

Patient Centered Care Advocacy Group

Information Quality Request for Correction

February 14, 2019

Pursuant to the *HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public*¹, the undersigned individuals and organizations request that information about antimicrobial prophylaxis for the prevention of Lyme disease disseminated by the Centers for Disease Control and Prevention (CDC) be removed from all CDC publications, presentation materials, and websites.

The basis for this request is that the CDC-endorsed information lacks utility, objectivity, and integrity and misleads patients and healthcare providers. This not only can potentially result in human harm but can increase the number of long-term Lyme disease cases, worsening the current Lyme epidemic and increasing the financial impact on our country in terms of lost productivity, disability, and increased medical expenses.

Description of Information

In the CDC publication, *Tick-Borne Diseases of the United States, 5th Edition 2018*, the section on Tick Bite Prophylaxis states the following:

“The Infectious Disease Society of America (IDSA) does not generally recommend antimicrobial prophylaxis for prevention of Lyme disease after a recognized tick bite. However, in areas that are highly endemic for Lyme disease, a single dose of doxycycline may be offered to adult patients (200 mg) who are not pregnant and to children older than 8 years of age (4 mg/kg up to a maximum dose of 200 mg) when all of the following circumstances exist:

- 1. Doxycycline is not contraindicated.*
- 2. The attached tick can be identified as an adult or nymphal I. scapularis tick.*
- 3. The estimated time of attachment is ≥ 36 h based on the degree of tick engorgement with blood or likely time of exposure to the tick.*
- 4. Prophylaxis can be started within 72 h of tick removal.*
- 5. Lyme disease is common in the county or state where the patient lives or has recently traveled, (i.e., CT, DE, MA, MD, ME, MN, NH, NJ, NY, PA, RI, VA, VT, WI).*

Corrections are needed in the print, PDF, and HTML versions of this publication:

- Print: Page 49
- PDF: www.cdc.gov/ticks/tickbornediseases/TickborneDiseases-P.pdf
- HTML: www.cdc.gov/ticks/tickbornediseases/tick-bite-prophylaxis.html

Problems with Quality

The recommendation for single-dose tick bite prophylaxis is from the IDSA's 2006 guidelines for diagnosis and treatment of Lyme disease.² Not only is the recommendation dated, but it is based on a single study from 2001 that has not been reproduced.³ This single study has the following scientific limitations:

1. The "primary endpoint" used to determine whether the prophylactic treatment "prevented" Lyme disease was the appearance of a "bull's eye" erythema migrans (EM) rash at the site of the tick bite. However, more recent studies consistently show that the rate of any type of skin rash is less than 50%, and the rate of EM is less than 10%.⁴ Therefore, this study excludes more than half of true cases of Lyme disease from the data analysis.
2. Subjects who developed subjective symptoms of Lyme disease such as headaches, profound fatigue, brain fog, joint pain without swelling, weakness, numbness, or difficulty controlling specific muscles were excluded from the data analysis.
3. Participants were only observed for 6 weeks before being considered "negative" for Lyme disease, and therefore persons who developed symptoms after 6 weeks were excluded from the data analysis.

In addition to being more than a decade out of date, the IDSA guidelines are based on low-quality evidence and are widely regarded as critically flawed. The National Academy of Medicine report, [Clinical Practice Guidelines We Can Trust](#),⁵ cites the 2006 IDSA Lyme guidelines to illustrate the problems of conflicts of interests, lack of transparency, and scientific bias in guidelines development.

Furthermore, the IDSA guidelines represent only one of two standards of care for Lyme disease. More comprehensive evidence-based, peer-reviewed guidelines for Lyme disease were published by the International Lyme and Associated Diseases Society (ILADS) in 2014.⁶

The ILADS guidelines, which adopted the "Grading of Recommendations Assessment, Development and Evaluation" (GRADE) system as the basis for evidence assessment and guidelines development, specifically recommend *against* a single dose of doxycycline for prevention of Lyme disease.

Instead, the ILADS guidelines say: "*Clinicians should promptly offer antibiotic prophylaxis for known Ixodes tick bites in which there is evidence of tick feeding, regardless of the degree of tick engorgement or the infection rate in the local tick population. The preferred regimen is 100–200 mg of doxycycline, twice daily for 20 days.*"

Impact

CDC's publication of the single-dose tick bite prophylaxis recommendation from the IDSA guidelines is an endorsement of an unvalidated prevention method for a disease with more than 427,000 estimated cases annually in the United States alone. This endorsement has the potential to cause serious harm to Lyme patients for whom the prophylaxis fails to prevent infection with *Borrelia burgdorferi*, the bacterium that causes Lyme disease.

Additionally, there have been no clinical trials to assess if this prophylaxis would also prevent infection by other strains of *Borrelia* or any other tick-borne microbe. The antibiotic would not prevent infection with parasites, such as *Babesia*, or viruses.

With the current CDC-endorsed prophylaxis, patients and healthcare providers alike are given a false sense that a tick-borne disease has been prevented. Therefore, full treatment may be delayed or denied. Research shows that delayed treatment increases the rate of treatment failure.⁷ In addition, this partial treatment has been shown to result in false negative blood test results for Lyme disease.^{8,9}

Recommended Actions

We request that CDC take the following actions:

1. Remove IDSA's recommendation on tick bite prophylaxis for Lyme disease from all CDC publications, presentation materials, and websites.
2. Publish a notice in CDC's Morbidity and Mortality Weekly Report that CDC no longer endorses IDSA's recommendation for antimicrobial prophylaxis to prevent Lyme disease.
3. Issue other notices as necessary to ensure that affected patients and healthcare providers are aware of the risks of relying on IDSA's recommended prophylaxis for Lyme disease.

Thank you for your attention to this matter. We look forward to your timely response.

Lead Complainant



Bruce Alan Fries, President
Patient Centered Care Advocacy Group
(202) 617-1592, PCCAGroup@Gmail.com

References

- ¹ HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public <https://aspe.hhs.gov/report/hhs-guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information-disseminated-public>
- ² The Infectious Diseases Society of America Lyme guidelines: A Cautionary Tale about the Development of Clinical Practice Guidelines. www.ncbi.nlm.nih.gov/pmc/articles/PMC2901226
- ³ Prophylaxis with Single-Dose Doxycycline for the Prevention of Lyme Disease after an Ixodes scapularis Tick Bite. www.nejm.org/doi/full/10.1056/NEJM200107123450201
- ⁴ An update on the diagnosis and treatment of early Lyme disease: "focusing on the bull's eye, you may miss the mark". www.ncbi.nlm.nih.gov/pubmed/17945460
- ⁵ Clinical Practice Guidelines We Can Trust. www.nap.edu/read/13058/chapter/1
- ⁶ Evidence assessments and guideline recommendations in Lyme disease: the clinical management of known tick bites, erythema migrans rashes and persistent disease. www.ncbi.nlm.nih.gov/pmc/articles/PMC4196523
- ⁷ The Clinical, Symptom, and Quality-of-Life Characterization of a Well-Defined Group of Patients with Post treatment Lyme Disease Syndrome. www.frontiersin.org/articles/10.3389/fmed.2017.00224/full
- ⁸ Persistence of Immunoglobulin M or Immunoglobulin G Antibody Responses to Borrelia burgdorferi 10 20 Years after Active Lyme Disease. <https://academic.oup.com/cid/article/33/6/780/328918>
- ⁹ Survival of Borrelia burgdorferi in antibioticly treated patients with Lyme borreliosis. www.ncbi.nlm.nih.gov/pubmed/2613324