

Noah is green font Plus Noah also asks all the questions in bold black

Pat Smith is black font

Bob Bransfield is blue font

I. Introduction of Speakers/Background of IDSA

A. Description of Panelists

Robert Bransfield, MD

- Associate Clinical Professor, Rutgers-RWJ School of Medicine
- Private practice in psychiatry, NJ
- Past President, NJ Psychiatric Association,
- Past President International Lyme & Associated Diseases Society (ILADS) & of its educational foundation (ILADSEF)
- Member, LDA Scientific & Professional Advisory Board

Pat Smith, President, Lyme Disease Association, Inc.

- Member, Columbia University Lyme & Tick-Borne Diseases Research Center Advisory Committee
 - In 2020 completed, 2 Terms as a Member, HHS Tick-Borne Disease Working Group &
 - 4-Year Member, Department of Defense, Congressionally Directed Medical Research Programmatic Panel
 - Former Chair, Governor's Lyme Disease Advisory Council (NJ)
 - Testified before 2 Congressional committees
-

B. Who is IDSA?

The Infectious Diseases Society of America is a powerful medical specialty society of over 12,000 physicians, scientists, and public health experts who specialize in infectious diseases. Members are considered by the government agencies to be the experts in Lyme and tick-borne diseases.

C. What is IDSA's relationship to Centers for Disease Control & Prevention, CDC?

The CDC has always posted the IDSA Lyme Guidelines on its website until about a year ago. At that time, they asked 3 advocates to be on a call with them to show CDC's new Lyme guidelines' page, which, they said, does not have IDSA guidelines on it. I (Pat) was on that call. I pointed out that on that page, CDC had taken the Lyme treatment regimens out of the IDSA Guidelines and posted them there, along with references CDC claim support those treatment regimens, but their page actually shows the IDSA protocols for Lyme. CDC response: nowhere does it mention IDSA Lyme Guidelines here on our page.

However, CDC did place references there to other "forms" of Lyme disease— neurologic, carditis, and arthritis—with a note they may require longer treatment course, also noted in IDSA guidelines. CDC also includes a statement that in a small % of Lyme patients, symptoms continue after treatment, PTLDS, or chronic Lyme.

D. What are the IDSA guidelines?

The "2020 Guidelines for the Prevention, Diagnosis and Treatment of Lyme Disease" have 3 sponsoring organizations, the IDSA (12,000 members), American Academy of Neurology (AAN) (36,000 members), and American College of Rheumatology (ACR)(7,700+ members) and were announced Nov. 30 with 33 listed

co-authors, 2 from Canada, one from Slovenia, remainder from the US. They contain 43 recommendations for clinicians treating patients with Lyme disease.

The guidelines summary indicates there was a 36 member panel, including three patient reps, whose identity would remain secret. We feel in the Lyme community that these reps cannot be construed to be meaningful patient representatives as they are not part of a transparent process, their identities and ties are unknowns, and they have no accountability to any patient constituency.

II. IDSA Guidelines Themselves

A. When were the last IDSA Lyme guidelines set published?

IDSA last published Lyme Guidelines in 2006. Disease guidelines were considered “stale” after 5 years by the Federal government’s National Guidelines ClearingHouse; however, IDSA guidelines were allowed to remain on that government site until 2016. The Guidelines Clearing House was closed in 2018 due to being defunded.

B. What changed from the IDSA 2006 guidelines?

GRADE assessed

Do not mention PTLTD

These guidelines have a section on psychiatry and child psychiatry

C. What is GRADE (Grading of Recommendations, Assessment, Development and Evaluations) and how does it relate to these guidelines?

IDSA claims it has complied with GRADE for these Guidelines but those familiar with the process feel they have not actually, although they list the strengths and weaknesses of their recommendations and the evidence.

Grade is a systematic review of a body of evidence on a specific clinical question officially endorsed by 100+ organizations throughout the world. Grade examines the evidence in terms of bias, imprecision, inconsistency between studies, indirectness and publication bias.

