Development, evaluation and implementation of a COMplex INtervention to support the rational use of ANtimicrobial Drugs for Older people in nursing homes (COMINANDO)

A Data Management Plan created using DMPonline.be

Creator: Indira Coenen

Affiliation: KU Leuven (KUL)

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Principal Investigator: Veerle Foulon

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Project abstract:

Resistance to antimicrobials (AMR), as a result of their widespread use, poses a major threat tohuman health. Nursing home (NH) residents, who are most vulnerable to infections, are at high riskfor antimicrobial misuse. The aim of COMINANDO is to improve the rational use of antimicrobials in NHs by developing andevaluating a complex antimicrobial stewardship intervention, involving the pharmacist. As a proof ofconcept, the intervention will focus on urinary tract infections (UTIs). The project is structured in 4 phases. First, the needs and opportunities for rational use ofantimicrobials in NHs will be quantitatively and qualitatively elaborated. Based on this knowledge andon previous successful interventions integrating the pharmacist in the optimization ofpharmacotherapy of NH residents (COME-ON study), the complex intervention and the protocol for acluster RCT will be detailed and pilot tested (phase 2). In the evaluation phase, the impact of theintervention on the number of antibiotic prescriptions for UTIs per 1000 resident-days and on rationalprescribing will be measured. Additionally, the cost-effectiveness of the intervention will beinvestigated. Finally, a process evaluation will be performed to aid larger implementation (phase 4).The co-design approach, involving all stakeholders right from the beginning, will contribute to thesearch for evidence-based interventions in NHs, which is of utmost importance to tackle AMR.

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Application DMP

Questionnaire

Describe the datatypes (surveys, sequences, manuscripts, objects …) the research will collect and/or generate and /or (re)use. (use up to 700 characters)

The following data will be collected:
- qualitative data (interviews and focus groups)
- data on characteristics of the NH (application form)
- data on antimicrobial use in NHs (type and dose of drug, duration of therapy, resident risk factors, diagnostic parameters and lab values, hospital transfers, deaths)
- process measures (data on interventions of community pharmacists, data on participation in training and local interdisciplinary meetings)
- survey data (questionnaires for health care professionals affiliated to intervention NHs)

Specify in which way the following provisions are in place in order to preserve the data during and at least 5 years after the end of the research? Motivate your answer. (use up to 700 characters)

Data will be stored on the Research Data Repository of the KU Leuven to ensure safe, secure and sustainable storage. Only the researcher and supervisors will have access to the data. Data will never be deleted. If it is required to delete data (e.g. request by participant) this will be documented.
Supervisors will be responsible for data management, they will closely collaborate with the Data Protection Officer on participant data. Final datasets and/or meta data will be stored in Lirias for long-term archiving. Final manuscripts will preferably be published in open access journals. Public versions will be available through Lirias and Flanders Research Information Space.

What's the reason why you wish to deviate from the principle of preservation of data and of the minimum preservation term of 5 years? (max. 700 characters)

NA

Are there issues concerning research data indicated in the ethics questionnaire of this application form? Which specific security measures do those data require? (use up to 700 characters)

NA

Which other issues related to the data management are relevant to mention? (use up to 700 characters)

Data collection will be performed using a secure web-platform (REDCap), building on the experience obtained in the COME-ON study. Efforts will be made to make the whole process of data collection and data management as secure as possible

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DPIA

DPIA

Have you performed a DPIA for the personal data processing activities for this project?

Question not answered.

Development, evaluation and implementation of a COMplex INtervention to support the rational use of ANtimicrobial Drugs for Older people in nursing homes (COMINANDO)
GDPR

GDPR

Have you registered personal data processing activities for this project?

Question not answered.

Development, evaluation and implementation of a COMplex INtervention to support the rational use of ANtimicrobial Drugs for Older people in nursing homes (COMINANDO)
FWO DMP (Flemish Standard DMP)

1. 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.

