HHS Tick-Borne Diseases Working Group
Recommendations Related to Lyme Infection-Associated Chronic Illnesses (LIACI)

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HHS Tick-Borne Disease Working Group

- Established by Congress in 2016 under the 21st Century Cures Act
- Federal Advisory Committee convened by HHS/OASH
- Comprised of federal and public members with diverse backgrounds and views on tick-borne diseases
- Charged to report to Congress and HHS Secretary every two years, through 3 cycles
- Responsibilities included reviewing Federal research efforts and advances, and identifying research gaps
- Inaugural meeting occurred in December 2017 and concluding meeting in November 2022
- Working group formally sunset in December 2022

AUTHENTICATED U.S. GOVERNMENT INFORMATION GPO

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3rd Report

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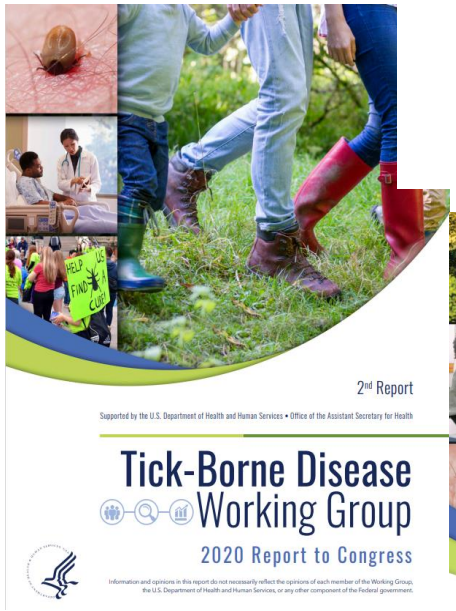
Tick-Borne Disease Working Group

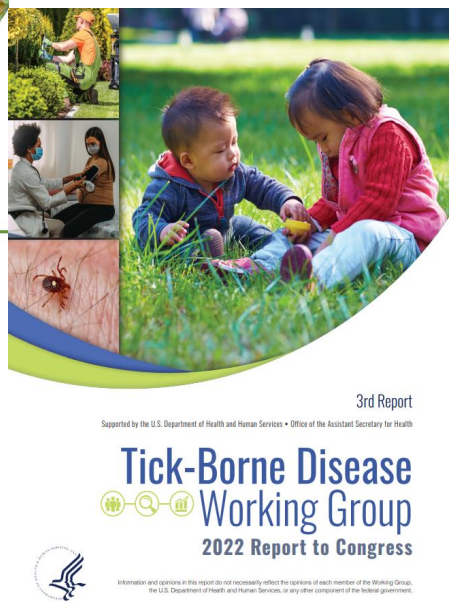
2022 Report to Congress

Information and opinions in this report do not necessarily reflect the opinions of each member of the Working Group, the U.S. Department of Health and Human Services, or any other component of the federal government.

HHS Tick-Borne Disease Working Group

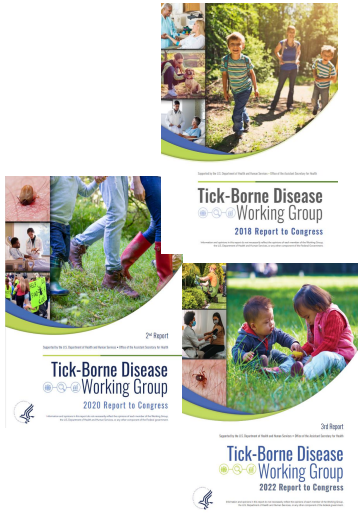
- 25 official public meetings over 6 years (not including subcommittee calls)
- Three reports (2018, 2020, and 2022)
  - 20 individual subcommittee and inventory reports
- 76 total recommendations
  - 28 in 2018 report
  - 27 in 2020 report
  - 21 in 2022 report
- 11 recommendations directly address LIACI, and ~4 others indirectly address the topic (diagnostics, pathogenesis, etc.)





