

Tick-Borne Disease Working Group

Meeting #3

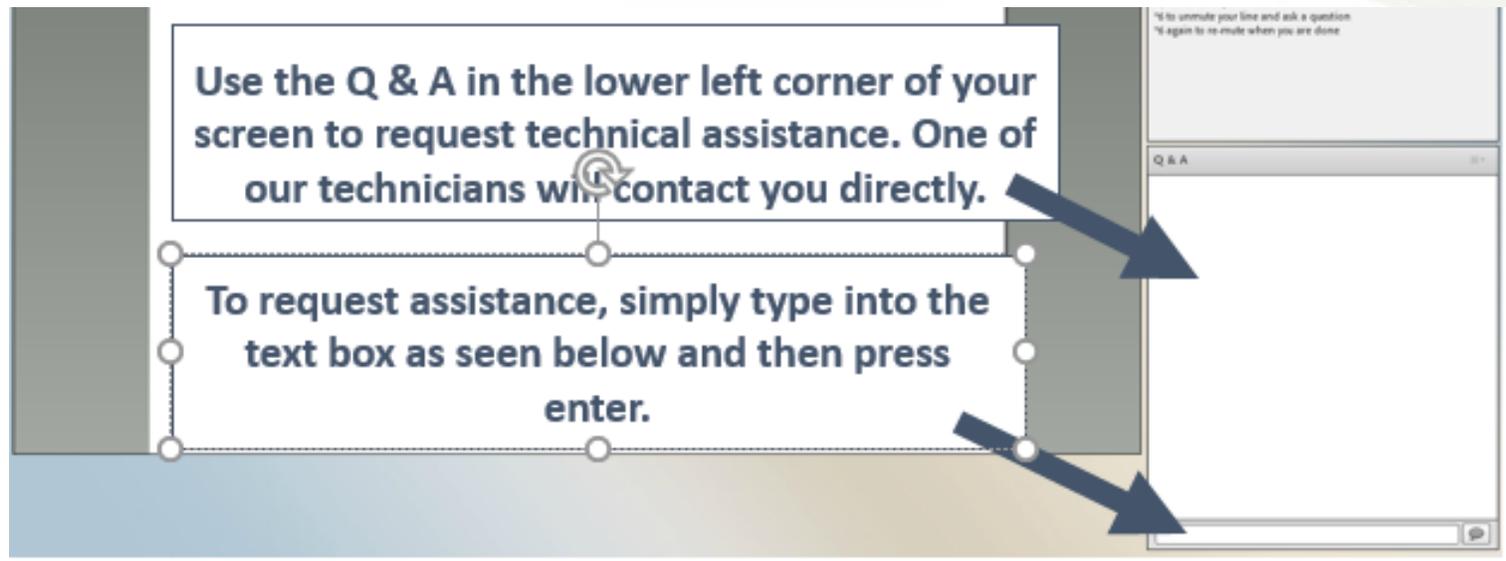
February 12, 2018

Noon – 4pm EST

Technical Assistance



- If you need technical assistance, please comment in the Q&A box. One of our technicians will contact you directly.



Disclaimer



Information and opinions are those of the presenter and do not necessarily reflect the opinions of Working Group Members, or the Department of Health and Human Services.

Contact Information



Check out our Webpage at:

<https://www.hhs.gov/ash/advisory-committees/tickbornedisease/index.html>

Reach us by email at: tickbornedisease@hhs.gov.

Tick-Borne Disease Working Group

Report to Congress and HHS Secretary

Richard Wolitski

Third Meeting of the Working Group

February 12, 2018

Legal Mandate



21st Century Cures Act requires that the Working Group:

- Submit report every 2 years after enactment regarding its activities and recommendations to:
 - Committee on Energy and Commerce of the House of Representatives
 - Committee on Health, Education, Labor, and Pensions of the Senate
- Make report publicly available on the Internet website of the Department of Health and Human Services
- First report due December 13, 2018

Legally Mandated Content



The Working Group's Report must address:

- **On-going tick-borne disease research**
 - Including research related to causes, prevention, treatment, surveillance, diagnosis, diagnostics, duration of illness, and intervention for individuals with tick-borne diseases;
- **Research advances**
- **Federal activities related to tick-borne diseases, including**
 - Epidemiological activities related to tick-borne diseases
 - Basic, clinical, and translational tick-borne disease research related to the pathogenesis, prevention, diagnosis, and treatment of tick-borne disease
 - Gaps in tick-borne disease research
 - Working Group's meetings
 - Comments received by the Working Group
 - Recommendations to the Secretary
- **Solicit input from States, localities, and nongovernmental entities, including**
 - Organizations representing patients, health care providers, researchers, and industry regarding scientific advances, research questions, surveillance activities, and emerging strains in species of pathogenic organisms.

