MyLymeData

A PROJECT OF LYMEDISEASE.ORG

Celebrating 10 Years of MyLymeData:

A Patient-Driven Revolution in Lyme Disease Research

2025 Research Chartbook

MyLymeData 2015 10 YEARS 2025 PATIENT-POWERED RESEARCH

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Source Of Data

Over 19,000 patients have enrolled in MyLymeData. This chartbook includes analyses of relevant samples that were drawn from Phase 1 and Phase 2 of the registry. To enroll in the registry patients must be US residents who have been diagnosed with Lyme disease by a clinician. MyLymeData is a fully consented patient registry that has been approved by the Advarra Institutional Review Board.

Suggested Citation

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Additional Resources

This report can be downloaded at www.lymedisease.org/mylymedata-10-year-research-chartbook

To enroll in MyLymeData, visit www.MyLymeData.org

Conflicts of Interest

The authors declare no conflicts of interest.

Support

Funding for this project was provided by grants from the Bill and Marian Cook Foundation and the Bruce Lindorf Memorial Foundation.

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We thank the patients participating in MyLymeData, without whom this research could not have been done.

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Collaborations

MyLymeData collaborates with academic researchers at the University of California Los Angeles, Johns Hopkins University, the College of New Jersey, and the University of Washington. The National Science Foundation has provided funding for the registry through its work with UCLA. The Congressionally Directed Medical Research Program provides funding for a collaboration with UCLA and The College of New Jersey.

We also collaborate with the Bay Area Lyme Foundation and the Lyme Biobank tissue collection project. This collaboration permits patients donating tissues to enroll in MyLymeData and connect their data with their donated tissue samples.

MyLymeData 2015 10 YEARS 2025 PATIENT-POWERED RESEARCH

Our Impact

19,000+
participants enrolled

>10 million
data points collected

8
peer-reviewed studies published

100+
citations in peer-reviewed studies

2
textbook highlights

4
scientific posters

7
white papers

40+
professional presentations

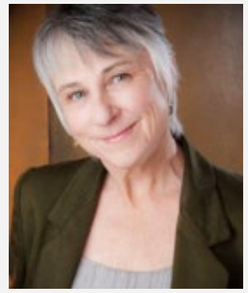
100+
references in federal reports

4
MyLymeData conferences

2
clinical trials recruited

4
NSF awards

CDMRP
award recipient



Lyme disease community, friends and supporters

This year marks a major milestone for the MyLymeData patient registry—our 10th anniversary. Over the past decade, we've worked to transform the landscape of Lyme disease research. Since its launch, MyLymeData has enrolled over 19,000 patients, collected tens of millions of data points, and contributed to multiple National Science Foundation awards.

We have published eight peer-reviewed, big-data studies based on patient-generated data, which have been cited by over a hundred other publications. Most recently, we received a Congressionally Directed Medical Research Program grant to use artificial intelligence and data from the registry to better define and understand persistent neurological Lyme disease.

MyLymeData collaborates with the Lyme Disease Biobank (a Bay Area Lyme project), academic researchers from institutions including the University of California, Los Angeles; the University of Washington; Johns Hopkins University; the College of New Jersey; and industry researchers. We have also served on panels, boards, or as advisors to the National Academies of Sciences, Engineering, and Medicine; the Tick-Borne Disease Working Group; the International Lyme and Associated Diseases Society; and the Columbia Clinical Trials Research Network.

We are deeply grateful to all who have supported this work. Finally, we extend our heartfelt thanks to the patients with Lyme disease who make this work possible by generously sharing their information with the registry. Your contributions drive meaningful change.

Lorraine Johnson, JD, MBA
CEO of LymeDisease.org
Principal Investigator of MyLymeData

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Community Support

"The MyLymeData project has been one of the most important and impactful advocacy initiatives that I have seen over the past 15 years of working in the emerging infectious disease space. MyLymeData is one of the largest real-world Lyme disease registries, with over 19,000 enrolled patients contributing data on symptoms, treatments, and disease progression. These data have helped fill major gaps in Lyme disease research that traditional clinical trials have struggled to address…"

- Amanda Elam, Galaxy Diagnostics Inc. Board Member/Cofounder

"MyLymeData provides a trove of information that researchers can use to fully understand the patient's lived experience. This can help guide the research process in terms of prioritizing research questions and optimizing study design. Working with MyLymeData also provides a unique opportunity for patients and researchers to work collaboratively.

- Professor Cherie Marvel, Johns Hopkins University

MyLymeData is one of the most significant programs in Lyme disease research. It provides data that is not available from other sources to help us understand this complicated and challenging disease. Plus, patients are the true experts, and MyLymeData leverages the Lyme community's lived experience. It's been an honor to partner with MyLymeData on the Tissue Bank.

- Liz Horn, PhD, MBI, Lyme Disease Biobank

"MyLymeData has been very important in helping us to understand the vast community of those being treated for Lyme disease and struggling with ongoing symptoms.

- Dr. Brian Fallon, Director of the Lyme and Tick-Borne Diseases Research Center at Columbia University

MyLymeData is a tremendous resource for researchers, policy makers and patients who are engaging with the complexities of Lyme disease and other tick-borne illnesses. The ability to systematically collect real-world data directly from patients, without third-party filtering, is critical to having a fuller understanding of this patient population, the impact of illness on their lives, and which therapies actually work and which do not. Congratulations to MyLymeData for its many accomplishments over the past 10 years.

- Dr. Elizabeth Maloney, VectorWise

"Platforms like MyLymeData, which leverage patient-reported data, have the ability to profoundly impact the community and our clinical understanding of disease. This approach is particularly suited for machine learning applications because it generates large-scale datasets with minimal patient burden, accelerating both knowledge generation and research productivity.

- Professor Deanna Needell, UCLA

*In God we trust, all others must bring **data.***

- W. Edwards Demming

*If you don't have the pathobiology figured out, you try things. **You don't just slow, slow, slow, walk it.***