For more information: https://www.hhs.gov/ash/advisory-committees/tickbornedisease/index.html

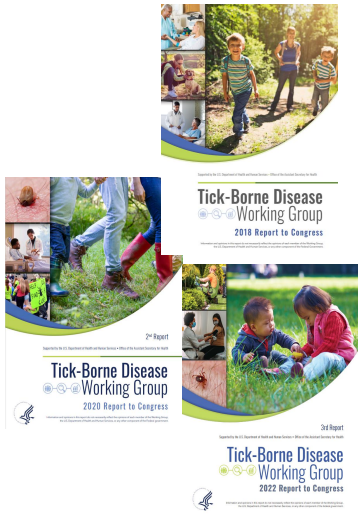
Key recommendations related to LIACI



2018

Recommendation 6.1: Prioritize research into the **potential pathogenic mechanisms** (such as immune response, cross-reactivity, autoimmunity, bacterial persistence, coinfections, and other mechanisms) **of persistent symptoms** in patients who have received standard **treatment regimens** for tick-borne diseases, including Lyme disease.

Key recommendations related to LIACI

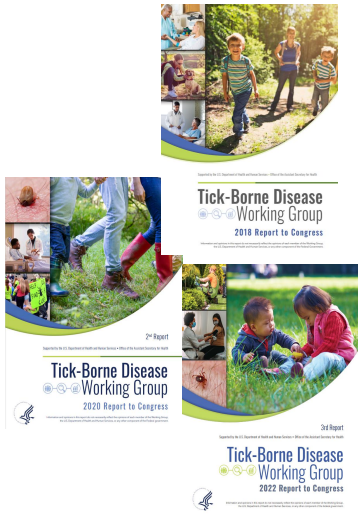


2020

Recommendation 5.2: Support the targeted funding of research to **understand** the **role of persistence** of bacteria and bacterial products in the **pathogenesis** and **management** of Lyme disease (e.g., **antibiotic regimens and other therapeutics**)

Recommendation 6.1: Encourage **clinical trials** on early and **persistent Lyme** disease.

Key recommendations related to LIACI

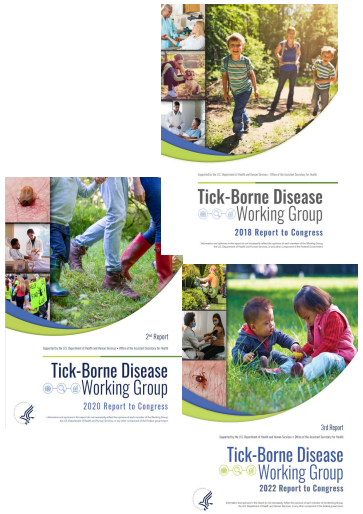


2020 (continued)

Recommendation 7.1: Recommend Federal government **websites** and educational materials and seminars for clinicians, the public, and public health departments, which discuss Lyme disease, provide information that the **state of the science relating to persistent symptoms associated with Lyme disease, is limited, emerging, and unsettled**; and increase public awareness that there are **divergent views on diagnosis and treatment**. Consider that shared medical decision-making may be appropriate in some circumstances.

Recommendation 9.3: Recommend that if the CDC posts any **Lyme treatment** guidelines, that they include guidelines on **persistent Lyme Disease**.

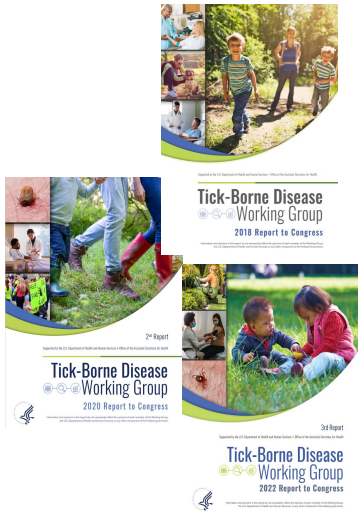
Key recommendations related to LIACI



2022

Recommendation 3.1: Provide funding for the U.S. Department of Health and Human Services to sponsor the National Academy of Medicine (NAM) within the National Academies of Science, Engineering and Medicine (**NASEM**) to conduct an objective, **comprehensive review** of the basic science and **clinical evidence** for diagnosis and **treatment** of Lyme disease, with emphasis on acute and **Persistent Lyme Disease/Chronic Lyme Disease** (PLD/CLD). The purpose for conducting an objective review would be **to establish what is definitely known**, what is **partially understood**, and what remains **unknown** about Lyme disease. The review mechanism shall be transparent and include public stakeholders and patient representatives, experts in trial design and execution, as well as a diversity of experts who represent the full spectrum of scientific perspectives on Lyme disease. The expert panel will produce a comprehensive public report, which will be used to inform federal and state initiatives.

