Plan Overview

A Data Management Plan created using DMPonline.be

Title: Development of complex PRIMED Antimicrobial Stewardship Intervention to ensure optimal antimicrobial therapy in a multicenter tertiary healthcare settings in Ethiopia

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Project abstract:

Antimicrobial resistance (AMR) is one of the top global public health and development threats. The overuse and misuse of antimicrobials in humans, next to animals and plants are the main drivers in the development of drug-resistant bacteria. AMR affects countries in all regions and all income levels, but its consequences are exacerbated by poverty and equality. Therefore, low- and middle-income countries, such as Ethiopia, are more affected. AMR makes infections harder to treat and makes other medical treatments, such as surgery and cancer chemotherapy, much riskier. Antimicrobial stewardship (AMS), bundling different types of interventions and approaches to warrant correct use of antimicrobials, is very important to combat emergence of AMR. In western Europe, AMS is nowadays accepted as standard-of-care in hospital setting. However, low income countries, such as Ethiopia, AMS is implemented in a very fragmented way or absent. Objectives The aim of this PhD project is to develop and implement a complex PRIMED-AMS intervention' in different tertiary care setting, ensuring optimal preparedness, initiation, modification, de-escalation, and discontinuation of antimicrobials in patients admitted with (severe) infections. With this, we aim to show that antimicrobial consumption will be reduced while maintaining the same efficacy (clinical cure rate) and safety. The primary endpoint is reduction in antimicrobial prescribing, and antimicrobial consumption (DDD/100 patient days) and the secondary endpoint includes reduction of emergence of antimicrobial resistance. After completion of the study, the data will be analyzed and finalized at the KU Leuven. A dissemination protocol, including barriers and facilitators, will be developed to allow dissemination in other Ethiopian hospitals.

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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	
AMR data in Ethiopia	Secondary data on AMR in Ethiopia, extracted from published systematic reviews and meta-analyses, includes raw data, processed (cleaned, validated, checked), and analyzed (graphs, tables, texts)	E	D	N, T, I	CSV (.csv) R (.R, .RData) PDF/A (.pdf) ODT (.odt)	<1GB	
AMS national survey	Primary observation data from an online survey includes raw data from AMR/AMS task forces at the Ministry of Health and regional health bureaus, processed data (digitized, cleaned, validated, checked), and analyzed data (graphs, tables, texts)	N	D	T, N, SO	SQL (.sql) R (.R, .RData) PDF/A (.pdf) ODT (.odt)	<1GB	
AMS healthcare settings survey	Primary observational data from an online survey includes raw data from tertiary hospitals, processed data (digitized, cleaned, validated, checked), and analyzed data (graphs, tables, texts)	N	D	SO T N	SQL (.sql) R (.R, .RData) PDF/A (.pdf) ODT (.odt)	<1GB	
AMS intervention development	Primary data on AMS interventions from various experts includes raw data from guidelines, protocols, and research articles, processed data (digitized, cleaned, validated, checked), and analyzed data (tables, texts)	E	D	T, M,	PDF/A (.pdf) ODT (.odt)	<1GB	

Prospective AMS intervention study	Primary experimental data collected prospectively via REDCap from patient charts includes raw data from selected study site hospitals, processed data (digitized, cleaned, validated, checked), and analyzed data (graphs, tables, texts)	N	D	SO N T	SQL (.sql) R (.R, .RData) PDF/A (.pdf) ODT (.odt)	<1GB	
Qualitative study on AMS intervention feedback and challenges	Primary focus group discussion data from healthcare professionals working in AMS interventions includes raw data from participants, processed data (digitized, cleaned, validated, checked), and analyzed data (graphs, tables, texts)	N	P	A S SO	MP3 (.mp3 REFI-QDA (.qdpx)	<100GB	

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, human subject data (Provide SMEC or EC approval number below)

Ethical approval will be obtained from home Institution (Ethiopia Ministry of Education) and all human-related data will be fully pseudonymized.

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)

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).

To keep data clear and accessible, Electronic Lab Notebooks will record methodological procedures and store all project-related data, from raw data to final figures and tables, including seminar and event presentations, manuscript drafts, and final versions. Data will be stored on KU Leuven servers and personal OneDrive accounts, with documentation outlining procedures and standards. Standard operating procedures for data collection, processing, and analysis will be prepared. An index will explain each code and project, with links to data file locations.

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.

- Yes

Descriptive metadata like authors, title, abstract, and keywords, aligned with schemes like DataCite, will be essential to make data findable and citable. Structural metadata will detail units of analysis, sample types, instruments, settings, and methodologies, adhering to best practices for clarity and reproducibility. Metadata will be generated during data collection, enriched with Research Data Management tools, and supplemented upon repository deposit. Data will be shared via the KU Leuven Research Data Repository, using the DataCite standard for discoverability, documentation, and citation.

Data Storage & Back-up during the Research Project

Where will the data be stored?

- Large Volume Storage
- ManGO
- Personal network drive (I-drive)

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 data will be stored on the personal OneDrive cloud service provided by KU Leuven and accessed by only the researcher. This storage space is very secure, with automatic backups and advanced protections such as the two factor authentication of KU Leuven provides secure storage against other unauthorized personnel access.
- Sharing of data to authorized persons will be done via TEAMS, which is also a secure platform.
  After the end of the project, final data files will be archived on the Archive/'K:' network drive, which has restricted access (only professors and postdocs of the research group)

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)?

- Large Volume Storage (longterm for large volumes)
- KU Leuven RDR

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

No extra costs are expected, 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 open data
- Yes, as restricted data (upon approval, or institutional access only)

Digital (figures, tables, excel files, text files) raw and processed data (including statistical analysis files) will be made available upon request or will be freely available after scientific publication

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.
Teklu Gebrehiwot Gebremichael (PhD researcher)
Promoter (Prof. Veerle Foulon)

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
- Yes, intellectual property rights

Where will the data be made available?

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

- Other data repository (specify below)
- KU Leuven RDR (Research Data Repository)

Published data in academic peer reviewed journals and will as such be available in existing and relevant repositories (e.g. KU Leuven repository: Lirias).
Unpublished data will be available with restricted access on network drives

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.

- Yes, a PID will be added upon deposit in a data repository

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

None

Responsibilities

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

Teklu Gebrehiwot Gebremichael (PhD researcher)
Promoter (Prof. Veerle Foulon)

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?

During the PhD project: Teklu Gebrehiwot Gebremichael (PhD researcher), the Promoter (Prof. Veerle Foulon)
After the PhD project: Promoter (Prof. Veerle Foulon).

Who will update and implement this DMP?

Teklu Gebrehiwot Gebremichael (PhD researcher)
Promoter (Prof. Veerle Foulon)