

Tick-Borne Disease Working Group

Meeting #9 | June 4, 2019



Tick-Borne Disease Working Group



Welcome



David Hughes Walker, M.D. (Co-Chair)

Professor, Department of Pathology, The Carmage and Martha Walls Distinguished University Chair in Tropical Diseases; and Executive Director, UTMB Center for Biodefense and Emerging Infectious Diseases



Leigh Ann Soltysiak, M.S. (Co-Chair)

Owner, Principal, Silverleaf Consulting, LLC; Adjunct Professor, Stevens Institute of Technology, Entrepreneurial Thinking

Tick-Borne Disease Working Group



Review of Meeting #9 Agenda

1. Welcome | Member Swear In & Introduction
2. Member Introductions
3. Overview of Charter, Mission, Vision, Values
4. TBDWG Milestones & Action
5. Roles, Responsibilities, Voting Procedures
6. Objective, Timeline and Tasks for 2020 Report to Congress
7. Public Comment Subcommittee
8. Public Comments
9. CDC presentation
11. NIH presentation
12. Subcommittee Break-Out
13. Discussion on Topic Development Briefs
14. Next Steps/Other
15. Adjournment

Tick-Borne Disease Working Group



Official Welcome and Swearing in of Members



**Rear Admiral Sylvia Trent Adams, PhD, RN,
FAAN**

Principal Deputy Assistant Secretary for Health,
U.S. Department of Health and Human Services (HHS)

Tick-Borne Disease Working Group



New Special Government Employees (SGEs)



Scott Palmer Commins, BS, MD, PhD
Associate Professor of Medicine &
Pediatrics, University of North Carolina;
Member, UNC Food Allergy Initiative,
Thurston Research Center



Bob Sabatino
Founder and Executive Director of Lyme Society
Inc.
(term expires August 2019)



Sam T. Donta, MD
Infectious Disease Consultant, Falmouth
Hospital; and Former Member, US
Department of Defense Tick Borne Disease
Research Programmatic Review Panel

Tick-Borne Disease Working Group

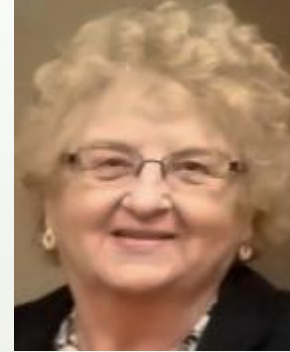


New Special Government Employees (SGEs) (continued)



Eugene David Shapiro, M.D.

Professor of Pediatrics, Epidemiology, and Investigative Medicine, Yale University School of Medicine; Vice Chair for Research of the Department of Pediatrics; Co-Director of Education for the Yale Center for Clinical Investigation; and Deputy Director of Yale's PhD Program in Investigative Medicine.



Patricia V. Smith

President, Lyme Disease Association

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Regular Government Employees



Charles Benjamin (Ben) Beard, PhD
Deputy Director, Division of Vector-Borne Diseases
Centers for Disease Control and Prevention (CDC),
U.S. Department of Health and Human Services
(DHHS)



Angel M. Davey, PhD
Program Manager, Tick-Borne Disease
Research Program, Congressionally Directed
Medical Research Programs, U.S. Department
of Defense (DoD)



Commander Rebecca Bunnell, MPAS, PA-C
Senior Advisor, Learning and Diffusion Group,
Innovation Center, Centers for Medicare and
Medicaid Services (CMS), U.S. Department of
Health and Human Services (DHHS)



Dennis M. Dixon, PhD
Chief, Bacteriology and Mycology Branch,
National Institute of Allergy and Infectious
Diseases (NIAID), National Institutes of
Health (NIH), U.S. Department of Health
and Human Services (DHHS)

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Regular Government Employees (continued)



Captain Estella Jones, DVM
Deputy Director, Office of Counterterrorism and Emerging Threats, Food and Drug Administration (FDA), U.S. Department of Health and Human Services (DHHS)



Adalberto (Beto) Pérez de León, DVM, MS, PhD
Director, Knippling-Bushland U.S. Livestock Insects Research Laboratory, United States Department of Agriculture - Agricultural Research Service

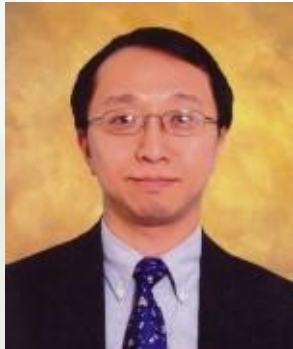


Leith Jason States, MD, MPH (FMF)
Deputy Chief Medical Officer, Office of the Assistant Secretary for Health (OASH), U.S. Department of Health and Human Services (DHHS)

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Alternate Regular Government Employees