Challenges



- Has not been done before!
- Start 10 months from enactment to establishment of Working Group
 - August 10, 2017--Working Group charter established
 - December 11, 2017--Members appointed , first meeting held
 - February 5, 2018--Subcommittee members identified
 - February 12, 2018--First meeting with Working Group and Subcommittee members
- In order to have public and agency comment on report, draft needs to be ready for public review in July
- Hiring freeze
- Intense interest in this work
 - Managing and responding to stakeholder input has been more challenging than expected
- Large number of activities and issues to cover

Challenges



- There are known gaps in research that has been conducted to date
 - Great deal of evidence exists outside of published scientific literature
 - Considerable controversy on some issues
- Evidence can include:
 - Systematic reviews
 - Research articles published in the peer reviewed literature, other publications, and conference presentations
 - Reports and other documents published by agencies, organizations, and programs
 - Presentations from subject matter experts, patients, family members, and their providers
 - Input from public
 - Inventories of programs and activities

First Year Report



- **Written by Working Group**
 - Information from Subcommittees may be used in whole or in part
 - Technical assistance from DFO's office and Communicate Health
- **Focus on HHS and Department of Defense Activities**
 - Draft inventory to be discussed today
- **Will focus on core set of priorities within each subgroup**
 - Review evidence, assess current activities, identify gaps and opportunities, develop potential solutions
- **Review of evidence—emphasis on United States, but will look outside of US for solutions**
 - Identification of key studies, reports, guidelines, and documents by members and subject matter experts
 - Presentations by experts to subcommittees and Working Group
 - Existing reviews
 - Some additional searches of the scientific literature and online resources
 - Second report will incorporate systematic review of evidence by Working Group

First Year Report—Draft Outline



- Table of Contents
- Executive Summary
- Introduction/Background
 - Statement of the problem
 - Congressional action
 - Establishment of WG
 - Goals/content of the report
- Methods of Working Group
 - What has been done
 - How the report was developed

First Year Report—Draft Outline



- For issues addressed by each subcommittee:
 - Description of subcommittee's topic
 - How the Subcommittee approached the topic
 - Identification of Issues and Questions
 - Prioritizations of Issues and Questions
 - For each prioritized issue
 - Evidence regarding issue/question
 - What is known about the problem
 - What is being done
 - Possible opportunities to improve federal response
 - Threats or challenges to implementation or change
 - Possible actions for working group to consider
 - Vote of subcommittee members in support of proposed solution
 - If disagreement, provide opportunity for minority opinion to be written

First Year Report—Draft Outline



- **Results and Recommendations**
 - Overall summary of federal response
 - Identification of key gaps and opportunities to improve federal response
 - Consideration of which actions are likely to have greatest impact
 - Which are feasible now with existing resources
 - Which are feasible now, but would require additional resources
 - Which are not currently feasible, but should be prioritized for research and demonstration projects
 - Minority opinions will be represented
- **Discussion/Conclusion**
 - Reflect on importance of taking action – what could be achieved vs. what is being achieved
 - Consider barriers to implementation and strategies for overcoming them
 - Planned improvements

First Year Report—Draft Outline



- Appendices (online)
 - Working Group Members and Activities
 - Subcommittee Members and Activities
 - Inventory of HHS and DoD Activities
 - Public Comment

First Year Report—Draft Outline



- Considering side bars, video elements, etc. to make the experiences of patients, family members, providers, civic leaders, researchers, etc.
 - Infographics (e.g., how the WG works, Tick-Born Diseases by the Numbers)
 - On the Front Line (programs in the community, health dept)
 - Opposing Views or Head to Head (something that we can use to focus in on some of the most heated controversies so that they can be framed and acknowledged up front.)
 - In Their Own Words—insights from public comment

Timeline



Key Milestones	Completed
Begin writing	Tomorrow
Inventory sent to HHS and DoD	Feb 23
Completed inventories due back	March 23
Subcommittee reports to working group	May 4th
Interim deadlines for individuals segments	Starting 2/23
Working Group report submitted for public and agency comments	July
Comments due	August
Comments reviewed and summarized	September
Revision submitted for final HHS and DoD reviews and clearance	October
Final formatting and 508 compliance	November
Submitted to Congress and the HHS Secretary & Posted on HHS website	December

Vision — defined



VISION STATEMENT = FUTURE IDEAL

An aspirational description of what an organization would like to achieve or accomplish in the mid-term or long-term future. It is intended to serve as a clear guide for choosing current and future courses of action.