- Ezekiel Emanuel, University of Pennsylvania, Advisor to Obama & Biden

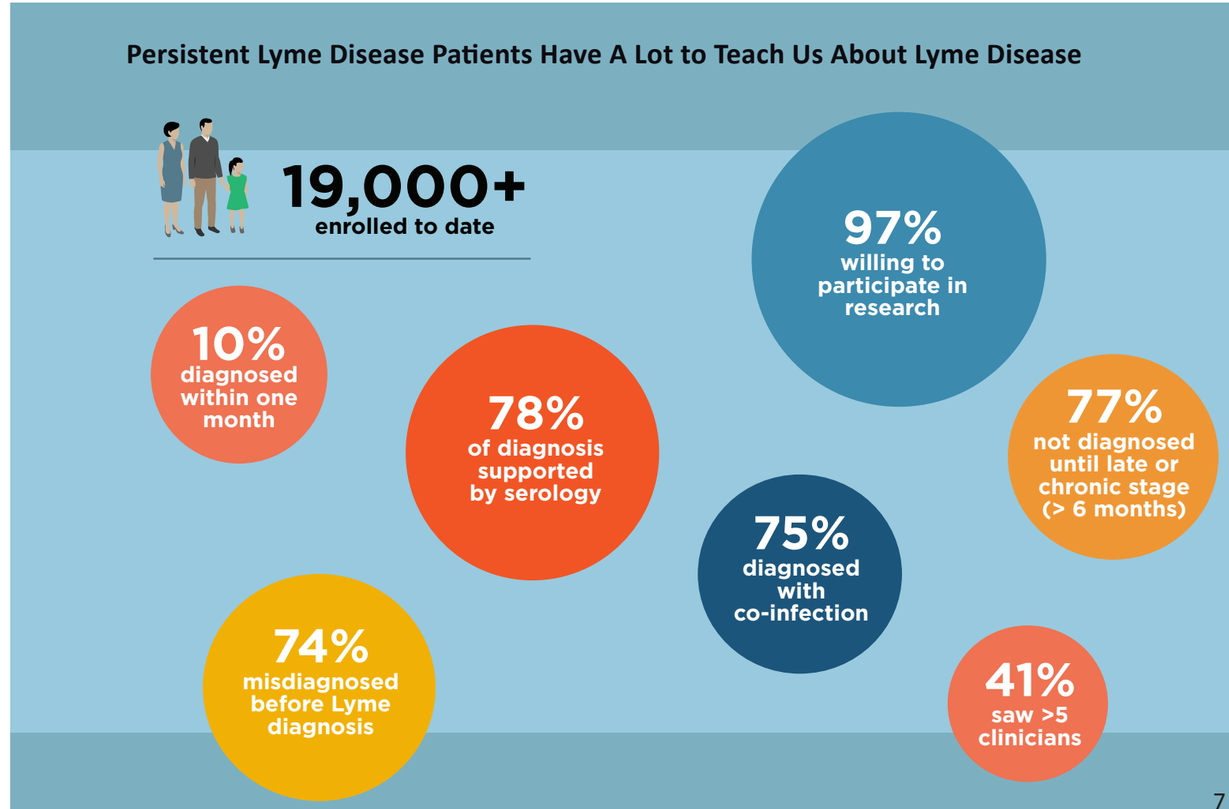
Overview

MyLymeData is a patient-powered big data research project. It was conceived by patients, is run by patients, and addresses the issues that matter most to patients. Although many patients treated early with antibiotics recover, as many as 43% remain ill six months or more after treatment (Aucott 2022). These patients are classified as having persistent Lyme disease (PLD) and are the focus of this chartbook. Despite the growing number of these cases, very little research has been conducted on how best to treat them.

MyLymeData was developed to accelerate research in Lyme disease. Its goals are to better characterize the disease (e.g., symptom expression, phenotypes, and stages), evaluate the safety and effectiveness of treatments, inform research priorities, and support research efforts—for example, by facilitating patient recruitment.

Most participants in the registry (64%) report having PLD. Only 10% of PLD patients were diagnosed within the critical first month of illness when treatment is more likely to be successful.

A majority (77%) were not diagnosed until six or more months after symptom onset, and 74% were initially misdiagnosed. Seventy-five percent were diagnosed with a co-infection. Most (78%) reported that their condition was supported by laboratory testing.



Lyme Disease

The CDC estimates that roughly 500,000 cases of Lyme disease occur each year. However, the rate has gone up dramatically in the last few years. Common clinical manifestations of PLD in adults include musculoskeletal pain, neurologic impairment, fatigue and heart-related conditions. An estimated two million Americans have PLD, with 72% reporting fair or poor health status, compared to 13% in the general population (Delong 2019). The disease is also linked with a higher risk of suicide (Fallon 2021).

Lyme Disease - Total Reported Cases by Year, United States

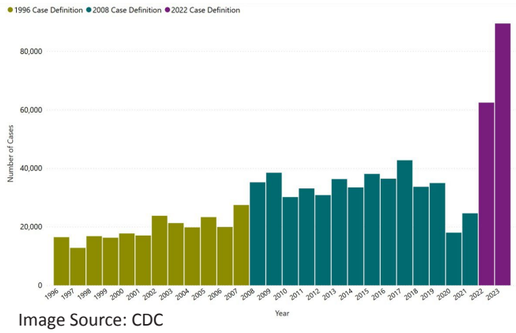


Image Source: CDC

Top 10 Lyme Disease Research Questions

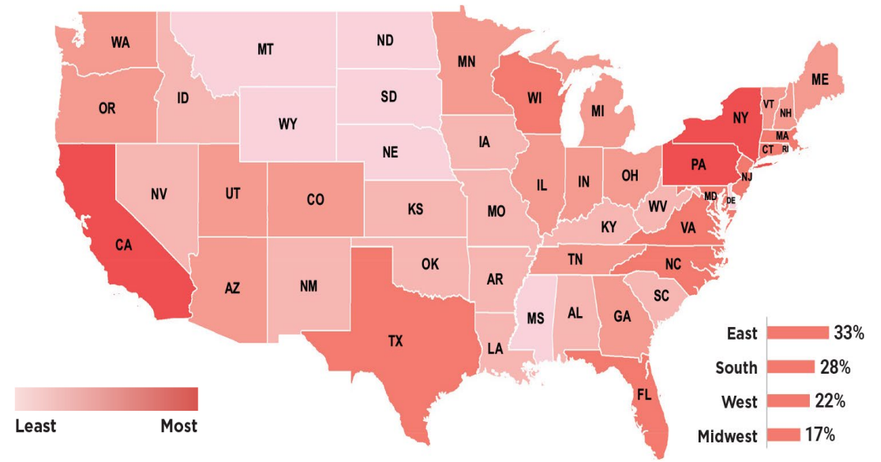
A broad-based collaboration of over 7,000 researchers, treating physicians, advocacy groups, and Lyme disease patients in the United States took part in a comprehensive research priority-setting process over a two-year period from 2015 to 2017. The first round of priority setting took place at a 2015 conference held by the American Association for the Advancement of Science (AAAS). At that forum, 50 physicians, researchers, and patients developed a list of high-priority questions for Lyme disease. LymeDisease.org then invited participants in MyLymeData to rank the priorities established at the AAAS conference and to submit additional research questions. This more extensive list was then distributed to more than 5,000 patients in the community at large, who ranked priorities to establish the final list of top-ten research priorities, which are reflected in the figure below.

1. **What direct diagnostic test would be both highly sensitive and specific for Lyme disease and co-infections?**
2. **What is the most effective treatment protocol to restore health to patients with Lyme disease?**
3. **What is the impact of delayed diagnosis on the course of Lyme disease?**
4. **What natural therapies and protocols are most effective?**
5. **What other diseases (e.g. MS, Parkinson's) may be caused by Lyme disease?**
6. **What are the most effective methods for rehabilitating the brain in neurologic Lyme disease?**
7. **Why do some people develop chronic Lyme disease after antibiotic treatment?**
8. **What triggers reactivate chronic/late-stage Lyme disease or co-infections after remission?**
9. **How do co-infections affect the immune response and course of illness in patients with Lyme disease?**
10. **Are treatment regimens tailored for specific symptoms more effective? (e.g. neurologic)**

Sources: DeLong et al. 2019; Fallon et al. 2021; Johnson et al. 2025

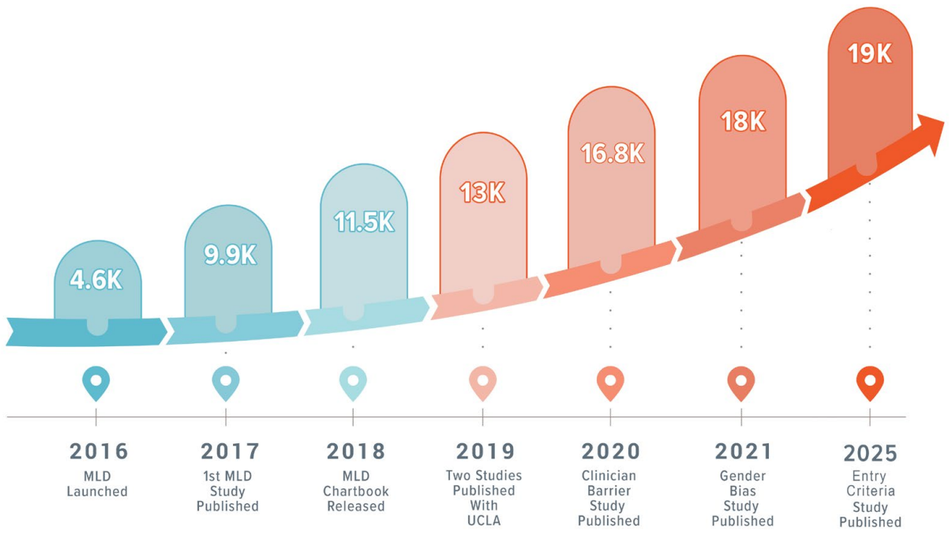
MyLymeData Patient Registry

MyLymeData is a patient registry and research platform that was developed and launched by LymeDisease.org in 2015. It uses big-data research tools that allow patients to quickly and privately pool their data to determine which treatments work best. The registry includes patients enrolled from every state. This map reflects the percent of patients enrolled in each state in the contiguous United States in 2025.



One of the Fastest Growing Registries

With over 19,000 patients enrolled, MyLymeData is now among the largest patient-driven registries in the nation. It is also one of the fastest-growing registries, with eight peer reviewed publications.



MyLymeData Patient Registry

What Type of Data Is Collected in the Registry?

