

Tick-Borne Disease Working Group

Meeting #5 | May 15-16, 2018

Arlington, VA

Day 1

Tick-Borne Disease Working Group

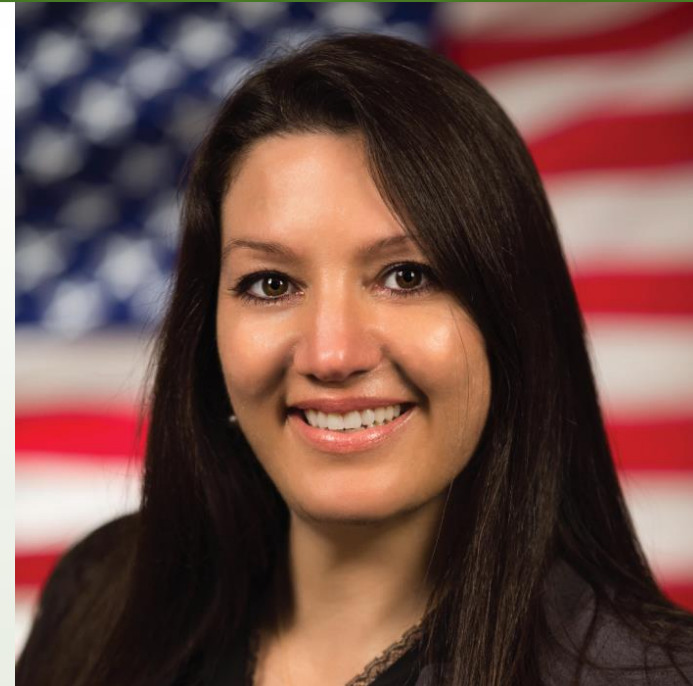


Welcome



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)

Senior Policy Analyst, OMB, Executive Office of the President;
Senior Research Scholar, Stanford University;
Member, Stanford University Lyme Disease Working Group

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New Alternate DFO



Kaye Hayes, MPA

Alternate Designated Federal Officer, Tick-Borne Disease Working Group
Deputy Director
Office of HIV/AIDS and Infectious Disease Policy
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services

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Recap of Meeting #4

- Subcommittee reports were prepared to inform the Working Group and its 14 voting members
- Subcommittees offer insights into gaps, opportunities, and potential actions to be considered by the Working Group for the report to Congress and HHS
- Mission statement volunteers were recruited

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Recap of Meeting #4 (Continued)

- Subcommittee meeting summaries are posted online
- Subcommittee reports are all complete 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 weekly
- 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

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Overview of Meeting #5

- Focus on producing the Working Group report to Congress and HHS
 - Identify areas of agreement and controversy
 - Identify overlap/synergies in content of subcommittee reports
 - Incorporate additional sources of information:
 - Inventories of federal actions
 - Public input
- Decide process for writing the report with specific actions, recommendations

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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 pursue for that accomplishment

- Our core purpose and focus that normally remains unchanged over time
- Present day, given reality of today

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Mission Statement

Proposal for 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 interagency 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.

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Overview of the Report: Requirements and Rules

21st Century Cures Act – December 2016

- A. No later than 2 years after the date enactment, and then every 2 years, the Working Group shall submit a report on its activities under para(2)(A):
 - i. Ongoing tick-borne disease research
 - ii. Advances made pursuant to such research
 - iii. Federal activities related to tick-borne diseases
 - iv. Gaps in tick-borne disease research
 - v. The Working Group meetings
 - vi. Comments received by the Working Group

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Overview of the Report: Requirements and Rules

21st Century Cures Act – December 2016

- B. Make recommendations to the Secretary regarding any appropriate changes or improvements to such activities and research
- C. Solicit input from states, localities, and nongovernmental entities

Reporting

- Submit a report to the Secretary; the Committee on Energy and Commerce of the House of Representatives; the Committee on Health, Education, and Labor; and Pensions of the Senate
- Make such report publicly available on the HHS website

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Next Steps

- May 15–16, 2018: Meeting 5: Working Group drafts content for the report
- June 21, 2018: Meeting 6: Working Group finalizes draft report
- August–September 2018: Draft report available for agency comments and clearance
- December 2018: Report submitted to Congress and the HHS Secretary
- December 2018: Report publically available on TBDWG website
- January 2019: Working Group and subcommittees will evolve over time
 - HHS will issue a new public call for Working Group nominees
 - Planning begins for second report

