Tick-Borne Diseases and Associated Illnesses National Community Engagement Initiative Public Meeting

Meeting Summary

Tuesday, June 11, 2024
San Francisco, CA
Hybrid Meeting

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Executive Summary

Hosted by the Office of the Assistant Secretary for Health (OASH) within the U.S. Department of Health and Human Services (HHS), this meeting was the first in a series of national community engagement sessions related to tick-borne diseases and associated illnesses impacting the American public. Held at the University of California San Francisco, the meeting featured: updates from five federal agencies on programs, activities, and research that have been developed or initiated since the conclusion of the federal Tick-Borne Disease Working Group in 2022; presentations about the epidemiology and prevention of tick-borne diseases in California and Arizona; verbal comments from members of the public; and a panel discussion by federal agency representatives of questions submitted by the public in advance of the meeting.

Meeting Summary

Introduction and Welcome Remarks

James (Jim) Berger, MS, MT(ASCP), SBB, Senior Advisor for Blood and Tissue Policy, Office of Infectious Disease and HIV/AIDS Policy (OIDP), welcomed everyone to the first meeting of the Tick-Borne Diseases and Associated Illnesses National Community Engagement Initiative. He explained that the initiative is the result of the final recommendation of the Tick-Borne Disease Working Group to ensure the public can receive updates on federal activities and have a means for providing input.

Mr. Berger introduced the moderator of today's meeting, B. Kaye Hayes, MPA, Deputy Assistant Secretary for Infectious Disease, Director, OIDP. Ms. Hayes thanked audience members for their continued interest and involvement in federal activities related to tick-borne diseases and associated illnesses. She praised the Tick-Borne Disease Working Group for generating three Reports to Congress, the recommendations of which informed the development of the National Public Health Strategy to Prevent and Control Vector-Borne Disease in People. She explained that a primary objective of the meeting is to hear from federal partners about progress made toward those recommendations. Ms. Hayes outlined the agenda for the day, noting that the afternoon session would be devoted to receiving public comments and hearing a panel discussion by federal agency representatives, who will answer questions submitted by the public.

Ms. Hayes introduced Admiral Rachel L. Levine, MD, HHS Assistant Secretary for Health. Admiral Levine expressed her gratitude to attendees for their continued commitment to the important and complex issue of tick-borne diseases and associated illnesses. She underscored the devastating impact of these diseases and conditions, such as Alpha-gal Syndrome (AGS), on individuals, families, and communities. Admiral Levine explained that input received from the public through

these engagement sessions will guide efforts within her office and inform future updates to the Vector-Borne Disease (VBD) National Strategy, which prioritizes tick-associated illnesses and conditions. She highlighted the ambitious goal of the VBD National Strategy to reduce the number of Lyme disease cases by 25 percent by the year 2035, adding that meaningful collaboration with the public will help achieve this goal.

Next, Mr. Berger introduced Leith J. States, MD, MPH, MBA, FACPM, Acting Director in the Office of Science and Medicine and OASH Chief Medical Officer. Dr. States acknowledged the important strides that have been made over the past decade: the creation and work of the Tick-Borne Disease Working Group, the passage of the Kay Hagan Tick Act, the development of a National Public Health Framework for the Prevention and Control of Vector-Borne Diseases in Humans, and the establishment of the VBD National Strategy. He credited this progress to the collective coordination of all interested parties, including government agencies, researchers, advocacy groups, health systems, and legislative bodies. Dr. States encouraged the audience to continue collaborating and building relationships with the shared goal of reducing the impacts of tick-borne diseases and associated illnesses in humans.

U.S. Federal Agency Report-Outs

Representatives from five federal agencies provided updates on recently developed or ongoing programs, research, and initiatives in tick-borne diseases and associated illnesses.

CDC Tick-Borne Disease Updates

C. Ben Beard, MS, PhD, Principal Deputy Director, Division of Vector-Borne Diseases, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention

Dr. Ben Beard's presentation included information on the state of the science in vector-borne diseases with a primary focus on tick-borne diseases and associated illnesses. He provided an overview of current burdens and trends in disease incidence and tick distribution, followed by a description of the Centers for Disease Control and Prevention (CDC)'s responses to specific Tick-Borne Disease Working Group recommendations related to CDC web content and clinician education.

Dr. Beard highlighted significant activity in vector-borne diseases in 2023, including localized outbreaks of malaria and dengue fever, and increased attention on AGS, Rocky Mountain spotted fever (RMSF), and Lyme disease. Over 1 million cases of vector-borne diseases were reported in the United States from 2003 to 2023, with the annual number of cases doubling during this period (CDC, 2024a). These statistics are likely a substantial underestimation of true burden, as exemplified by the approximately 476,000 new Lyme disease cases diagnosed and treated each year in the United States (CDC, 2024g). Local

outbreaks are becoming more common, and tick-borne diseases now comprise over 80 percent of all reported vector-borne disease cases (CDC, 2024h, 2024i).

Over the last 20 years, there has been a significant increase in Lyme disease cases, particularly in the 15 states where 95 percent of cases are reported (CDC, 2024e). Dr. Beard showed a bar graph featuring a steady rise in cases; however, he pointed out that the numbers are based on three different case definitions used during that timeframe (CDC, 2024f). Therefore, the demonstrated trends are approximate. Similarly, Powassan virus disease cases have been rising over the past decade (CDC, 2024c). The distribution of the black-legged tick (*Ixodes scapularis*), the primary vector of Powassan virus, Lyme disease, anaplasmosis, and babesiosis, has also expanded in line with the increase in cases (CDC, 2024b).

RMSF, part of the spotted fever rickettsioses group, has shown varying trends over the past 25 years (CDC, 2024d). A notable decrease in cases in 2021 is attributed to COVID-19's impact on reporting and changes in diagnostic criteria (CDC, 2024d). RMSF disproportionately affects indigenous communities in Arizona, with the brown dog tick (*Rhipicephalus sanguineus*) as the main vector. There have been over 530 cases and 28 deaths from RMSF, and nearly 80 percent of these were reported in Tribal communities (CDC, 2024d). Last year, six RMSF cases were reported in California, and all were associated with travel to Tecate, Mexico (CDC, n.d.).

AGS, a severe allergic reaction primarily due to the bite of a lone star tick (*Amblyomma americanum*), has also been on the rise. Though not nationally notifiable, AGS is estimated to affect up to 450,000 people in this country. This statistic is the first nationwide estimate based on the identification of 100,000 suspected cases (Thompson et al., 2023). AGS cases tend to occur primarily in the southeastern and central United States, which correlates with the distribution of the lone star tick. However, there is a high proportion of cases in Suffolk County, New York, and parts of upper Minnesota and Wisconsin (Thompson et al., 2023), suggesting that these cases are likely associated with other tick species, possibly the black-legged tick (*I. scapularis*). A survey revealed that 42 percent of U.S. healthcare providers had never heard of AGS (Carpenter et al., 2023), which prompted CDC to enhance clinician education and awareness about the condition.

Next, Dr. Beard transitioned to CDC's responses to specific recommendations by the Tick-Borne Disease Working Group federal advisory committee. In its 2022 Report to Congress, the Working Group requested that CDC prioritize the following two recommendations from the 2020 Report to Congress:

> Recommendation 7.1: Recommend Federal government websites and educational materials and seminars for clinicians, the public, and public health departments, which discuss Lyme disease, provide information that the state of the science relating to persistent symptoms associated with Lyme disease, is limited, emerging, and unsettled; and increase public awareness that there are divergent views on

> diagnosis and treatment. Consider that shared medical decision-making may be appropriate in some circumstances.
>
> Recommendation 7.2: Fund and support a directive for CDC (or other appropriate HHS OPDIV or agency) to develop (either directly or through an approved federal contract) a multi-leveled and nationwide curriculum on Lyme disease for clinicians-in-training as well as continuing medical education modules to increase the pool of qualified and practicing clinicians. Provide funding for the U.S. military to participate in this nationwide training and education on Lyme disease and other tick-borne diseases and conditions. This curriculum should be introduced and encouraged at the State level. The final curriculum shall incorporate feedback from patients, clinicians, and research scientists with expertise/experience that represents diverse scientific and clinical experiences on the full spectrum of Lyme disease and other tick-borne diseases/conditions.

In response to Recommendation 7.1, Dr. Beard displayed the "Clinical Care of Lyme Disease: Treatment Best Practices" page on CDC's website, which features the following statement:

> Some patients report prolonged symptoms of pain, fatigue, or difficulty thinking even after treatment for Lyme disease. The state of the science relating to prolonged symptoms associated with Lyme disease is limited, emerging, and unsettled. Additional research is needed to better understand how to treat, manage, and support people with prolonged symptoms associated with Lyme disease.