Survey items in the MyLymeData patient registry were drawn from standard government question banks, such as the CDC Behavioral Risk Factor Surveillance System, National Health Interview Survey, National Ambulatory Medical Care Survey, and National Center for Health Statistics, as well as the AHRQ Medical Expenditure Panel Survey. They are also drawn from published literature and prior surveys. Treatment response items include the Global Rating of Change scale to assess whether a patient's health condition has improved or deteriorated over time. A beta version of the MyLymeData survey was pilot-tested and adjusted as recommended by AHRQ.

Diagnosis

- Recollection of tick bite
- Diagnosis by clinician
- Supporting lab tests
- Stage of illness at diagnosis

Demographics

- Sex
- Race
- Education
- State of residence

Quality of Life

- Health status
- Bad physical days
- Bad mental days
- Bad bed days

Functional Impairment

- Ability to work
- Ability to go to school
- Impact on social activities
- Disability

Treatments

- Antibiotics
- Alternative
- No treatment
- Treatment duration

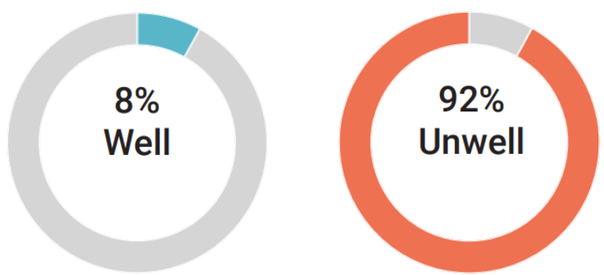
Symptoms

- Severity
- Present at diagnosis
- Most common
- Percent of Improvement

Who Participates in the Registry

The registry includes a broad range of participants. These include those who report being well in addition to those who remain ill. All stages of the disease are also included: early Lyme disease, late untreated Lyme disease and persistent Lyme disease.

Percentage of Well and Unwell Patients



Source: Johnson et al. 2018

MyLymeData classifies patients as having acute, late-stage, or persistent Lyme disease based on their response to a question about current disease stage. Early Lyme disease refers to illness lasting less than six months, with or without prior antibiotic treatment.

Patients clinically diagnosed with Lyme disease who remain ill for six or more months after antibiotic treatment are categorized as having persistent Lyme disease (PLD). Those who remain ill for six or more months but were never treated with antibiotics are considered to have late-stage untreated Lyme disease.

These categories are based on clinical diagnosis and differ from the research term Post-treatment Lyme Disease (PTLD). PTLD is primarily used in academic studies to describe a much smaller subgroup of clinically diagnosed patients after exclusion criteria are applied. In fact, such criteria typically disqualify about 90% of patients seeking to enroll, meaning PTLD study populations represent a highly restrictive subset of those with PLD.

Another term gaining use is Lyme Infection Associated Chronic Illness (Lyme IACI), an umbrella concept for infection-associated chronic conditions, such as chronic fatigue syndrome or long COVID.

Acute/Early Lyme Disease Definition

Patients who:

- Are clinically diagnosed with Lyme disease,
- May or may not have been treated with antibiotics, and
- Have had symptoms of Lyme disease for < 6 months

Late Untreated Lyme Disease Definition

Patients who:

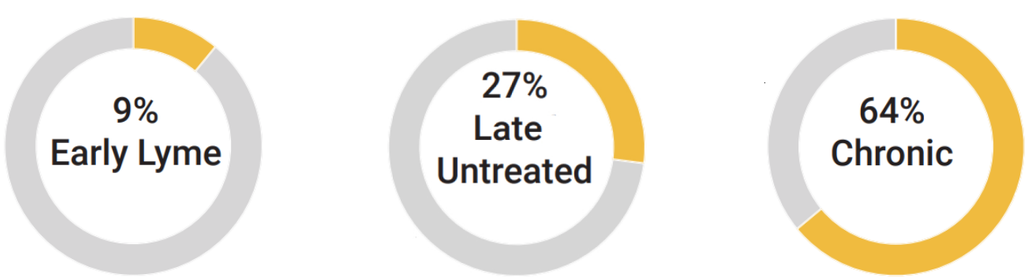
- Are clinically diagnosed with Lyme disease, and
- Have late-stage untreated Lyme disease (≥ 6 or more months following symptom onset)

Persistent/Chronic Lyme Disease Definition

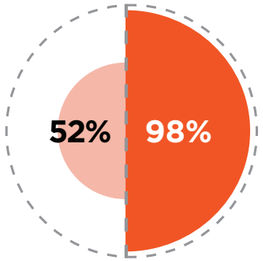
Patients who:

- Are clinically diagnosed with Lyme disease, and
- Remain ill for 6 or more months following treatment with antibiotics

Disease Stage of Patients



PLD Symptoms



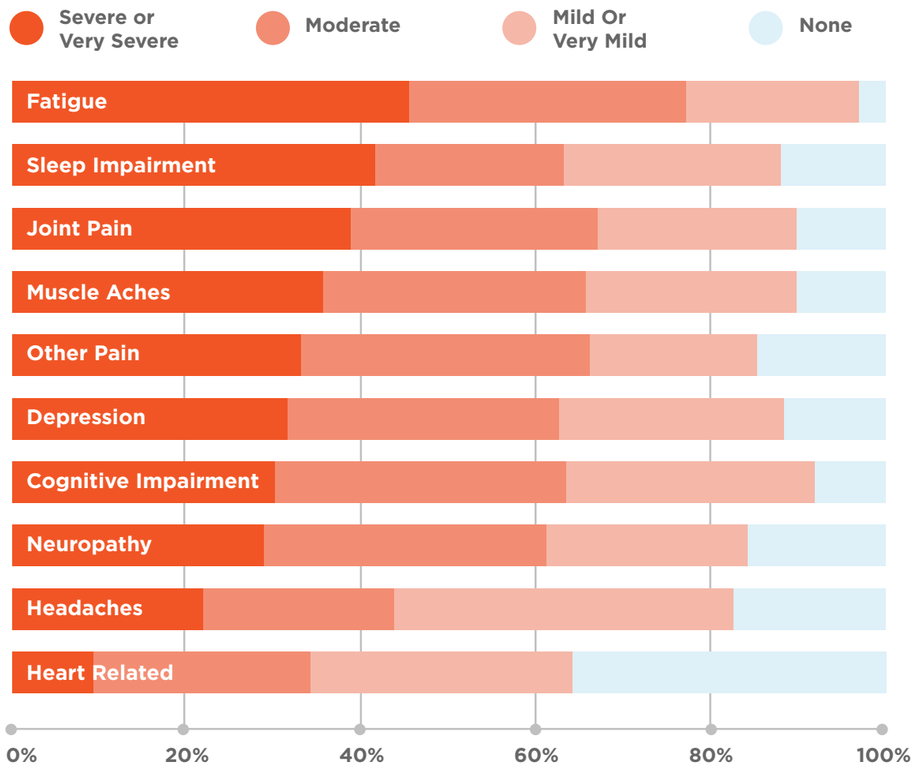
98% of PLD patients report ≥ 2 moderate to very severe symptoms;

52% of PLD patients report ≥8 moderate to very severe symptoms

Patients with PLD report a number of common symptoms including fatigue, headache, joint pain, muscle aches, neuropathy, twitching, memory loss, cognitive impairment, sleep impairment, psychiatric, heart related and gastrointestinal disorders.

Many symptoms are also present in other diseases and are common in the general population. Strikingly, almost all (98%) of PLD patients report at least two moderate to very severe symptoms, and 52% report eight or more moderate to very severe symptoms.

Symptom Severity for Persistent Lyme Disease



Sources: Data set dated March 21, 2023; Johnson et al. 2014

Diagnosis of Lyme Disease

I was infected on a trip to a Lyme-endemic area but live in an area with few infected ticks. I could not get a local doctor to test or treat for Lyme early on, despite the tick bite and rash.

- Patient

Lyme disease is a clinical diagnosis based on patient history, symptom onset, characteristic signs, rash history, lab tests, treatment response, and overall clinical judgment. The adjacent figure shows the percentage of PLD patients meeting some of these criteria. While nearly all report at least two moderate to severe symptoms, only 45% recall a rash.

