



**2017-2018
BOARD OF DIRECTORS**

President

Paul G. Auwaerter, MD, MBA, FIDSA
JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE
BALTIMORE, MD

President-Elect

Cynthia L. Sears, MD, FIDSA
JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE
BALTIMORE, MD

Vice President

Thomas M. File, Jr., MD, MSc, FIDSA
SUMMA HEALTH
AKRON, OH

Secretary

Larry K. Pickering, MD, FIDSA
EMORY UNIVERSITY SCHOOL OF MEDICINE
ATLANTA, GA

Treasurer

Helen W. Boucher, MD, FIDSA
TUFTS MEDICAL CENTER
BOSTON, MA

Immediate Past President

William G. Powderly, MD, FIDSA
WASHINGTON UNIVERSITY SCHOOL OF MEDICINE
ST. LOUIS, MO

Angela M. Caliendo, MD, PhD, FIDSA
BROWN UNIVERSITY/RHODE ISLAND HOSPITAL
PROVIDENCE, RI

Henry F. Chambers, MD, FIDSA
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
SAN FRANCISCO, CA

Victoria J. Fraser, MD, FIDSA
WASHINGTON UNIVERSITY SCHOOL OF MEDICINE
ST. LOUIS, MO

Daniel P. McQuillen, MD, FIDSA
LAHEY HOSPITAL & MEDICAL CENTER
BURLINGTON, MA

Thomas A. Moore, MD, FIDSA
IDC OF KANSAS
WICHITA, KS

Ighowwera Oforokun, MD, MSc, FIDSA
EMORY UNIVERSITY SCHOOL OF MEDICINE
ATLANTA, GA

Trish M. Perl, MD, MSc, FIDSA
UT SOUTH-WESTERN MEDICAL CENTER
DALLAS, TX

Susan J. Rehm, MD, FIDSA
CLEVELAND CLINIC
CLEVELAND, OH

Tina Q. Tan, MD, FIDSA
NORTH-WESTERN UNIVERSITY FEINBERG SCHOOL
OF MEDICINE
CHICAGO, IL

Chief Executive Officer

Christopher D. Busky, CAE

IDSAs Headquarters

1300 Wilson Boulevard
Suite 300
Arlington, VA 22209

TEL: (703) 299-0200

FAX: (703) 299-0204

EMAIL ADDRESS:

info@idsociety.org

WEBSITE:

www.idsociety.org

IDSAs

Infectious Diseases Society of America

May 3, 2018

Tick-Borne Disease Working Group
Office of the Assistant Secretary for Health
US Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Members of the Tick-Borne Disease Working Group:

The Infectious Diseases Society of America (IDSAs) appreciates the opportunity to submit comments to the Tick-Borne Disease Working Group and commends the group for tackling this important issue. IDSAs is the largest infectious diseases medical society in the United States, representing more than 11,000 physicians and scientists. Our members care for patients of all ages with serious infections, including tick-borne diseases. IDSAs is committed to ensuring that patients receive the highest quality care for infectious diseases, including Lyme disease. Society members focus on the epidemiology, diagnosis, investigation, prevention, and treatment of infectious diseases in the U.S. and abroad.

We have great sympathy for patients—and their loved ones—who suffer from both short- and long-term effects of Lyme disease or other conditions. Our goal as infectious diseases physicians, public health practitioners, and scientists is to have all patients achieve the best possible outcomes.

IDSAs has worked over the years to educate policymakers, healthcare providers and the public about Lyme disease and other tick-borne diseases to advance prevention strategies, improve diagnosis, prevent unnecessary and potentially harmful antibiotic use, and ensure all patients receive the best available care.

IDSAs strongly supports increased funding for the National Institutes of Health to enable enhanced Lyme disease-related research and for the Centers for Disease Control and Prevention to improve public health approaches to the epidemiology and prevention of Lyme disease and other tick-borne illnesses that help guide clinicians and keep people healthy.

We believe there is a great opportunity in this Working Group and its Subcommittees to address outstanding issues and gaps in knowledge around Lyme disease. We look forward to the results of these efforts. For each subcommittee, we outline the areas that we believe would most benefit from further attention and research. We offer recommendations to help advance each of these areas.

Testing and Diagnostics:

Lyme disease is diagnosed by a combination of medical history, physical exam, and if needed, diagnostic testing. The current FDA-approved serologic tests work best for patients who have symptoms beyond two to four weeks as this is the typical response time for the human immune system to make antibodies against a pathogen, such as *Borrelia burgdorferi*. In patients who are just infected, the diagnosis is best made if the characteristic rash, erythema migrans is present as patients are frequently seronegative. Currently, clinically-validated FDA tests are the best available tests for diagnosis of Lyme disease when the characteristic rash or history is not present. Scientific advances are needed to improve testing strategies for the earliest phases of Lyme disease.

As serologic tests may remain positive for decades after successful treatment of Lyme disease, development of a test that provides supportive evidence that a patient has been microbiologically cured of infection would be of great benefit. Particularly for a patient who has persistent symptoms after antibiotic therapy, this would assist in guiding their clinician to avoid unnecessary additional antimicrobial therapy. IDSA has long advocated for more funding and research into more accurate and specific diagnostics. Progress in this area would greatly reduce misdiagnosis and link patients to effective treatments more quickly.

Important strides have been made to support the development of new diagnostic testing procedures. The NIH and CDC initiated a Serum Reference repository in 2008 and, at the end of 2011, began making standardized Lyme disease cases with serum samples available to the scientific community on a broad basis for testing and comparison of new diagnostic tests. The repository enables comparison of newly developed and existing diagnostic tests under identical conditions using the same panel of well-characterized reference specimens. CDC is also developing next-generation direct diagnostic tests (e.g., biomarkers) to improve upon current serological tests. However, the development, validation and commercial distribution of new tests can take years and millions of dollars. IDSA encourages the working group to recommend greater federal support to advance research and development of new diagnostics.