Key recommendations related to LIACI

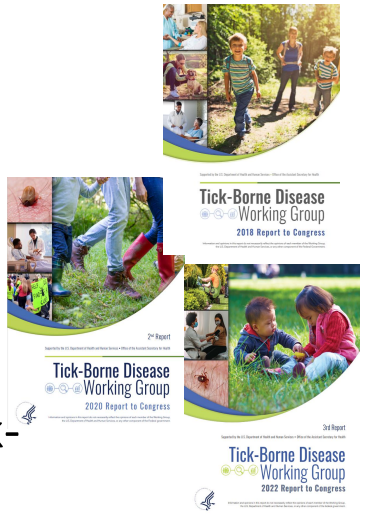


2022 (continued)

Recommendation 3.3: Fund and support continued and ongoing modification of the federal government **websites**, starting with the CDC and NIH websites, as well as educational materials and seminars for clinicians, the public, and public health departments to reflect the current state of the **science related to Persistent Lyme Disease/Chronic Lyme Disease (PLD/CLD), which is limited, emerging, and unsettled**, and to acknowledge that there are **divergent views on diagnosis and treatment** of patients with PLD/CLD.

Recommendation 3.5: Fund, support, and encourage community-based **participatory research programs for Persistent Lyme Disease/Chronic Lyme Disease (PLD/CLD)** and complex presentations of late Lyme disease and other tick bite-associated illnesses. This includes the development and growth of community research capacity to accelerate the fundamental knowledge base using "big data" **registries**, data-sharing platforms, specimen and tissue sample repositories, and genomic and **precision medicine** approaches that reflect the underlying heterogeneous nature of tick-borne diseases and associated illnesses.

Key recommendations related to LIACI



2022 (continued)

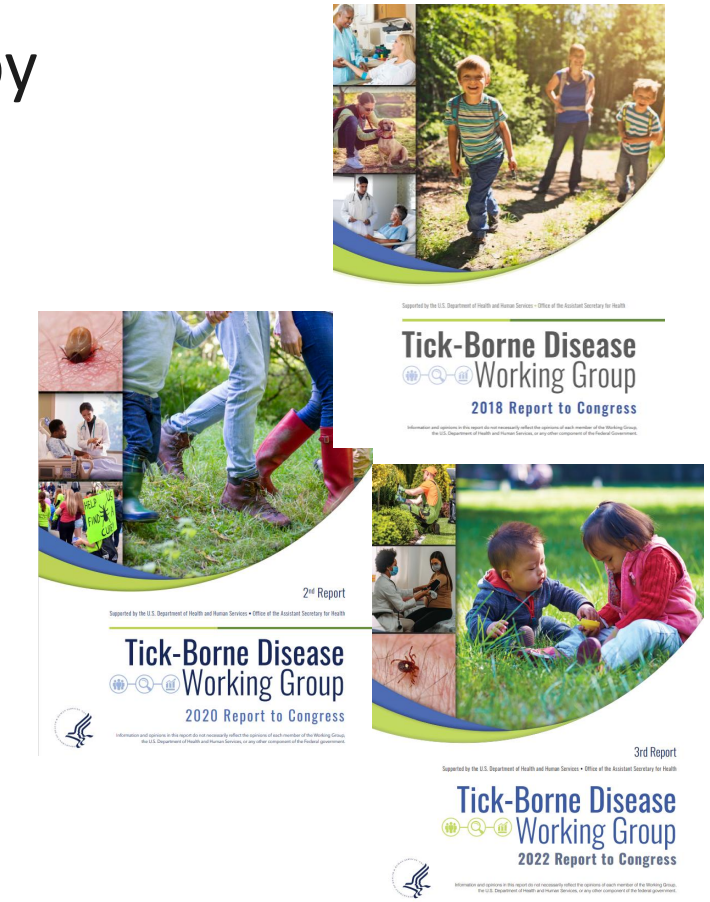
Recommendation 5.1: Support additional **research** on the mechanisms of **pathogenesis** of tick-borne disease, with a particular focus on central nervous system infection (including neuropsychiatric illness and neuropathic injury), **persistent symptoms**, allergy (Alpha-gal Syndrome), immunity, autoimmunity, pregnancy, and adverse fetal outcomes.

Recommendation 5.4: Provide funding for studies, particularly prospective studies, that **evaluate clinical similarities**, mechanisms of pathogenesis, and common etiologies for **long COVID** and other infection-associated chronic illnesses, with **tick-associated chronic illness** and/or persistent symptoms associated with tick-borne diseases.