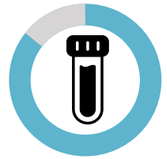
The majority of commercial tests detect antibodies, revealing past exposure rather than current infection. However, these tests can yield false negatives and false positives, highlighting the need for better diagnostic methods. Many PLD patients report their clinician initially failed to test—particularly those living outside CDC-defined “high-incidence” states on the East Coast.

Reliance on surveillance data can mislead. For example, according to the Wall Street Journal, California is regarded as a low-incidence state, but ranks among the highest for Lyme-related insurance claims based on the FAIR Health claims data base. This mismatch creates a false impression that Lyme disease is rare locally, discouraging clinicians from including it in their differential diagnosis.

Even when testing occurs, patients report that positive results are sometimes disregarded because the clinician believes Lyme is not present in their state. In fact, Lyme disease has been documented in every U.S. state. Lyme disease can be treated successfully with antibiotics, but if undiagnosed or inadequately treated, the consequences may be severe.

How Many PLD Patients Test Positive or Had a Rash?

98% of PLD patients report at least 2 moderate-very severe symptoms



85% of PLD patients report diagnosis supported by positive lab test

73% of PLD patients had a rash or CDC-positive Western blot

46% of PLD patients had a positive Western blot

45% of PLD patients had a rash

Sources: Johnson et al. 2014; Waldman et al. 2025; Mandel et al. 2025; McGinty, 2018

Co-infections

In addition to Lyme disease, ticks carry other pathogens, including Babesia, Bartonella, Mycoplasma, Ehrlichia/Anaplasma, and Rocky Mountain Spotted Fever. These co-infections must be treated individually, although some antibiotics may treat more than one tick-borne infection.

Many physicians do not test for co-infections, which results in treatment delays. In MyLymeData, 33% of acute patients have a co-infection compared to 75% of PLD patients. This suggests that the presence of co-infections may be a primary driver of developing PLD.

Research by Dr. Cherie Marvel at Johns Hopkins using MyLymeData found that PLD patients with co-infections reported greater symptom severity than did those without co-infections. Notably, the co-infected group was far more likely than the Lyme-only group to report high symptom severity related to cognition, sleep, and gastrointestinal distress. These findings underscore the importance of early testing for co-infections.

Co-infection Rates for Persistent Lyme Disease

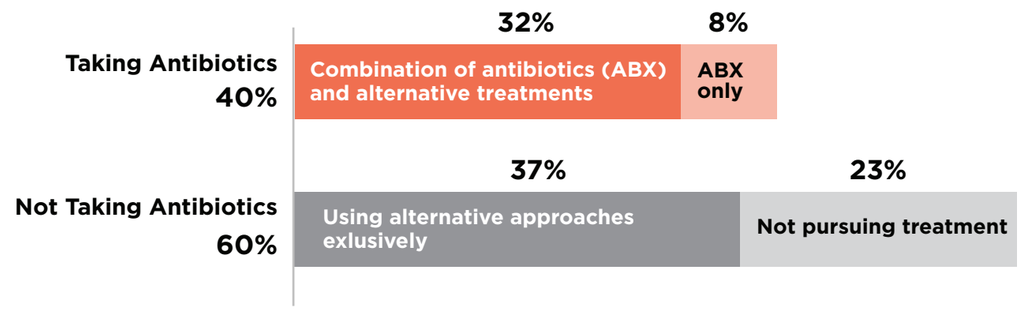
Co-infection	Diagnosis	With labs	Without labs
Diagnosed w/ Co-infection	75%		
Babesia	73%	64%	36%
Bartonella	70%	63%	37%
Mycoplasma	28%	78%	22%
Ehrlichia/Anaplasma	25%	74%	26%
RMSF	14%	76%	24%

Sources: Data set dated March 21, 2023; Walden et al. 2025

Persistent Lyme Disease Treatment

PLD patients use different approaches to treatment. Forty percent report taking antibiotics, while 60% do not take antibiotics. Thirty-two percent take a combination of antibiotics and alternative treatments, while 37% use alternative medicine approaches exclusively. Some patients (23%) report that they do not pursue any treatment for their illness.

PLD Patients Using Antibiotics and/or Alternative Treatments



PLD patients who are not taking antibiotics—whether using alternative treatments or none at all—cite a range of reasons. The most commonly reported are lack of access to treating clinicians and cost concerns, pointing to a fundamental issue with access to care. Over the past decade, the percent of PLD patients who report being unable to find a treating clinician has nearly doubled, rising from 15% to 27%. Additionally, half of all patients say their physician does not accept insurance, further compounding financial barriers to care.

Reason Persistent Lyme Disease Patients Do Not Take Antibiotics

I've made significant progress with individualized treatment, but I have had to FIGHT for it every step of the way, and it has cost me my dream job in NYC, my retirement, my savings, and my social life. Lyme patients deserve better from the medical field.

- Patient

Source: Data set dated March 21, 2023

The Importance of Early Diagnosis

Only **10%** of PLD patients are diagnosed < 1 month

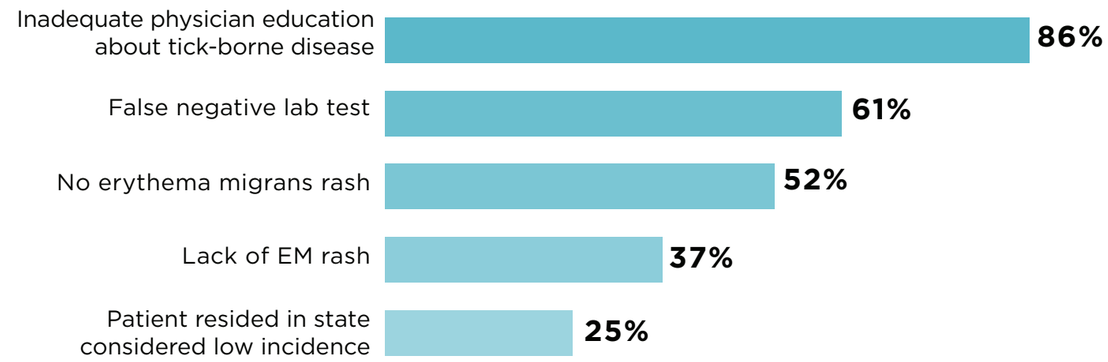
77% of PLD patients are not diagnosed until late Lyme (≥ 6 months)

Diagnostic and treatment delays increase the probability that patients will develop PLD and complicate care. Only 10% of PLD patients in MyLymeData are diagnosed within the first month of symptom onset, when treatment is more likely to be successful. More than 75% are not diagnosed until six or more months. At that point, the bacteria are widely dispersed in the body and may require longer more aggressive antibiotic treatment. In the registry, roughly 20% of patients diagnosed early develop PLD compared to 77% of those diagnosed late.

A much larger proportion of patients who identify as being "unwell" (70%) were diagnosed late compared to those who identify as being well (47%).

Educational efforts aimed at addressing these problems could reduce the number of Lyme disease cases, which would reduce the number of cases of PLD in turn. In addition, reducing the number of Lyme disease patients who develop PLD by improving treatment success for early Lyme disease is essential to prevent these patients from developing PLD.

Reasons for delayed Lyme disease diagnosis:



In a recent survey, clinicians who focus on treating Lyme disease identified the reasons for diagnostic delays as inadequate physician education, false negative lab tests, prior misdiagnosis, and lack of an erythema migrans rash.

Both clinicians and patients have identified misdiagnosis as a major source of treatment delays. Most PLD patients (75%) report being initially misdiagnosed. Primary misdiagnoses include chronic fatigue syndrome (31%), fibromyalgia (31%) and psychiatric conditions (38%).

Source: Johnson et al. 2022

PLD Patients Have Worse Health

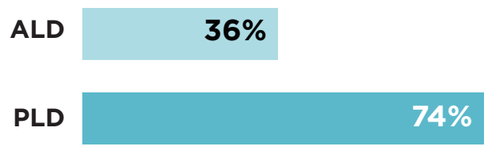
Although the side effects of antibiotics may concern the health profession...the risk of delaying treatment or under-treating someone comes at a much higher cost. Lives are RUINED by this disease.

- Patient

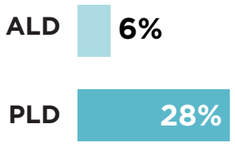
Acute Lyme disease (ALD) and PLD differ both in severity and in diagnostic factors. People with PLD report much worse health overall than those with acute Lyme disease. For instance, 74% of PLD patients describe their health as fair or poor, compared to only 36% of acute patients. Disability is also far more common: 28% of PLD patients report being disabled, compared to just 6% of those with acute disease. Similar differences appear when looking at activity limitations, days of poor physical health, and days of poor mental health.