Disease Vectors, Surveillance, and Prevention:

IDSA also acknowledges there are gaps in our understanding of the epidemiology and prevention of tick-borne diseases. In areas of the country where Lyme disease is endemic, the disease epidemiology is better understood and, in some locales, well-defined and, hence, may not need expanded surveillance for the disease. However, Lyme and other emerging tick-borne diseases have begun to spread past historically endemic areas to threaten new populations. IDSA supports enhanced surveillance to monitor the spread of Lyme, as well as other diseases such as anaplasmosis, babesiosis, ehrlichioses, tularemia, rickettsial infections, and Powassan virus. Good surveillance is needed to help researchers and epidemiologists understand the increasing prevalence of these diseases over the last 15-20 years. Clinicians can only make informed decisions in these emerging and border regions with timely and accurate data about whether certain tick-borne infections exist in their community. Surveillance of both tick and human populations is critical.

CDC studies have yet to demonstrate that interventions such as acaricidal sprays that noticeably reduce tick populations reduce the incidence of tick-borne diseases.^{1,2} Personal tick prevention strategies such as DEET and wearing long clothing have not staunched the vector-borne diseases as well-outlined in the recent CDC study finding a tripling of such infection.³ New measures are needed, and they will require careful study and evaluation to confirm effectiveness. IDSA encourages the working group to recommend increased funding for CDC to strengthen prevention and surveillance of tick-borne diseases.

Vaccines and Therapeutics:

Vaccination has been shown to be an effective way to prevent Lyme disease. Several new vaccine candidates are currently under consideration, but progress has been slow. Manufacturers are concerned that there may not be sufficient uptake of a Lyme vaccine to provide an adequate return on investment. IDSA encourages the working group to review the pipeline for these vaccines and make recommendations to spur development and uptake. The potentially vulnerable populations in the U.S. alone should be more than sufficient; however, enthusiasm has been dampened by prior experiences prompting the manufacturer of Lymrix to withdraw their vaccine in 2001.⁴ Safe immunization against a vector-borne disease such as *B. burgdorferi* is the most cost-effective method to keep people healthy and free of disease.

Pathogenesis, Transmission, and Treatment:

There is no robust scientific evidence supporting the use of long-term antibiotic therapy in patients with Lyme disease that gains them sustained benefit. In fact, there is evidence that long-term antibiotic therapy for patients can lead to serious and life-threatening complications and can accelerate the development of antibiotic-resistant bacterial infections in patients. Patients who have been on long-term antibiotic therapy after diagnoses of chronic Lyme disease have later developed *Clostridium difficile*, *Pseudomonas aeruginosa*, *Acinetobacter*, and other infections. Some of these patients developed septic shock and died.⁵ IDSA supports increased research to understand why some patients develop persistent symptoms after treatment for Lyme disease. Improved understanding of mechanisms should help lead to the development of safe and effective therapies to reduce or eliminate the symptoms of this condition. We urge the Working Group to support evidence-based care for Lyme disease and other tick-borne illnesses and to recommend additional research to understand better and safely and effectively treat symptoms that long linger following Lyme disease treatment.

Other Tick-Borne Diseases and Co-Infections:

There are many other serious and potentially fatal tick-borne diseases such as Powassan virus, babesiosis, anaplasmosis, ehrlichiosis, tularemia, Rocky Mountain Spotted Fever and other spotted fever group rickettsioses, anaplasmosis, and others. These diverse infections may present

¹ AF Hinckley et. al. Effectiveness of Residential Acaricides to Prevent Lyme and Other Tick-borne Diseases in Humans. *Journal of Infectious Diseases*. Vol. 214, Issue 2, Pages 182-188. July 15, 2016.

² L Eisen, R Eisen. Critical Evaluation of the Linkage Between Tick-Based Risk Measures and the Occurrence of Lyme Disease Cases. *Journal of Bacterial Entomology*. Vol. 53, Issue 5, Pages 1050-1062. September 1 2016.

³ Centers for Disease Control and Prevention. Vital Signs: Trends in Reported Vectorborne Disease Cases- United States and Territories, 2004-2016. *MMWR Weekly*. May 1, 2018.

⁴ LE Nigrovic, KM Thompson. The Lyme vaccine: a cautionary tale. *Epidemiol Infect*. Jan 2007; 135(1): 1-8.

⁵ Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report. Serious Bacterial Infections Acquired During Treatment of Patients Given a Diagnosis of Chronic Lyme Disease. *Weekly*. June 16, 2017.

with symptoms and signs somewhat similar to early Lyme disease including fever, aches, and rashes. Some of these diseases are also expanding into new geographic areas. Thus, increased surveillance and epidemiology, as well as additional research into these diseases would be greatly beneficial. We encourage the Working Group to ensure that its recommendations appropriately cover the breadth of tick-borne diseases.

Access to Care Services and Support to Patients:

To ensure optimal patient outcomes, IDSA supports access to evidence-based care and policies to protect patients from treatments that lack rigorous scientific evidence regarding efficacy and any potential toxicity. We encourage the Working Group to focus its efforts on recommendations to expand access to evidence-based care that is safe, effective, and in the best interests of patients.

We look forward to the Working Group and Subcommittees' findings and areas of consensus regarding the need for better diagnostics, expanded epidemiology, and enhanced prevention approaches to control Lyme and other tick-borne diseases. IDSA stands ready to lend expertise that the Working Group may find helpful.

Sincerely,

A handwritten signature in black ink, appearing to read "Paul G. Auwaerter". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Paul G. Auwaerter, MD, MBA, FIDSA
President, IDSA