Chien-Chung Chao, PhD

Research Chemist, Viral and Rickettsial Diseases
Department Infectious Diseases Directorate, Naval
Medical Research Center, U.S. Department of Defense



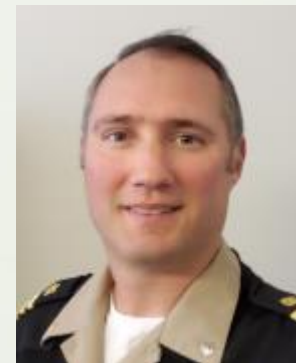
David A. Leiby, PhD

Chief, Product Review Branch, Division of
Emerging & Transfusion-Transmitted
Diseases, Office of Blood Research & Review
(OBRR), Center for Biologics Evaluation &
Research (CBER), Food and Drug
Administration (FDA), U.S. Department of
Health and Human Services (DHHS)



Captain Scott J. Cooper, MMSc, PA-C

Senior Technical Advisor and Lead Officer for
Medicare Hospital Health and Safety Regulations,
Centers for Medicare and Medicaid Services (CMS),
U.S. Department of Health and Human Services
(DHHS)



**Commander Todd Myers, PhD, HCLD (ABB), MB
(ASCP)**

Office of Counterterrorism and Emerging
Threats (OCET), Office of the Chief Scientist,
Office of the Commissioner, U.S. Food and Drug
Administration, U.S. Department of Health and
Human Services (DHHS)

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Alternate Regular Government Employees (continued)



Samuel S. Perdue, PhD

Section Chief, Basic Sciences and Program Officer, Rickettsial and Related Diseases, Bacteriology and Mycology Branch, Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health, U.S. Department of Health and Human Services (DHHS)



Susanna N. Visser, DrPH, MS

Associate Director for Policy, Division of Vector-Borne Diseases Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services (DHHS)

Shahla Jilani, MD

Deputy Chief Medical Officer, Office of the Assistant Secretary for Health (OASH), U.S. Department of Health and Human Services (DHHS)



Tick-Borne Disease Working Group



Mission Statement

The Tick-Borne Disease Working Group's mission, as mandated through the 21st Century Cures Act, is to provide **expertise** and to review all efforts within the Department of Health and Human Services related to all tick-borne diseases, to help **ensure inter-agency coordination and minimize overlap, and to examine research priorities**. As part of this mandate, and in order to provide expertise, we will ensure that the membership of the working group represents a **diversity of scientific disciplines and views and is comprised of both federal and non-federal representatives, including patients, and family members or caregivers, advocates of non-profit in the interest of the patient with tick-borne illness, scientists and researchers**. A major responsibility of our mission will be **develop and regularly update the action of HHS from the past, present and the future**.

Tick-Borne Disease Working Group



One Common Purpose



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

Tick-Borne Disease Working Group



Core Values (1 of 2)



RESPECT: Everyone is valued

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.



INNOVATION: Shifting the paradigm, finding a better way

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.



HONESTY & INTEGRITY: Find the truth, tell the truth

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, to not manipulate facts and data to a particular end or agenda, and to acknowledge and speak the truth where we find it.



EXCELLENCE: Quality, real-world evidence underlies decision-making

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.

Tick-Borne Disease Working Group



Core Values (2 of 2)



COMPASSION: Finding solutions to relieve suffering

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.



COLLABORATION: Work with citizens and patients as partners

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 maximum public health impact.



ACCOUNTABILITY: The buck stops here

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 American people.

Tick-Borne Disease Working Group



2018 Report to Congress Milestones and Actions

February 12, 2018

- Subcommittees Created

May 10, 2018

- Subcommittee Reports Submitted to TBDWG

June 21, 2018

- Writing begins for TBDWG Report to Congress

December 8, 2018

- Final Meeting of the 2018 TBDWG

2018

Jan.

Feb.

Mar.

Apr.

May

Jun.

Jul.

Aug.

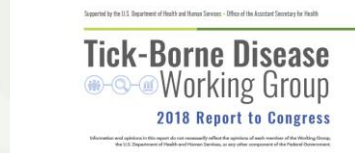
Sept.

Oct.

Nov.

Dec.