The International Lyme & Associated Diseases Society (ILADS) and UK’s National Institute for Health Care & Excellence (NICE) Lyme Guidelines’ outcomes of interest were on treatment effectiveness and both found that the quality of the evidence was low or very low. Next ILADS did a risk-benefit analysis and considered patient values. Given the low evidence quality and the r-b assessment, allowed us to offer options instead of a single recommendation.

The IDSA also included adverse events as an outcome of interest. Because the evidence on adverse events is of higher quality, this raised the overall evidence quality to moderate. That allows for stronger recommendations, not options.

D. What is included and what are excluded?

The guidelines are 48 pages, the recommendations are summarized in the first 6 pages. There is a 241 page supplement.

- Publishing separate guidelines for some of the other TBD. *Anaplasma* and *Babesia* are discussed. STARI (Master’s Disease is discussed but no recommendations.)

- Much of scientific evidence regarding TBD is not included. E.g., only 4 of 400 peer reviewed articles on Lyme, psychiatric symptoms & TBD are included. They state they only include controlled trials. The Bransfield article on Lyme & psychiatric symptoms had 3 control groups and was not included. Well controlled articles showing an association between Lyme and psychiatric illness were dismissed because they did not demonstrate association between Lyme disease and *specific* psychiatric illnesses.
- Surveillance criteria is used as diagnostic criteria.
- “Non-specific symptoms.”
- Retreatment, in their opinion and recommendations, is not supported
- PTLDS not discussed and chronic Lyme disease not discussed
- Shared medical decision-making lacking (a critical part of evidence-based medicine)
- They view side effects of treatments as a critical factor in situations where benefits are uncertain
- Failure to reconcile with the ILADS guidelines
- Failure to adequately recognize most coinfections & interactive coinfections (just Ehrlichia & Babesia)
- Disregard animal studies, except length of attachment, based upon animal studies
- Inappropriate reliance on European trials (document is for treatment of patients in North America, but many of their recommendations for EM patients & neuroborreliosis are based on trials performed in Europe. European Lyme is dominated by *B. afzelii* and *B. garinii*, it’s wrong to assume their findings apply to *B. burgdorferi* infections.

E. Review of the guidelines

- III. Prophylaxis: antibiotics given only to adults & children within 72 hrs. of removal of ID’ed high-risk tick bite. High risk: tick attached for \geq 36 hrs.; from ID’ed Ixodes spp. Vector; from highly endemic area
- IV. single dose of doxy if high risk tick bite.
- VI. “preferred” antibiotic treatment 10 days doxy. 14 days cefuroxime (Ceftin) & amoxicillin.
- IX. “preferred” testing for neuroborreliosis paired sera.
- X. don’t test for Lyme in work-up of these neurological conditions: ALS, MS, Parkinson’s, seizures, cognitive decline, MRI white matter findings. (correct question should be whether patients should be evaluated for Lyme not just tested)
- XI. recommend against testing for Lyme disease in psychiatric illness. There is no controlled prospective evidence that treatment for Lyme disease is effective for any specific psychiatric illness.”
- XII. recommend against testing children w/psychiatric illness, behavioral disorders & developmental disorders.

XXV. patients with persistent “non-specific” symptoms such as fatigue, pain, cognitive impairments who lack “objective evidence” should not be retreated after “standard antibiotic treatment.”

F. How do these guidelines compare to standards of care?

Standard of care is established by the physicians who actually treat the illness, not the physicians who dismiss the illness. The disclaimer is critical in pointing out guidelines to assist, but do not dictate assessment treatment.

G. How does IDSA’s guideline compare to those of patient focused guidelines such as ILADS?

ILADS International Lyme & Associated Diseases Society (ILADS) is an international multidisciplinary medical society dedicated to the appropriate diagnosis and treatment of Lyme disease and its associated illnesses. The ILADS doctors believe in clinical diagnosis.

