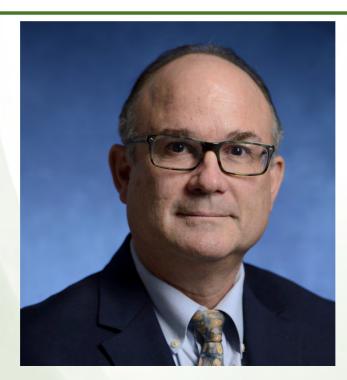


Welcome to the 4th meeting of the TBDWG



John N. Aucott, M.D. (Chair) Associate Professor, Division of Rheumatology, Johns Hopkins University School of Medicine; Director, Johns Hopkins Lyme Disease Clinical Research Center



Kristen Honey, PhD, PMP (Vice-Chair) Senior Policy Analyst, OMB, Executive Office of the President; Senior Research Scholar, Stanford University; Member, Stanford University Lyme Disease Working Group 1



* Making History



- First report to Congress on this issue
- Bringing together many people, including patients and patient advocates, with diverse backgrounds and perspectives—many of whom had not worked together before
- Creating new tools, like the Inventory of Federal Actions, that will be useful in the future
- Co-creating a Lyme disease "reset" a shift in focus from problems and blame to solutions and collaborations
- Moving forward, together



* Shared Vision

A nation free of tick-borne diseases where new infections are prevented and infected patients have access to affordable care that restores health



Core Values

- **Respect**: Everyone is valued
- **Innovation**: Shifting the paradigm, finding a better way
- Honesty and Integrity: Find the truth, tell the truth
- Excellence: Quality, real-world evidence underlies decision-making
- **Compassion**: Finding solutions to relieve suffering
- Collaboration: Work with citizens and patients as partners
- 7. Accountability: The buck stops here



* What have we accomplished?

2018 Progress



* Changes

One Working Group and three subcommittee positions changed

All were filled by a patient or former patient





New Working Group Member



Robert Sabatino

Founder and Executive Director Lyme Society Inc.,

New York

Public Voting Member and Patient Representative



Recap of Meeting #3

- 1st meeting with Working Group and all 6 subcommittee members
- Concurrent breakout groups of the 6 subcommittees
 - Volunteer introductions
 - Reviewed drafts for inventory requests from HHS/DoD/VA
 - Began identifying priorities for subcommittee reports
- Technical difficulties arose and affected amount of work done in Meeting #3, yet did not stall progress or delay schedule
 - 1st time using the software with this group
 - HHS changed online meeting platform for all future meetings



* 6 Subcommittees Composition

- 53 additional volunteers from diverse sectors
- Mix of existing Working Group members and other individuals with TBD expertise and knowledge
- Each subcommittee is led by 2 co-chairs
 - At least 1 co-chair is a Working Group member
 - Co-chairs were originally selected from existing Working Group members by Chair and Vice-Chair with input from DFO
 - Subcommittee members were nominations through a public process and were chosen by subcommittee co-chairs





6 Subcommittees Composition (cont.)

- 67 people engaged as Working Group and/or subcommittee members
- 1 in 4 Working Group members is a patient or family member
- Each subcommittee included one or more patients
- Most members had not worked together before
 - Diverse backgrounds, many different disciplines
 - Many had differing points of view
 - Understanding, trust, and respect had to be developed and continues to be developed, as this is an on-going process



Subcommittees and Co-chairs

- Disease Vectors, Surveillance, and Prevention
 - C. Ben Beard, MS, PhD, CDC
 - Patricia Smith, Lyme Disease Association
- 2. Pathogenesis, Transmission, and Treatment
 - Wendy Adams, MBA, Bay Area Lyme Foundation
 - Captain Estella Jones, DVM, FDA
- 3. Testing and Diagnostics
 - Lise Nigrovic, MD, MPH, Boston Children's Hospital
 - David Roth, JD, Retired, Private Equity Firm (Blackstone)



Subcommittees and Co-chairs (cont.)

