

Tick-Borne Disease Working Group

Meeting #8 | December 3, 2018

Tick-Borne Disease Working Group



Welcome



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)

Innovator in Residence with HHS CTO,
U.S. Department of Health and Human Services (HHS);
Senior Research Scholar, Stanford University

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Review of Meeting #8 Agenda

1. Welcome and Recap of Meeting #7
2. Leadership Remarks
3. Recognition and Thanks of Working Group and Subcommittee Members
4. Overview of work since Meeting #7
5. Communications Plan Summary
6. Public Comments
7. Public Comment Subcommittee
8. Next Steps/Transition
9. Other Business
10. Adjournment

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Recap of Meeting #7

- Voted on recommendations
- Voted on full report
- New public subcommittee created from working group members

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Leadership Remarks



ADM Brett Giroir, MD

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

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Recognition & Thanks



2018 Report Acknowledgements on TBDWG website

- Working Group Members
- Subcommittee Members
- Invited Speakers
- Everyone who took the time to give public comments and input

Supported by the U.S. Department of Health and Human Services • Office of the Assistant Secretary for Health

Tick-Borne Disease
 **Working Group**
2018 Report to Congress

Information and opinions in this report do not necessarily reflect the opinions of each member of the Working Group, the U.S. Department of Health and Human Services, or any other component of the Federal Government.

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Subcommittee Recognition

6 Subcommittees created at meeting # 1&2

- 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 Coinfections

1 Addition subcommittee added at meeting # 7

- Public Comments

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Subcommittee Recognition (continued 1 of 2)

- **Subcommittee Membership – broad range of perspectives**
 - At least one patient or patient advocate on each subcommittee
 - Led by two Co-Chairs – at least one was a public member or non-government volunteer
- **Weekly meetings over a 3-month period**
- **Identified several priorities, developed a Subcommittee report to the Working Group**
 - Current efforts
 - Gaps in research
 - Potential actions to address each priority

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Subcommittee Recognition (continued 2 of 2)

- **Subcommittee Reports**
 - Experts
 - Advocates
 - Patient presentations
 - Collective subcommittee member knowledge
 - Informal Literature reviews
- **Meeting #4**
 - Subcommittee Co-Chairs presented their findings to Working Group
 - Basis for Working Group Report to Congress
- **Monumental undertaking in short period of time**

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Disease Vectors, Surveillance, and Prevention

- Co-Chairs: Pat Smith and Ben Beard
 - Jill Auerbach
 - Neeta Connally, PhD, MSPH
 - Thomas N. Mather, PhD
 - Phyllis Mervine
 - Colonel Robin Nadolny, PhD
 - Adalberto Perez de Leon, DVM, PhD, MS
 - Daniel E. Sonenshine, PhD
 - Jean I. Tsao, PhD
 - Monica M. White
 - Stephen Wikel, PhD

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Pathogenesis, Transmission and Treatment

- Co-Chairs: Wendy Adams and Estella Jones
 - Nicole Baumgarth, DVM, PhD
 - Pat K. Coyle, MD
 - Sam Donta, MD
 - Brian Fallon, MD, MPH
 - Lorraine Johnson, JD, MBA
 - Elizabeth Maloney, MD
 - Jon Skare, PhD
 - Brian Stevenson, PhD

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Testing and Diagnostics

- Co-Chairs: Lise E. Nigrovic and David Roth
 - Holly Ahern, MS, MT (ASCP)
 - Charles Y. Chiu, MD, PhD
 - Roberta DeBiasi, MD, MS
 - Noel Gerald, PhD
 - Deborah Hoadley, MD, MPH
 - Maliha Ilias, PhD
 - Bobbi Pritt, MD, MSc
 - Steven Schutzer, MD

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Access to Care Services & Support to Patients

- Co-Chairs: Scott Cooper and Paula Jackson Jones
 - Ana Frost, PhD
 - Robert C. Bransfield, MD, DLFAPA
 - Sherrill Franklin
 - Holiday Goodreau
 - Colonel Nicole Malachowski
 - Leonard Schuchman, DO, MPH, FAAFP
 - Sheila M. Statlender, PhD
 - Kathleen Steele, LCSW
 - Karen Vanderhoof-Forschner
 - Enid Haller, LCSW, PhD

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Vaccine and Therapeutics

- Co-Chairs: Dennis Dixon and Robert Smith
 - Felipe C. Cabello, MD
 - Monica E. Embers, PhD
 - Maria Gomes-Solecki, PhD
 - Utpal Pal, PhD
 - Stanley A. Plotkin, MD
 - Juan Salazar, MD, MPH, FAAP
 - Leigh Ann Soltysiak, MS

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Other Tick-Borne Diseases and Co-Infections

- Co-Chairs: Richard Horowitz and Allen Richards
 - Megan Dulaney, MS
 - Marna Ericson, PhD
 - Christine Green, MD
 - Charles Lubelczyk, MPH
 - Ulrike G. Munderloh, DVM, PhD
 - Garth Nicolson, MD, PhD (H)
 - Christopher D. Paddock, MD, MPHTM
 - Samuel S. Perdue, PhD
 - Sam R. Telford III, ScD