TBDWG Vision — proposed



TBDWG Vision Statement #1

- “A nation free of tick-borne disease and associated chronic disorders where new infections are prevented, and infected patients are rapidly and accurately diagnosed and restored to wellness with person-centered, evidence-based, accessible, and affordable treatment and care.”

TBDWG Vision Statement #2

- “A nation free of tick-borne disease and associated chronic diseases where new infections are prevented and patients have access to affordable care that restores them to full wellness.”

TBDWG Vision Statement #3

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

Mission — defined



MISSION STATEMENT = PRESENT TODAY

A written declaration of our core purpose and focus that normally remains unchanged over time. Properly crafted mission statements (1) serve as filters to separate what is important from what is not, (2) clearly state which markets will be served and how, and (3) communicate a sense of intended direction to the entire organization.

TBDWG Mission — proposed



The Tick-Borne Disease Working Group's mission, as mandated through the 21st Century Cures Act, is to review and report on all ongoing tick-borne disease research, including research related to causes, prevention, treatment, surveillance, diagnosis, diagnostics, duration of illness, and intervention for individuals with tick-borne diseases and to provide recommendations to Congress and the HHS Secretary as part of an overall effort to contain and cure tick-borne diseases in humans.

We provide subject matter expertise and review U.S. Federal government efforts related to all tick-borne diseases in order to:

- **Catalyze** interdisciplinary collaborations, public-private partnerships, and input from States, localities, and non-governmental entities, academia, non-profit organizations including those representing patients, health care providers, researchers, industry, and surveillance activities of pathogenic organisms.
- **Ensure** interagency coordination and minimize overlap.
- **Examine** U.S. research priorities, programmatic priorities, outreach, and awareness efforts.
- **Recommend** to Congress and the HHS Secretary any appropriate changes or improvements to tick-borne disease activities and research.

Core Values — defined



CORE VALUES = HOW WE OPERATE

Values are the operating philosophies or principles that guide an organization's internal conduct as well as its relationship with its customers, partners, and shareholders. Core values are usually summarized in the mission statement or in the company's statement of core values.

TBDWG Core Values — proposed



RESPECT	INNOVATION	HONESTY/ INTEGRITY	EXCELLENCE	COMPASSION	COLLABORATION	ACCOUNTABILITY
Everyone is valued.	Shifting the paradigm. Finding a better way.	Find the truth. Tell the truth.	Quality, real world evidence underlies decision making.	Finding solutions to relieve suffering.	Work with citizens and patients, as partners.	The buck stops here.
We respect all people, treating them and their diverse experiences and perspectives with dignity, courtesy, and openness, and ask only that those we encounter in this mission return the same favor to us. Differing viewpoints are encouraged, always, with the underlying assumption that inclusivity and diversity of minority views will only strengthen and improve the quality of our collective efforts in the long term.	We strive to have an open mind and think out of the box. We keep what works and change what doesn't. We will transform outdated paradigms when necessary, in order to improve the health and quality of life of every American.	We are honest, civil, and ethical in our conduct, speech, and interactions with our colleagues and collaborators. We expect our people to be humble, but not reticent, and to question the status quo whenever the data and the evidence support such questions. We pledge to be objective, to not manipulate facts and data to a particular end or agenda, and to acknowledge and speak the truth where we find it.	We seek out rigorous, evidence-based, data-driven, and human-centered insights and innovations—including physician and patient experiences—that we believe are essential for scientific and medical breakthroughs. We foster an environment of excellence that strives to achieve the highest ethical and professional standards, and which values the development of everyone's skills, knowledge, and experience.	We listen carefully with compassion and an open heart in order to find solutions which relieve the suffering of others. We promise to work tirelessly to serve the greater good until that goal is achieved.	The best results and outcomes won't be created behind closed doors, but will be co-created in the open with input of the American public working together with these core values as our guide. We actively listen to the patient experiences shared with us, respect the lived experiences of patients and their advocates, and learn from their experiences in our pursuit of objective truth. Across diverse audiences, we communicate effectively and collaborate extensively to identify shared goals and leverage resources for maximize public health impact.	We, as diligent stewards of the public trust and the funds provided by our fellow citizens, pledge to be transparent in all of our proceedings and to honor our commitments to ourselves and others, while taking full responsibility for our actions in service to the American people.

Health and Human Services (HHS) Biannual Conference Call on Lyme and other Tick-borne Diseases

Anna Perea, M.S.