- 4. Access to Care Services and Support to Patients
 - Commander Scott Cooper, MMSc, PA-C, CMS
 - Paula Jackson Jones, Midcoast Lyme Disease Support & Education
- 5. Vaccine and Therapeutics
 - Dennis Dixon, PhD, National Institute of Allergy and Infectious Diseases
 - Robert Smith, MD, MPH, FACP, FIDSA, Maine Medical Center, Tufts University School of Medicine
- 6. Other Tick-Borne Disease and Co-Infections
 - Richard Horowitz, MD, Hudson Valley Healing Arts Center
 - Allen Richards, PhD, Naval Medical Research Center



New Roles for 2 Subcommittee Members

David Roth, JD

Co-Chair, Testing and Diagnostics





Paula Jackson Jones

Co-Chair, Access to Care Services and Patient Support



* New Subcommittee Member



Sherill Franklin

Patient Advocate and Small **Business Owner**

Pennsylvania

Member, Access to Care Services and **Patient Subcommittee**



* Subcommittee Progress

- Subcommittee meeting summaries posted online
- Subcommittee reports all completed and posted online with content synthesized from diverse information sources:
 - Published studies
 - Information from patients and other experts
 - Experience/expertise of subcommittee members and invited speakers
- Subcommittees will no longer meet on weekly basis
- Subcommittees still exist to answer questions and provide input to Working Group
 - Subcommittee information given to the Working Group will be provided in writing and made available to the public through the HHS website



* What is happening today?

Goals for Meeting 4



Meeting 4 Overview

- Today's focus is subcommittee reports
- Subcommittee reports were prepared to inform the Working Group and its 14 voting members
- Subcommittees offer insights into gaps, opportunities and potentials actions to be considered by the Working Group for the report to Congress and HHS

Session Description	Presenter
- Subcommittee Presentation: Disease Vectors, Surveillance and Prevention	Pat Smith Ben Beard
- Break	
- Subcommittee Presentation: Pathogenesis, Transmission, and Treatment	Wendy Adams Estella Jones
- Lunch Break	
- Subcommittee Presentation: Testing and Diagnostics	Lise Nigrovic David Roth
- Subcommittee Presentation: Access to Care and Support to Patients	Scott Cooper Paula Jackson Jones
- Break	
- Subcommittee Presentation: Vaccine and Therapeutics	Dennis Dixon Robert Smith
- Subcommittee Presentation: Other Tick-Borne Diseases and Co-infections	Richard Horowitz Allen Richards
- Public Comment	John Aucott Kristen Honey
Review of Meeting Four,Next StepsAdjournment	John Aucott Kristen Honey
	- Subcommittee Presentation: Disease Vectors, Surveillance and Prevention - Break - Subcommittee Presentation: Pathogenesis, Transmission, and Treatment - Lunch Break - Subcommittee Presentation: Testing and Diagnostics - Subcommittee Presentation: Access to Care and Support to Patients - Break - Subcommittee Presentation: Vaccine and Therapeutics - Subcommittee Presentation: Vaccine and Therapeutics - Subcommittee Presentation: Other Tick-Borne Diseases and Co-infections - Public Comment - Review of Meeting Four, Next Steps



* Today's Agenda

- Six subcommittee presentations are the result of 3+ months of work
 - Enormous amount of work from a diverse group of stakeholders
- Subcommittee presentations today are:
 - Pre-decisional for consideration by the Working Group
 - **NOT** the Working Group report to Congress and the HHS Secretary



Moving forward, together



* Key Logistics and Process

- Subcommittee reports are online in their entirety, without modification to the text. Images will be posted at a later date.
- Subcommittee work and reports are inputs for the Working Group
 - Subcommittees were voluntary groups established to address a wide range of scientific and technical issues to help the Working Group deliver on 2018 schedule, given resource constraints and ambitious goals
 - Subcommittees framed issues and identified "potential actions"
 - Working Group will decide what to use, not use, and/or modify from the subcommittee reports in order to finalize recommendations
- Only the Working Group not the subcommittees issue the official report with recommendations to Congress and the HHS Secretary



Report Due by December 2018

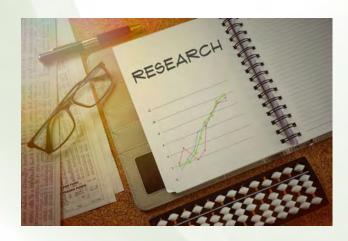
- In this first-ever report to Congress and the HHS Secretary, the Working Group will use information from:
 - Subcommittee reports
 - Other quantitative data including surveillance, research, program monitoring and evaluation
 - Other qualitative data including case studies, patient/provider experience, public comment
 - Inventory of Federal activities
 - Public input