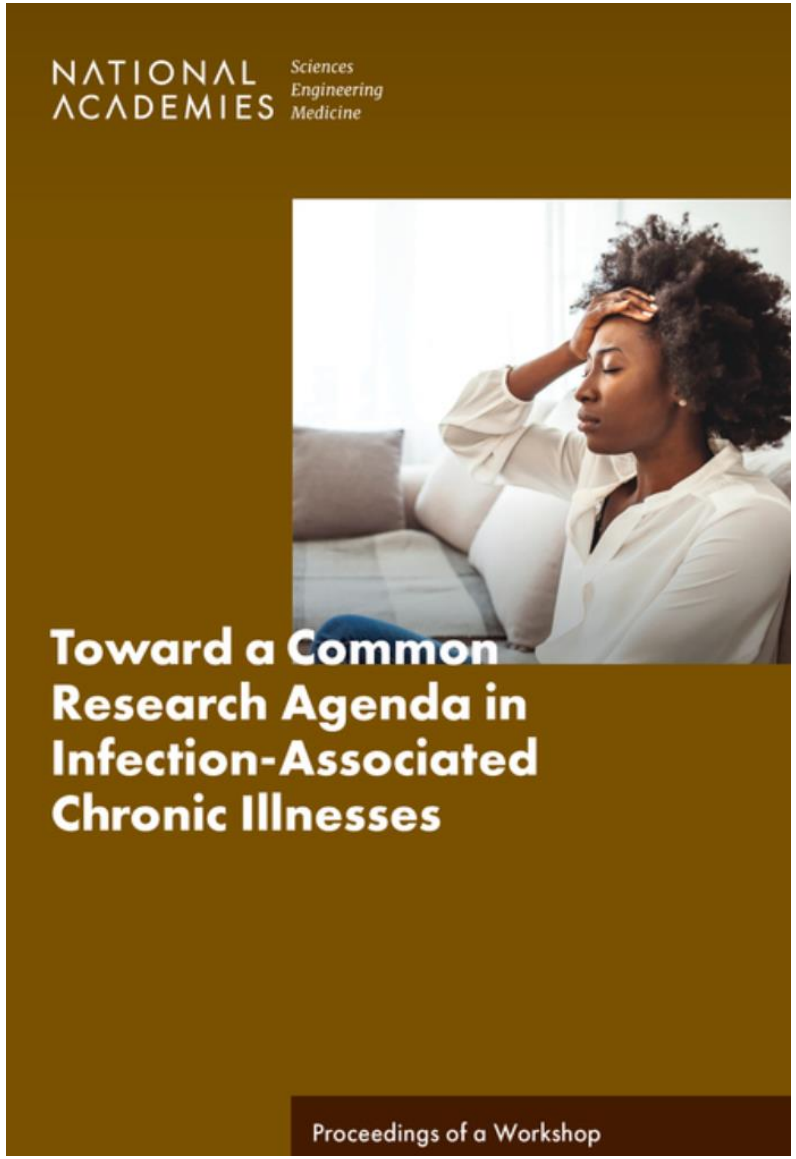
Recommendation 7.3: Accelerate discovery, preclinical and **clinical development** of effective **treatments** for tick-borne diseases. Increase funding for research into understudied areas of treatment for tick-borne diseases, including but not limited to pediatric neuropsychiatric illnesses, pregnancy outcomes in infected women, and **persistent post-treatment symptoms** in all age groups, with emphasis on Lyme disease.

Implementation of recommendations

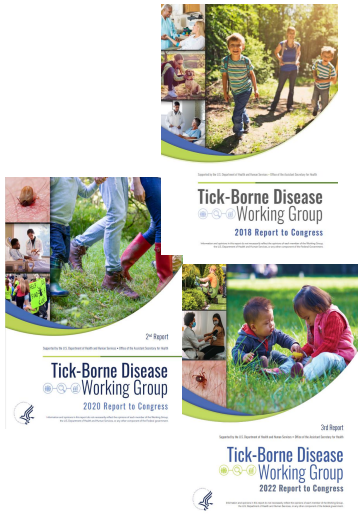
- Significant implementation progress made to date by multiple federal agencies in addressing all 76 recommendations
  - Increased research efforts
  - Enhanced surveillance systems (human and vector)
  - Improved diagnostics
  - Expanded education and communications
  - Efforts to develop and validate effective prevention and control tools
- Public meetings hosted by HHS/OASH to provide updates and community engagement