Policy and Communications Lead

Bacterial Diseases Branch | Division of Vector-Borne Diseases

National Center for Emerging and Zoonotic Infectious Diseases

Centers for Disease Control and Prevention

**Tick-borne Disease Working Group Advisory Committee, Third Meeting
February 12, 2018**



HHS Biannual Conference Call on Lyme and Other Tick-Borne Diseases

Date of establishment: September 6, 2011

Name: Health and Human Services (HHS) Internal Working Group on Lyme and Tick-Borne Diseases

Group status: Informal/non-chartered

Purpose: To foster continued coordination, collaboration and communication on activities and shared interests relating to Lyme disease and other tick-borne illnesses

Participation: HHS staff from operating divisions with responsibilities and activities related to Lyme disease (various offices within Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA) and National Institutes of Health (NIH)/National Institute of Allergy and Infectious Diseases (NIAID), HHS' National Vaccine Program Office, etc.)

HHS Biannual Conference Call on Lyme and Other Tick-Borne Diseases

Venue: Two meetings (via conference call) per year

Typical Meeting agenda:

- Brief updates from each HHS operating division/program (NIH, FDA, HHS, CDC)
- Discussion of shared interests and activities
- Announcements of upcoming meetings and events
- Action items and timelines if relevant

HHS Biannual Conference Call on Lyme and other Tick-Borne Diseases

Key activities:

- Two meetings/conference calls per year (internal to HHS)
- Jointly-hosted annual public webinar on various topics of interest related to Lyme and other tick-borne diseases (over 87,000 views to-date)
 - Archived webinars located at the bottom of <https://www.cdc.gov/lyme/> under the header, HHS Special Webinars on Lyme and Tickborne Diseases

HHS Biannual Conference Call on Lyme and Other Tick-Borne Diseases

Key accomplishments:

- Organized, hosted, and posted six webinars addressing the following topics
 - Updates on Tickborne Disease Diagnostics (2017—**2,289** views)
 - Trends in Tickborne Diseases (2016—**5,562** views)
 - Vaccines for Lyme Disease – Past, Present, and Future (2015—**8,153** views)
 - Lyme Disease Persistence (2014—**12,446** views)
 - Novel and Emerging Tickborne Diseases – Agents, Clinical Features, and Surveillance (2013—**19,507** views)
 - Lyme Disease Diagnostics (2012—**39,878** views)

HHS Biannual Conference Call on Lyme and Other Tick-Borne Diseases

Key accomplishments:

- Established a 280 sample, well-characterized serum panel for distribution for investigators who are working on new diagnostic tests for Lyme disease.
 - The samples were obtained by CDC, with financial assistance from NIH and in collaboration between CDC, FDA, and NIH, in a joint effort to make the process more simple and less expensive for the development and validation of new Lyme disease diagnostic tests.
 - As of 2016, CDC had released 85 panels to 56 individuals across 48 institutions.

HHS Biannual Conference Call on Lyme and Other Tick-Borne Diseases

- **Current status:** The group continues to meet twice per year by conference call under the modified name HHS All Federal Working Group on Lyme and Tick-Borne Diseases (to avoid confusion with the new HHS federal advisory committee working group of the same name).
- Most recent call, February 2, 2018
 - No HHS Webinar in 2018 due to many HHS personnel being involved in this current Advisory Committee and time demands entailed with the hosting of the International Conference on Lyme Borreliosis and Other Tickborne Diseases Conference in September.

Questions?

**Final Report of the Lyme Disease Task Force
A Report to the Governor of Virginia**



**Lyme Disease Task Force
June 30, 2011**

**AREAS FOR
STUDY AND
RECOMMENDATION**

Diagnosis

Treatment

Prevention

Impact on Children

Public Education

TASK FORCE COMPOSITION

Twelve Members

Two Cabinet Officers

(Health and Natural Resources)

Four Medical Doctors

(Three from Virginia Dept. of Health including the Secretary and State Epidemiologist)

PhD School Psychologist

Veterinarian

PhD Clinical Pharmacist

Virginia Secretary of Natural Resources

Executive Director of the Department of Game and Inland Fisheries

Three Lyme Patient Representatives/
Advocates

Nine Hearings

Five Listening Sessions for Patients and Families

**FOUR HEARINGS
ON TOPICS
(EXPERT TESTIMONY)**

Diagnosis & Treatment

Prevention

Impact on Children

Public Education

GENERAL OBSERVATIONS:

Lyme and other tick-borne illnesses are affecting a significant and growing number of Virginians.

GENERAL OBSERVATIONS:

There is much that remains to be understood about Lyme and related diseases in every relevant sector including diagnosis, treatment, and prevention.

GENERAL OBSERVATIONS:

There is an acute need for greater research in all relevant spheres.