Dr. Beard outlined additional CDC efforts to address chronic symptoms associated with Lyme disease. Specifically, he described a collaborative National Academy of Science and Engineering Medicine workshop focused on infection-associated chronic illness. The workshop resulted in two new CDC webpages: one is dedicated to chronic symptoms following infections; and the other describes chronic symptoms associated specifically with Lyme disease.

In response to Recommendation 7.2, Dr. Beard outlined CDC's evidence-based training modules on tick-borne diseases and associated illnesses. The modules were developed in collaboration with the American Medical Association, healthcare provider organizations, specialists, and patient advocates, and they were pilot tested by multi-specialty clinicians. Available through CDC's website, the trainings include interactive material about prevention, clinical presentation, testing, diagnosis, treatment, and management, as well as supplementary videos with responses to frequently asked questions. Dr. Beard displayed several examples of content for Lyme disease, including forthcoming content about improving care for patients with prolonged symptoms, RMSF, and AGS. These materials have been, and will continue to be, promoted through many different social media outlets, as well as through

healthcare provider organizations, state and local health departments, and through paid advertising. More than 2,000 healthcare providers have been awarded continuing education credit for CDC's Lyme disease modules. In addition, more than 300 clinicians have taken the RMSF training, which CDC promotes to southwestern states and counties that border Mexico, where RMSF is localized and hyperendemic.

Dr. Beard also provided an update on CDC's response to the following recommendation from the Tick-Borne Disease Working Group's 2020 Report to Congress:

> Recommendation 8.2: Recommend that CDC work with the Council of State and Territorial Epidemiologists (CSTE) to streamline the surveillance process and to reduce the burden on both clinicians and public health departments by permitting direct laboratory reporting of positive cases.

In response to the recommendation, CDC worked with CSTE to change the Lyme disease surveillance case definition, as defined on CDC's website, to make positive diagnostic tests reportable in high-incidence states and in the District of Columbia. The revised 2022 case definition is based on findings published in CDC's MMWR, Volume 73, Number 6. The more permissive surveillance reporting criteria resulted in a significant increase in the number of reported cases in 2022 (CDC, 2024f). Over time, the revised case definition is expected to lessen the issue of underreporting in states with a high burden of illness.

Updates on DOD-Funded Research and Activities Focused on Tick-Borne Diseases

Gabriela Zollner, PhD, Armed Forces Pest Management Board, Office of the Deputy Assistant Secretary of Defense (Environmental Management and Restoration), U.S. Department of Defense

Angel Davey, PhD, Congressionally Directed Medical Research Programs, U.S. Army Medical Research and Development Command, Army Futures Command, U.S. Department of Defense

Dr. Gabriela Zollner and Dr. Angel Davey updated the audience on Department of Defense (DOD) programs that address tick-borne diseases and associated illnesses. Specifically, they provided information about the Tick-Borne Disease Research Program (TBDRP), the Deployed Warfighter Protection Program (DWFP), and Global Emerging Infections Surveillance (GEIS).

Dr. Zollner began by sharing statistics that demonstrate the significant issue of tick-borne diseases within DOD. From 2016 to 2020, there were 681 confirmed, probable, and suspected tick-borne disease cases, representing 64 percent of the DOD vector-borne disease data set for that timeframe (ODonnell, 2021). From 2010 to 2022, the four most prevalent vector-borne diseases were Lyme disease, RMSF, malaria, and dengue fever. Of

those diseases, 85 percent were confirmed, probable, and suspected cases of Lyme disease or RMSF (Stidham et al., 2024).

Next, Dr. Davey described the TBDRP, a part of DoD's Congressionally Directed Medical Research Programs (CDMRP). CDMRP funds are appropriated annually by Congress and independent of the President's budget. Established in fiscal year (FY) 2016 as a result of Lyme disease advocacy efforts, the TBDRP is designed to address research gaps in tick-borne diseases for the benefit of service members, Veterans, and the American public. The strategic priorities of the program are to: 1) support conceptually innovative early ideas that will ultimately lead to discoveries or advancements in reducing the burden of tick-borne diseases; 2) support product-driven, established research, including evaluation or validation of therapeutics and diagnostics; and 3) advance career development and grow the field of tick-borne disease researchers. The total budget for FY 2016 through FY 2023 was $48 million, and the portfolio covered prevention and pathogenesis, with a growing focus on diagnostics and treatment (CDMRP, 2024a). The budget for FY 2024 is $7 million with a focus on disease pathogenesis, diagnostics, and treatment (CDMRP, 2024a). Focus areas are adapted annually based on current gaps and need. However, a consistent area of study within pathogenesis and diagnostics is maternal-fetal transmission.

Dr. Davey displayed three pie charts to show how funding was allocated from FY 2019 through FY 2023 by research priority, disease or condition, and funding strategy (CDMRP, 2024b). During that period, 36 awards were given to study tick-borne diseases, including bacterial, viral, and parasitic infections, as well as tick-borne allergic conditions. Approximately 60 percent of the funding was allocated to study Lyme disease and associated coinfections; and half of those awards involve studies of persistent symptoms. Dr. Davey provided several examples of specific TBDRP studies (Table 1). She highlighted one that uses functional MRI and diffusion sensor imaging to show frontal lobe white matter differences in patients with post-treatment Lyme disease syndrome compared to healthy individuals. Dr. Davey added that a complete list of funding awards and opportunity announcements can be found on the CDMRP website using the "Search Awards" function.

Table 1. Tick-borne Disease Research Program (TBDRP) Products/Outcomes Under Development

Focus Area	Research Product or Outcome
Pathogenesis	Studies to elucidate mechanisms and immune responses associated with Lyme disease, post-treatment Lyme disease syndrome, babesiosis, rickettsiosis, and tick bite-induced Alpha-gal Syndrome
	Studies to assess the impact of tick-borne coinfections
Prevention	Wearable device for controlled release of tick repellants • With additional funding provided by the Deployed Warfighter Protection Program to get closer to Environmental Protection Agency product registration

	Pre-exposure prophylaxis (PrEP) for Lyme disease • Entering a Phase 3 trial with funding outside the TBDRP
	Vaccine candidates to protect against ehrlichiosis, rickettsiosis, Powassan virus, and Lyme disease
Treatment	Pre-clinical studies of optimal drug combinations to eradicate *Borrelia* persisters for more effective treatment of persistent Lyme disease
	High-throughput screening to identify chemical inhibitors of Crimean Congo hemorrhagic fever
Diagnosis	Lateral flow diagnostic assay for rickettsiosis
	Pathogen-host molecular biosignature Lyme disease assay
	Host-based and pathogen-based proteomic biosignatures for the diagnosis of Lyme disease in children

Source: CDMRP, 2024b

Dr. Zollner presented information about the DWFP, established in FY 2004. The program operates on an approximately $5 million annual budget, and its mission is to develop products that protect service members, as well as Veterans and the American public, from vector-borne diseases (Armed Forces Pest Management Board, n.d.). As of 2024, 32 percent of its active projects are focused on ticks and tick-borne diseases and associated illnesses. The four research priorities of the DWFP involve the development of: 1) public health pesticides with new active ingredients, formulations, and application methods; 2) new personal protection tools for passive bite prevention; 3) software applications to improve disease forecasting and vector management strategies; and 4) surveillance tools for improved tick collection, identification, and pathogen detection.

Next, Dr. Zollner gave updates on four specific research projects undertaken through the DWFP. The first relates to the development of a new acaricide application method to control ticks. For this project, BanfieldBio™ created electrostatically charged microparticles that attach to rodents and other small animals. These hosts then disseminate the particles as they travel in difficult-to-reach spaces, similar to the way pollen is transferred to and from flowers by bees. The particles' structure enables the release of the acaracide at a mixed rate. Therefore, ticks—both on the host and free living—can be exposed in the short, medium, and long terms, including in the next season. The microparticles are also being used in related National Institutes of Health (NIH) studies.

The second DWFP project was conducted through the Walter Reed Army Institute of Research (WRAIR) and involved the evaluation of topical repellants against ticks. A laboratory in Thailand performed forearm bioassays on 30 human volunteers to evaluate the effectiveness of picaridin (20 percent) and nootkatone (10 percent)

compared to ChiggAway (20 percent sulfur and 10 percent benzocaine) in repelling an endemic strain of the brown dog tick (*R. sanguineus*). The study revealed that the median duration of protection for picaridin and nootkatone was 7.0 hours compared to 7.5 hours for ChiggAway, considered the current gold standard. Additional repellant studies are planned against the Asian longhorned tick (*Haemaphysalis longicornis*).

