

## Plan Overview

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*A Data Management Plan created using DMPTool*

**Title:** Risk Characterization of Lyme Borreliosis in the endemic Midwest

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### **Project abstract:**

Lyme Borreliosis is the most common vector borne disease in North America; reported rates are underestimations due to both challenges in diagnosis and misunderstood risk so less care seeking. Therefore, there is a critical need to understand how people are experiencing risk in environments with varied presence of ticks; how and how successfully patients are accessing care for potential Lyme Borreliosis; and how patient characteristics affect clinical outcomes. Our long-term goals are to understand risk in environments of varied likelihood of exposure to infected ticks; increase accurate, timely diagnoses for tick-borne diseases; and improve clinical outcomes for Lyme Borreliosis patients. The overall objective for this project is to broaden our understanding of risk as it pertains to Lyme Borreliosis acquisition; how patients are interacting with healthcare related to that risk; and, how that is affecting clinical outcomes. Our central hypotheses are that human exposure plays an integral role in experienced risk regardless of results of surveillance for ticks capable of transmitting *Borrelia burgdorferi*; and, that differences between individuals, accessed level of care, and at what point in their clinical syndrome care is sought leads to delays in diagnosis, as well as avoidable adverse outcomes. The rationale that underlies this research is that the information obtained here will lead to improved risk management, patient outcomes, and a decrease in morbidity associated with Lyme Borreliosis. We have three main aims. First, we will estimate differences in time from initial contact with healthcare system to diagnosis of Lyme and determine what sociodemographic and clinical characteristics lead to higher rates of mis- and delayed diagnosis. To accomplish this, we will evaluate whether time to diagnosis differs depending on level of care sought by patient, sociodemographic and clinical factors using cox proportional hazard regression. Second, we aim to analyze the effect alternate diagnoses and coinfection with additional pathogens—especially potential co-transmitted tick-borne pathogens—has on outcomes for Lyme Borreliosis. To accomplish this, we will examine whether initial misdiagnosis with an alternate disease affects level of care received and whether it leads to higher odds of adverse clinical outcomes using logistic regression. Lastly, we aim to quantify and compare the effects of presence of *Ixodes scapularis* as well as ticks overall in the environment and human activities that may lead to exposure on the risk of contracting Lyme Borreliosis. Based on tick density and human exposure, we will

identify predicted geographic categorizations of risk using bivariate spatial autocorrelation. We will then compare these risk categorizations with human cases of Lyme using negative binomial regression. Upon successful completion of the proposed research, we expect to contribute a better understanding of risk as it pertains to exposure, as well as patient experiences and factors associated with late and misdiagnoses of Lyme Borreliosis towards improved case management.

**Start date:** 07-01-2024

**End date:** 06-30-2026

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## **Risk Characterization of Lyme Borreliosis in the endemic Midwest**

This project will consolidate and transform data from clinical records, public health and entomologic surveillance, and crowd-sourced nature observations. This could include thousands of cases of suspected and confirmed Lyme Borreliosis, thousands of tick observations, and hundred to a thousand crowd-sourced observations. For the purpose of descriptive analytics and tests, the data will be managed in SAS. ArcGIS and other visual analytic tools will be employed for geospatial analysis. The project is not anticipating decodable information regarding patient identity.

Pending authorization by the data owners (e.g., Mayo Clinic, Minnesota Department of Health, Metropolitan Mosquito Control District, others as applicable) for each distributable format, we hope to make transformed data available for use by other researchers in support of the Open Data movement.

To facilitate interpretation of the data, our data dictionary, statistical analysis plans, and related data protocols will be available on request by groups seeking to re-create our results or pursue analogous analyses.

Our data will be readily employed in usual statistical and mapping software, though tailored to how we ultimately undertake analyses. In our case, this will begin with SQL platforms for initial data handling from the relevant electronic health record databases, Microsoft Excel, SAS, and ArcGIS.

In this novel, integrative work, we are not aware of specific data standards. However, as we will be transforming the data for use in standard analytic tools, we anticipate that other researchers and stakeholders similarly will have access for its use.

We have searched the NIH support Scientific Data Repositories employing key words tick, Lyme, One Health, and Borrelia. With the exception of a genomics-focused repository on eukaryotic pathogens, there is not an obvious repository for this integrated data. The set as refined will remain accessible to PCORNet investigators who attain the appropriate permissions. We remain open as an investigator group to advice on repositories which we may have overlooked. And, we look forward to supporting requests for data that we may receive, in accordance with the constraints set by data owners.

Contact information appropriate to discuss data access will be available with publication and presentation. An appropriate standing repository has not yet been identified.

It is the intent that data will be available by the end of the performance period with initial publication, appropriate to data owner permissions.

Data use agreements with data owners are pending award and the ability to proceed with the work. While in general major limitations that will affect the access, distribution or reuse of the scientific data generated by the proposal are not anticipated, data from clinical sources and agencies may require further transformation for public release by data owners. We look forward to facilitating such requests, which may result in persons seeking access to data undertaking independent authorizations from the relevant source.

As required for full release, we intend to directly provide or reduce as directed by data owners research data for direct, uncurated access. However, fuller data sets may inherit curation restrictions by the data owners.

We will be working with non-personally identifiable data.

The principal investigator's team, the Emerging Threats Epidemiology Group, has an internal quality assurance

process led by a clinical research nurse that involves assessing each study regularly (monthly to quarterly depending upon requirements) for adherence to regulatory requirements. This plan will be folded into the trackable process, originally designed for human subject research protocol reporting and auditing requirements. The team has experience tracking data and sample requests from leadership of prospective emerging infectious diseases cohorts.

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## Planned Research Outputs

### Service - "Stakeholder briefings"

The research team will keep data owners (e.g., Mayo Clinic, Minnesota Department of Health, Metropolitan Mosquito Control District) apprised of study progress and outputs with virtual and, as appropriate, in person meetings. These will be with the intent both to garner stakeholder feedback on the utility and impact of research outputs, and also to inform clinical and public health risk management actions on a rolling basis.

### Data paper - "Peer reviewed presentation and publication"

We will pursue presentation and publication in open access, whenever possible, of discovery in clinical, public health, and broad risk management aspects of this project. This will include professional society meetings (e.g., American Society of Tropical Medicine and Hygiene), and technical publications (e.g., Emerging Infectious Diseases; Journal of Infectious Diseases; Clinical Infectious Diseases).

### Dataset - "Alternative posting in lieu of repository"

Should an appropriate repository not become available, following initial publication we will work with data owners to identify appropriate open access venues to make relevant data available. This may result in more than one product reduced to providing agency's requirements. Options for dissemination may include UNMC website, or other agency websites. We will continue to review broad-based, customary repositories to identify good fits for useability.

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## Planned research output details

Title	Type	Anticipated release date	Initial access level	Intended repository(ies)	Anticipated file size	License	Metadata standard(s)	May contain sensitive data?	May contain PII?
Stakeholder briefings	Service	2025-06-30	Closed	None specified		None specified	None specified	No	No
Peer reviewed presentation and publication	Data paper	2026-08-30	Open	None specified		Custom Data Use Agreements/Terms of Use	None specified	No	No
Alternative posting in lieu of repository	Dataset	2026-08-31	Open	None specified		Creative Commons Attribution 4.0 International	None specified	No	No