Implementation of recommendations



Implementation of recommendations – HHS/OASH



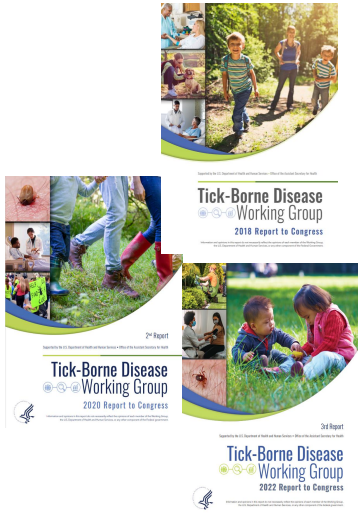
Tick-Borne Diseases & Associated Illnesses: National Community Engagement Initiative

Tick-borne diseases are a serious public health problem. Join us at one of our engagement meetings to

- Learn about relevant initiatives and developments
- Hear updates from federal agencies
- Submit questions and provide input about patient concerns and priorities

For more information see: https://www.hhs.gov/oidp/initiatives/tick-borne-diseases-associated-illnesses-national-community-engagement-initiative/index.html

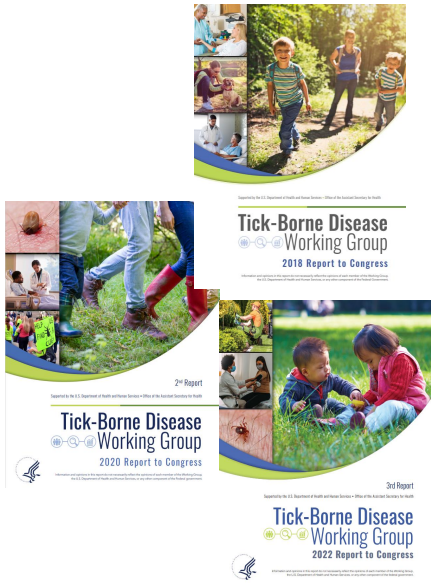
Implementation of recommendations – NIH*



1. NIH developed and released a strategic TBD research plan (2019) that includes increasing efforts to understand the cause(s) of persistent symptomatology in Lyme disease.
2. NIAID released a targeted funding initiative in 2022 seeking research proposals to address the cause(s) of persistent symptoms attributed to Lyme disease. NIAID funded seven projects in 2023, that will run through 2028.
3. NIAID continues to pursue avenues for a prospective study that follows Lyme disease patients from initial diagnosis over time, with an aim to assess the incidence, types and potential causes of chronic or recurring symptoms.

*Source: Dr. Sam Perdue (NIH/NIAID)

Implementation of recommendations – CDC



Treatment best practices

These regimens are consistent with guidance published by the by the Infectious Diseases Society of America, American Academy of Neurology, and American College of Rheumatology.

- Erythema migrans
- Neurologic Lyme disease
- Lyme carditis
- Lyme arthritis

Some patients report prolonged symptoms of pain, fatigue, or difficulty thinking even after treatment for Lyme disease. The state of the science relating to prolonged symptoms associated with Lyme disease is limited, emerging, and unsettled. Additional research is needed to better understand how to treat, manage, and support people with prolonged symptoms associated with Lyme disease.