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Timeline of Report to Congress

Report Process	Due Dates
Writing of report begins	May 21, 2018
Draft report with recommendations due	June 21, 2018
Review and revision of report due	July 6, 2018
Draft report released for HHS agencies, DoD, and VA for comment	July 20, 2018
HHS agencies, DoD, and VA review due	August 17, 2018
Document revision due	October 1, 2018
Final HHS agencies, DoD, and VA clearance complete	November 1, 2018
Revision and final desktop publishing complete	November 14, 2018
Final review for typographical errors plus 508 compliance complete	November 21, 2018
Submit final report to Congress	December 18, 2018
Final report posted on the TBDWG webpage for public comment	December 18, 2018

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Discussion of Report Template

Example reports and plans to consider

- Report on Title XII to Congress
 - <https://www.usaid.gov/sites/default/files/documents/1867/TitleXIIReportCongressFY2016.pdf>
- The Way Forward: Federal action for a system that works for all people living with SMU and SED and their families and caregivers
 - <https://store.samhsa.gov/shin/content/PEP17-ISMICC-RTC/PEP17-ISMICC-RTC.pdf>
- 11th Report to Congress on USAID and CDA Malaria Project
 - <https://www.pmi.gov/docs/default-source/default-document-library/pmi-reports/2017-pmi-eleventh-annual-report.pdf>

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Discussion of Report Template

Review of report template and technical issue brief

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 What do subcommittee reports agree on ?

Moving forward, together

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Commonalities Emerged

Begin Working Group brainstorming, for example:

1. X
2. Y
3. Z

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BREAK 10:40 A.M. eastern

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 Where do potential controversies exist?

Identifying differences, together

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Controversies Emerged

Begin Working Group brainstorming, for example:

1. X
2. Y
3. Z

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 What is happening today?

Goals for Meeting #5

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Focus on TBDWG Recommendations

- Identify common areas of overlap between subcommittees
- Identify differences or controversies warranting attention
- Discuss each of the 6 subcommittee reports
 - Prioritize issues for the Working Group report
 - Combine overlapping content

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What are the Types of Actions Presented

1. Types of recommendations
 1. Resources for research and programs
 2. Educational and prevention recommendations
 3. Other types of recommendations
2. Who receives our recommendations
 1. HHS and the Executive Branch
 2. Congress and the Legislative Branch
3. Could recommendations impact other institutions?
 1. Recommendations to states and non-federal government
 2. Recommendations to professional and policy organizations

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Discussion of Recommendations:



Subcommittee Report on

Disease Vectors, Surveillance, and Prevention

Tick-Borne Disease Working Group



Disease Vectors, Surveillance, and Prevention

Begin Working Group brainstorming and prioritization, for example:

1. X
2. Y
3. Z

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DVSP Potential actions – Key Issue 1



Key issues:

- The need for a better understanding of the geographic distribution of tick vectors, disease ecology, and vectorial capacity
- how these are changing over time and
- the key entomological determinants of risks to humans, including tick behavior and vector competence

Potential actions:

- Disrupt tick-borne disease infection and transmission
- Fund research on modern molecular and genetic techniques (for example, gene knockdown, CRISPER/Cas9) to disrupt infection in the tick vector and transmission of tick-borne pathogens to humans and animals
- Develop and disseminate vaccines against ticks to prevent the spread of these tick-borne disease agents
- Tick basic research – Fund research on pathogen-binding receptors and regulatory factors that enable tick-borne pathogens to infect the tick tissues, proliferate, and survive for transmission to humans and animals
- Genetically modified tick population – Fund research to create a genetically modified tick population, especially for the Lyme disease ticks, *Ixodes scapularis* and *Ixodes pacificus*, for release into highly endemic regions
- Fund research to study the human dimensions of acceptance/barriers of acceptance of releasing GMO ticks



DVSP Potential actions – Key Issue 2



Key issue:

The need for novel safe and effective tick or host-targeted interventions that have been adequately validated to reduce human disease incidence

Potential actions:

- Further study proven tick-control measures (as evidence by lab and field studies) at the scale of population-based prospective studies to validate these measures for preventing human diseases
- Field-trials and human studies evaluating effective natural tick-control products and natural skin repellents for tick control, tick bite, and human disease prevention (for example, use of skin lotions, soaps and repellents or tick control products containing nootkatone or other botanically-based ingredients)
- Assessment of integrated tick management tools that have the greatest effectiveness for vector control while minimizing negative environmental impacts (such as groundwater pollution and non-target effects) and pesticide resistance
- Continued study and development of promising novel tick- and pathogen-control measures, including molecular technologies, for impacting pathogen prevalence in ticks and animal reservoir hosts (for example, rodent vaccination, transgenic ticks, RNAi, semiochemical control, and so forth)
- Promotion of private and public partnerships to engage industry and other professionals to develop novel and effective products that can be marketed to the public for tick-borne disease prevention
- Assessment of barriers to public adoption of prevention practices (for example, studies evaluating willingness-to-pay, social acceptability, environmental concerns, behavioral preferences, and knowledge, attitudes, and perceptions of prevention measures)



DVSP Potential actions – Key Issue 3



Key issue:

The need for improvements in national disease surveillance and reporting and the potential role of other data sources and patient registries in defining national disease burdens and trends

Potential actions:

- Provide a more complete picture of disease risk by supplementing and integrating traditional public health surveillance data with other data sources, such as tick surveillance data, tick testing data, companion animal tick-borne disease testing data, medical claims data, weather data, other patient data sources, and data from other federal agencies including the U.S. Department of Defense
- Have public health authorities formally recognize (for example, include on official websites and in official publications, such as CDC annual reports) and provide resources for systematically determined and regularly conducted studies to determine estimates of the actual number of cases of tick-borne disease (“burden of illness” studies); base allocations on the estimated actual number of cases of disease in addition to reported case counts



DVSP Potential actions – Key Issue 3



Key issue:

The need for improvements in national disease surveillance and reporting and the potential role of other data sources and patient registries in defining national disease burdens and trends

Potential actions:

- Have public health authorities formally recognize alternative, validated systematic approaches to tick-borne disease surveillance, such as systematic sampling of tick-borne disease reports for investigation, that reduce the burden on tick-borne disease reporters but allow for comparability of surveillance findings across states and over time
- Make it easier and more likely for tick-borne disease cases to get reported to public health agencies by leveraging electronic exchange of health data and educating and incentivizing providers to report
- Public health authorities shall annually and when opportune (such as during Tick-Borne Disease Awareness Month) inform doctors, insurers, state and local health departments, the press and the public through official communication channels (including the MMWR, CDC, and other official websites) that the Lyme disease surveillance criteria are not to be used for diagnostic purposes



DVSP Potential actions – Key Issue 3

minority response



Key issue:

The need for improvements in national disease surveillance and reporting and the potential role of other data sources and patient registries in defining national disease burdens and trends

Minority subcommittee member response (4-7-2A):

There was a unanimous vote to accept the proposed actions for this key issue, and although much is discussed and agreed to in the body of the report, there remained significant concern about the CSTE/CDC Lyme surveillance case definition and its misuse in clinical diagnosis

Based on the minority members' input over decades from patients and Lyme treating physicians, the report states that misuse of the overly narrow surveillance case definition led to widespread failure by physicians to diagnose and treat Lyme disease in patients who did not meet the surveillance criteria and by laboratories who would only report out CDC-recommended bands

The report's focus is that the government has not been responsive to the situation, did little to nothing to rectify the situation, and exclusively promoted a set of guidelines that had been developed to use those surveillance criteria



DVSP Potential actions – Key Issue 4



Key issue:

Detection, identification, and characterization of novel and emerging pathogens in ticks, including *Bartonella*, and the transmission risks of these agents by ticks to humans

Note: The group voted to select one potential action from all options in each of the 5 bullets it drafted for Working Group consideration. However, the group felt that all the 5 possible actions selected were equally important. The consensus was to take a theme approach to synthesize the 5 possible actions selected, and it presents a theme encompassing the potential action for the Working Group to consider. The theme and the 5 actions are presented below.

Potential action:

- **Theme:** Encourage commitment to establish a nationwide tick and tick-borne disease surveillance network that is a partnership among public interest groups; academic institutions; and local, state and federal government agencies to provide coordinated, standardized protocols for tick-borne disease surveillance, tick collection, identification, and analysis to identify established, emerging, and enzootic transmission cycles with zoonotic potential. Proposed network includes the coordination of local Mosquito and Tick Control Programs.
- Rather than create a stand-alone tick and tick-borne disease network, the logical approach is to combine all medically important vectors, primarily mosquitoes and ticks, within one comprehensive operational scheme. Such an integrated surveillance and response system is reported to be effective and result in significant cost savings over specific vector and related disease approaches (Wu et al., 2016); 3) establish state and federal partnership to safeguard public health that is also linked to the National Animal Health Laboratory Network (<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/nahln/ct-national-animal-health-laboratory-network>).
- Establish interdisciplinary technical committee between the American Medical Association, the Veterinary Medical Association, and the Entomological Society of America (<http://www.entsoc.org/PDF/2015/ESA-PolicyStatement-Tick-borneDiseases.pdf>) to produce guidance based on state of the science to study and validate tick-borne pathogens and tick vectors.