2019



November 2018

- Report submitted to Assistant Secretary of Health and Congress
- Final Report to Congress accessible on the TBDWG website

January 2019

- CDC – National Strategy for Vector-Borne Disease Prevention and Control
- NIH – Tick-Borne Disease RIF

Tick-Borne Disease Working Group



Charter

Established in the 21st Century Cures Act of 2016, the Tick-Borne Disease Working Group is charged with:

- Providing expertise and reviewing all efforts within HHS related to tick-borne diseases
- Helping to ensure interagency coordination and minimizing overlap
- Examining research priorities

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Relevant Laws & Key Requirements



**+ Federal Advisory Committee Act +
Government in the Sunshine Act =**



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Relevant Laws & Key Requirements (continued)

The Federal Advisory Committee Act (FACA) requires that

- Meetings be open to the public except where a closed or partially closed meeting has been determined proper and consistent with the exemptions of the Government in the Sunshine Act , 5 U.S.C. 552b(c).
- Public notice of meetings be published in the Federal Register at least 15 days in advance of the meeting.
- Any member of the public is permitted to file a written statement with the advisory committee and may speak to or otherwise address [verbal comment] the advisory committee if the agency's guidelines so permit.
- Recommendations be “objective and accessible to the public”.
- Subcommittees report and make recommendations to an established advisory committee. Recommendations of a subcommittee must be fully discussed and deliberated by the advisory committee before adopting.
 - Subcommittees are not subject to FACA openness requirements

Tick-Borne Disease Working Group



Roles and Responsibilities

Co-Chairs

- ✓ Develop meeting agendas
- ✓ Convene and adjourn meetings
- ✓ Conduct meetings
- ✓ Approve minutes for meeting they convene
- ✓ Plan work of committee
- ✓ Work with DFO to ensure alignment with Charter, FACA regulations, and committee support



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Roles and Responsibilities (continued)

Members

- ✓ Provide independent subject matter advise and expertise
 - Procedures and processes
 - Ensure relevant information is available
- ✓ Participate in meetings
- ✓ Vote on issues presented
- ✓ Contribute to work of working group including report recommendations
- ✓ Participate on subcommittee(s)



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Roles and Responsibilities (OHAIDP)



James (Jim) Berger

Senior Advisor, OHAIDP; Designated Federal Officer (DFO)

Kaye Hayes

Deputy Director, OHAIDP; Alternate Designated Federal Officer (DFO)

Role Includes:

- ✓ Ensure compliance with FACA and any other laws and regulations
- ✓ Approve Agendas
- ✓ Call, attend, and adjourn Working Group Meetings
- ✓ Ensure efficient operations
- ✓ FACA-governed groups cannot meet without DFO or their designate
- ✓ Maintain required records

Tick-Borne Disease Working Group



Roles and Responsibilities (CH/KAI)



CommunicateHealth/Kauffman & Associates, Inc.

Contracted to provide meeting, writing, and communications support

Role Includes:

- ✓ Assist with planning and staffing public meetings
- ✓ Attend public meetings to take notes and draft summaries
- ✓ Coordinate and attend all subcommittee meetings
- ✓ Draft meeting agendas and summaries for all subcommittee meetings
- ✓ Draft the Congressional Report summarizing the recommendations of the Tick-Borne Disease Working Group

Tick-Borne Disease Working Group



Objectives & Scope of Activities for 2020 Report to Congress

- (A) Not later than 2 years after the date of enactment of the authorizing legislation, **update** a summary of:
- (1) ongoing tick-borne disease research, including research related to **causes, prevention, treatment, surveillance, diagnosis, diagnostics, duration of illness, and intervention**
 - (2) **advances made pursuant to such research;**
 - (3) **federal activities related to tick-borne diseases**, including: (a) epidemiological activities related to tick-borne diseases; (b) basic, clinical, and translational tick-borne disease research related to the pathogenesis; prevention, diagnosis, and treatment of tick-borne diseases
 - (4) **gaps in tick-borne disease research** described in clause 3b;
 - (5) the **Working Group's meetings; and the comments received** by the Working Group
- (B) Make recommendations to the Secretary regarding any appropriate changes or improvements to such activities and research; and
- (C) Solicit input from States, localities, and non-governmental entities, including organizations representing patients, health care providers, researchers, and industry regarding scientific advances, research questions, surveillance activities, and emerging strains in in species of pathogenic organisms

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Meeting Goals

1. Patient/Stakeholder Input
2. Establish Subcommittees
3. Identify Topic Development Briefs/Ad hoc

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Meeting #9 | June 4, 2019

BREAK



Tick-Borne Disease Working Group



Subcommittee on Public Comments

- Formed at public meeting #7 on July 24, 2018
- Meets 3rd Wednesday of each month, beginning September 2018
- Since Subcommittee formation, we've reviewed nearly 1,000 written comments to tickbornedisease@hhs.gov
- Former Members:
 - Kristen Honey (Chair)
 - Richard Horowitz
 - Scott Cooper
- Current Members:
 - Bob Sabatino



Tick-Borne Disease Working Group



Discussion of Submitted Public Comment

Since TBDWG formation in December 2017 until April 30, 2019, HHS has received approximately 15,000 sentences from nearly 1000 emails sent to tickborndisease@hhs.gov. When printed in 12-point font, these public comments span 290 pages. In addition to these emails, the Working Group has received approximately 837 pages of written public comments from individuals who submitted to the email address and comments at public meetings.