In a third DWFP project, researchers at Purdue University used different assays to evaluate the efficacy of a substrate releasing the volatile chemical transfluthrin against adults and nymphs of three tick species (Murgia et al., 2021). In a contact toxicity assay, blacklegged ticks (*I. scapularis*) and lone star ticks (*A. americanum*) were exposed to the treated substrate for 10 seconds, and American dog ticks (*Dermacentor variabilis*) ticks were exposed for 3 minutes, yielding greater than 90 percent knockdown. In a short-range spatial assay, where ticks were placed in a tube with a treated substrate at one end, all species exhibited knockdown and mortality, with the blacklegged tick having the highest rates. Lastly, in a perimeter of protection assay involving the placement of blacklegged ticks in a large square arena with treated substrate around the edge, the researchers observed over 90 percent knockdown and mortality.

Dr. Zollner described a fourth DWFP project in which researchers at Columbia University developed a computer simulation model to evaluate the effectiveness of three different approaches for managing blacklegged tick (*I. scapularis*) nymphs: reductions in white-tailed deer population, broadcast-area application of Met52® (a product containing a *Metarhizium* fungus that can kill ticks and other insects), and the use of fipronil small rodent bait boxes. The model assumed low, intermediate, and high impacts on tick reductions for each management approach and evaluated each approach individually as well as in different combinations. The highest overall impact on tick populations was observed when all three treatments were combined. These computer simulations are valuable for identifying optimal deployment strategies for individual and combined tick management approaches.

Finally, Dr. Zollner described tick-focused activities conducted by GEIS, a branch in the Armed Forces Health Surveillance Division that monitors infectious diseases, including an increasing focus on tick surveillance by 11 labs in 24 countries around the world. GEIS is also expanding its capabilities to detect novel pathogens in ticks collected from its various sites internationally. For example, a lab in Turkey has been using nanopore-based metagenomic sequencing to detect Crimean-Congo hemorrhagic fever virus and Jingmen tick virus in tick specimens (Ergunay et al., 2023). In addition, several of the labs perform insecticide resistance testing on locally collected ticks. For instance, GEIS is developing a rapid visual communication tool that identifies where tick species have demonstrated resistance to permethrin, an insecticide commonly used to treat military uniforms.

Updates on NIAID-Funded Research and Activities Focused on Lyme and Other Tick-Borne Diseases

Nadine Bowden, DVM, PhD, Program Officer for Lyme Disease and Other Borrelioses, National Institute of Allergy and Infectious Diseases, National Institutes of Health

Dr. Nadine Bowden provided a summary of NIH funds distribution and described the process by which National Institute of Allergy and Infectious Diseases (NIAID) encourages research in areas of need. She concluded with updates on current NIAID activities and research.

Dr. Bowden began by explaining that NIAID receives its funding from Congress. A small percentage (10–15 percent) is used for intramural research within NIH's own laboratories, while the vast majority goes to extramural research conducted by universities and training centers. To determine how extramural research funding will be distributed each year, NIAID solicits applications for proposed research from principal investigators. Experts in the field review and score the applications. NIAID then uses those scores, along with its annual paylines, to identify which applicants will receive funding.

Dr. Bowden provided a snapshot of currently funded research topics within NIAID's Lyme disease portfolio, with some examples provided for each topic (Table 2).

Table 2. NIAID Lyme Disease Portfolio Snapshot

Pretranslational Research	Mechanisms of persistent symptoms
	Mouse model for neuroborreliosis
	Coinfections
	Microbial and host determinants of disease
	Genetic basis for infectivity
	Innate and adaptive immunity in *B. burgdorferi* infection
	How *B. burgdorferi* moves through the body
	Role of unique cell wall of *B. burgdorferi* in Lyme disease
Ecology	Role of OspC in host range
	Immune response of the white-footed mouse to tick-borne disease
	Modeling tick-borne disease infections
	Role of birds in Lyme disease
Diagnostics	Direct detection
	Rapid tests
	Advanced serology test
	Predictive biomarkers
	Urine testing
Treatment	Lyme meningitis
	Novel therapies

	Using monoclonal antibodies
Prevention	Peptide and mRNA human vaccines
	Multi-pathogen vaccines
	Anti-tick vaccines
	Peptide and heritable reservoir vaccines

Dr. Bowden explained that while the nature of each study is driven by the principal investigators, NIAID can encourage applications in specific topic areas by two means: a notice of special interest (NOSI) and a request for applications (RFA). NOSI can be published relatively quickly and can be used by NIAID to highlight areas of the VBD National Strategy where more research is needed. NOSI examples include "Advancing Research for Tickborne Diseases," issued in November 2022; and "Understanding Immune Evasion in Tickborne Diseases," issued in July 2023. RFAs are more time-intensive because they undergo multiple rounds of internal review and discussion, including approval by the NIAID Advisory Council, before they can be announced for competition. Examples of recent RFAs are "Genetic Tools for Understanding Rickettsial and Related Infections," awarded in December 2023; and "Understanding Persistent Signs and Symptoms Attributed to Post-Treatment Lyme Disease Syndrome," awarded in June–September 2023.

The second half of the presentation was devoted to updates on NIAID activities and research. Dr. Bowden described two virtual NIH meetings held in 2023 about bacterial, viral, and parasitic tick-borne diseases. The first, entitled "Understanding Immune Evasion in Tickborne Diseases," was open to the public and featured presentations from both intramural and extramural researchers. The second was a mid-award meeting for the 14 laboratories awarded grants in "Targeted Prevention for Tickborne Diseases" to hear progress about each other's ongoing research. The goal of both meetings was to foster information sharing and collaboration in the tick-borne disease field.

Dr. Bowden summarized the following seven grants awarded through the Understanding Persistent Signs and Symptoms Attributed to Post-Treatment Lyme Disease Syndrome RFA.

Determinants of Post-Treatment Phenotypes in Post-Treatment Lyme Disease Syndrome (PTLDS)
John Aucott, MD, of Johns Hopkins University is focused on how patient factors may contribute to Lyme disease outcomes after treatment with antibiotics (NIH Project Number 5R01AI178726-02). He will look at individuals in different stages of illness and—using both biorepository and new patient samples—compare their clinical presentations and immune responses to those of people that fully recover and to those with no history of the disease. The goal is to develop a clinical assessment tool to identify patients at risk for developing Post-Treatment Lyme Disease Syndrome (PTLDS), potentially leading to new treatment and prevention strategies.

Auto-Antibodies as Predictive Markers for PTLDS
Linden Hu, MD, of Tufts University is investigating the role of autoantibodies in post-treatment Lyme disease (NIH Project Number 5R01AI178725-02). *B. burgdorferi* takes phospholipids from the host's cell membrane for its own functioning. When the host's body encounters these altered phospholipids, it may no longer recognize them as "self" and can mount an immune response against them. These anti-phospholipid autoantibodies tend to appear earlier than the IgM and IgG antibodies against *B. burgdorferi* proteins, which are typically used to diagnose Lyme disease. Dr. Hu strives to determine if anti-phospholipid autoantibodies: 1) contribute to the development of PTLDS; 2) could be used as biomarkers for PTLDS; and 3) could enable earlier diagnosis of Lyme disease. He is also developing an animal model based on one used for fibromyalgia. In his model, mice are infected with serum from people with the illness to see if the mice show some of the clinical signs seen in people.

Role of Unusual Peptidoglycan Fragments in Persistent Lyme Disease
Brandon Jutras, PhD, of Northwestern University (formally of Virginia Polytechnic Institute and State University is examining how the unique qualities of the *B. burgdorferi* cell wall may drive persistent symptoms of Lyme disease (NIH Projects 7R01AI173256-02 and 7R01AI173256-02). His research has revealed the presence of a unique peptidoglycan in the *B. burgdorferi* cell wall. Dr. Jutras's work has also shown that *B. burgdorferi* recycles its cell wall less than other bacteria do, and sheds about 50 percent of its cell walls into the host. Moreover, its peptidoglycan can be found in the joint fluid of individuals with Lyme arthritis. The goals of his current research are to build on his previous findings to enhance understanding of patient illness and determine if monoclonal antibodies can be used to treat antibiotic-refractory Lyme arthritis.

Neuroimaging and Blood Markers in Patients with PTLDS With Persistent Neurologic Symptoms
Cherie Marvel, PhD, of Johns Hopkins University is using neuroimaging and blood markers as a means of determining the mechanism of neurologic symptoms observed in people with PTLDS. Her study involves imaging patient brains immediately after antibiotic treatment, six months after treatment, and 12 months after treatment to determine if changes in brain images are predictive of health outcomes. If so, Dr. Marvel seeks to correlate study findings with clinical scales and blood markers with the goal of developing a practical prognostic tool for clinical settings.