PLD patients are also more likely to have been misdiagnosed before receiving a Lyme disease diagnosis—74% versus 42% of acute patients. Misdiagnosis often leads to delays in treatment, which can increase the risk of developing persistent illness. In addition, PLD patients are more likely to have co-infections (75% versus 33%). Higher rates of misdiagnosis and more co-infections may contribute to the risk of developing PLD.

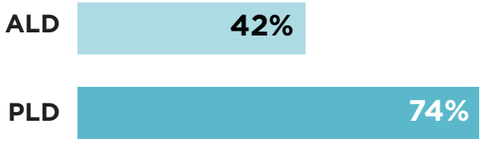
In general, I would say my health is... (fair/poor)



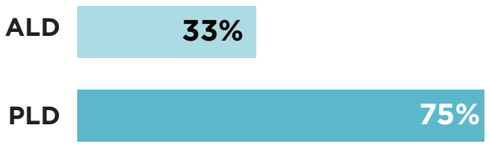
I would describe my main form of work as... (disabled)



Before being diagoned with Lyme disease, I was misdiagnosed with another condition...



I have been diagnosed with a tick-borne co-infection...



Source: Data set dated March 21, 2023

Patient Barriers to Obtaining Care

The limited availability of knowledgeable clinicians and the growing population of patients with PLD has produced a significant supply and demand imbalance that creates an access to care issue for patients that urgently needs to be addressed.

PLD patients encounter many barriers to care including insurance coverage, healthcare costs, travel time, distance, and availability of care providers.

Most patients see more than four physicians before they are diagnosed, creating delays that may impact their quality of life.

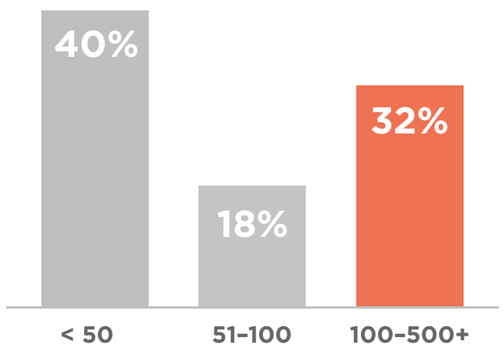
To obtain care, 49% of patients travel more than 50 miles; 32% report traveling 100 miles or more for care. The cost, inconvenience, and work-related impact of traveling these distances may result in some patients forgoing care all together.

96% of patients are diagnosed by primary care clinicians.

Only 4% of patients are seen by infectious disease specialists.

Only 4% of PLD patients are treated by infectious disease specialists. Most are seen by other clinicians, often Lyme-literate doctors who focus on tick-borne diseases, pursue continuing education in this area, and belong to the International Lyme and Associated Diseases Society.

How many miles to treatment?



32% travel **100 or more** miles for treatment.

Sources: Data set dated March 21, 2023; Johnson et al. 2011

Clinician Barriers to Providing Care

"This patient population requires exponentially more care and attention than the typical patient. I knew that at some point I would be forced to stop taking insurance and move forward on a cash-pay-only basis. Looking at the numbers, taking commercial insurance for these patients just doesn't make any sense.

- Clinician

Clinicians whose practice focuses on treating PLD patients report many barriers to providing care, including supply and demand constraints, difficulty providing care under an insurance model of practice, and regulatory or legal challenges.

Time constraints associated with the length of visits required to provide care as well as administrative insurance burdens pose significant challenges. Time constraints include extended duration of initial consult and follow-up visits. Twenty-five percent report that initial consultations last more than 2 hours, while 44% report these visits last one to two hours. In addition, 40% report that follow-up visits last one or more hours.

Prior authorization of medications (77%), insurance denials (71%), other insurance-related issues (49%), and the inability of patients to pay for out-of-pocket costs (75%) are also practice burdens.

The time required to treat these patients makes an insurance-based practice impractical. Acceptance of insurance by clinicians was limited, with roughly 75% of clinicians reporting that they do not participate in insurance networks or directly bill insurers. Most (77%) do not participate in Medicare, Medicaid, or other government supported plans.

75%

of clinicians who treat PLD have felt stigmatized or disrespected by professional colleagues because they treat Lyme disease.

39%

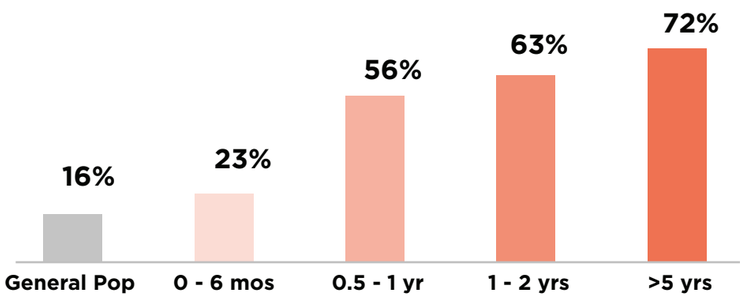
of clinicians report having been reported to a medical board, an insurer, or subjected to a hospital-based quality improvement inquiry

Source: Johnson et al. 2022

Quality of Life

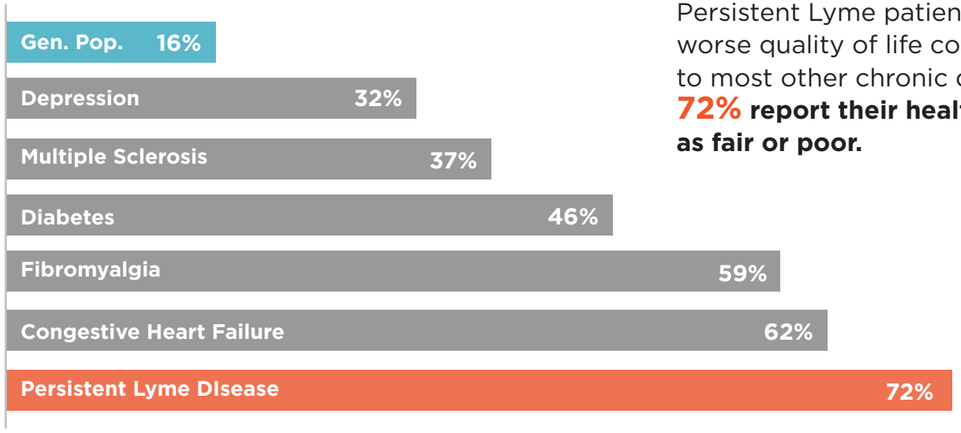
The importance of early diagnosis and effective treatment is underscored by the fact that patients' quality of life declines over time. Quality of life was evaluated in a study that measured using the Self Rated Health Status question developed by the CDC: "In general, would you say your current health status is excellent, very good, good, fair, or poor?" At six months, only 23% reported fair/poor health status compared to 56% at one year, and 72% at five years.

Lyme Patients Reporting Fair/Poor Health Based on Time from Diagnosis



Compared to the general population and patients with many other diseases, PLD patients report substantially lower health-quality status, more bad mental and physical-health days, a significant symptom-disease burden, and greater activity limitations. As the chart below reflects, a higher proportion of PLD patients (72%) described their health status as fair/poor compared to the general population (16%). The quality of life for PLD patients is also far worse than most other diseases, including multiple sclerosis (37%), diabetes (46%), fibromyalgia (59%), and congestive heart failure (62%).