DVSP Potential actions – Key Issue 4



- Establish global tick microbiome consortium similar to the Global Virome Project (<http://www.globalviromeproject.org>)
 - tick species to be included in tiered approach for further characterization of their microbiomes include the following ixodid vectors of zoonoses in the United States (Eisen, Kugeler, et al., 2017): *Amblyomma americanum*, *Amblyomma maculatum*, *Dermacentor andersoni*, *Dermacentor occidentalis*, *Dermacentor variabilis*, *Ixodes pacificus*, *Ixodes scapularis*, and *Rhipicephalus sanguineus*, *Ornithodoros* spp., which will enable the systematic identification of microbes potentially pathogenic to humans and animals through further research and testing as described in theme 2 above.
- Establish a state and federal tick-borne disease council to develop best practices for maximal dissemination of science-based information, including interactive sites for tick identification in real time.
- Study each of the major zoonotic tick-borne diseases in different ecosystems using harmonized protocols to understand the variability in qualitative and quantitative characteristics of ecological drivers.



DVSP Potential actions – Key Issue 5



Key issue:

The need for better prevention education for patients and physicians, including providing accurate information and removing both personal and public obstacles

Potential actions:

- Focus future tick prevention education on those practices and activities with positively measured outcomes, such as reductions in the number of ticks found on study participants or outcomes related to the tick encounters (bites, disease) a documented increase in knowledge, or the adoption of specific prevention behaviors; encourage a pipeline of innovation to science-based prevention education by providing additional funding for practitioners (both individuals and entities) proposing to conduct objective assessments of their intervention or tool
- Recommend significant additional funding for CDC-supported regional Centers of Excellence in Vector-borne Disease (CoEs) to expand their training, internship, and cross-discipline collaboration opportunities in high priority tick prevention education programs, including: servicing national crowd-sourced tick surveillance programs, conducting health promotion and social marketing studies, conducting applied studies to validate or dispel commonly promoted tools and strategies for tick prevention, and science communications training
- Incentivize innovation in best K-12 learning practices and evaluate the effectiveness of available and new learning kit resources



DVSP Potential actions – Key Issue 5



Key issue:

The need for better prevention education for patients and physicians, including providing accurate information and removing both personal and public obstacles

Potential actions:

- Invest in programs that already effectively link the best of tick science to peoples' lived experiences with ticks (that is, Cooperative Extension, academic-based tick prevention resources, advocacy groups), and update existing regionally and occupationally relevant targeted public health intervention programs (including federal agency safety manuals and handbooks) to reduce physical and behavioral tick exposure risk by addressing specific gaps in knowledge and prevention
- Develop best practice tick control training materials (online training, videos) for PCOs, and make continuing education (CE) compliance a requirement for continuing PCO licensure



DVSP Potential actions – Key Issue 5 minority response



Key issue:

The need for better prevention education for patients and physicians, including providing accurate information and removing both personal and public obstacles.

Minority subcommittee member response (3-7-2abstain-1A):

- While there was a unanimous vote to accept the proposed actions for this key issue, the minority response addresses the need to remove the word “already,” which limits the potential action to programs already in place for decades, but which are primarily focused in regions with prevalence of blacklegged ticks and high incidence of Lyme
- Large areas of the country are characterized as being low tick or low tick-borne disease incidence and thus lack awareness and resources for prevention measures relevant to their home states
- New innovative or regionally relevant programs that can link the current best science to peoples' actual experiences with ticks is essential to improving prevention education in these underserved areas

Tick-Borne Disease Working Group

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LUNCH BREAK 1:00 P.M. eastern

Tick-Borne Disease Working Group

Discussion of Recommendations:



Subcommittee Report on

Pathogenesis, Transmission, and Treatment

Tick-Borne Disease Working Group



Pathogenesis, Transmission and Treatment

Begin Working Group brainstorming and prioritization, for example:

1. X
2. Y
3. Z



PTT Results and Potential Actions - Priority 1



What mechanisms of *B. burgdorferi* pathogenesis allow it to persist in some animal species despite a competent immune system and/or antimicrobial therapy?