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Public Comment

Order of Public Comment is:

- Kristina Bauer
- Jennifer Platt
- Michael Bauer
- Mira Shapiro
- Melissa Potter
- Stephen McFadden
- Deborah Olsen
- Trey Cahill



- 30 minutes of public speaking today
- 5 speakers
- 3 minutes each
- Email comments may be sent to: tickbornedisease@hhs.gov

3 ways to engage:

- Verbal public comment at meetings
- Written public comment at meetings, available on website
- Email comments 24/7 to tickbornedisease@hhs.gov

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Timeline for 2020 Report to Congress



TBD

- Formation of Subcommittees
- Next meetings?
- Subcommittee work and report (milestones and deliverables to be worked out)



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Presentations

- National Strategy for Vector-Bourne Disease Prevention and Control
 - Ben Beard, CDC
- NIH Tick-Borne Disease Request for Applications
 - Sam Perdue, NIH

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 Recap of the morning

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Meeting #9 | June 4, 2019

LUNCH



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Subcommittee Discussion

- Primary Goal of the day: What subcommittees should be formed?
- Secondary Goal of the day: Identification of Subcommittee Members (*time permitting*)
 - Selection of Subcommittee Members from the Working Group
 - How to ensure membership is a balanced coordination of efforts with working group?
 - What is their charge?
 - What is their deliverable?

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Objectives & Scope of Activities for 2020 Report to Congress

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 - (5) the **Working Group's meetings; and the comments received** by the Working Group
- (B) Make recommendations to the Secretary regarding any appropriate changes or improvements to such activities and research; and
- (C) Solicit input from States, localities, and non-governmental entities, including organizations representing patients, health care providers, researchers, and industry regarding scientific advances, research questions, surveillance activities, and emerging strains in in species of pathogenic organisms

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Timeline for 2020 Report to Congress



TBD

- Formation of Subcommittees
- Next meetings?
- Subcommittee work and report (milestones and deliverables to be worked out)

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Topic Development Brief Discussion

- The purpose of this project is to conduct several Topic Development Briefs (Briefs) related to tick-borne diseases in order to garner a preliminary understanding of available evidence for unresolved issues that fall within relevant domains, such as prevention, diagnosis, diagnostics, and treatment
- There are funds currently available that need to be used by the end of the fiscal year
- 3 topic development briefs would be conducted simultaneously
 - 3 ad hoc subcommittees to work with vendor to discuss unresolved priorities and questions for evidence review
- 3 reports and database are due September 20, 2019
- Will inform the literature review in the next fiscal year

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Topic Development Brief Example

Major topic area of the guideline	Question for Systematic Review
Probability of transmission of HIV, BV, or HCV through solid organ transplantation (SOT)	What are the prevalence and incidence rates of HIV, HBV, and HCV along potential solid organ donors?
	What are the rates of transmission to recipients' donors infected with HIV, HBV, or HCV? Do the rates vary by the organ transplanted or when the donor was infected?
Methodology to better estimate donor infection with HIV, HBV, or HCV	What behavioral risk factors are associated with an increased probability of infection with HIV, HBV, or HCV? What is the prevalence of these characteristics among potential solid organ donors?
	What nonbehavioral factors are associated with an increased probability of infection. With HIV, HBV, or HCA? What is the prevalence of these factors among potential solid organ donors?
	What are the test characteristics of the screening methods available to detect HIV, HBV, and HCV in potential solid organ donors? Do test characteristics differ in particular populations and with donor clinical status (i.e., donation after brain death versus donation after cardiac death OR adult vs. pediatric donors)?
Donor interventions to decrease transmission of HIV, HBV, or HCV from infected donors	Which donor interventions reduce the probability of pathogen transmission from an organ donor infected with HIV, HBV, or HCV to a previously uninfected recipient?
Potential risks and benefits of transplanting, or not transplanting, solid organs from donors positive HIV, HBV, or HCV	How do the clinical outcomes of recipients of organs from donors infected with HIV, HBV, or HCV compare to those who remain on the transplant list?
Potential risks and benefits of transplanting, or not transplanting, organs from donors with risk factors for HIV, 1--1BV, or HCV	How do the clinical outcomes of transplant recipients who receive organs from donors with behavioral or nonbehavioral risk factors compare to those who remain on the transplant list?
	What is the impact of excluding potential solid organ donors with behavioral or nonbehavioral risk factors on the organ donor pool?
	What is the impact of false positive tests on the organ donor pool?

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Next Steps

- Recap of decisions made
- Next meeting

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 Before We Adjourn . . .

Thank You!

**to everyone who worked to make
this meeting possible, and
to everyone who has provided input and suggestions,
and to those of you who have joined us today.**

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Meeting #9 | June 4, 2019

END 4:30 P.M. EDT