Health Status As Fair Or Poor



Persistent Lyme patients suffer worse quality of life compared to most other chronic diseases. **72% report their health status as fair or poor.**

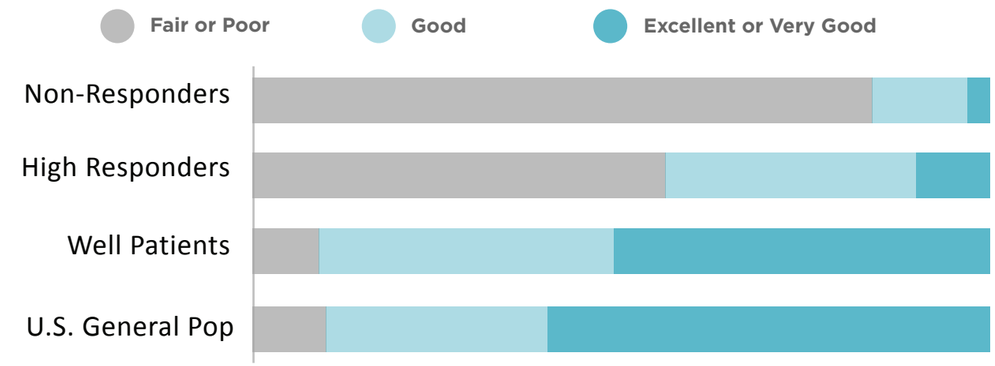
Source: Johnson et al. 2014

Quality of Life Is A Marker of Treatment Improvement

Quality of life improves for PLD patients who are high responders to antibiotics—those reporting moderate to significant improvement—and for those who now consider themselves to be well.

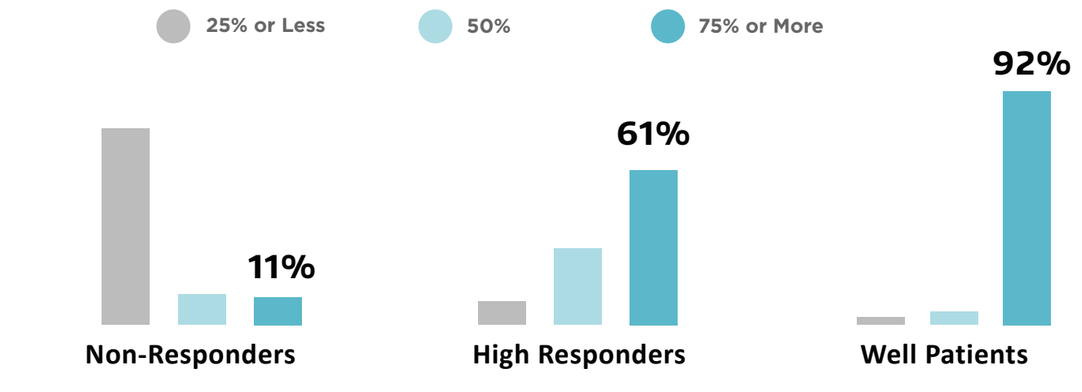
The percentage of "well" PLD patients (50%) who rate their quality of health as excellent or very good is comparable to the US general population (60%).

Self-Rated Health is Greater for High Responders and Well Patients



Moreover, high responders and well patients are more likely to report improving 75% or more as a result of antibiotic treatment.

Percent Improvement Is Greater in High Responders and Well Patients



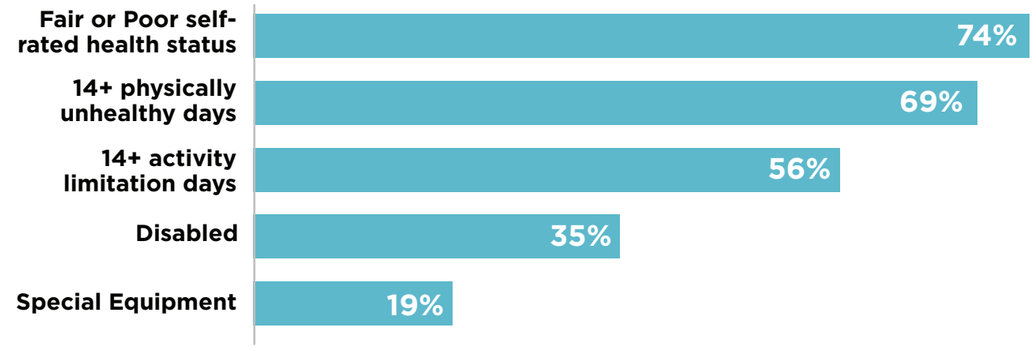
Source: Johnson et al. 2020

Activity Limitations

PLD is associated with substantial quality of life and functional impairments. MyLymeData includes a number of CDC health-related quality of life indicators that are widely used in the general population to determine the burden of disease. This allows us to compare PLD patients with the general population. The percent reporting 14 or more activity limitation days (56%) exceeds the general population (40%).

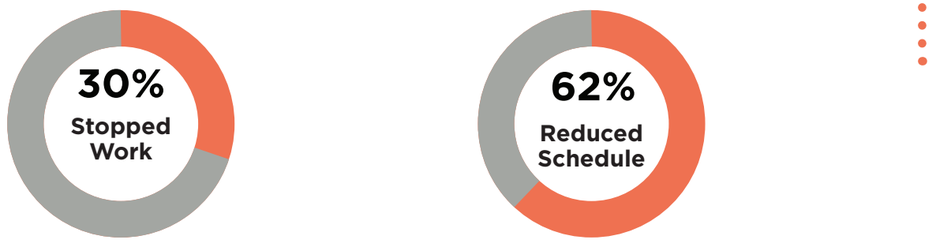
Similarly, the percentage of participants who report having to rely on special equipment due to their Lyme disease is quite high (>19%) compared to the US general population (11%). Almost 70% report 14 or more physically unhealthy days, and 35% report their employment status as disabled.

Quality of Life Impairment



Poor health status not only affects activity limitations, it also affects employee productivity. Approximately 80% of the cost of chronic illness is productivity losses. A substantial percentage of PLD patients report that Lyme disease impairs their ability to work currently or has in the past, resulting in either a reduction in work hours (62%) or quitting work altogether (30%).

Changes to Work Schedule



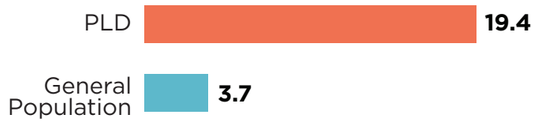
Sources: Data set dated March 21, 2023; Centers for Disease Control and Prevention 2018; Johnson et al. 2023; Johnson et al. 2014; Johnson et al. 2011; Gerbi et al. 2016.

Healthcare Utilization

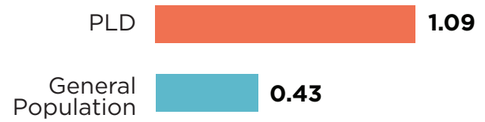
Chronic illnesses account for 84% of healthcare costs, and those with chronic illnesses are the greatest users of healthcare services. People in the highest 5% of the medical expense category are 11 times more likely to be report their health status as fair/poor.

In MyLymeData, we measure healthcare utilization using the Agency for Healthcare Research and Quality's Medical Expenditure Panel Survey. PLD patients were five times more likely to visit doctors and healthcare professionals and twice as likely to be seen in an emergency department compared with the general population. In addition, they were almost twice as likely to stay overnight in a hospital and roughly six times more likely to receive home care visits.

Annual Doctor's Visits

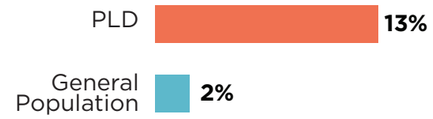


Annual ER Visits



% with Hospital Inpatient Stays

% with Home Care Visits



A big data study out of Johns Hopkins using insurance claims records of over 50,000 Lyme patients found increased healthcare utilization costs. Dr. Emily Adrion, lead author of that study states:

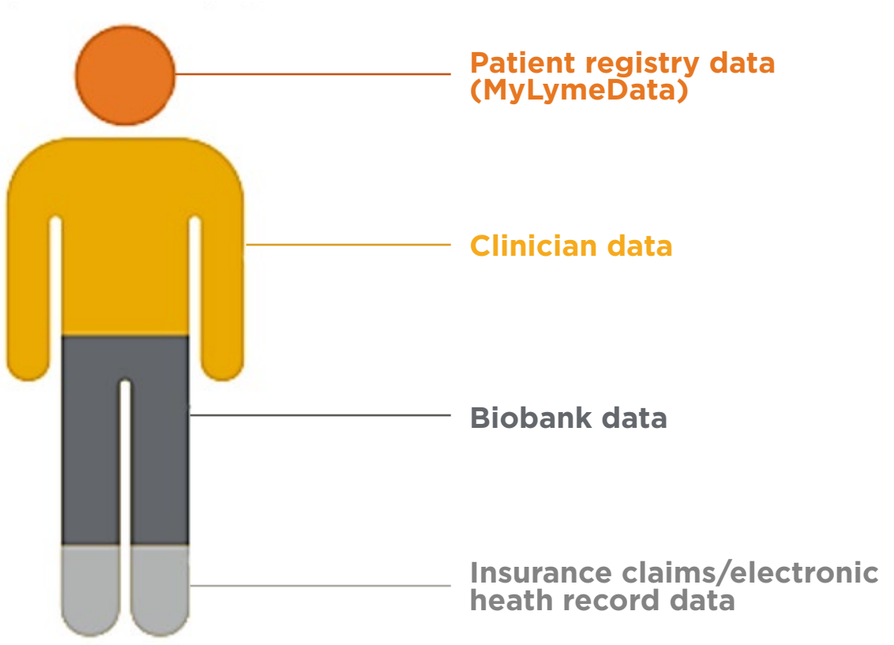
> ***Our data show that many people who have been diagnosed with Lyme disease are in fact going back to the doctor complaining of persistent symptoms, getting multiple tests and being retreated. They cost the health care system about $1 billion a year and it is clear that we need effective, cost-effective and compassionate management of these patients to improve their outcomes.***
>
> *- Emily Adrion, PhD, Johns Hopkins Bloomberg School of Public Health*

Sources: Johnson et al. 2014; Adrion et al. 2015; Anderson et al. 2010; Stanton et al. 2006.

Sources of Big Data

Unlike randomized controlled trials, big data is acquired from real-world sources. All data sources have their strengths and limitations. For example, convenience samples that are drawn from clinical practice have small sample sizes and reflect the geographic location of their office as well as their treatment approach. Although insurance databases are large, they only include data for insured services. This limitation is important because 50% of PLD patients report that their provider does not accept insurance. Electronic health records are limited by their intended utilitarian focus, which is to gather information related to insurance-billing claims. In contrast, patient registries are designed for research purposes and have large clinically relevant information.

Big Data Comes in Many Forms



Sources for broadened data sampling that also improve the patient-centeredness of research endeavors would include patient registries that collect self-reported data directly from patients and biobanks. Both patient registries and biobanks are underused in Lyme IACI research.

- National Academies of Science, Engineering, and Medicine

Heterogeneity and Subgroups

One of the biggest advantages of big data is that it includes very large numbers of patients. Large samples make it possible to look at subgroups and see how different patients respond to treatment.

Subgroups also help reveal benefits that may be important to patients but that are too small to be detectable in studies with smaller samples. When an illness is complex or treatment effects are modest, as they may be in Lyme disease, thousands of patients may be needed to get reliable answers. Running trials that large is usually only possible with industry funding.

Big data helps solve this problem. In the past, clinical trials for persistent Lyme disease have included only 37 to 129 patients. Because of these small samples, findings have been mixed and often required unrealistically big improvements to count as a success. By comparison, a recent MyLymeData study included nearly 4,000 patients, showing how big data can deliver insights small trials cannot.

Examples of MyLymeData Subgroups

State/status of disease	Treatment Responders	Biological Sex	Symptoms
Sick/Well	Well	Male	Fatigue
Acute	High-responder	Female	Joint Pain
Chronic	Low-responder	Other	Muscle Aches
Late Untreated	Non-responders		Cognitive
			Neuropathy
			Sleep Impairment
			Psychiatric
			Gastrointestinal
			Headache
			Memory Loss
			Heart-Related
			Twitching

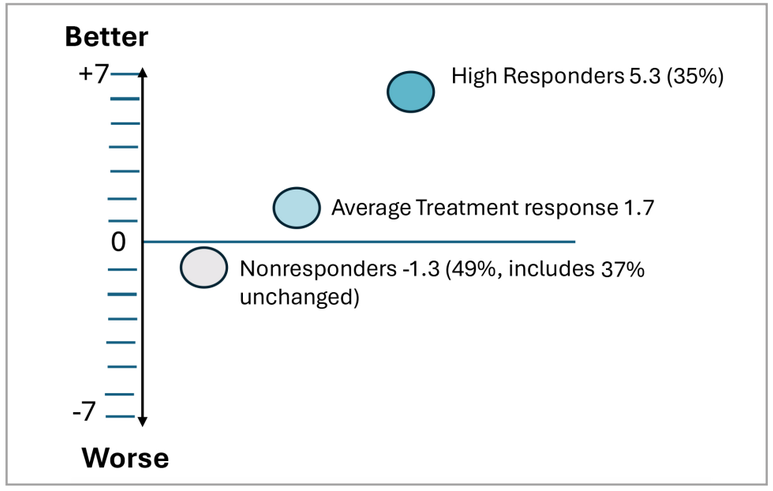
Sources: Fallon et al. 2008; Krupp et al. 2003; Klempner et al. 2001; Johnson et al. 2018; National Academy of Science 2017; Guyatt et al. 2008

Response to Antibiotics

In a recent study, we partnered with Dr. Jennifer Mankoff at the University of Washington to analyze data from nearly 4,000 MyLymeData participants using the Global Rating of Change scale. We compared overall treatment outcomes with results from three subgroups: High Responders, Low Responders, and Nonresponders.

At first glance, the average treatment effect seemed minimal. But a deeper look told a different story: 52% of patients reported improvement, and 35% were classified as High Responders. This shows how relying only on averages can be misleading and may result in patients being denied treatments that could improve their health.

High Responders Respond Positively to Antibiotic Treatment



Past studies of treatment effectiveness have focused on averages that blur important differences between patients, especially those who respond better—or worse—than the norm. To deliver truly personalized care, clinicians need data that reflects the wide variation of patients seen in clinical practice.

Traditional PLD studies have excluded more than 89% of real-world patients. By contrast, our study had a large enough sample to permit subgroup analysis and thus was able to reveal which patients benefit from treatment and which do not.

The vast majority of drugs... only work in 30 or 50 percent of the people. Drugs out there in the market work, but they don't work in everybody... The idea is to identify 'responders' - people who benefit from the drug.

- Dr. Allen Roses, Head of Genetics Research at GlaxoSmithKline

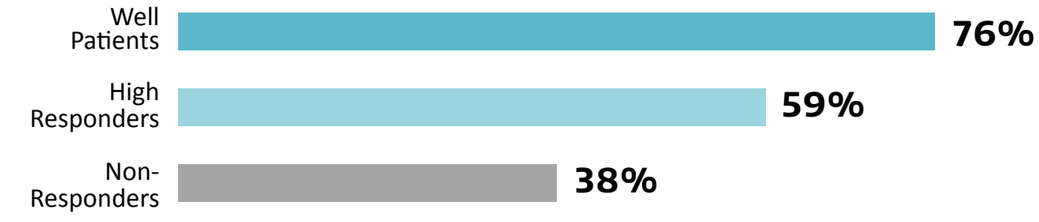
Source: Johnson et al. 2025

Treatment Response

In 2020, the MyLymeData team partnered with researchers at UCLA, led by Dr. Deanna Needell, to expand on our earlier work examining treatment responsiveness using machine learning. Patients were categorized as Nonresponders, Low Responders, High Responders, or Well, and we used both artificial intelligence and traditional statistical methods to identify the factors most strongly linked to better outcomes.

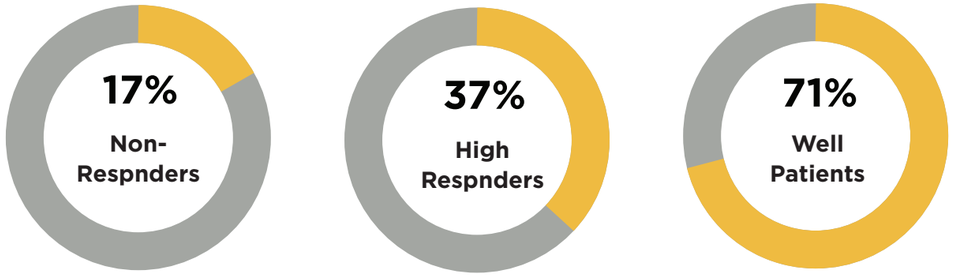
Most RCTs test a single therapy for a fixed period (for example, 90 days of Rocephin). These narrowly designed studies can't capture the variety of treatment strategies patients actually experience. Patient registries, by contrast, reflect care from many clinicians using diverse approaches over different lengths of time. This broader perspective allows researchers to identify patterns of care and outcomes that traditional trials often miss.