(What are the gaps in human research that need to be addressed to explore this model of pathogenesis in humans?)

- Potential actions:
 - Promote research on animal models of *B. burgdorferi* infection and the mechanisms of disease processes in humans with an emphasis on pathologies that are currently lacking, e.g., neuroborreliosis
 - Insufficient understanding of mechanisms of disease in animal models
 - Need to understand how applicable these are to human disease
 - Pursue further study of mechanisms of *B. burgdorferi* survival during infection processes and its tolerance to antibiotics and other stresses
 - Immune system is affected by *B. burgdorferi* to enable establishment and maintenance of infection in immunocompetent hosts
 - Animal models and human case studies show that the pathogen may persist after antibiotic treatment
 - If *B. burgdorferi* is still present, is that the etiology of continuing signs and symptoms?



PTT Results and Potential Actions– Priorities 2 & 3



- What is the pathogenesis of persistent symptoms in antibiotic-naïve and antibiotic-treated patients? Are there biomarker(s) to determine the continuing presence of infection?
- What is/are the best treatment regimens for acute Lyme disease and for patients with ongoing symptoms who have or have not been previously treated?



PTT Results and Potential Actions – Priority 2 & 3



Potential actions:

- Conduct clinical trials using more inclusive entry criteria representing the heterogeneity of patients seen in clinical practice and including different treatment approaches
 - Insensitive testing has led to a data set that may not be representative
 - Current data from trials are not generalizable to clinical practice
 - Use innovative, patient-centered trial designs and big data tools to accelerate research
 - Promote shared medical decision-making in clinical practice
- Develop and disseminate more comprehensive clinician education that highlights diverse symptomology, expanding geography of infecting ticks, and limitations of current testing procedures
 - Include diverse group of stakeholders, including clinicians, research scientists, and patients who represent the spectrum of scientific and medical expertise and perspectives on Lyme disease



PTT Results and Potential Actions– Key Themes



Limited knowledge of human pathophysiology impedes patient care; additional research into pathogenesis is needed

- Animal models useful, but no single, well-characterized animal model reflects the spectrum of human disease, e.g., neuroborreliosis
- Basic mechanisms of immune evasion are not well understood
- Persistent infection is sometimes seen in vitro, in animals and in humans
Does this cause ongoing symptoms in patients?
- Could understanding molecular mechanisms better inform therapeutic choices?
- What is the potential role of pro-inflammatory cytokines, *B. burgdorferi* lipoproteins, autoantibodies, and cross-reactive antibodies?
- Do strain variations impact therapeutic outcomes?
- Does the addition of another pathogen(s) affect the disease process, diagnosis, or treatment of the infections?



PTT Results and Potential Actions– Key Themes



- Clinicians need better tools to diagnose and treat patients
 - Lack of direct biomarkers of infection
 - No biomarker for untreated and previously treated infection, or test of cure
 - Lack of biomarkers that can predict risk of failure
- Given the massive improvement in basic science technologies, novel clinical trial design, access to large databases, and new data mining techniques, can more effective treatments be identified more rapidly and efficiently?
 - May be most timely way to improve patient care
- Use innovative, patient-centered trial designs to accelerate research and promote shared medical decision-making in clinical practice

Tick-Borne Disease Working Group

Discussion of Recommendations:



Subcommittee Report on

Access to Care Services/Support to Patients

Tick-Borne Disease Working Group



Access to Care Services / Support to Patients

Begin Working Group brainstorming and prioritization, for example:

1. X
2. Y
3. Z



ACSSP Awareness & Education



- **Potential Action 1:** Provide education regarding prevention and recognition of tick-borne diseases, ticks, tick bites, and how to remove a tick correctly; audience-specific messaging; and outreach
- **Potential Action 2:** Have a more comprehensive and interactive website at the federal level; app/technology (e.g., TickTracker.com)
- **Potential Action 3:** Federal government to include TBD curriculum in the school system, especially in endemic regions
- **Potential Action 4:** Treat Lyme and other tick-borne diseases as chronic illnesses
 - Even without definitive or settled science determining the exact cause, there is agreement on all sides that debilitating symptoms linger for up to 20 percent of Lyme disease patients
 - The approach for other chronic conditions is to address and manage the medical, social, economic, and psychological challenges faced by those with chronic conditions or chronic symptoms; Lyme and tick-borne illness should be no exception



