Plan Overview

A Data Management Plan created using DMPonline.be

Title: Molecular Epidemiology of tuberculosis at Human-Animal interface in the pastoral areas of Ethiopia with subsequent development of improved diagnostic approach.

Creator: Gemechu Chala Hunderra

Principal Investigator: Gemechu Chala Hunderra

Data Manager: n.n.

Project Administrator: n.n.

Affiliation: KU Leuven (KUL)

Template: KU Leuven BOF-IOF

Principal Investigator: Gemechu Chala Hunderra https://orcid.org/0000-0001-6565-3844

Data Manager: n.n. n.n.

Project abstract:

- Against the available diagnosis and treatment advances, tuberculosis remains a relentless disease that is one of the leading causes of death from a single infectious agent worldwide. Human-to-animal transmission of *Mycobacterium tuberculosis* complex, including *M. tuberculosis*, is well documented in many parts of the world, including Ethiopia, which could have an implication in the epidemiology and control of tuberculosis in human and animal populations. However, livestock farmers and other herdsmen and slaughterhouse workers can also contract the disease via contaminated air droplets via aerosols from infected animals with pulmonary tuberculosis. This is particularly important in Ethiopia, where tuberculosis is endemic, milk pasteurization is limited and human-animal interaction is unavoidable. Reverse transmission of *Mycobacterium tuberculosis* complex and other atypical *mycobacteria* between camel and humans in areas of intense human-animal contact is one of the driving factors for the onset and maintenance of tuberculosis in environments such as camel-herding pastoral areas of Ethiopia. By endorsing the "Global End TB Strategy" by 2035, Ethiopia's National End TB Strategy aimed to eliminate tuberculosis epidemics by reducing tuberculosis-related deaths by 95% and by reducing incidental tuberculosis cases by 90% between 2015 and 2035. One of the huge obligations of this programme is to improve access and equitable tuberculosis services for vulnerable and marginalized populations where tuberculosis is concentrated and where most delays occur due to socio-economic and legal barriers. Tuberculosis in dromedaries threatens the well-being and livelihoods of pastoral communities, and creating barriers to international trade in dromedaries and their products. It would therefore be very important to assess the occurrence of *Mycobacteria* infection at the human-animal interface in the pastoral communities of camel rearing in Ethiopia, describe the type species and/or strain circulating among humans and camels, and relate the transmission risks while describing the epidemiology and transmission dynamics of *Mycobacteria*. Such a study is also essential in devising context-appropriate tuberculosis control and prevention interventions. However, the accuracy of diagnostic tests for tuberculosis infection used in animals, mainly camels, is often elusive when diagnosing tuberculosis, and yet there is no reliable diagnostic test for accurate early ante-mortem diagnosis of tuberculosis in dromedaries, indicating the need for exploration and development of a new diagnostic tool. Against this background, this project is designed to study the molecular epidemiology of tuberculosis at the human-animal interface and to assess the bidirectional zoonotic transmission of *Mycobacteria* species between humans and animals in the dromedary camel-rearing pastoral communities in Ethiopia, and the subsequent development of proof-of-concept for an improved diagnostic tool using camelids, nanobodies and phage technology.

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Molecular Epidemiology of tuberculosis at Human-Animal interface in the pastoral areas of Ethiopia with subsequent development of improved diagnostic approach.

Research Data Summary

List and describe all datasets or research materials that you plan to generate/collect or reuse during your research project. For each dataset or data type (observational, experimental etc.), provide a short name & description (sufficient for yourself to know what data it is about), indicate whether the data are newly generated/collected or reused, digital or physical, also indicate the type of the data (the kind of content), its technical format (file extension), and an estimate of the upper limit of the volume of the data.

Dataset name / ID	Description	New or reuse	Digital or Physical data	Data Type	File format	Data volume	Physical volume
		Indicate: ***N****(ew data) or* ***E****(xisting data)*	Indicate: **D**(igital) or **P**(hysical)	Indicate: **A**udiovisual **I**mages **S**ound **N**umerical **T**extual **M**odel **SO**ftware Other (specify)		Indicate: <1GB <100GB <1TB <5TB >5TB NA	
Human Blood/sputum will be collected	Laboratory analysis	N	P/D	I, N, T and others	.tab, txt, pdf, other	<1GB	
Camel milk/blood will be collected	Laboratory analysis	N	P/D	I, N, T and others	.tab, txt, pdf, .csv Excel, other	<1GB	
Demographic and epidemiological data	Questionnaire survey	N	D	N and T	.tab, txt, pdf, .csv Excel	<1GB	
Phage utilization	Phage-based mycobacteria detection	N	P/D	Observational, N, others	NA	NA	
Bacterial isolate	Molecular typing	N	P/D	Sequences, Images, N	NA	<1GB	
PBMC	Nanobody isolation and engineering	N	P/D	Sequences, N, Others	NA	<1GB	

If you reuse existing data, please specify the source, preferably by using a persistent identifier (e.g. DOI, Handle, URL etc.) per dataset or data type:

No

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? If so, refer to specific datasets or data types when appropriate and provide the relevant ethical approval number.