More Well Patients and High Responders Report Using Antibiotics



High treatment response or wellness was most closely associated with (1) the use of antibiotics, or a combination of antibiotics and alternative therapies, (2) longer treatment durations, and (3) oversight by clinicians specializing in tick-borne diseases. Notably, most high responders and well patients were treated with antibiotics for more than one year, highlighting the importance of personalized care over a longer period of time to achieve better outcomes.

Most High Responders and Well Patients Take Antibiotics > 1 Year



Source: Johnson et al. 2020

Gender Differences

Very few studies have examined sex differences in Lyme disease. In 2023, MyLymeData partnered with a research team at the University of Washington, led by Dr. Jennifer Mankoff, to investigate this issue. The study, which included over 2,000 patients with PLD, found women reported more tick-borne co-infections, longer diagnostic delays, greater symptom severity, and worse functional impairment than men. They were also more likely to be misdiagnosed—particularly with CFS, FMS, or psychiatric disorders. No differences were reported in antibiotic treatment response or side effects.

Clinical studies of Lyme disease patients with persisting symptoms following antibiotic treatment have applied different definitions for enrollment. In comparison, samples drawn from registries and clinical practice are more reflective of real-world patients and include a higher percentage of women than RCTs. For example, in MyLymeData, 85% of participants are women. Biological sex should be integrated into Lyme disease research as a distinct variable for subgroup analysis to provide insights on sex-based differences that may exist between men and women with PLD.

Average Percentage of Females by Study and Category (Acute/PTLD/PLD)

Category	Study/Data Source	Count	Percentage of Females per study
Acute Avg 42% Range 37% - 47%	Aucott (2022)	234	47%
	Horn 1 (2020)*	196	41%
	Horn 2 (2020)*	102	37%
	CDC Surveillance (Schwartz 2017)	269,973	43%
RCT/PTLD Avg 58% Range 44% - 72%	Aucott (2022)**	32	72%
	Fallon (2008)	23	61%
	Krupp (2003)	28	54%
	Klempner 1 (2001)*	25	60%
	Klempner 2 (2001)*	39	44%
PLD/CLD Avg 77% Range 66% - 88%	Donta (1997)	277	66%
	Donta (2003)	235	73%
	Fallon (1999)	23	70%
	Citera 1 (2017)*	537	73%
	Citera 2 (2017)*	782	77%
	Citera 3 (2017)*	236	80%
	MyLymeData (Johnson 2022)	2,170	85%
	Lyme Biobank (Horn 2022)**	73	88%

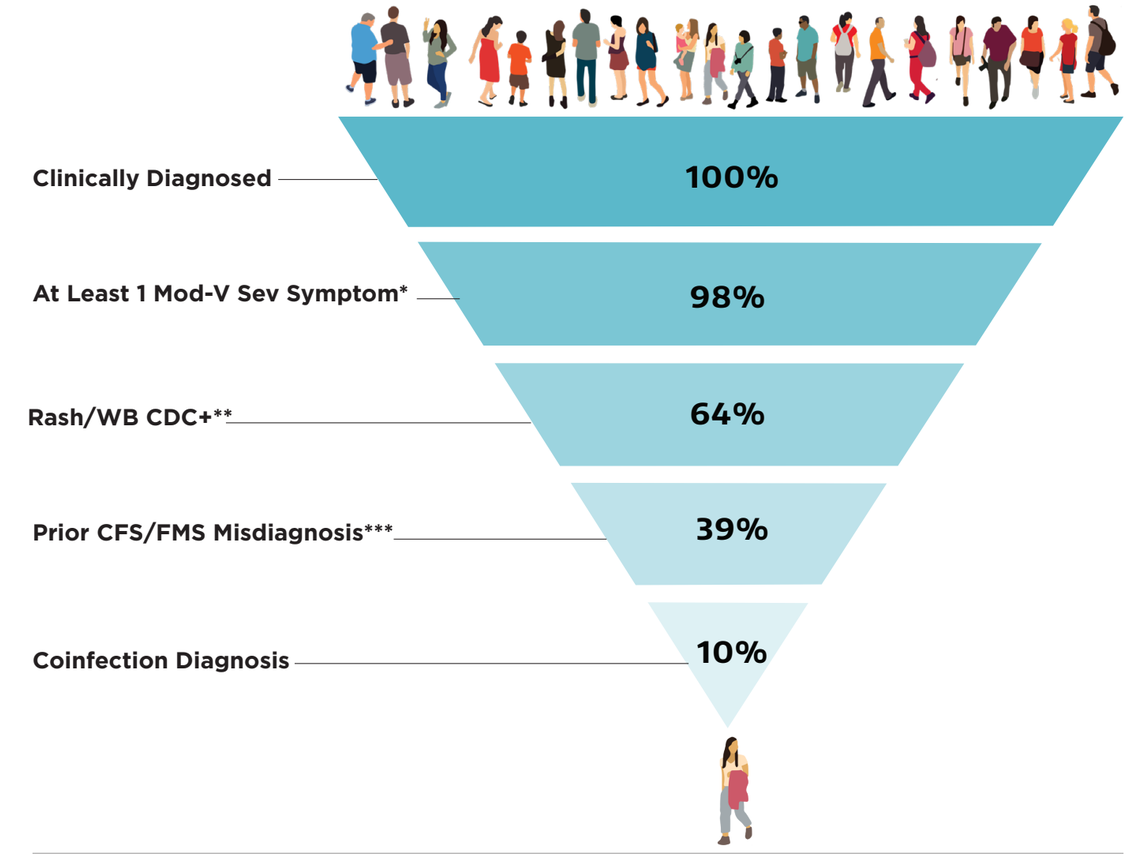
Source: Johnson et al. 2023

Clinical Trials Exclude Most PLD Patients

Overly restrictive eligibility criteria in clinical trials can lead to small sample sizes that compromise the ability of a study to detect meaningful treatment effects. This is particularly true in conditions like PLD, where treatments may benefit some patients significantly while not helping others.

Many studies adopt eligibility criteria from previous research without carefully evaluating whether they are necessary. However, each individual exclusion criterion decreases the sample yield and generalizability of the results of that study to the clinical population. Randomized PLD retreatment trials have excluded between 89-99% of patients who sought to enroll. Trials this restrictive cannot provide clinically relevant insights.

In 2025, MyLymeData collaborated with Dr. Deanna Needell at UCLA to examine the effect of exclusion criteria on sample size. The figure below shows the effect of different exclusion criteria on sample size. Carefully considering the impact of each eligibility criterion during study design is essential.



Source: Johnson et al. 2025

What Is Persistent Neurological Lyme Disease?

Needell, D; Shapiro, M.; Gevertz, J.; Stricker, R.; Johnson, L.

Overview

Although 84% of PLD patients report severe neurological symptoms, persistent neurological Lyme disease (NPLD) remains poorly understood. Using real-world data from over 9,000 patients, this study uses artificial intelligence to determine whether a distinct NPLD subgroup can be identified and how it differs from other PLD groups. Identifying symptom clusters and phenotypes is key to advancing research and clinical care in diseases that lack a clear biomarker.

Objectives

- Define NPLD using AI
- Compare NPLD with other subgroups
- Explore differences for clinical practice

Study Group

9,000 patients enrolled in MyLymeData responded to survey questions regarding their disease and related diagnostic circumstances.

About the Study

Funded by the Congressionally Directed Medical Research Program at the Department of Defense

Title: Uncovering the Neurological Dimensions of Persistent Lyme Using Machine Learning & Registry Data

Team:

- Dr. D. Needell, UCLA (PI)
- Dr. J. Gevertz, The College of New Jersey
- L. Johnson, LymeDisease.org
- Dr. R. Stricker (Clinical Consultant)

Term: June 2025-2028

Do Subgroups Differ?

- Symptom patterns/severity
- Rash or + lab test
- Tick-borne co-infections
- Quality of life/impairment
- Disease progression
- Response to treatment

Improve Clinical Care

- Guide individualized care
- Tailor treatment to improve outcomes
- Enhance diagnostic precision
- Inform prognosis
- Explain variation in impact

MyLymeData
A PROJECT OF LYMEDISEASE.ORG

THE COLLEGE OF NEW JERSEY

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2025 Research Chartbook

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