



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Director
Tel: 970-221-6428
Fax: 970-266-3575

Centers for Disease Control and Prevention
National Center for Emerging & Zoonotic Diseases
Division of Vector-Borne Diseases
3156 Rampart Road
Fort Collins, Colorado 80521

June 12, 2019

Bruce Alan Fries, President
Patient Centered Care Advocacy Group
3320 Belle Cote Drive
Burtonsville, MD 20866
PCCAGroup@Gmail.com

Dear Mr. Fries,

We have reviewed your information quality request for correction related to antimicrobial prophylaxis for the prevention of Lyme disease that appears on CDC's website, publications, and presentations. This request is listed as #64 on the HHS website on Information Quality Requests at: <https://aspe.hhs.gov/information-requests-corrections-and-hhs-responses>. We do not believe that the evidence supports a revision of these materials.

The request for correction refers to a study published in the New England Journal of Medicine that evaluated the efficacy of single dose doxycycline for preventing Lyme disease after tick bite. Endpoints in the study included erythema migrans (EM), isolation of *Borrelia burgdorferi* in culture, or seroconversion. The study design was randomized, double-blind, and involved over 450 subjects.¹

The statements made in the request for correction misrepresent several aspects of the study. The primary endpoint was not a "bull's eye" erythema migrans, as claimed, but simply "erythema migrans."¹ The clinicians conducting the study were well aware that EM need not always present as a "bull's eye" with central clearing: some were coauthors of a contemporaneous publication making precisely this point.² The complainant's reference to "more recent studies" cites a single case report involving a young woman with EM who was treated successfully with 10 days of doxycycline.³

The claim regarding subjects who developed subjective symptoms is also inaccurate. As shown in Table 3 of the NEJM article, three subjects—one in the treatment group and two in the placebo group—had nonspecific symptoms and evidence of *B. burgdorferi* infection. Asymptomatic infections were assessed but none were detected.¹

Regardless of the endpoints used, if the study had excluded half the cases of Lyme disease as claimed, the effect would be to **reduce** the likelihood of finding a significant difference between treatment arms (so-called "bias toward the null"). A significant difference between treatment arms was detected nevertheless. In this respect, the findings of the doxycycline study are more robust, not less.

The request for correction also misrepresents several issues related to the IDSA treatment guidelines that are not directly relevant to the request. While the IDSA guidelines reference the study, the findings and conclusions in the NEJM article stand independently. After careful consideration, we respectfully decline to retract or change CDC's website, publications, and presentations related to antimicrobial prophylaxis for

the prevention of Lyme disease.

If you wish to appeal this response to your request for a correction, you may send a written hard copy or electronic request for reconsideration within 30 days of receipt of the agency's decision. The appeal must state the reasons why the agency response is insufficient or inadequate. You must attach a copy of their original request and the agency's response to it. Clearly mark the appeal with the words, "Information Quality Appeal," and send the appeal by mail to CDC/ATSDR, Attn: Mailstop H21-8 (attn.: Office of Science Quality); 1600 Clifton Road, N.E., Atlanta, GA 30333 or by e-mail to InfoQuality@cdc.gov.

Best Regards,

/S/

Lyle Petersen, MD, MPH
Director, Division Of Vector-Borne Diseases
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

References

1. Nadelman RB, Nowakowski J, Fish D, *et al.* *N Engl J Med.* 2001;345:79-84.
2. Smith RP, Schoen RT, Rahn DW, Sikand VK, Nawakowski J, *et al.* *Ann Intern Med.* 2002;136:421-8.
3. Stonehouse A, Studdiford JS, Henry CA. *Emerg Med* 2010;39:e147-e151