www.cdc.gov/lyme/hcp/clinical-care/index.html

Implementation of recommendations – CDC

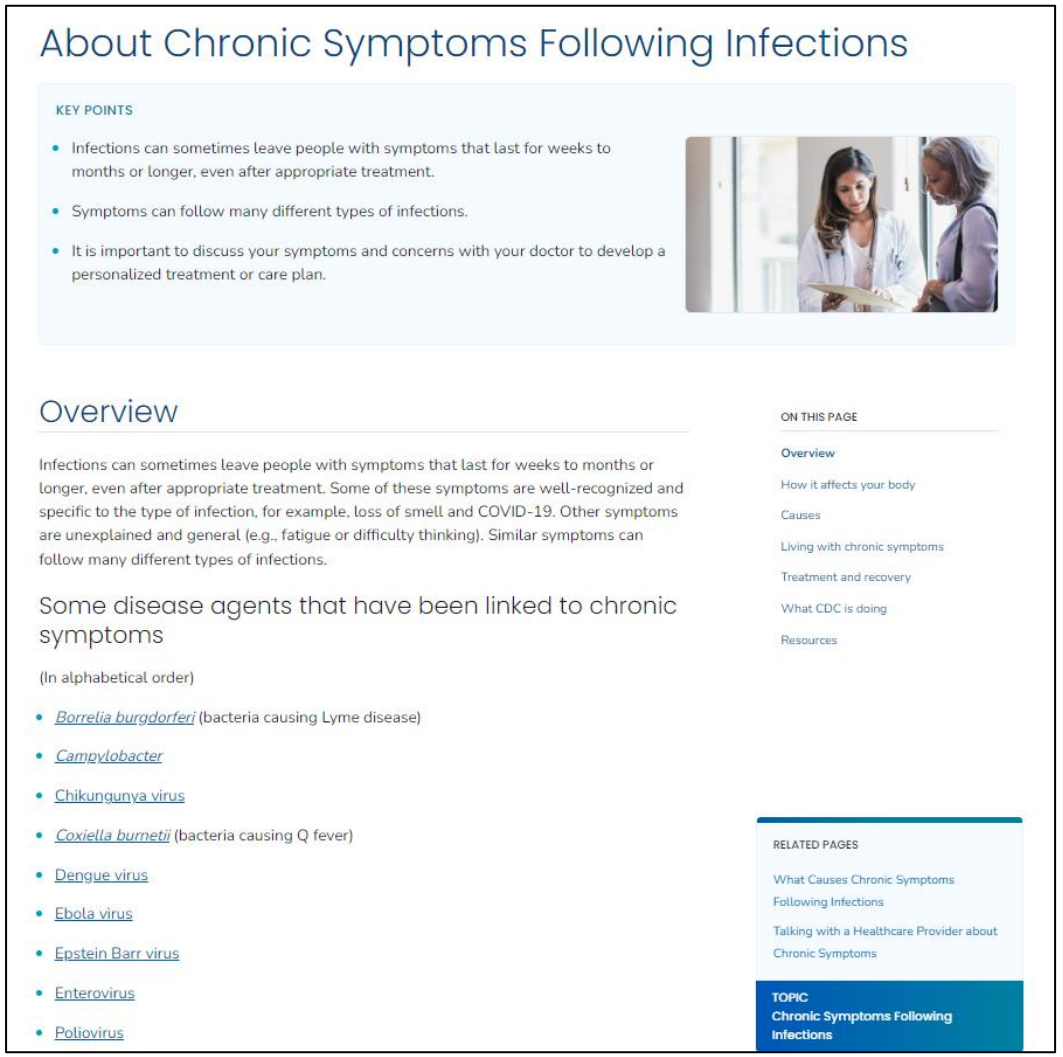
Lyme disease training modules and materials

- Sourced from evidence-based research
- Reviewed by Lyme disease specialists and patient advocates
- Pilot-tested by multi-specialty clinicians

www.cdc.gov/lyme/hcp/training/index.html

www.cdc.gov/lyme/hcp/communication-resources/index.html

Implementation of recommendations – CDC



About Chronic Symptoms Following Infections

KEY POINTS

- Infections can sometimes leave people with symptoms that last for weeks to months or longer, even after appropriate treatment.
- Symptoms can follow many different types of infections.
- It is important to discuss your symptoms and concerns with your doctor to develop a personalized treatment or care plan.

Overview

Infections can sometimes leave people with symptoms that last for weeks to months or longer, even after appropriate treatment. Some of these symptoms are well-recognized and specific to the type of infection, for example, loss of smell and COVID-19. Other symptoms are unexplained and general (e.g., fatigue or difficulty thinking). Similar symptoms can follow many different types of infections.

Some disease agents that have been linked to chronic symptoms

(In alphabetical order)

- *Borrelia burgdorferi* (bacteria causing Lyme disease)
- *Campylobacter*
- Chikungunya virus
- *Coxiella burnetii* (bacteria causing Q fever)
- Dengue virus
- Ebola virus
- Epstein Barr virus
- Enterovirus
- Poliovirus