- Yes, dual use (Provide approval number below)

The Ethical approval was obtained from home Institution (Hawassa University, Ethiopia) and the number is HU-RERC-19-24

Will you process personal data? If so, please refer to specific datasets or data types when appropriate and provide the KU Leuven or UZ Leuven privacy register number (G or S number).

- Yes (Provide PRET G-number or EC S-number below)

The ethical approval is already obtained from home Institution (Hawassa University) with the EC number of (HU-RERC-19-24)

Does your work have potential for commercial valorization (e.g. tech transfer, for example spin-offs, commercial exploitation, …)? If so, please comment per dataset or data type where appropriate.

- No

Do existing 3rd party agreements restrict exploitation or dissemination of the data you (re)use (e.g. Material or Data transfer agreements, Research collaboration agreements)? If so, please explain in the comment section to what data they relate and what restrictions are in place.

- No

Are there any other legal issues, such as intellectual property rights and ownership, to be managed related to the data you (re)use? If so, please explain in the comment section to what data they relate and which restrictions will be asserted.

- No

Documentation and Metadata

Clearly describe what approach will be followed to capture the accompanying information necessary to keep data understandable and usable, for yourself and others, now and in the future (e.g. in terms of documentation levels and types required, procedures used, Electronic Lab Notebooks, README.txt files, codebook.tsv etc. where this information is recorded).

All data will be documented on KU Leuven servers, and personal One drive. All data will be accompanied with appropriate documentation styles and tabs outlining procedures and standards followed during data collection and processing. Standard operating procedures and guidelines to be followed during data collection, processing and laboratory work will be well documented in the lab. All team members have access to these metadata.
Moreover, all data related to sample collection will be documented in the form of soft copies (pdf, Excel, word, Codebook.tsv etc). All collected samples will be processed and the results of which will be stored in appropriate cold chain (example: +4°C, -20°C or -80°C freezers)
other data to be generated from the questionnaire survey will be documented using pdf, txt, word or other documentation formats
Molecular and sequence associated data will be documented in soft copies, README.txt files etc

Will a metadata standard be used to make it easier to find and reuse the data?
If so, please specify which metadata standard will be used.

If not, please specify which metadata will be created to make the data easier to find and reuse.

- No

The aforementioned methods of data documentation clearly ensures the exact documentation and finding of the data. Any specific data related to this project can be retrieved from the above documentation methods

Data Storage & Back-up during the Research Project

Where will the data be stored?

- Shared network drive (J-drive)
- OneDrive (KU Leuven)

How will the data be backed up?

- Standard back-up provided by KU Leuven ICTS for my storage solution
- Personal back-ups I make (specify below)

Researcher-based personal data back-up will be made using external drives that will be available upon request

Is there currently sufficient storage & backup capacity during the project?

If no or insufficient storage or backup capacities are available, explain how this will be taken care of.

- Yes

How will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

All the shared data related to this particular project will be accessed only by promoters (co-promoters) and the research team. Moreover, the two factor authentication of KU Leuven provides secure storage against other unauthorized personnel access.

What are the expected costs for data storage and backup during the research project? How will these costs be covered?

The current KU Leuven central server is enough for the full storage and back-up of all data to be generated from this project with out additional cost.

Data Preservation after the end of the Research Project

Which data will be retained for 10 years (or longer, in agreement with other retention policies that are applicable) after the end of the project?

In case some data cannot be preserved, clearly state the reasons for this (e.g. legal or contractual restrictions, storage/budget issues, institutional policies...).

- All data will be preserved for 10 years according to KU Leuven RDM policy

Where will these data be archived (stored and curated for the long-term)?

- KU Leuven RDR
- Shared network drive (J-drive)

What are the expected costs for data preservation during the expected retention period? How will these costs be covered?

The KU Leuven's servers are enough for the full storage and back-up of all the data to be obtained from this project with out additional cost.

Data Sharing and Reuse

Will the data (or part of the data) be made available for reuse after/during the project?
Please explain per dataset or data type which data will be made available.

- Yes, as restricted data (upon approval, or institutional access only)

If access is restricted, please specify who will be able to access the data and under what conditions.

Access to all stored data related to this project will be granted upon approval from the Promoters and/or researcher or Institutional access only

Are there any factors that restrict or prevent the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions)?

Please explain per dataset or data type where appropriate.

- No

Where will the data be made available?

If already known, please provide a repository per dataset or data type.

- KU Leuven RDR (Research Data Repository)

When will the data be made available?

- Upon publication of research results

Which data usage licenses are you going to provide?

If none, please explain why.

- Data Transfer Agreement (restricted data)

Do you intend to add a persistent identifier (PID) to your dataset(s), e.g. a DOI or accession number? If already available, please provide it here.

- No

What are the expected costs for data sharing? How will these costs be covered?

Freeware such as WeTransfer can be used to transfer and share the files.

Responsibilities

Who will manage data documentation and metadata during the research project?

The researcher and promoters of the project

Who will manage data storage and backup during the research project?

The Researcher and promotor of the project, together with the IT service that is responsible for the implementation of the storage and regular back up on the shared drivers.

Who will manage data preservation and sharing?

The researcher and promoters of the project

Who will update and implement this DMP?

The researcher will remain responsible for updating and implementing this DMP (day-to-day management), while the promotor will be responsible for overall data management.