Identifying Serology Biomarkers to Predict Lyme Disease Progression and Recovery
Michal Tal, PhD, of The Massachusetts Institute of Technology seeks to identify a serology biomarker that can accurately predict patient outcomes after treatment with antibiotics (NIH Project Number 5R01AI178713-02). Her lab has developed an antibody profiling technique that maps not only a patient's IgM and IgG antibodies, but also subclasses of IgG antibodies (IgG1 and IgG2) as well as antibodies not typically evaluated in Lyme patients, specifically IgA and IgE. The goal is to determine if there is an optimal combination of antibodies for responding to infection and if certain combinations of antibody responses

are more likely to lead to the development of PTLDS. Another goal of the project is to use the antibody profiling technique to identify candidates for PTLDS clinical trials.

Genetic Basis for Persistence of *B. Burgdorferi*
Rafal Tokarz, PhD, of Columbia University Health Sciences is studying the genetics of *B. burgdorferi*, as well as the human immune response to the bacteria, to better understand the role of bacterial persistence in PTLDS. To conduct this work, Dr. Tokarz's team has developed two assays: the TBDCapSeq assay sequences *B. burgdorferi* in tissue samples; and the TBD-Serochip identifies antibodies produced in response to the bacteria. The goal of this research is to identify the parts of the bacteria (epitopes) that cause antibody production in humans and to identify triggers for spirochete persistence.

Using Machine Learning to Discover Early Immunologic Biomarkers to Predict Risk of PTLDS
Neal Woodbury, PhD, of Arizona State University is using machine learning to search for early immunologic biomarkers that could predict the risk of developing PTLDS (NIH Project Number 5R01AI178727-02). His approach examines all antibodies that circulate in humans during *B. burgdorferi* infection, not just those that occur in response to the bacteria itself. The goal is to determine if antibodies responding to both *Borrelia* and non-*Borrelia* factors contribute to PTLDS, and to predict and validate which antibodies are associated specifically with PTLDS development.

For anyone interested in learning more about NIH-supported research, both current and past studies, Dr. Bowden recommended using the search application at https://reporter.nih.gov.

National Public Health Strategy to Prevent and Control Vector-Borne Diseases in People

Leith J. States, MD, MPH, MBA, FACPM, Acting Director in the Office of Science and Medicine and Chief Medical Officer for the Office of the Assistant Secretary for Health

Dr. Leith States highlighted OASH's commitment to addressing tick-borne diseases and associated illnesses through the Tick-Borne Disease Working Group. He described the recent development of the National Public Health Strategy to Prevent and Control Vector-Borne Diseases in People and identified the federal partners involved in the process. Dr. States outlined the content of the strategy and concluded with an example of how the VBD Disease National Strategy is being implemented.

Dr. States began by explaining that, from 2017 through 2022, OASH led the Tick-Borne Disease Working Group federal advisory committee, enabling its members to develop three reports to Congress with over 70 recommendations (OASH, n.d.). The process and resulting recommendations fostered collaboration among a diverse group of interested parties and catalyzed new efforts, new laws, and new budgets for tick-borne response.

Concurrently, CDC led five participating departments and the Environmental Protection Agency (EPA) in the development of A National Public Health Framework for the Prevention and Control of Vector-Borne Diseases in Humans (NCEZID, 2020). The framework outlined strategic priorities for the federal government and laid the groundwork for the development of the 2024 VBD National Strategy, authorized by the Kay Hagan Tick Act (S.1657, 116th Congress, 2019-2020). Led by OASH and CDC, the strategy is a collaboration of 17 federal entities across multiple agencies and departments with a mission "to protect people from illness, suffering, and death due to vector-borne disease" (HHS & CDC, 2024). Dr. States emphasized that the Tick-Borne Disease Working Group recommendations informed much of the strategy and are reflected throughout its content.

The VBD National Strategy features five overarching goals (Table 3), within which there are 19 strategies, 43 objectives, and 124 sub-objectives. Dr. States noted that the strategy is designed to be adaptive to the current state of vector-borne diseases at any given time and will be updated by the HHS Secretary as appropriate. Target public health outcomes include the elimination of RMSF in Arizona tribal communities by 2025; 25 percent reduction of laboratory-confirmed Lyme disease cases by 2035 (compared to 2022); elimination of sustained local spread of dengue fever by 2035; and reduction of the annual number of West Nile virus neuroinvasive disease cases to below 500 by 2035.

Table 3. Goals of the National Public Health Strategy to Prevent and Control Vector-Borne Diseases in People

Goal 1	Better understand when, where, and how people are exposed to and get sick or die from vector-borne diseases.
Goal 2	Develop, evaluate, and improve tools, methods, and guidance to diagnose vector-borne diseases and their pathogens.
Goal 3	Develop, evaluate, and improve tools, methods, and guidance to prevent and control vector-borne diseases.
Goal 4	Develop and assess drugs and treatment strategies for vector-borne diseases.
Goal 5	Disseminate and implement public health tools, programs, and collaborations to prevent, detect, diagnose, and response to vector-borne disease threats.

Source: HHS & CDC, 2024

To conclude, Dr. States highlighted LymeX Innovation Accelerator's Diagnostics Prize as an example of how the strategy is being implemented. Since its inception in 2020, LymeX has been working to spur the development and delivery of new Lyme disease diagnostics to the market. During phases 1 and 2, LymeX awarded a total of $3 million in prize money to ten recipients with promising and innovative tools for Lyme disease diagnosis. During phase 3, five winners will move forward to the process of validation and preparation for submission to the U.S. Food and Drug Administration (FDA). Dr. States underscored the importance of

collaboration within and outside the federal government for the successful implementation of the VBD National Strategy.

Surveillance and Integrated Management of Ticks of Human Importance

Robert J. Miller, PhD, National Program Leader for Veterinary, Medical, and Urban Entomology, Agriculture Research Service, U.S. Department of Agriculture

Dr. Robert Miller described recent tick-borne disease research conducted by U.S. Department of Agriculture (USDA)'s Agriculture Research Service (ARS). Glen Scoles, PhD, and Andrew Li, PhD, of the Invasive Insect Biocontrol and Behavior Lab, currently lead Ticks and Animal Health, an ARS project that operates on a five-year cycle. Their research objectives are to 1) develop novel approaches and improve upon existing technologies for surveillance of ticks of medical importance; 2) develop novel approaches and improve upon technologies for control of ticks of medical importance; and 3) conduct fundamental research on established and invasive ticks to understand the roles of tick species in disease transmission (ARS Research Project #437417).

In 2021 and 2022, Dr. Scoles conducted a study on the use of artificial mouse nest boxes as a means of targeting mice for disease surveillance and control of ticks. Within a one-hectare wood lot, the researcher used 47 nest boxes and additional Sherman traps to test the mouse and associated tick populations for pathogens, and to determine if the use of nest boxes could enable effective administration of tick control products. Sampling over 18 months revealed that the nest boxes enabled surveillance of the entire mouse population. The study also demonstrated that ticks could be controlled by using nest boxes to administer insecticides, topical acaricides, and bait products containing systemic acaricides, antibiotics, and vaccines. Dr. Miller highlighted that targeting mice for control blocks both acquisition and transmission, reducing the capacity of mice to serve as reservoirs for zoonotic pathogens.

Virtual Poll 1

During the break, meeting participants were provided with a scannable QR code through which they could respond to a poll question.

Question

What themes would you like to see covered in our upcoming community engagement sessions? (Select up to three)

Results

A total of 61 participants voted as follows.

Topic	Number of Votes
Emerging treatments	28
Diagnostics	27
Tick-borne diseases and mental health	26

Clinician education	21
Impact of climate change on tick-borne diseases	19
Tick-borne diseases and pregnancy	13
Citizen science and community surveillance models*	12
Equity and high-risk groups	12
Vaccines	11
Tick-borne diseases in children	9
Patient education	7

*Tied votes are listed in alphabetical order.

State Efforts to Prevent and Control Tick-Borne Diseases and Associated Illnesses

Epidemiology and Prevention of Tick-Borne Diseases in California

Anne M. Kjemtrup, DVM, MPVM, PhD, Infectious Diseases Branch, Vector-Borne Disease Section, California Department of Public Health (CDPH)

Dr. Anne Kjemtrup discussed the epidemiology of tick-borne diseases in California and the multi-pronged approach to prevention, based on data, science, and collaboration. She explained that California has at least nine endemic tick-borne diseases. The well-established infections are Lyme disease, tick-borne relapsing fever, anaplasmosis, babesiosis, Colorado tick fever, and tularemia. Other diseases are emerging or re-emerging: hard tick relapsing fever, RMSF, and spotted fever group Rickettsia 364D.