ON THIS PAGE

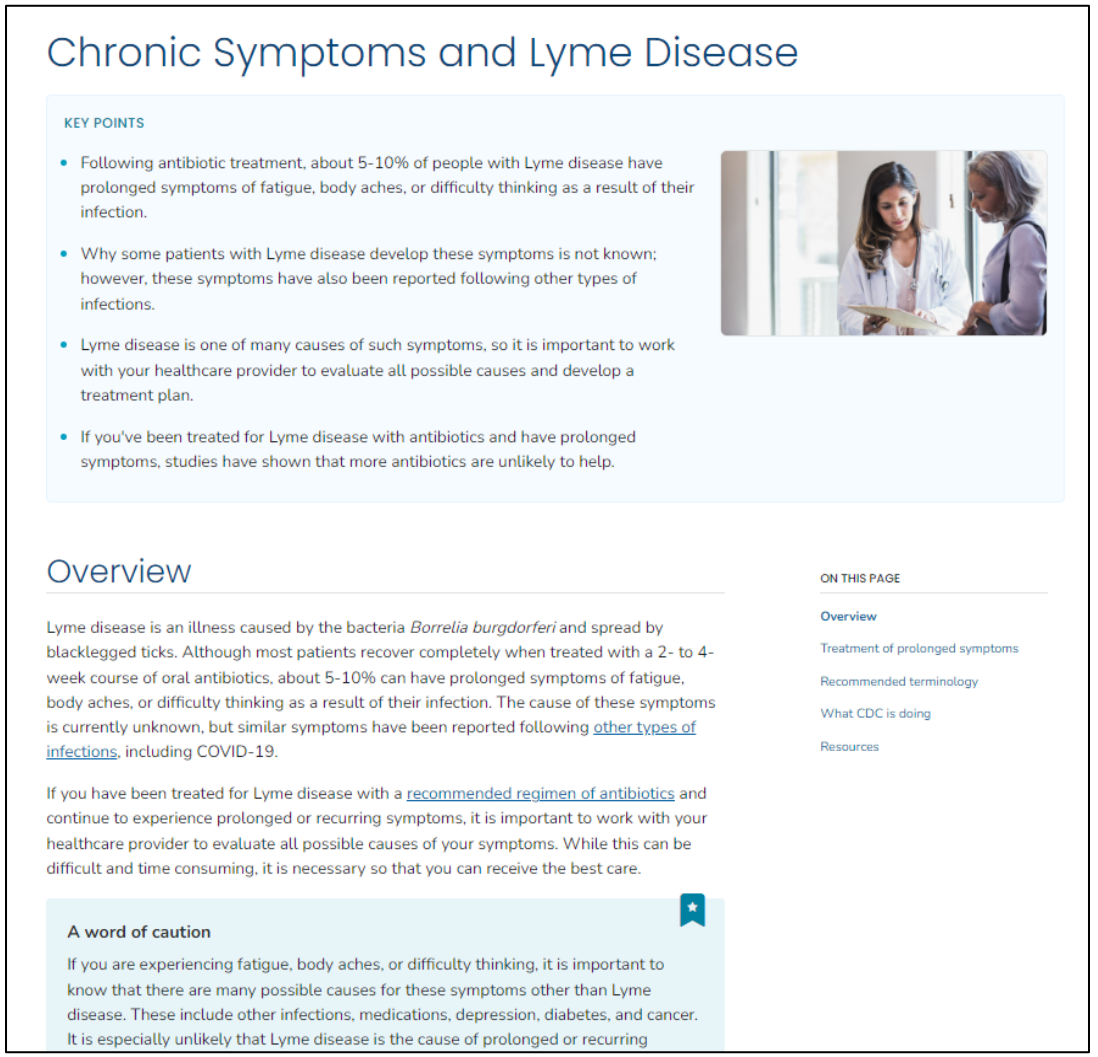
Overview
How it affects your body
Causes
Living with chronic symptoms
Treatment and recovery
What CDC is doing
Resources

RELATED PAGES

What Causes Chronic Symptoms Following Infections
Talking with a Healthcare Provider about Chronic Symptoms

TOPIC
Chronic Symptoms Following Infections

www.cdc.gov/chronic-symptoms-following-infections/about/index.html



Chronic Symptoms and Lyme Disease

KEY POINTS

- Following antibiotic treatment, about 5-10% of people with Lyme disease have prolonged symptoms of fatigue, body aches, or difficulty thinking as a result of their infection.
- Why some patients with Lyme disease develop these symptoms is not known; however, these symptoms have also been reported following other types of infections.
- Lyme disease is one of many causes of such symptoms, so it is important to work with your healthcare provider to evaluate all possible causes and develop a treatment plan.
- If you've been treated for Lyme disease with antibiotics and have prolonged symptoms, studies have shown that more antibiotics are unlikely to help.