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Subcommittee on Public Comments

- Co-Chair: Kristen Honey
 - Richard Horowitz
 - Bob Sabatino
 - Scott Cooper

The only Subcommittee still meeting on a regular basis (monthly)

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Overview of Work since Meeting #7

- Report copyedited by contractor at least 4 times
- Report sent to CMS, NIH, and CDC for information purposes
 - Only factual discrepancies and copyedits made
- Report sent to HHS Legislative Affairs for review
- Report submitted to Congress and Assistant Secretary for Health
 - Committee on Energy and Commerce of the House of Representatives
 - Committee on Health, Education, Labor, and Pensions of the Senate

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Communications Plan Summary

- 1-2 weeks before Report was released – ADM Giroir and other relevant federal agencies were briefed
- 2 days before report was released – embargoed interviews occurred
- Day the report was released –
 - Press Release sent widely;
 - Posted on HHS.gov and OASH website;
 - Sent to ASL;
 - Outreach to stakeholders and advocates
 - Social Media
 - Twitter
 - Email marketing

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Communications Plan Summary (part 2)

- First story on the report/CDC new numbers: <https://www.nbcnews.com/health/health-news/tickborne-diseases-such-lyme-hit-record-highs-u-s-cdc-n935971>
- Press release live link: <https://www.hhs.gov/about/news/2018/11/14/tick-borne-disease-working-group-calls-more-resources.html>

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Communications Plan Summary (part 3)

Articles that linked to TBDWG Report to Congress

[ABC Newsletter 11/16/18 \(#39\)](#)

- Report to Congress by Tick-borne Disease Working Group Published

Asbury Park Press: <https://www.app.com/story/news/health/2018/11/15/lyme-disease-congress/2010815002/>

ScienceNews: <https://www.sciencenews.org/article/cases-lyme-and-other-tickborne-diseases-rising?tgt=nr>

CNN: <https://www.cnn.com/2018/11/14/health/tick-report-hhs-bn/index.html>

NY Daily News: <http://www.nydailynews.com/news/national/ny-news-tick-population-causing-fears-20181114-story.html>

CIDRAP: <http://www.cidrap.umn.edu/news-perspective/2018/11/task-force-spotlights-us-tick-borne-disease-cases-set-records>

OSH Online: <https://ohsonline.com/articles/2018/11/15/hhs-working-group-calls-for-strategic-plan.aspx?m=1>

Lakewoodcoop.com/Congressman Chris Smith: <http://www.thelakewoodscoop.com/news/2018/11/congressman-smith-2018-tick-borne-disease-working-group-report-confirms-lyme-is-spreading-time-for-action-is-now.html>

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Communications Plan Summary (part 4)

Articles that linked to TBDWG Report to Congress

- STAT News also ran a short mention of the report.
- <https://www.bayarealyme.org/blog/bay-area-lyme-foundation-endorses-first-recommendations-of-new-hhs-working-group-focused-on-tick-borne-diseases/>
- <https://www.precisionvaccinations.com/tick-borne-pathogens-include-lyme-disease-which-impacts-all-50-states>
- https://www.foxcarolina.com/news/us_and_world/exploding-tick-population----and-illnesses-they-bring/article_6dde90ea-667f-510c-8dca-1dacc33ce6a2.html
- <https://consumer.healthday.com/health-technology-information-18/press-medical-and-health-reporting-news-552/health-highlights-nov-14-2018-739668.html>
- <https://www.360dx.com/policy-legislation/lyme-disease-diagnoses-needs-new-technologies-report-congress-says#.W-yLLfIKhnl>

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One Common Purpose



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

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Core Values



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.



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.

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Public Comment

○ Order of Public Comment is:

- Peg Strickland
- Jennifer Platt
- Lorraine Johnson
- Betty Gordon
- Deborah Fleshman
- Dorothy Leland
- Phyllis Mervine
- Kathy Nodolf
- Carl Tuttle
- Bethany Welch



- 30 minutes of public speaking today
- 10 speakers
- 3 minutes each
- 25 written comments for Meeting #8; <https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/2018-12-3/index.html>
- Email comments may be sent to: tickbornedisease@hhs.gov

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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 all 700+ written comments to tickbornedisease@hhs.gov
- Members:
 - Kristen Honey (Chair)
 - Richard Horowitz
 - Bob Sabatino
 - Scott Cooper

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Discussion of Submitted Public Comment

If you took the time to submit written comments, we read them.

Public Input Takeaway:

- Lyme disease and tick-borne diseases are not being addressed sufficiently by mainstream medicine and government programs today – this warrants increased research funding, further scientific exploration, and unbiased/fresh review of the latest information from across all disciplines/sectors.