The current 2014 ILADS Guidelines: “Evidence Assessments and Guideline Recommendations in Lyme Disease: The Clinical Management of Known Tick Bites, *Erythema Migrans* Rashes and Persistent Disease,” already used GRADE assessment in their development.

ILADS Guidelines 2014-current

- Clinical diagnosis (patient oriented)
- Clinical signs & symptoms with lab tests supportive of the clinical manifestations.
- Longer term treatments may be appropriate
- Persisting Infection may be present
- Retreatment with emphasis on shared medical decision-making and patient education, regardless of type of late-stage presentation and severity of illness.
- Patient-oriented outcomes
- Clinical judgment emphasis
- Shared medical decision-making is encouraged with patient/physician shared decisions focused on individual patient values as well as individual patient details and his/her experience of illness; Acknowledgement of IDSA guidelines and recommendations for full disclosure to patient; Retreatment with emphasis on shared medical decision-making coupled with patient education.

IDSA Guidelines 2020

- Disease-oriented diagnosis (Ebel al 2004)
The diagnosis, with the exception of EM rashes, requires positive laboratory values. This means negative lab results can override a carefully constructed clinical diagnosis.
- *Erythema migrans* rash alone or physical findings consistent with Lyme disease accompanied by positive two-tier test results
- Short-term treatment protocols
- No persisting infection (do not treat)
- Retreatment of late stage presentations: 2x for Lyme arthritis; only 1x for other late stage presentations; limited in nature.
- Disease-oriented outcomes (Ebell et al 2004)
- Clinical judgement emphasis limited
- Shared medical decision-making limited or precluded in order to present more uniform approach to treatment, and the individual patient experience of illness is generally not a factor; No acknowledgement of ILADS guidelines and no recommendation for disclosure to patient; Retreatment, except for Lyme arthritis, is strongly discouraged.

III. Impacts of the IDSA Guidelines on the Community

A. Who uses/supports these guidelines?

- Most infectious disease physicians, many neurologists and rheumatologists, and a large segment of primary care doctors use these guidelines to diagnose and treat patients.
- Epidemiologist, those in public health and government agencies, including the military, by and large support the IDSA guidelines.
- Medical boards often support them.
- Insurers also use them.
- IDSA says Guidelines provide recommendations which include those for primary care, infectious diseases specialists, emergency physicians, internists, pediatricians, family physicians, neurologists, rheumatologists, cardiologists, dermatologists.

B. How do these guidelines impact your average patients?

Patients often unable to be diagnosed in timely fashion or correctly diagnosed with Lyme/other TBD, leads to chronic illness.

- *My Lyme Data Patient Registry*: 12,000+ patients enrolled,
- 72% see 4+ physicians before diagnosis,
- 84% of Lyme patients were not diagnosed within the first 4mo. of illness.
- 36% were unable to get diagnosed before at least 6 years.

The costs to the patient and family to travel to see a doctor can be very high.

- MyLymeData: 31% had to travel 100-500+ miles for treatment.
- Significant for patients in Midwest (except Upper), West Coast, parts of the South.
- CDC surveillance criteria: ID states as being high risk or low risk states for Lyme disease.
 - So docs already afraid to diagnose/treat anyway, treaters generally use IDSA guidelines.

Misdiagnosis has patients taking unnecessary medications, medications with serious side effects which may have caused permanent damage to body, medication which may have worsened their Lyme/TBD, caused more serious debilitating TBD symptoms due to time lag.

- MyLyme Data 72% were initially misdiagnosed:
 - Psychiatric disorders, (52%),
 - FM (44%),
 - CFS 943%),
 - Thyroid (26%)
 - Rheumatoid (17%)
 - MS (12)
 - Lupus (9%)
 - Learning Disabilities (6%)
 - Parkinson's, ALS, etc. (5%)

Also, parents who have had their children diagnosed and treated long-term by licensed physicians have sometimes found themselves being brought up on charges of Munchausen by proxy—i.e., a caregiver makes up or causes an illness or injury in a person under his/her care.