Over the past decade in California, Lyme disease has been the most reported tick-borne disease, followed by anaplasmosis, tick-borne relapsing fever, and babesiosis. Dr. Kjemtrup underscored that understanding where and how people are getting infected within the state is key to the development of public and clinician messaging. Certain diseases, such as tick-borne relapsing fever, tularemia, and Pacific Coast tick fever, are highly endemic to California, with most cases acquired locally. Other diseases like anaplasmosis, babesiosis, and RMSF often involve travel, with a significant portion of cases linked to exposure outside of the state. Of note, 64 percent of Lyme disease cases have no travel history while approximately one-third of cases are acquired through travel out of state. This distinction between local and travel-related infections guides California's public health messaging, which emphasizes both in-state prevention and travel-related risk awareness for the general population and healthcare providers.

Dr. Kjemtrup explained that there are over 50 species of ticks in California. However, only seven are known to bite people: five hard (Ixodid) and two soft (Argasid) tick species. Among hard tick species, the American dog tick (*D. variabilis*) and the brown dog tick (*R. sanguineus*) are distributed throughout California, whereas the Pacific Coast tick (*Dermacentor occidentalis*) and the western blacklegged tick (*Ixodes pacificus*) are

distributed primarily in the coastal and foothill regions of the state. Hard tick species tend to be found on or along trails, and soft tick species (*Ornithodorus hermsi* and *Ornithodorus parkeri*) occur in rodent nests and closer to human habitation at elevations above 3000 feet. For example, they could be found in a rodent nest in a tree or in a cabin wall. The California Department of Public Health (CDPH) has published on its website a Guide to Ticks and Diseases They Transmit in California to help clinicians and the public identify which ticks they may have been exposed to in different parts of state and what diseases they may carry.

Dr. Kjemtrup highlighted several ongoing surveillance projects taking place within the state. Surveilling and testing western blacklegged ticks for *B. burgdorferi* has enabled CDPH to create a county-level Lyme Disease incidence map. The highest risk for local transmission of Lyme disease is in the northwest coastal regions and western Sierra Nevada slopes. There are about six reported cases per year of anaplasmosis, also transmitted by the Western Black-legged tick and often linked to travel to the eastern United States or Midwest. Local transmission tends to occur in northern coastal counties like Marin and Sonoma. RMSF is emerging as a significant concern, particularly in Southern California and among travelers to and from Mexico, with several recent fatalities. Pacific Coast tick fever, unique to California, is less severe but widespread, with most cases confirmed in northern coastal counties. Soft tick relapsing fever, associated with rodent nests in high mountain cabins, also poses a risk, with 4-16 cases reported annually.

CDPH places a strong focus on prevention and outreach activities, directed at both the public and healthcare providers. California's Lyme Disease Advisory Committee, legislatively established in 2000, is among the first of its kind, bringing together experts from various sectors, including public health departments, the California Medical Association, local vector control agencies, and academia. The committee's mission is to advise CDPH on strategies to increase awareness about Lyme disease and other tick-borne diseases. This collaboration has enabled the development of outreach materials tailored to diverse audiences, including local vector control agencies, healthcare providers, and the public.

Recognizing that preventing bites is the most effective method of disease prevention, CDPH has shifted its focus from disease-specific brochures to broader tick bite prevention strategies. Key resources include the widely used tick identification cards and toolkits for both the public and healthcare providers, particularly regarding emerging concerns like RMSF. These materials are disseminated through multiple channels, including web pages, social media, newsletters, and print, with messaging strategically timed to coincide with peak tick activity and relevant awareness events, such as Lyme Disease Awareness Month in May. In addition, biologists who conduct statewide tick surveillance distribute educational materials as they encounter the public, ensuring that the most at-risk populations are informed and protected.

Great Arizona Tick Check, Rocky Mountain Spotted Fever Surveillance and Prevention

Kathleen Walker, PhD, Medical Entomologist, The University of Arizona
Irena Ruberto, PhD, MPH, Program Manager, Vector-Borne and Zoonotic Diseases and Mycotic Diseases, Arizona Department of Health Services

Dr. Walker gave a presentation about the incidence and surveillance of RMSF and the brown dog tick (*R. sanguineus)* in Arizona. She also discussed other tick vectors in the state and concluded with information about the Great Arizona Tick Check.

Dr. Walker began by highlighting the unique tick-borne disease challenges facing Arizona, particularly the issue of RMSF. The geography of Arizona is complex, and most of the population is concentrated in urban areas. However, there are many remote rural populations, including Tribal communities, that have high risk of tick exposure, fewer opportunities for public health outreach, and limited access to prompt medical care.

The brown dog tick is the primary vector of RMSF in Arizona and is found throughout the state, thriving in a hot, dry climate. This tick's close association with domestic dogs enables infestations in and around homes. Free-roaming dogs in Tribal communities and areas near the Mexico border increase people's risk of exposure to these RMSF tick vectors. Children are especially vulnerable. Arizona's first reported human case was a healthy child who, in 2002, became dramatically sick and died within the span of one week. This case brought significant attention to the illness and recognition that many other people had likely contracted the infection without ever having been diagnosed. During the next two decades (2003–2023), Arizona saw 570 RMSF cases, with a 5 percent case fatality rate in six Arizona Tribes. On the Mexico border, there have been thousands of cases with a case fatality rate of up to 30 percent.

Dr. Walker emphasized that the clear path for surveillance and prevention of RMSF lies with monitoring and treating Arizona's dog population. Instead of testing for infected ticks, the state's approach is to monitor dog seroprevalence. Within a given community, if more 10 percent of the dogs show signs of current or past infection, the human population is at increased risk. In some Arizona Tribal communities, as many as 50 percent of the dogs have shown signs of a previous infection.

With leadership from the Tribes, the state employs two prevention programs to address RMSF risk: the RMSF Rodeo and mobile rabies/tick clinics. The RMSF Rodeo is a biannual (spring and fall) campaign involving house visits, during which the outreach team provides education, sprays insecticide around the perimeter of the houses, checks dogs for ticks, and applies canine tick prevention products. The mobile rabies/tick clinics involve similar activities but enable 1) greater reach into more remote villages, and 2) cost savings by addressing two public health risks (rabies and RMSF) simultaneously.

Through public outreach, dog testing, clinician education, and case reporting, Arizona has been able to lower its annual case fatality rate to zero since 2020. Dr. Walker attributed this success to partnerships and collaboration between the Arizona Department of Health Services and many interested parties. These include Tribal leaders and members, Indian Health Services, CDC, academic institutions, healthcare providers, local health departments, community health representatives, animal control and environmental officers, and veterinary providers.

Beyond RMSF and the brown dog tick, Arizona has other tick species capable of transmitting human disease. A recent discovery in Arizona is the Gulf Coast tick (*Ambyomma maculatum*), which is known to transmit *Rickettsia parkeri*, a spotted fever disease that is less serious than RMSF. The first case was reported in 2014 in Arizona. Dr. Walker explained that it is unclear if this tick is invasive or endemic but previously undiscovered. Western blacklegged ticks (*I. pacificus*), which cause Lyme disease, also occur in Arizona (Olson et al., 1992); however, there are no confirmed cases. The Rocky Mountain wood tick (*Dermacentor andersoni*), a vector of RMSF, Colorado tick fever, and tularemia, has been found through citizen science efforts as far south as Tucson. Finally, the soft tick (*Ornithodoros* spp.) can transmit tick-borne relapsing fever and is associated with rodent nests, sometimes in rural cabins.

The state of Arizona employs citizen science as means for both data collection and public education. The "Great Arizona Tick Check" is a cooperation between the University of Arizona (UA) Cooperative Extension and Arizona Department of Health Services. A four-year project (2023–2027), the Tick Check aims to generate community awareness and fill knowledge gaps about tick distribution and pathogens across the state, particularly in rural areas where ticks are abundant and researchers scarce. Ticks collected by the UA team, county and tribal health departments, county animal shelters, and citizens scientists can be sent to the university for testing. The resulting data will be used to create accurate, dynamic county-level maps to track tick movements and detect tick-borne diseases proactively rather than relying on human illness cases. Future plans involve press releases to encourage public involvement, increased efforts to collect ticks from non-domestic wildlife, and enhanced pathogen testing. Dr. Walker highlighted that this research is crucial for understanding tick distribution, movement, and risk to human health.

Virtual Poll 2

During the lunch break, meeting participants were provided a scannable QR code through which they could respond to a poll question.

Question

What do you think are the most pressing needs for people with tick-borne diseases and/or associated illnesses? (Select up to three)

Results

A total of 67 participants voted as follows.