Since 2018 report publication, tone shifted to more positive

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2018 Report Feedback

*grave concerns
about the content
in the Access to
Care chapter*

*grave concerns
about the
vaccines
discussion*

“The handling of public emails has been somewhat mysterious as to response and access, and although it is not my personal experience, there have been intimations of possible censorship in verbal/written comments.”

“I would like to extend my congratulations to everyone involved over the past 18+ months in the gargantuan effort that culminated in the 2018 Report to Congress. These comments use that report as a springboard for continued work.”

“This has the potential of a national health crisis in the making. Thank you for your efforts to dispel the darkness and make a real difference in peoples lives.
May God Bless”

“I, along with the thousands diagnosed with Alpha-gal Syndrome are so deeply appreciative for your willingness to listen to ALL who have been affected by a tick-borne condition.”

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Public Comments: Process

- Improve transparency and opportunities for meaningful public input
 - Improve communication, email responsiveness, website timeliness
 - Give people more time to review draft materials before meetings
- Requests for Working Group voluntary disclosure of COIs
- Make available Federal Inventory results for public to see
- Many offered to volunteer and help with some interested in joining the Working Group

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Themes of Comments

- Improve education and prevention for ALL tick-borne diseases
- Improve diagnostic tests, especially direct pathogen testing
- Improve treatment options for those with chronic illness related to TBD
- Evaluate role of Lyme/TBDs in other conditions with unknown etiology
- Patients suffering, need help NOW
 - Repeated calls to government to make this high priority, urgent priority
 - Patient-provider partnership is a 2-way exchange, mutual decision making
 - Evidence-based care/policies must be based on rigorous scientific evidence

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Public Comments: Looking Forward

- Inadequate funding is a serious constraint to progress
 - Increased resources are essential
 - Important that new resources will not impact current funding for other diseases
- Strong public interest to help
 - Patients want to be part of the solution
 - Medical practitioners want to be part of the solution
 - Researchers/students want to be part of the solution
- Support new thinking, new collaborations, public-private partnerships

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Subcommittee Thanks to the Community

The Working Group is an iterative process and **YOUR** feedback is helping us to improve this 6-year endeavor

We thank everyone who took time to share feedback

<https://www.hhs.gov/ash/advisory-commi>



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Everyone is valued

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Timeline for Report to Congress

| Report Process | Dates |
|---|-------------------|
| Contractor submitted final Report to Congress to HHS | October 1, 2018 |
| HHS submitted the final Report to Congress to Legislative Affairs | October 2, 2018 |
| Contractor submitted 508 compliant Report to Congress to HHS | October 6, 2018 |
| HHS submitted compliant version to ASPA for compliance review | October 8, 2018 |
| ASPA approves compliance version | October 18, 2018 |
| Report submitted to Assistant Secretary of Health and Congress | November 14, 2018 |
| Final Report to Congress accessible on the TBDWG website | November 14, 2018 |

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What Happens After Report is Submitted?

- Report is submitted to Congress / HHS Secretary for further action
- TBDWG has NO budgetary authority
- TBDWG does not have programmatic status to implement changes
- Second phase of Working Group 2020 will pick up unfinished business and move forward with new analysis and new recommendations

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Next Steps/Transition

- Transition in membership
- How to apply to be on next Working Group
 - <https://www.hhs.gov/ash/advisory-committees/tickbornedisease/notices/index.html>
 - Instructions near the bottom of the FRN, please be sure to review the full instructions
 - Deadline to apply is **December 14, 2018 at 5:00 pm EST**

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Possible Next Steps

Possible tasks for Working Group 2020

- Literature Review
 - AHRQ (fees required)
 - NIH Library Systematic Review Services (no fees)
- Federal Inventory Action/Updates
 - New inventory to federal agencies early 2020
 - Include any changes or actions made based upon 2018 report

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Possible Next Steps (continued 1 of 3)

Looking Forward Chapter of the Report to Congress

- Public-private partnerships and collaborations
- Federal research and activities related to tick-borne diseases
- Systematic review of adverse effects from overdiagnosis and unsubstantiated treatment for presumed tick-borne diseases
- Systematic review of adverse effects from underdiagnosis and undertreatment for tick-borne diseases

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Possible Next Steps (continued 2 of 3)

Looking Forward Chapter of the Report to Congress

- Systematic review of unresolved priorities and questions:
 - Nomenclature challenges
 - Chronic Lyme, Post-treatment Lyme Disease Syndrome, co-infection
 - Rising healthcare costs in the US due to Lyme disease, other tick-borne diseases, and coinfections
 - Shortcomings and limitations of vaccine and diagnostic clinical trials
 - Inclusion of vulnerable and high-risk populations in clinical trials
 - Transmission unknowns

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Possible Next Steps (continued 3 of 3)

Looking Forward Chapter of the Report to Congress

- Incorporation of patient experiences into conventional scientific approach
- Trust building and communication
- Other ideas

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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.**

Tick-Borne Disease Working Group



Shared Vision

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

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Meeting #8 | December 3, 2018

END 4:00 P.M. EDT