- State agencies have taken children being treated for Lyme disease away from families.

- Sometimes in divorce cases, the Lyme diagnosis/treatment decisions have been used by one spouse, usually the husband, against the wife, and
- it has gone so far as the spouse legally goes after the treating physician also.

C. How do these guidelines affect clinicians and practitioners?

Doctors who treat using ILADS guidelines are often investigated by medical boards and charged with malpractice.

- Over decades, treating doctors have lost licenses, have been fined, been monitored, or have not been allowed to diagnose and treat Lyme disease.
- Hospitals have threatened their privileges, insurers have threatened them from removal from plans if they are treated long-term.
- Doctors who practice under IDSA guidelines have reported doctors treating with antibiotics long-term to medical boards and testified against them in insurance cases.
- Many of the treating physicians are no longer in any insurance plans, and some have spent hundreds of thousands of dollars to defend their right to treat Lyme patients long-term when they determine it is necessary.

IV. What Happens Next?

A. What would you change to help the patient?

When science is unsettled, that is usually when there is more than one set of guidelines.

- The National Academy of Medicine, (NAM), formerly Institute of Medicine (IOM) indicates it is not possible to base all care on sound scientific evidence certainly not on randomized trials, which narrowly define populations and exclude/control factors relevant in real-world care settings. (IOM, 2001).

Government agencies, CDC, NIH, military, insurance companies, hospitals, and medical schools need to

- acknowledge that the science surrounding Lyme is unsettled,
- accept the two standards of care for Lyme disease
- educate physicians and the public about the existence of both on websites, in education programs, and in literature.

A national Lyme disease curriculum needs to be developed with the participation in the process by all stakeholders in a transparent process.

- Participation, including patients & long-term treating physicians, must occur at every level of curriculum development.
- Curriculum then needs to be promoted to State governments.
- Government agencies to date have refused to agree to accept patient participation at all levels in the development of such guidelines.

There should be a push to adopt the term chronic Lyme disease or persistent Lyme disease.

- Significant amount of literature from credible institutions, researchers and peer review demonstrating Lyme spirochete survives short-term treatment through several methods including biofilm formation and also through persister cells (other stages of the bacteria), which may require other antibiotics to kill it

- IDSA, government agencies, some researchers have pushed back against this for decades, yet no one has provided no gold standard test and one which shows active Lyme infection, and those entities have provided no treatments for people with persisting symptoms.

B. What are our options for response?

- Persuading insurers to accept long-term treatment into their plans by providing them with the statistics which show the cost differential between early diagnosed/appropriately treated Lyme and chronic Lyme.
- Seeking actions in each state through state medical boards to recognize two standards of care exist for Lyme disease (MN has had agreements w/medical board).
- *State legislation that protects treating physicians, (have done in several states already, RI, CT, MA, NH, NY, ME, CA), legislation that requires insurers to pay for long-term treatment (RI, IL, CT limited fashion)
- *Federal legislation requiring development of national Lyme disease guidelines recognizing all stages of Lyme developed by all stakeholders at all stages of the process.
- Federal investigation such as GAO into aspects of Lyme disease
- Legal actions
 - **Current--** Civil suit by 23 patients in 2017 in Texas.
 - Four counts under Racketeer Influenced & Corrupt Organizations Act (RICO),
 - one count of antitrust violations of Sherman Act,
 - Defendants: IDSA, 8 insurers, IDSA panelists: Wormser, Dattwyler, Shapiro, Halperin, Nadelman (dec.), Sigal, Steere. All 8 insurers have settled. Tentative trial date Sept 2021

The IDSA, Insurance Defendants, and the IDSA Panelists, acting through their officers, agents, employees and affiliates, committed numerous predicate acts of “racketeering activity,” as defined in 18 U.S.C. §1961(5), prior to and during the period made the basis of this suit, and continues to commit such predicate acts, in furtherance of their scheme to prevent treatment of chronic Lyme disease and to prevent the proper testing of potential Lyme disease patients, including (a) mail fraud, in violation of 18 U.S.C. §1341, and (b) wire fraud, in violation of 18 U.S.C. §1343.