Topic	Number of Votes
Access to care	42
Clinician education	33
Improved diagnostics	30
Improved treatment for viruses and persistent symptoms	27
Tick control and tick bite prevention	19
Nervous system and psychiatric studies	13
Patient education	10
Effects on pregnancy	7
Disease and tick surveillance*	5
Disease pathogenesis studies	5
Food labeling for Alpha-gal Syndrome (AGS) sufferers	5
Basic biology and ecology studies	3
Vaccines	3

*Tied votes are listed in alphabetical order.

Public Comments

The meeting featured five public commenters, who described their experiences with tick-borne diseases and associated illnesses and conditions, and advocated for issues of importance to the patient community.

Jennifer Platt

Jennifer Platt explained that she is co-founder of Tick-Borne Conditions United through which she advocates for awareness of tick-borne diseases and conditions prevalent in the southern United States and better treatment for patients. She expressed gratitude that CDC now includes AGS in its public outreach. Jennifer Platt underscored the importance of word choice to ensure inclusion of underrepresented populations. Specifically, she pointed out that the expression "Lyme disease and coinfections" promotes the assumption during diagnosis that Lyme disease is always present. However, because infections such as ehrlichiosis and rickettsioses can occur in the absence of Lyme disease, especially in southern states, they are often underdiagnosed. Jennifer Platt encouraged replacing the phrase "infection-associated chronic illness" with "infection-associated chronic conditions" to ensure inclusion of individuals with AGS. She also asked for increased attention and awareness of the lone star tick (*A. americanum*).

Lorrie Yeschik

Lorrie Yeschik of Minnesota described herself as a Lyme disease patient who has had several different infections and coinfections over a 20-year span and who now suffers from severe Lyme arthritis. She explained that her initial tick bite resulted in a bull's-eye rash for which she received the recommended treatment of oral antibiotics. All of her test results have come back negative except for a recent blood culture that produced positive results for multiple infections. Lorrie Yeschik underscored the lack of awareness among today's clinicians, noting that she has even encountered practitioners who deny the existence of Lyme disease. She outlined the many treatments she has received, including intravenous

antibiotics, adding that her ordeal has caused permanent long-term damage. She highlighted the expense of treatments and the lack of insurance coverage as a major obstacle to receiving care.

Dorothy Leland

Dorothy Leland commented that she is president of LymeDisease.org and lives in California. She explained that 19 years ago, her daughter was misdiagnosed because clinicians in California denied the existence of Lyme disease in the state. As a result, her daughter faced significant delays in receiving the correct diagnosis. Dorothy Leland stated misdiagnosis and underdiagnosis of Lyme disease persist in California and numerous states throughout the South and West because the disease is labeled "low incidence." She noted that the issue is compounded because reporting cases in these states demands more time and effort from clinicians than in states designated "high incidence," where the process is streamlined. She emphasized that California is a large ecologically diverse state, yet its case counts are grouped together, resulting in an oversimplification of the tick and tick-borne disease landscape. Dorothy Leland called attention to the high number of canine Lyme disease cases in the state compared to the low number of human cases. She called for an improved surveillance system that better reflects the reality of tick-borne diseases in California.

Phyllis Bedford

Phyllis Bedford stated that she is the executive director and co-founder of LymeLight Foundation, dedicated to providing treatment grants to children and young adults through age 25. The focus of her comment was congenital Lyme disease. She explained that, based on three years of recipient applications that matched the clinical profile of congenital Lyme disease, an estimated 50 percent of her organization's grant recipients (about 700 children) were likely born with Lyme disease. Phyllis Bedford stated that, unlike other congenital infections such as West Nile virus, Zika virus, or Chagas disease, Lyme disease lacks specific diagnostic and treatment guidelines for pregnancy. She added that most healthcare professionals are unaware of congenital Lyme disease, resulting in delayed diagnosis and treatment. She highlighted the detrimental effects and health complications of children with congenital Lyme disease and urged the development of evidence-based clinical guidelines to diagnose, treat, and monitor pregnant people with Lyme disease and their babies who risk exposure.

Betty Gordon

Betty Gordon commented that she and her late husband, Jack Gordon, never saw evidence of ticks or tick bites; yet they both contracted Lyme disease, which went undiagnosed for more than three decades. She explained that her husband's diagnosis came only after a brain autopsy, which revealed Lewy body dementia as well as the presence of *Bartonella* bacteria and parasitic nematodes containing *B. burgdorferi*, the causative agent of Lyme disease. Betty Gordon described the many institutions and researchers that have studied her husband's brain over the past nine years, noting that she expects a case study to be published later this year. She urged further study of the parasites and pathogens within ticks and highlighted the associated risks.

Panel Discussion of Questions Pre-Submitted by the Public

Moderator: B. Kaye Hayes, MPA (OIDP)

Panelists: C. Ben Beard, PhD, MS (CDC); COL Michelle Colacicco-Mayhugh, PhD, PMP (DOD); Samuel Perdue, PhD (NIH); Leith J. States, MD, MPH, MBA, FACPM (OASH); Robert J. Miller, PhD (USDA)

During the panel discussion, moderator Kaye Hayes asked panelists questions solicited from the public before the meeting. The goal of the session was to provide an opportunity for all interested parties to hear directly from federal agencies about topics of special concern to the public.

Efforts to Address Tick-Borne Disease Working Group Recommendations

Questions

Many of the Tick-Borne Disease Working Group recommendations to Congress have been grouped under the goals, strategies, and objectives of VBD National Strategy. Can you provide examples of how the VBD National Strategy addresses specific Tick-Borne Disease Working Group recommendations? What are the recommendations, and how are they being addressed through the strategy?

Response

Dr. Ben Beard explained that during the development of the VBD National Strategy, CDC worked with OASH to align the strategy's goals and objectives with the Working Group's recommendations. He demonstrated the alignment, which has served as the road map for the VBD National Strategy, with the following example:

VBD National Strategy

- Goal 2: Develop, evaluate, and improve tools and guidance for the diagnosis and detection of vector-borne diseases.
- Strategic Priority 1: Identify and characterize novel VBD pathogens and their clinical manifestations.

Working Group Reports to Congress

- Recommendation 3.2 (2018): Fund systematic studies and activities to identify and characterize novel tick-borne disease agents in the United States.
- Recommendation 4.3 (2020): 2020 Working Group Recommendation 4.3 Establish and fund research for sensitive and specific diagnostic tests for the broader range of tick-borne diseases, including tick-borne relapsing fever, Powassan virus, and other emerging tick-borne pathogens. Encourage development of these tests as in vitro diagnostics approved by FDA.

Dr. Beard noted that the alignment, or "cross walk," is documented in a request for information published on the Federal Register.

Funding

Questions

According to the VBD National Strategy, approximately 90 percent of reported vector-borne diseases are tick-borne. Yet within the federal government and throughout the country, tick-borne diseases are grouped into the broad category of vector-borne diseases. Mosquito-borne diseases, like Zika virus and dengue fever, tend to cause emergent outbreaks that receive a lot of press and funding. Can you provide some examples of how the funding structure works for tick-borne diseases? For example, within the federal government, is tick-borne disease funding protected, proportional, and continuous over the long term? How can the public be sure that tick-borne diseases resources are not diverted to other vector-borne diseases?

Response(s)

Dr. Sam Perdue described how NIH funding for tick-borne disease research works, noting that the funding process is dynamic, dependent largely on what is submitted for review, and so funding levels can vary annually. Most funding is for investigator-initiated research, as described by Dr. Nadine Bowden earlier in the meeting. NIH has a limited amount of money each year that is applied to targeted research. Approximately 240 program officers managing different pathogen portfolios compete for those funds. Some years, additional "end-of-year" funding may be available for specific priorities. When such funding is available, NIAID considers tick-borne diseases to be a priority topic, particularly Lyme disease. However, sometimes extra funding is associated with a Congressional appropriation, which dictates how it must be used. Dr. Perdue noted that Lyme disease funding has doubled since 2017, but the exact amount fluctuates from year to year.

Because Dr. Davey had described funding for DOD's congressionally directed programs earlier in the meeting, COL Michelle Colacicco-Mayhugh focused her response on DOD's funding structure for non-congressionally directed programs. She explained that DOD takes a global approach to disease research funding, focusing on the health threats that pose the highest risk to service members worldwide. Within its funding programs, DOD further prioritizes research based on specific focus areas. For example, the DWFP, led by Dr. Gabriela Zollner, is narrowly focused on vector-borne disease prevention, including the development of practical tools such as repellents, risk assessments, and decision-making tools that can protect service members from a wide range of diseases. The DWFP excludes areas like diagnostics, vaccines, and therapeutics.

COL Colacicco-Mayhugh explained that for tick-borne diseases, DOD seeks opportunities to fund research that not only addresses the specific threat of ticks but also has broader applications. For instance, a repellent effective against multiple vectors like ticks, sandflies, and mosquitoes is considered a better investment than one that targets only a single type of vector. DOD often guides principal investigators to broaden their research proposals to include solutions that address multiple threats, including tick-borne

diseases. This strategic approach ensures that investments have the widest possible impact in protecting service members from diverse disease threats.