ACSSP Awareness & Education



Issue: Patient Education

- Recognizing that they have a tick-borne disease
- Having current information to work with
- Knowing where to find the resources in their own state
- **Potential Action 1:** Add existing resources to state public health pages and behavioral health associations
- **Potential Action 2:** Use public service announcements to educate people
- **Potential Actions 3:** Have pamphlets available at doctors' offices (tick removal, availability of tick testing, etc.) outlining symptoms in very patient-friendly language
- **Potential Action 4:** Educate that patients can present with any number of symptoms and in differing intensity; advise of many different types of rashes
- **Potential Action 5:** Dispel myths and promote reality, update (and keep up-to-date) information that is promoted to provider and the public



ACSSP Awareness & Education



Issue: Provider Education

- Prevention and recognition of TBDs, tick bites
- Diagnosis and treatment
- Medical causation for mental health conditions
- Lyme literate workshops (peer-to-peer training)
- ILADEF
- Free CME modules
- Primary care practitioners
- Specialty care practitioners
- Mental health practitioners
- **Potential Action 1:** Formal and continuing education on tick-borne diseases, starting in medical schools and allied health programs and including, but not limited to: behavioral health practitioners, nurses, family nurse practitioners, physician assistants, nurse assistants



ACSSP Awareness & Education



- **Potential Action 1:** Mandatory insurance coverage
- **Potential Action 2:** Enforcement existing laws
- **Potential Action 3:** Laws to protect patients' rights, including informed consent regarding the 2 published standards of care for Lyme disease
- **Potential Action 4:** Laws to protect physicians who wish to treat according to clinical criteria and/or ILADs guidelines
- **Potential Action 5:** Implement federal demographic reporting
 - Include a Lyme/Tick-borne Disease checkbox on health forms within the federal government to gather accurate data about prevalence, health impact, and cost of tick-borne diseases
 - Include a checkbox on medical intake forms within government health care institutions and programs



ACSSP Awareness & Education



- Potential Action 6: Hold Congressional hearings to gather data and correct Lyme public health and human rights issues
 - Legislative oversight and investigative hearings or some combination of hearings may be critical to correct the public health and human rights issues facing tick-borne disease patients
- Potential Action 7: Adapting Maryland’s “Patient Information Disclosure Act” as a model for legislation
 - Notifies patient when any diagnostic test is performed that lack a high level of reliability (not necessarily restricted to Lyme testing)
- Potential Action 8: Federal government – Extend to Medicare and ERISA law



ACSSP Access to Affordable Medical Care



- **Potential Action 1:** Revert back to 2011 language on the CDC website that distinguished surveillance criteria vs. diagnostic criteria
- **Potential Action 2:** Post ILADS guidelines on CDC website
- **Potential Action 3:** Draw attention to footnote on the IDSA guidelines
- **Potential Action 4:** Allocate more balanced funding for Lyme and tick-borne diseases to match communication
- **Potential Action 5:** Establish tick-borne disease centers of excellence (Centers of Excellence already exist to serve patients facing serious health and public health challenges ranging from autism to cancer to minority health disparities)



ACSSP Access to Affordable Medical Care



- **Potential Action 6:** Hold a Congressional hearing about tick-borne diseases
- **Potential Action 7:** Allocate increased funding for tick-borne disease in the area of research, treatment, and prevention (Proportional to cancer, HIV/AIDS)
- **Potential Action 8:** Protection from job discrimination due to Lyme and TBDs
- **Potential Action 9:** Protection for students of all ages from discrimination due to Lyme and TBDs
- **Potential Action 10:** Increase research funding through Department of Defense Congressionally Directed Medical Research Program (DOD CDMRP)



ACSSP Access to Affordable Medical Care



- **Potential Action 2:** Insurance to cover Lyme treatment and limited Lyme testing
- **Potential Action 2:** Streamline reimbursement process for patients
- **Potential Action 3:** Streamline patient/doctor PA/appeal process
- **Potential Action 4:** Include mental health coverage



ACSSP Access to Affordable Medical Care



- **Potential Action 1:** For health care provision to be available across demographics
- **Potential Action 2:** Educational materials in multiple languages
- **Potential Action 3:** Require entities that take federal money provide education
- **Potential Action 4:** Ob/Gyn TBD training for potential gestational transmission during pregnancy



