Plan Overview

A Data Management Plan created using DMP Tool

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 pathogensespecially 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.

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Risk Characterization of Lyme Borreliosis in the endemic Midwest

Data Type

Types and amount of scientific data expected to be generated in the project: Summarize the types and estimated amount of scientific data expected to be generated in the project.

Describe data in general terms that address the type and amount/size of scientific data expected to be collected and used in the project (e.g., 256-channel EEG data and fMRI images from ~50 research participants). Descriptions may indicate the data modality (e.g., imaging, genomic, mobile, survey), level of aggregation (e.g., individual, aggregated, summarized), and/or the degree of data processing that has occurred (i.e., how raw or processed the data will be)

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.

Scientific data that will be preserved and shared, and the rationale for doing so: Describe which scientific data from the project will be preserved and shared and provide the rationale for this decision.

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.

Metadata, other relevant data, and associated documentation: Briefly list the metadata, other relevant data, and any associated documentation (e.g., study protocols and data collection instruments) that will be made accessible to facilitate interpretation of the scientific data.

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.

Related Tools, Software and/or Code

State whether specialized tools, software, and/or code are needed to access or manipulate shared scientific data, and if so, provide the name(s) of the needed tool(s) and software and specify how they can be accessed.

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.

Standards

State what common data standards will be applied to the scientific data and associated metadata to enable interoperability of datasets and resources, and provide the name(s) of the data standards that will be applied and describe how these data standards will be applied to the scientific data generated by the research proposed in this project. If applicable, indicate that no consensus standards exist

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.

Repository where scientific data and metadata will be archived: Provide the name of the repository(ies) where scientific data and metadata arising from the project will be archived.

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.

How scientific data will be findable and identifiable: Describe how the scientific data will be findable and identifiable, i.e., via a persistent unique identifier or other standard indexing tools.

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

When and how long the scientific data will be made available: Describe when the scientific data will be made available to other users (i.e., no later than time of an associated publication or end of the performance period, whichever comes first) and for how long data will be available.

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

Access, Distribution, or Reuse Considerations

Factors affecting subsequent access, distribution, or reuse of scientific data: NIH expects that in drafting Plans, researchers maximize the appropriate sharing of scientific data. Describe and justify any applicable factors or data use limitations affecting subsequent access, distribution, or reuse of scientific data related to informed consent, privacy and confidentiality protections, and any other considerations that may limit the extent of data sharing.

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.

Whether access to scientific data will be controlled: State whether access to the scientific data will be controlled (i.e., made available by a data repository only after approval).

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.

Protections for privacy, rights, and confidentiality of human research participants: If generating scientific data derived from humans, describe how the privacy, rights, and confidentiality of human research participants will be protected (e.g., through de-identification, Certificates of Confidentiality, and other protective measures).

We will be working with non-personally identifiable data.

Oversight of Data Management and Sharing

Describe how compliance with this Plan will be monitored and managed, frequency of oversight, and by whom at your institution (e.g., titles, roles).

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.

Planned Research Outputs

Service - "Stakeholder brieings"

The research team will keep data owners (e.g., Mayo Clinic, Minnesota Department of Health, Metropolitan Mosquito Control District) appraised 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).

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.

Planned research output details

Title	Туре	Anticipated release date	Initial access level	Intended repository(ies)	Anticipated file size	License	Metadata standard(s)	May contain sensitive data?	May contain PII?
Stakeholder brieings	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