Overview

Lyme disease is an illness caused by the bacteria *Borrelia burgdorferi* and spread by blacklegged ticks. Although most patients recover completely when treated with a 2- to 4-week course of oral antibiotics, about 5-10% can have prolonged symptoms of fatigue, body aches, or difficulty thinking as a result of their infection. The cause of these symptoms is currently unknown, but similar symptoms have been reported following other types of infections, including COVID-19.

If you have been treated for Lyme disease with a recommended regimen of antibiotics and continue to experience prolonged or recurring symptoms, it is important to work with your healthcare provider to evaluate all possible causes of your symptoms. While this can be difficult and time consuming, it is necessary so that you can receive the best care.

A word of caution

If you are experiencing fatigue, body aches, or difficulty thinking, it is important to know that there are many possible causes for these symptoms other than Lyme disease. These include other infections, medications, depression, diabetes, and cancer. It is especially unlikely that Lyme disease is the cause of prolonged or recurring

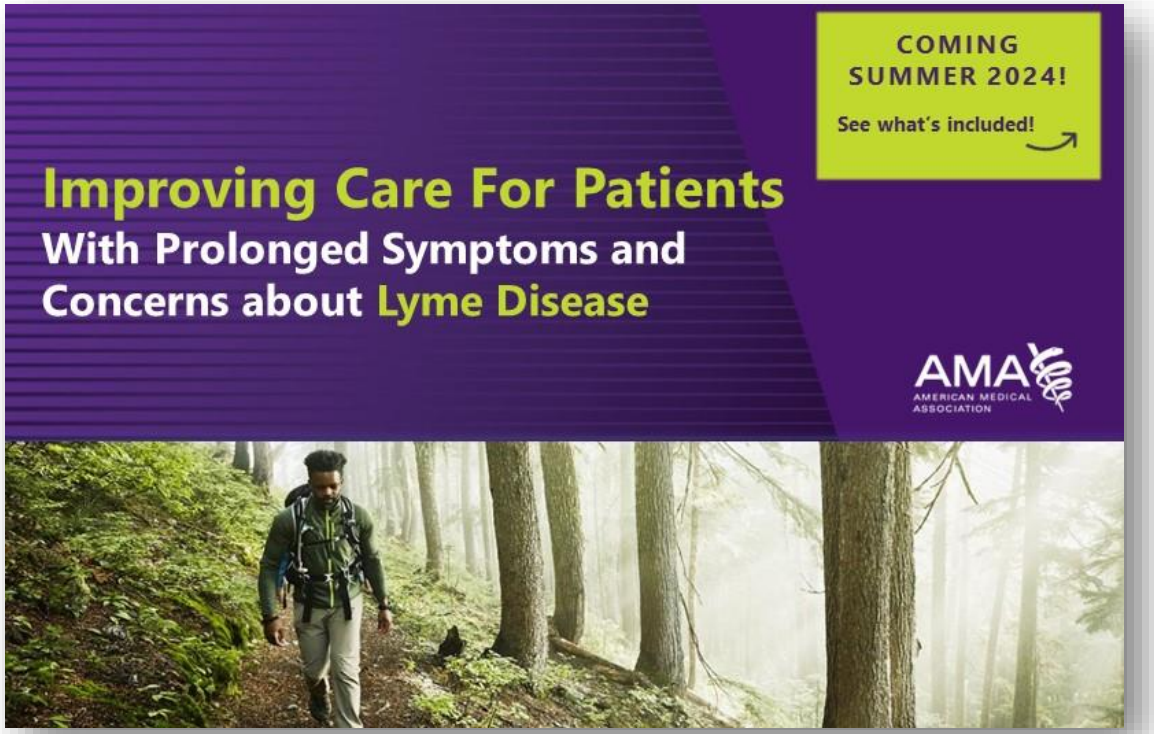
ON THIS PAGE

Overview
Treatment of prolonged symptoms
Recommended terminology
What CDC is doing
Resources

www.cdc.gov/lyme/signs-symptoms/chronic-symptoms-and-lyme-disease.html

Implementation of recommendations – CDC

Coming soon, in collaboration with the American Medical Association



- Educational module with CME
- Online toolkit with resources for physicians and patients
- Sourced from evidence-based research and qualitative clinician data
- Informed by multi-specialty clinicians, including:
  - Lyme disease specialists
  - National healthcare provider organizations

Thank You!

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The findings and conclusions in this presentation are those of the author and do not necessarily represent the views of the Centers for Disease Control and Prevention.