ACSSP Access to Proper Diagnosis & Treatment



- **Potential Action 1:** Funding research to lead to accurate diagnosis and treatment of all stages
- **Potential Action 2:** Better physician training – med schools, especially endemic areas
- **Potential Action 3:** Include tick-borne disease education with mental health training
- **Potential Action 4:** Introduce Informed Consent Form into medical visits



ACSSP Access to Proper Diagnosis & Treatment



Issue: Affordable treatment options

- Insurance blocks (denying services/treatment)
- Mainstream and Alternative options covered
- Long-Term Recovery & Support
- Physical & Occupational Therapy
- **Potential Action 1:** Update coding – currently for acute, need for chronic and co-infections – to increase coverage as new norm for Lyme and TBD and make care more affordable for more patients
- **Potential Action 2:** Expand insurance coverage for complimentary/alternative visits and treatment options (including but not limited to PT/OT, reiki, acupuncture)

Tick-Borne Disease Working Group

Meeting #5 | May 15-16, 2018

BREAK 4:10 P.M. eastern

Tick-Borne Disease Working Group

Discussion of Recommendations:
 Subcommittee Report on

Vaccines and Therapeutics

Tick-Borne Disease Working Group



Vaccines and Therapeutics

Begin Working Group brainstorming and prioritization, for example:

1. X
2. Y
3. Z



VT Summary: Potential Actions



Prioritized Issue 1: Human Vaccines to Prevent Lyme Disease

- Support for availability of human vaccine(s) for prevention of Lyme disease is a top priority.
- It is critical to prepare the market for a Lyme disease vaccine through proper disease awareness and education.

Potential Actions:

- Identify current barriers to public and industry acceptance of vaccines for Lyme disease, and address concerns as part of the process
- Support continued development for human Lyme disease vaccines



VT Summary: Potential Actions (cont.)



Prioritized Issue #2: Therapeutics for PTLDS

Potential Actions:

Continued research into the pathogenesis (that is, immune response, cross-reactivity, autoimmunity, bacterial persistence) of persistent symptoms in patients who have received standard treatment regimens

Tick-Borne Disease Working Group

Discussion of Recommendations:



Subcommittee Report on

Other Tick-Borne Diseases and Co-infections

Tick-Borne Disease Working Group



Other Tick-Borne Diseases and Co-infections

Begin Working Group brainstorming and prioritization, for example:

1. X
2. Y
3. Z



OTBDCI Babesia: Treatment



- **Potential Action 1:** Increase resources to improve diagnostics, broaden Babesia species testing panels (genetic diversity/multiple *Babesia spp.*)
- **Potential Action 2:** Provide health care education for not only family practice/internal medicine doctors, but subspecialists, (signs/symptoms/risks/laboratory evaluation/treatment challenges of *Babesiosis*)
- **Potential Action 3:** Conduct laboratory research and clinical trials to evaluate new treatment regimens for *Babesiosis*
 - Resistance to standard regimens has been reported (medications/alternative medicine protocols) for morbidity and mortality
- **Potential Action 4:** Conduct research on immunotherapy/human monoclonal antibodies to control parasitemia while on drug treatment



OTBDCI Other Borrelia Species: Treatment



- **Gaps:** Incidence of *Borrelia miyamotoi* disease? Role in other diseases with a chronic fatiguing/musculoskeletal component (Chronic Fatigue Syndrome, Fibromyalgia)?
- **Challenges:** Persistence (Bm, Sensu lato spp.) post treatment w/standard AB's
- **Potential Action 1:** Improve public education on prevention tick bites, and educate health care providers on the signs/symptoms/transmission *RF borrelia*
- **Potential Action 2:** Diagnostics: expand routine testing panels (5% of the U.S. population suffers from Chronic Fatigue Syndrome/Fibromyalgia)
- **Potential Action 3:** Treatment: Evaluate efficacy of treatment regimens against relapsing fever *borrelia* transmitted by hard/soft ticks, especially when different co-infections are present, as persistent infection has been reported



