utilized?
- What would success look like if different stakeholders were able to align on research priorities for Lyme IACI treatment? Are there any examples of successful collaboration for Lyme IACI research?

3:30 PM	<p>Panel Discussion: patient-defined priorities for research <i>Patient-centered outcomes</i> LORRAINE JOHNSON Chief Executive Officer LymeDisease.org</p>
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	<p><i>Patient participation in research and data collection</i> WENDY ADAMS Research Grant Director Bay Area Lyme Foundation</p> <p><i>Bridging between funder and patient priorities</i> TIMOTHY SELLATI Chief Scientific Officer Global Lyme Alliance</p>
4:00 PM	<p>Funder perspective LEITH STATES Chief Medical Officer Office of the Assistant Secretary for Health, HHS</p>
4:10 PM	<p>Industry perspective MATT TINDALL Co-Founder, President and Chief Executive Officer FlightPath Biosciences</p>
4:20 PM	<p>Regulatory perspective STACIE HUDGENS Chief Executive Officer Strategic Lead, Regulatory & Access Clinical Outcomes Solutions</p>
4:30 PM	<p>Discussion and Q&A</p>
Day 1 Wrap-Up	
4:55 PM	<p>Final Remarks KENT KESTER, <i>Committee Chair</i> Former Vice President, Translational Medicine IAVI</p>
5:00 PM	<p>ADJOURN DAY 1</p>

DAY 2 – FRIDAY, JULY 12, 2024

CLOSED SESSION	
9:00 AM	Committee meets in closed session
3:30 PM	ADJOURN MEETING