



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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National Center for Emerging & Zoonotic Diseases
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December 23, 2019

Dear Mr. Fries and Ms. Ahern,

We have reviewed your Information Quality Appeal: Request for Reconsideration related to information about the frequency of erythema migrans (EM) rash in patients with Lyme disease that appears on CDC's website, publications, and presentations. This request is listed as #65 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 changing the estimated occurrence of EM as it appears on CDC's website, publications, and presentations. For your information, an independent review of the information in your Request for Reconsideration was conducted by my office. My office provides scientific leadership that oversees the Division that provided the CDC response to your initial Request for Correction.

In your Request for Reconsideration, you state that all research studies published prior to the 1984 paper by Hanrahan et al.¹ show the rate of EM in patients to be much lower than 70-80%, referencing Steere et al. (1977)² and Steere et al. (1978)³ as evidence. The first article is the earliest description of Lyme arthritis, conducted before the association with EM had been described.² In the second article, 38 of 43 patients (88%) had erythema migrans.³ You have asked for citations predating Hanrahan et al. that show the rate of EM in patients with Lyme disease to be in the range of 70-80%. Steere et al. (1977)⁴ describes 32 patients, 75% of whom reported EM; a 1981 MMWR⁵ reports 226 cases, 86% of whom reported EM; and Bowen et al. (1984)⁶ describes 117 patients, 93% of whom reported EM.

As noted in our original response, such studies may be subject to ascertainment bias, hence our referral to the 2003 NEJM publication.⁷ You indicate that you consider this publication inadequate because it is a 600 word letter to the editor. However, the same information is presented in detail in a peer-reviewed publication by Smith et al (2002)⁸: 146 patients met the study criteria for having Lyme disease and 118 patients had culture proven or PCR confirmed EM for a rate of 80%.

The materials you reference do not support your claim that EM rashes occur at a much lower rate in humans. The CDC surveillance data you reference indicates that 69% of 248,074 passively-reported cases had EM.⁹ MyLymeData¹⁰ is a web-based registry of patients who are self-identified as having chronic Lyme disease. The registrants represent a distinct subset of patients. There is no reason to believe that the frequency of erythema migrans reported by these patients is representative of the general population presenting with early Lyme disease, nor is it clear if or how infection with *B. burgdorferi* was confirmed in many of the registrants. In the study of 10 rhesus macaques, the authors report that while only one monkey had "bona fide" EM at the tick bite site, the others also had erythematous rashes, with *Borrelia burgdorferi* detected by culture or PCR of skin in 9 of the 10 animals.¹¹ Given that this information is based on a small sample and an animal model, we do not believe it supersedes results from the multiple, larger studies of early Lyme disease in humans.^{2,3,4,5,6,7,8,9}

Based on our review of the information, we conclude that the available evidence does not support changing the estimated occurrence of EM as it appears on CDC's website, publications, and presentations.

Best Regards,

/S/

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References

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