OTBDCI Deer Tick Virus/Powassan virus: Treatment



- **Clinical Picture:** May result in asymptomatic infection
 - 50% of survivors with neurological symptoms have severe permanent neurological symptoms (recurrent headaches, weakness, memory problems)
 - 10% of infections are fatal
- **Increased Risk:** + serology for POWV in TBD samples was 9.4% in regions where Lyme is endemic (Thomm et al., 2018)
- **Gaps:** Transmitted from raw milk (TBEV), Persistent infection, Birth defects?
- **Treatment:** Supportive. No effective treatment exists for severe disease, with a 10-15% mortality rate. High dose steroids or IVIG may be helpful?
- **Potential Action 1:** More resources for research into effective treatment
- **Potential Action 2:** Conduct research (animal models) (modes of transmission & whether persistence exists after an acute infection, such as for Zika, WNV)



OTBDCI Rickettsia (Rocky Mountain Spotted Fever): Treatment



- **Increased Risk:** 15% of all reported fatalities of RMSF are children under 10 yo; Transmission via blood transfusion has also been described
- **Clinical Picture:** Difficult to diagnose in early stages due to non specific symptoms (fevers, headache, nausea, vomiting, muscle pain, abd pain, rash...)
- **Severe disease:** Cardiac, respiratory symptoms, renal failure, seizure, coma
Long-term sequelae: hearing loss, bladder/bowel problems, learning disabilities
- **Treatment:** Treat presumptively and immediately with doxycycline on clinical and epidemiological findings
 - Don't wait for a positive test, don't stop treating with negative test
- **Potential Action 1:** Educate health care providers on non-specific signs/symptoms; use doxycycline as 1st line therapy in children/pregnancy
- **Potential Action 2:** Treat RMSF presumptively; never delay/stop treatment



OTBDCI Bartonella: Treatment



- **Potential Action 1:** Improve and expand diagnostic assays, increase range of species Explore how multiple pathogens interact (Lyme, Bartonella): Effect on immunity?
- **Potential Action 2:** Conduct trials to evaluate more effective treatments. Failures/clinical relapses post antibiotic therapy have been reported
- **Potential Action 3:** Allocate resources to improve and expand research into the interaction between simultaneous infecting pathogens and the effect on the immune response of two or more pathogens
- **Potential Action 4:** Conduct animal and human clinical trials to evaluate more effective treatment protocols, as Bartonella has been shown to persist despite single or combination therapy
- **Potential Action 5:** Allocate resources to conduct research to determine the risk of transmitting multiple tick-borne pathogens via the blood supply



OTBDCI Role of Other Pathogens: Mycoplasma

Role of Other Sources of Inflammation



- **Challenges:** multiple species
 - *Mycoplasma* are difficult to detect by standard testing; manipulate the immune system; persist and can relapse post treatment
 - Approximately 70% of chronic LD patients have systemic Mycoplasma infections
- **Gaps:** Transmission by ticks; problems with establishing proof of infection (multiple species, intracellular)
 - Do *Mycoplasma* increase symptoms in PTLDS?
 - How can we effectively treat? (persistence is possible with single drug regimens)
- **Potential Action 1:** Review the role of overlapping causes of inflammation in LD patients, such as *Mycoplasma* infections and environmental toxins
 - These have both been associated with autoimmune phenomenon
- **Potential Action 2:** Conduct research on the role of free radical oxidative stress and cytokine production during tick-borne infection
 - Downstream effects of inflammation may result in disabling symptoms
 - Allocate resources to conduct clinical trials to identify contributing causes and confounding factors



OTBDCI Alpha Gal Meat Allergy



- **Background:** The bite(s) of a lone star tick (and other ticks) can result in an allergic reaction, leading to an anaphylactic reaction which can be life threatening; the reaction can be delayed (minutes to hours)
 - Alpha gal meat allergy is spreading, as is the range of the lone star tick in U.S.
- **Gaps:**
 - Lack of surveillance (true numbers of individuals affected are unknown)
 - Education and awareness is needed (preventing tick bites, range of potential triggers, i.e., the role of other triggers such as personal care/medical products/nutritional products needs further investigation)
- **Possible Action 1:** Increase education and awareness pre-diagnosis, and counseling after diagnosis. Labelling on food may be inadequate
- **Possible Action 2:** Dedicate additional resources to vector control
- **Possible Action 3:** Increase funding for immunologic and animal model research to identify and better understand the tick proteins that cause alpha-gal meat allergy

Tick-Borne Disease Working Group

Process Decisions

Let the writing begin!

Tick-Borne Disease Working Group



How to Create Crosscutting Writing

- New co-leads and/or sub-groups for writing
- SharePoint: Distributed content generation with documents for all to edit
- Ways to consider combining themes for new writing sub-groups

Tick-Borne Disease Working Group



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.**