(Sherman antitrust- Activities that restrict interstate commerce and competition in marketplace monopolization, conspiracy to monopolize)

(RICO- designed to combat organized crime, allows prosecution and civil penalties for racketeering activity as part of ongoing criminal enterprise)

C. What can your average person do to help out?

- Educate your physicians about two standards of care
- Check with active Lyme disease organizations such as the Lyme Disease Association Inc. and others who are monitoring the situation constantly and often ask for your help with legislative or other campaigns to force changes in the Lyme disease diagnostic and treatment status quo.

- Write, call, email, meet in person with your own legislators at the state and federal level, and tell them of your experiences. Ask your friends and relatives with similar stories to do the same.
- Remember: Legislation should only be a last resort as once legislation is passed, it is seldom repealed. Lyme disease is a very complex medical and political issue. Legislation is often commandeered by the opposing side. Slight language changes can be made which change the whole focus of the legislation. Legislators' interests may not always be the same as yours, and they may be persuaded to trust the "experts," those who try to suppress the seriousness of Lyme.

V. Questions from Callers

Share <https://projectlyme.org/donate/> to audience members and encourage them to donate.

Inform them of upcoming registration for Jan. 21st Lyme + COVID webinar with Dr. Cameron & Dr. Rawls.

Open the floor to Q&A

Save chat for future use

Additional resources:

Lorraine Johnson, Outbreak News podcast about the IDSA new guidelines.

<https://www.lymedisease.org/johnson-idsa-outbreak-podcast/>

Lyme Disease Guidelines <https://www.lymediseaseguidelines.org/>

American Psychiatric Association. The American Psychiatric Association Practice Guidelines for the Psychiatric Evaluation of Adults. Silverman JJ, Galanter M, Jackson-Triche M, Jacobs DG, Lomax JW 2nd, Riba MB, Tong LD, Watkins KE, Fochtmann LJ, Rhoads RS, Yager J; Am J Psychiatry. 2015 Aug 1;172(8):798-802. doi: 10.1176/appi.ajp.2015.1720501. PMID: 26234607.

Proposed Lyme Disease Guidelines and Psychiatric Illnesses. Bransfield RC, Cook MJ, Bransfield DR. Healthcare (Basel). 2019 Sep 9;7(3). pii: E105. doi: 10.3390/healthcare7030105.

<https://www.mdpi.com/2227-9032/7/3/105>

Differentiating Psychosomatic, Somatopsychic, Multisystem Illnesses and Medical Uncertainty. Bransfield RC, Friedman KJ. Healthcare (Basel). 2019 Oct 8;7(4). pii: E114. doi:

10.3390/healthcare7040114. <https://pubmed.ncbi.nlm.nih.gov/31597359/>

Review Indicates Inclusion of Psychiatric Illness Association in Proposed Lyme Disease Guidelines

Rheumatology Advisor October 16, 2019

<https://www.rheumatologyadvisor.com/home/topics/lyme-disease/review-indicates-inclusion-of-psychiatric-illness-association-in-proposed-lyme-disease-guidelines/>

Chronic Lyme Disease: An Evidence-Based Definition by the ILADS Working Group Shor S, Szantyr B, Green C, Bransfield RC, Phillips S, Liegner K, Burrascano, JJr, Maloney E. Antibiotics. 2019. 8(4), 269.

<https://doi.org/10.3390/antibiotics8040269>

A Clinical Diagnostic System for Late Stage Neuropsychiatric Lyme Borreliosis Based upon an Analysis of 100 Patients Bransfield RC, Cook MJ, Aidlen DM, Javia S. Healthcare (Basel). 2020, 8(1), 13;

<https://doi.org/10.3390/healthcare8010013>