* Report Submission

In December 2018, the report is submitted to:

- **HHS Secretary**
- House of Representatives Committee on Energy and Commerce
- Senate Committee on Health, Education, Labor, and Pensions



- Subsequent reports are due every 2 years after the first report
- Iterative updates and improvements over 6 years



* Iterative Process

- Cannot overstate the significance of this opportunity to change old narratives and co-create new recommendations on tick-borne disease (TBD)
 - 1st report due December 2018 is more than a report; it is also establishing Federal infrastructure and procedures to yield future value beyond 2018
 - 2nd report due December 2020 will include systematic literature review for 20+ TBD, more time for collection and analysis of inventory data
 - 3rd report due December 2022 will further improve and update
- Working Group and subcommittees will evolve over time
 - In early 2019, HHS will issue a new public call for Working Group nominees



* Near-Term Milestones

- Creating first-ever inventory of Federal Tick-Borne disease activities
 - Subcommittees provided input into design of inventory requests
- Took time to develop and submit inventory request to agencies
 - Differences in collecting and reporting information are anticipated and will need to be addressed
- HHS, DoD, and VA have received surveys
 - Responses due on May 11th
- Working Group will report on information received at our next meeting and establish a process for integrating inventories into the report



Inventory of Federal Activities

- First inventory to assess the breadth and depth of the federal response to TBDs developed and submitted to:
 - HHS, DoD, U.S. Department of Veterans Affairs (VA)
- The inventory includes:
 - Types of activities (like research, surveillance, prevention, care, and treatment)
 - Level of funding, reach, and duration
 - Number of staff devoted to tick-borne disease activities
- Responses due May 11, 2018
 - Agencies may need more time for complete reporting
 - Working Group will review available information and draw from it for the report
 - If data are incomplete or more time is needed, will seek input on case-by-case basis regarding ways to address remaining issues



* Public Input

- In-person public comment period is part of each Working Group meeting
 - In-person comments are limited to 3 minutes each
 - The total available time for all public comments is 30 to 60 minutes
 - Written comments are also accepted
- Comments can be sent via email at any time
 - More than 1,000 received to date
 - Personally identified information will be removed before it is shared with the Working Group
 - Exception: Names of Working Group and subcommittee members will NOT be removed





* Sharing Public Comments

- Verbal and written comments from meetings 1-3 have been posted online
- Other public comments submitted by email required special handling due to concerns about privacy and other issues
 - Comments will be considered by the Working Group while writing the report
 - Comments will have a visible presence in the final report



* We Need You! Contact Us

Check out the Tick-Borne Disease Working Group online:

https://www.hhs.gov/ash/advisorycommittees/tickbornedisease/index.html

Reach us by email at: tickbornedisease@hhs.gov

Participate in public meetings on May 15 & 16th



* The Human Dimensions

Working together, we are advancing patient-centered medicine and next-gen solutions

Anecdotes are not data,

yet we must remember that behind every data point is a human life and real-world story





I'm not just Vice Chair of the Tick-Borne Disease Working Group...







Join us! Together, We'll Realize Our Vision

- This work needs all of us
 - Lived experience and perspectives
 - Technical and scientific knowledge
 - Interdisciplinary and problem-solving skills
- We will not always agree, but debate is good
- We are stronger when we find the common ground that we share and, together, unite



- If we shout different things all at once, all of our voices will be lost
- If we shout the same thing all at once, our shared priorities magnify the message



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Mission Statement

A mission is different from a vision in that the former is the cause and the latter is the effect; a mission is something to be accomplished whereas a vision is something to be pursued for that accomplishment.

- Our core purpose and focus that normally remains unchanged over time
- Present day, given reality of today
- Volunteer(s) requested!



* Thank You



- Working Group and subcommittee members
 - Their organizations and employers for supporting their roles in this work
- Office of HIV/AIDS and Infectious Disease Policy, Office of the Assistant Secretary for Health, HHS
- Presenters and patients who have shared their knowledge with the Working Group and its subcommittees

Special thank you to the members of the public who have shared their stories and support for this effort