In a third response to the question, Dr. Ben Beard described CDC's funding structure. The agency receives annual appropriations through three budget lines, each with a clear purpose: 1) vector-borne diseases; 2) Lyme disease and related tick-borne illnesses; and 3) parasitic diseases and malaria. The third category includes babesiosis. The funding allocated for Lyme disease and related tick-borne diseases never falls below the appropriated level and generally remains stable or increases over time. All funds from the Lyme disease line are dedicated exclusively to Lyme disease and tick-borne diseases, while the vector-borne disease line is used more broadly to support all vector-borne diseases, including Lyme disease and RMSF.

Dr. Beard explained that in addition to these regular appropriations, CDC also receives specific directives from the appropriations committee through committee language. This language specifies which activities CDC should undertake, ultimately influencing how the budget is allocated and prioritized.

Apart from regular funding, CDC sometimes receives emergency funds, which are substantial one-time allocations typically received in response to specific outbreaks. For instance, during the Zika outbreak, CDC received nearly $400 million, which was used to establish the Centers of Excellence programs. Dr. Beard noted that while emergency funds are crucial for addressing immediate health crises, they can create the impression that resources are directed toward current outbreaks at the expense of ongoing priorities. However, diversion of funds away from a congressionally appropriated priority would be a violation the Antideficiency Act. In that way, funding for Lyme disease and other tick-borne illnesses is protected.

One Health

Question

Can you provide examples of recent interdisciplinary efforts that have yielded positive outcomes for addressing tick-borne diseases?

Response

COL Colacicco-Mayhugh underscored that DOD strongly embraces the One Health approach for infectious disease research, emphasizing interdisciplinary collaboration to address health threats that impact both military and global populations. An example is the establishment of a One Health branch at the WRAIR in Maryland. While this initiative is in the early stages, COL Colacicco-Mayhugh explained that the Military Tick Identification Infection Confirmation Kit (MilTICK) program is a long-standing program that highlights the success of the One Health approach within DOD. Established in 1995 under a different name (DoD Human Tick Test Kit Program) and administered by the Defense Centers for Public Health in Aberdeen, Maryland, MilTICK allows military hospitals, service members,

and their families to submit ticks for analysis. Once submitted, the ticks are identified by species and tested for pathogens. The program processes 2,000 to 3,000 ticks annually and has tested over 60,000 ticks to date. COL Colacicco-Mayhugh highlighted that MilTICK is highly valuable because it not only aids in the diagnosis and treatment of tick-borne diseases but also provides critical information for assessing the risk of these diseases for military personnel and their families living near military installations.

Vaccines

Question

Can you provide a status update on vaccines currently in development?

Response

Dr. Perdue stated that early-stage vaccine research is under way for all tick-borne diseases in the NIH portfolio. In his opinion, a vaccine for Lyme disease, which currently receives the most NIH funding and is farthest along in the development process, is the one most likely to be accepted by market investors in isolation because it has the largest demand. Other vaccine candidates would likely need to be multi-pathogen or tick-focused to receive market investment, but understanding the requirements for immune protection in each disease is critical to that step, so research on pathogen-specific vaccines remains valuable.

Regarding Lyme disease, Dr. Perdue explained that a Pfizer-Valneva vaccine is in clinical trials, and Moderna has announced the initiation of a Phase 1 trial for an mRNA vaccine targeting *B. burgdorferi* outer surface protein A (OspA). The focus on OspA is favored by many researchers because it has been shown to be effective in human trials and is the only one that was used in the first marketed Lyme disease vaccine for humans.

Human vaccine research also includes:

- **Intranasal Vaccines:** Early-stage research is underway on an OspA-based intranasal vaccine.
- **Chimeratope Vaccine:** This vaccine, initially developed for canines with proven effectiveness, is being modified for human use. It incorporates multiple antigens to offer broad protection. Additionally, it includes antigens for *Anaplasma*, a pathogen spread by the same tick that transmits Lyme disease.
- **Peptide Vaccines:** New formulations of peptide vaccines are being explored.
- **Rabies Virus-Vectored Vaccine:** Researchers are investigating the use of the rabies vaccine to induce immunity against *B. burgdoferi*.

Dr. Perdue outlined other types of vaccine research:

- **Anti-Tick Vaccines:** Researchers are developing vaccines that target tick salivary proteins, preventing ticks from successfully feeding and transmitting diseases.

- **Mouse Vaccine:** Currently in field trials, a mouse vaccine is in development to reduce the transmission of Lyme disease to humans by vaccinating white-footed mice in the wild. This bait-based vaccine could be deployed in areas frequented by both people and mice, providing a dual approach to disease prevention by vaccinating both the potential human hosts and the tick carriers.

Lastly, Dr. Perdue described research related to the use of monoclonal antibodies for pre-exposure prophylaxis. If effective, a single large dose at the beginning of the tick season could offer protection for the entire year.

Question

Do you feel that a vaccine gives the public a false sense of security and will reduce the public's engagement of preventative measures?

Response

Dr. Perdue noted that behavioral studies are needed to truly gauge what the public may do. He expressed his opinion that if someone is concerned enough to get a vaccine, they are perhaps also likely to take other precautions, such as applying repellants.

Public/Patient Empowerment

Questions

What can the public do to advance the Tick-Borne Disease Working Group's recommendations to Congress? Who can the public be in communication with to help the government create better practices and policies related to tick-borne diseases and associated illnesses?

Response

Dr. Leith States emphasized the importance of effective and continuous communication between the public, advocacy groups, and government officials to create better policies. He gave several insights and suggestions for initiating and maintaining this type of communication.

- Constructive engagement: Advocacy groups should not hesitate to provide constructive and honest feedback to government representatives. This approach is crucial for achieving a shared vision and avoiding adversarial positions that impede progress.
- Persistent advocacy: Continuous engagement with government officials, including Congress members and executive agencies, is essential. Although immediate results may not be apparent, these efforts contribute to shaping the conversation and can have incremental benefits.
- Unified messaging: The success of advocacy efforts is significantly enhanced when groups coordinate and present a unified message.

- Learning from past successes: Drawing lessons from successful coordination and collaboration in other advocacy efforts can help improve the timeliness and cost-effectiveness of current and future activities intended to enhance government practices and policies.

Treatment

Questions

The focus within the federal government on better testing and prevention is important. But what about the people who are already sick? What efforts are being made to help patients who are chronically ill and currently suffering today?

Response

Dr. Perdue agreed with Dr. State's commentary on the importance of coordinated advocacy efforts. He explained that some important research projects are taking place now thanks to the consistent work of patient advocates.

Regarding efforts to help people who are chronically ill, Dr. Perdue expressed his understanding of the intense frustration people feel with the lack of tangible progress in treatment options. He explained that as a research agency, NIH is focused on conducting research to better understand disease mechanisms and collect the data needed to develop new and enhanced treatment protocols. He acknowledged that the pace of discovery is slow; however, the agency continually strives to maximize available funding to help patients who are currently suffering.

Alpha-gal Syndrome (AGS)

Questions

Are studies being funded by the government to better understand AGS and how to help people who suffer from it? If yes, what is the nature of these studies?

Responses

Dr. Perdue described several studies related to the causes, consequences, and epidemiology of AGS. Studies include confirming the lone star tick bite as the cause of AGS. In addition, the group that first discovered AGS is investigating risk factors for development of the condition; they are also working to better understand where AGS occurs and how widespread it is. Research is also being conducted on the immunological and cardiovascular effects of AGS, as well as the variations in clinical presentation.

COL Colacicco-Mayhugh explained that through DOD's Tick-Borne Disease Research Program, funding was provided to the Uniformed Services University of the Health Sciences to study prevalence of Alpha-gal antibodies in a sample of 3,000 military recruits representing all U.S. states and territories. The investigation showed that 6 percent of the

recruits tested positive for Alpha-gal IgE, with the highest frequency of those results coming from states with lone star tick distribution, notably Arkansas, Oklahoma, and Missouri. This data enabled DOD to tailor and enhance its messaging to medical providers about tick bite prevention.

Question

Are there plans to make AGS a nationally notifiable illness, so that it can be tracked?

Response

Dr. Beard clarified that CDC does not control which diseases or conditions are nationally notifiable; rather, this designation is made by the CSTE. Along with experts from state health departments, CDC works with CSTE to identify which data should be collected for nationally notifiable diseases and determine how to collect the data in case report forms. Individual jurisdictions, such as states with a high incidence of AGS, can make a disease or condition reportable. However, nationally notifiable disease status is challenging to establish because it requires state, territorial, and local health departments to commit resources for case reporting. Should CSTE pursue this path, CDC is ready to support enhanced surveillance for AGS within jurisdictions or at the national level.

