Information Quality Request for Correction

Regarding frequency of EM Rash in patients with Lyme disease

March 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 inaccurate information disseminated by the Centers for Disease Control and Prevention (CDC) about the frequency of erythema migrans (EM) rash in patients with Lyme disease be corrected in all CDC publications, websites, and presentation materials.

The basis for this request is that the information lacks utility, objectivity and integrity and misleads patients, healthcare providers and research scientists. 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

The contested information includes statements in CDC publications, web pages and presentation materials that the erythema migrans rash "occurs in 70–80% of the patients with Lyme disease."

CDC Publications

In the CDC publication, *Tick-Borne Diseases of the United States, 5th Edition 2018*, the section on Lyme disease includes the following statement:

"The erythema migrans (EM) rash occurs in 70–80% of patients with Lyme disease."

Corrections are needed in the print and PDF versions:

- Print: Page 28
- PDF: www.cdc.gov/ticks/tickbornediseases/TickborneDiseases-P.pdf

CDC Websites

Similar statements are found on the following web pages.

1. www.cdc.gov/ticks/tickbornediseases/lyme.html

   "The erythema migrans (EM) rash occurs in 70–80% of patients with Lyme disease."

2. www.cdc.gov/ticks/symptoms.html

   "This rash occurs in approximately 70-80% of infected persons and begins at the site of a tick bite."

3. https://www.cdc.gov/lyme/signs_symptoms/index.html

   "Erythema migrans (EM) rash: Occurs in approximately 70 to 80 percent of infected persons."

4. https://phil.cdc.gov/Details.aspx?pid=14476

   "Rash occurs in approximately 70-80% of infected persons."

CDC Presentation Materials.

Inaccurate information about the frequency of the EM rash is also disseminated via presentation materials used by CDC's Lyme Corps program.

Problems with Quality

The assertion that an EM rash occurs in 70-80% of cases of Lyme disease is not supported by the scientific evidence reported in the majority of published research articles where this topic is explored.

This assertion stems from a 1984 study titled "Epidemiologic Features of Lyme disease in New York."[2] The study design introduced an inherent bias in that study participants (NYS physicians) were specifically advised by the NYS Department of Health to identify and report patients as having Lyme disease on **the sole reporting criteria** of an observed rash. The advisory included pictures of "classic" EM rashes, specifically those that had a "bulls-eye" appearance. Excluded from this study were persons with non-specific symptoms or other types of rashes who may have had Lyme disease.

This is a form of confirmation bias in research, in which study participants were selected to confirm a previous observation, rather than investigate the true incidence of EM rash in Lyme disease patients. Prior to this study, the rate of EM in Lyme disease was noted to be less than 50%.[3,4]

This study has never been reproduced, and numerous subsequent published studies show the rate of EM in Lyme disease to be significantly less than 70-80%. In a non-human primate model, the rate of EM was 10%.[5] This was also shown in a human case series titled "An Update on the Diagnosis and Treatment of Early Lyme disease: Focusing on the Bull's eye, You May Miss the Mark." In this study, the rate of the classic bull's-eye rash was shown to be 9%. In both of these and numerous other studies, the most common morphological feature was a small, red, raised rash around the site of a tick bite. Nearly 50% of the patients in the human case study developed no rash of any type. [6,7,8]

Impact

CDC's dissemination of inaccurate information about the EM rash is compounded by the fact that healthcare providers and research scientists rely on the CDC as a source of credible information on the subject.

With the inaccurate information about the frequency of EM, patients and healthcare providers alike are given a false sense that a tick-borne disease has been avoided. Therefore, full treatment may be delayed or denied. Research shows that delayed treatment increases the rate of treatment failure.9

Inaccurate information about the EM rash also skews research priorities and results in critically flawed studies that use the rash as the entry criteria and/or end point. Clinical practice guidelines based on this research can lead to worse health outcomes for patients who are misdiagnosed as a result of recommendations based on the faulty evidence.

For more information about how seminal research studies based on inaccurate assumptions about the EM rash created and perpetuated Lyme disease misconceptions, see the Appendix - A Critical Reappraisal of the Science of Lyme Disease.

Recommended Actions

We request that CDC take the following actions:

1. Replace the contested statements identified in the preceding section with the following:

   "The erythema migrans (EM) rash occurs in approximately 50% of the patients with Lyme disease. Absence of EM should not be used to exclude Lyme disease from the clinical diagnosis."

2. Conduct a systematic review of scientific evidence and publish a notice in CDC's Morbidity and Mortality Weekly Report about the frequency of EM rashes in patients with Lyme disease.

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

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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] Epidemiologic Features of Lyme Disease in New York www.ncbi.nlm.nih.gov/pubmed/6334940

[3] Lyme arthritis: an epidemic of oligoarticular arthritis in children and adults in three Connecticut communities. www.ncbi.nlm.nih.gov/pubmed/836338

[4] Erythema chronicum migrans and Lyme arthritis: epidemiologic evidence for a tick vector www.ncbi.nlm.nih.gov/pubmed/727200

[5] Variable manifestations, diverse seroreactivity and post-treatment persistence in non-human primates exposed to Borrelia burgdorferi by tick feeding https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0189071

[6] 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

[7] Diagnostic challenges of early Lyme disease: Lessons from a community case series https://bmcinfectdis.biomedcentral.com/articles/10.1186/1471-2334-9-79

[8] Comparison of Lyme Disease Prevalence and Disease Reporting in an Endemic Area http://article.sapub.org/10.5923.j.microbiology.20130306.11.html

[9] 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