GENERAL OBSERVATIONS:

Mandatory reporting mechanisms are not consistently followed by physicians.

GENERAL OBSERVATIONS:

The CDC case definition for Lyme disease is for epidemiological purposes only and is not now and never has been the single valid basis for a diagnosis for Lyme disease.

GENERAL OBSERVATIONS:

There is no serological test that can “rule out” Lyme disease.

GENERAL OBSERVATIONS:

Public awareness concerning the prevalence, symptoms and prevention of Lyme disease needs significant expansion.

CHAIRMAN'S OBSERVATIONS:

Balance of viewpoints is essential.

CHAIRMAN'S OBSERVATIONS:

Listening to patients and families was overwhelming and drove our unanimous recommendations as much or more than expert testimony.

CHAIRMAN'S OBSERVATIONS:

Voices that pronounce Lyme to be a simple disease that is readily diagnosed and easily treated were not credible.

CHAIRMAN'S OBSERVATIONS:

There is a huge need for more science.

CHAIRMAN'S OBSERVATIONS:

Unanimity is ideal and in the interest of all parties.

**WE
ACHIEVED
UNITY
THROUGH**

Balance

Fair-minded Science

Collegial spirit

A multi-disciplinary approach

**Desire to help people get
better**

The full report may be accessed at:

<https://www.loudoun.gov/DocumentCenter/View/84106>

Public Comment



• Public Comment Period

- Julia Wagner
- Beth Carrison-van der Heide
- Jennifer Burton
- Gary Sweeney
- Timothy Opiela
- Jennifer Platt
- Jena Blair
- Kathy Nodolf

Subcommittee Breakouts



- **Please click on the link to join subcommittee breakout during this time period**
- Disease Vectors, Surveillance, and Prevention:
<http://meetingconnect.adobeconnect.com/tbdwg-breakout1/>
- Pathogenesis, Transmission and Treatment:
<http://meetingconnect.adobeconnect.com/tbdwg-breakout2/>
- Testing and Diagnostics:
<http://meetingconnect.adobeconnect.com/tbdwg-breakout3/>
- Access to Care Services and Support to Patients:
<http://meetingconnect.adobeconnect.com/tbdwg-breakout4/>
- Vaccine and Therapeutics:
<http://meetingconnect.adobeconnect.com/tbdwg-breakout5/>
- Other Tick-Borne Diseases and Co-Infections
<http://meetingconnect.adobeconnect.com/tbdwg-breakout6/>

Subcommittees Report Back



- Disease Vectors, Surveillance, and Prevention:
- Pathogenesis, Transmission and Treatment:
- Testing and Diagnostics:
- Access to Care Services and Support to Patients:
- Vaccine and Therapeutics:
- Other Tick-Borne Diseases and Co-Infections

Subcommittee Timeline



TBDWG Meeting #3	Feb 12th 13 weeks to May 10th
Subcommittee Meetings	February - May
Separate subcommittee meetings every 1-2 weeks	
Chair, Vice-Chair, and DFO support subcommittees and monitor progress	
Inventory of HHS and DoD Activities	
Executive Secretary submits to HHS Operating Divisions & Staff Divisions and DoD	February 23
Data due back	March 23
Data management/analysis with subcommittees	April 23
National Town Hall Meeting	Mid-March (before halfway point)

Subcommittee Timeline



Draft subcommittee reports for presentation to Working Group	Beginning of May
Milestones due at intermediate times	
Issues/questions and priorities	February 23
Background	March 9
Methods	March 16
1 st Priority	March 23
2 nd Priority	April 7
3 rd Priority	April 14
Full Report/Program Assessment	May 4
Slides for May 10 meeting	May 4 (Deadline: All materials for meeting due, no exceptions)

Subcommittee Timeline



TBDWG virtual meeting for presentations of subcommittee reports	May 10th
TBDWG Meeting for discussion and voting on TBDWG Draft Report and Recommendations	Week of May 14 th
Writing of Working Group report starts including graphics and online appendices (e.g., inventory)	May 21 (3 weeks to draft)
Draft report with recommendations	June 21 (1 week comment, 1 week revision)
Review and revision of report	July 3 or July 6
Draft report released for Public and agency comment	July 20 (allows 2 weeks for clearance and prep for posting-would not need it all, but this first place for slippage) before draft is released
Public comment and agency review	August 17 (about 1 month)

Subcommittee Timeline



Review and summarize public comment	September 17
Document revision	October 1
Final agency clearance	November 1
Revision and final desktop publishing	November 14
Final review for typos/errors (not content) within TBDWG and 508 compliance	November 21
Submit final report	December 2018

Contact Information



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