Research

Question

What investments are currently being made for pathogenesis studies?

Response

Dr. Perdue commented that NIH has a strong focus on basic sciences, including pathogenesis. For the tick-borne disease portfolio, most researchers investigate fundamental aspects such as virulence, immune evasion, host immune responses, chemotaxis and motility (i.e., how the pathogens move through the body and from tissue to tissue), genetic predisposition to disease, and gene regulation. NIH also supports research on specific issues such as neuroborreliosis, Lyme arthritis, congenital Lyme disease, and coinfections. These fundamental studies are considered pre-translational research with the goal of informing translational research and ultimately results to clinical care.

Long COVID and Persistent Symptoms of Lyme Disease and Other Tick-Borne Diseases

Question

As of now, has there been any concrete cross-over between Long COVID research and studies of persistent symptoms associated with Lyme disease?

Response

Dr. Perdue responded that he is unaware of any studies that have revealed common causes shared between Long COVID and persistent symptoms of Lyme disease. He added that Long COVID is important to the field of Lyme disease because it has brought significant attention to the issue of persistent symptoms after a primary infection. The pandemic solidified and advanced the scientific discipline of persistent illness and post-infectious sequelae.

Health Equity

Question

How are people of color represented in Lyme disease CDC surveillance statistics?

Response

Dr. Beard explained that routine surveillance for Lyme disease includes the collection of race and ethnicity data. State health departments report these data, which CDC then aggregates and posts on its website in the form of interactive graphs, tables, and maps. He added that demographic data for Lyme disease are also published periodically in the MMWR. In addition, given the challenges of recognizing the variable appearance of erythema migrans (EM) rashes, particularly on darker skin tones, CDC features descriptions and photos of different EM rashes on its website and includes related diagnostic content in its clinical training modules for Lyme disease.

Question

Please highlight any initiatives, programs, and/or research that specifically address tick-borne diseases in (1) underserved populations and (2) rural populations.

Response

Dr. Beard highlighted collaborations between CDC's Division of Vector-Borne Diseases (DVBD) and two organizations that work to address the unique needs of migratory and seasonal farm workers, who are at higher risk of tick-borne diseases due to their outdoor work during periods when ticks, like the black-legged tick, are most active.

- **Collaboration with the National Center for Farmworker Health (NCFH):** A survey is currently being conducted in New Jersey, where in-depth interviews of farm workers are taking place to identify knowledge gaps regarding tick-borne diseases. Following this research phase, CDC and NCFH plan to develop and disseminate targeted educational materials, which will be tailored to various audiences, including outdoor workers, employers, and community health workers, to enhance awareness and preventive measures against tick-borne diseases.
- **Partnership with Yale University and the Connecticut River Valley Farm Worker Health Program:** In a similar collaboration with Yale School of Public Health and the Connecticut River Valley Farm Worker Health Program, CDC is developing

educational materials for migratory farm workers to improve their knowledge of tick bites and Lyme disease and reduce their risk of infection.

Prevention Products

Question

Has any progress been made to make nootkatone publicly available as a repellant?

Response

COL Colacicco-Mayhugh responded that DOD is interested in nootkatone as a potential repellent and is conducting research to determine its viability and effectiveness for broader use in protecting deployed personnel. The DWFP is currently funding a study in Thailand at the WRAIR, Armed Forces Research Institute of Medical Sciences. Elaborating on the information provided during her earlier presentation, COL Colacicco-Mayhugh explained that the study is focused on comparing the effectiveness of the following repellents against the brown dog tick (*R. sanguineus)*: picaridin (20 percent), a widely used insect repellent known for its effectiveness and low toxicity; nootkatone (10 percent), a natural compound found in grapefruit that has shown promise as a repellent; and ChiggAway (20 percent sulfur, 10 percent benzocaine), traditionally used for chigger bites but being evaluated for broader use. The initial series of studies against the brown dog tick has been completed, and there are plans to extend the research to include the Asian longhorned tick (*H. longicornis*). The results of these studies, particularly how nootkatone performs in comparison to other products, will be used to inform the DOD's recommendations on repellents.

Tick and Tick-Borne Disease Incidence

Questions

Ticks and tick-borne diseases are spreading into states that have not previously acknowledged issues with tick-borne diseases and that do not have active surveillance programs to capture new and evolving data.

- What is being done within the federal government to ensure emerging ticks and tick-borne diseases are acknowledged and surveilled in all states where they occur?
- What can people living in those states do to get increasing numbers of ticks and tick-borne disease infections recognized by their state and local governments?
- Given the spread of ticks and tick-borne diseases, why do we still use such terminology as “high-incidence” and “low-incidence” states?

Response

Dr. Beard expressed understanding about the lack of recognition and testing of Lyme disease, especially in states considered low incidence or where the primary vectors, the blacklegged tick and western blacklegged tick, are not commonly found. He underscored that tick populations and disease risk are changing and expanding due to evolving

environmental conditions, including climate change, which has created a dynamic situation in many states. Some physicians may rely on outdated maps or information, leading them to dismiss Lyme disease as a possibility and not test for it. CDC is working closely with state health departments and clinical providers to raise awareness about these changing risks. CDC also encourages patients to inform their healthcare providers about the presence of competent tick vectors in their area, even if Lyme disease is not yet commonly reported. Up-to-date information about where ticks are currently found, including areas where ticks are infected, can be found on CDC's website, as part of the National Tick Surveillance Program. Patients should also inform their providers about any potential travel exposure.

Regarding terminology, Dr. Beard explained that CDC continues to use "high-incidence" and "low-incidence" designations for states based on the prevalence of Lyme disease. While tick-borne diseases are reported in all 50 states, most Lyme disease cases (about 95 percent) are concentrated in 15 states. This terminology helps differentiate areas with established high-risk tick populations from those with lower risk. These designations are updated as the risk landscape changes. Dr. Beard added that the terminology is useful for providing clinical context for testing. For example, false positive tests may be more likely to occur in areas where Lyme disease is rare; on the other hand, a positive test result in a high-incidence area is more likely to reflect a true infection. This distinction underscores the importance of clinical suspicion and the utility of diagnostic tools based on regional risk.

Dr. Beard also highlighted CDC resources for tick prevention, which include tips on how to "tick-proof" yards and protect people, pets, and properties from ticks, as well as general guidance on avoiding bites from infected vectors. He emphasized the "Fight the Bite" campaign as a key resource for public education on these issues.

Question

Are tools being used that could identify ticks and pathogens simultaneously?

Response

COL Colacicco-Mayhugh responded that DOD's MilTICK program enables military personnel, their families, and hospitals on military installations to submit ticks for identification and testing. The program bypasses the need to decide whether to test a patient based on their location. Once a tick is submitted, the MilTICK program simultaneously identifies the tick species and any pathogens present, and provides an electronic report detailing the risks associated with the tick bite. For example, a patient hospitalized in Kentucky in 2023 submitted a tick to MilTICK for testing. The program's results were returned faster than the hospital's lab tests and confirmed the presence of *Ehrlichia* (the cause of ehrlichiosis). MilTICK testing enabled a quicker diagnosis and treatment, ultimately leading to a better outcome for the service member.

Concluding Remarks and Adjournment

James Berger, MS, MT(ASCP), SBB (OIDP)

What did we hear today?

Mr. Berger described the day's event, which included an address from Assistant Secretary Admiral Levine, along with comments from concerned patients and advocates. The meeting featured presentations about how the states of California and Arizona prevent, track, and address tick-borne diseases. In addition, several federal agencies gave report-outs on current funding, programs, and activities related to tick-borne diseases and associated illnesses, including information about the Vector-Borne Disease Strategy and federal agency implementation of the Tick-Borne Disease Working Group's recommendations to Congress. A Q&A session allowed attendees to hear a panel discussion of questions submitted by the public prior to the meeting. Throughout the meeting, presenters and panelists highlighted the importance of community engagement, advocacy, and collective effort to tackle these health challenges.

What's next?

Moving forward, a recording and meeting summary will be posted on the new website for this initiative. Also posted on the website will be information about upcoming community engagement sessions. A second in-person meeting is scheduled for June 2025 in Portland, Maine, with additional virtual sessions planned throughout the next year (2024–2025) based on feedback from polls conducted during this meeting. Mr. Berger emphasized the importance of continued public advocacy and engagement to drive progress, encouraging attendees to keep making their voices heard. In the meantime, federal agencies will continue to incorporate public input in the implementation of the Vector-Borne Disease Strategy to minimize the threat of tick-borne diseases and associated illnesses.

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