				Only for digital data	Only for digital data	Only for digital data	Only for physical data
Dataset Name	**Description**	**New or reused**	**Digital or Physical**	**Digital Data Type**	**Digital Data format**	**Digital data volume (MB/GB/TB)**	**Physical volume**
1. WP1: CAPTAIN	Quantitative baseline data of the appropriateness of antimicrobial prescriptions in NH (type and dose of drug, duration of therapy, resident risk factors, diagnostic parameters and lab values) (registrations n= 180)	Generate new data	Digital	Observational	.csv	<1GB	NA
2. WP1: CONSUMPTION DATA	Quantitative baseline antibiotic consumption data for UTI in NH (expected registrations = 29 200)	Generate new data	Digital	Observational	.csv	< 1GB	NA
3. WP2: NH APPLICATION FORM	Data on characteristics of the NH (general institutional and antibiotic policy data) (n=5)	Generate new data	Digital	Observational	.csv	< 100 MB	NA
4. WP2: INTERVIEWS + FOCUS GROUPS	Qualitative data of expectations and concerns of stakeholders (GPs, nurses, pharmacists, nursing home residents and their carers, and experts) (n=70)	Generate new data	Digital	Observational	.doc	< 100 MB	NA
5. WP3: PILOT	Data on antibiotic (type and dose of drug, duration of therapy), resident risk factors, diagnostic parameters and lab values, hospital transfers, deaths --> during 1 month in 2 NHs (expected registrations n =24)	Generate new data	Digital	Experimental	.csv	<100 MB	NA
6. WP4: cRCT CLINICAL OUTCOMES	Data on antibiotic use in NHs (type and dose of drug, duration of therapy), resident risk factors, diagnostic parameters and lab values, hospital transfers, deaths --> during 9 months in 34 NHs (expected registrations n= 3672)	Generate new data	Digital	Experimental	.csv	<100 GB	NA
7. WP4: cRCT PROCESS MEASURES	Process measures (data on interventions of community pharmacists, data on participation in training and local interdisciplinary meetings)	Generate new data	Digital	Experimental	.csv	<1 GB	NA

8. WP5: COST EFFECTIVENESS ANALYSIS	Quantitative data for the incremental cost-effectiveness ratio (pharmacist's time commitment, treatment lengths, allergic reactions, number of potential drug-drug interactions, resident transfers to hospital and incidents of secondary infections)	Generate new data	Digital	Experimental	.csv	<100 GB	NA
9. WP6: PROCESS EVALUATION SURVEY	Data on 1) satisfaction of HCPs with the blended training; 2) staff and pharmacists' perceptions on the usefulness of the local interdisciplinary meetings and check of appropriateness by the pharmacist; and 3) staff perceptions about the likelihood of sustaining the intervention	Generate new data	Digital	Observational	.csv	<100 MB	NA
10. WP6/ PROCESS EVALUATION INTERVIEWS	Qualitative data on specific barriers and facilitators to the implementation of the complex intervention	Generate new data	Digital	Observational	.doc	<100 MB	NA

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:

NA

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? Describe these issues in the comment section. Please refer to specific datasets or data types when appropriate.

- Yes, human subject data

- Dataset 1: Ethical approval by EC Research UZ/KU Leuven, S66823/B3222022000936/I/U
- Datasets 2-4: Ethical approval by EC Research UZ/KU Leuven, S67613
- Datasets 5-10: Protocol for the ethical approval will be submitted in December 2023.
- In datasets 5-8 collection of the experimental data will occur electronically using a web application. This web application will automatically encode names and dates of birth for the researchers (anonymous export). In addition, this web application will allow for sharing data between the involved health care professionals in the intervention group.

Will you process personal data? If so, briefly describe the kind of personal data you will use in the comment section. Please refer to specific datasets or data types when appropriate.

- Yes

- Identifying data (e.g. names, (e-mail) addresses): Datasets 1-10
- Personal characteristics (e.g. age, gender): Datasets 1-10
- Occupation and professional occupation: Datasets 1-10
- Audio recordings: Datasets 4+10
- Pseudonimised data on antibiotic use at resident level: Datasets 1+2+5+6+7+8

Privacy Registry Reference: PRET reference number G-2023-6432 (Datasets 2-4)

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

NA

Do existing 3rd party agreements restrict exploitation or dissemination of the data you (re)use (e.g. Material/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

NA

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

NA

2. 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).

During the research, all data and documents will be stored in a Microsoft Teams environment at KU Leuven (Team COMINANDO). The KU Leuven researchers involved will have access to all data after multi-factor authentication. Team COMINANDO has a logical folder structure and the files in it have meaningful file names.

Will a metadata standard be used to make it easier to find and reuse the data? If so, please specify (where appropriate per dataset or data type) which metadata standard will be used. If not, please specify (where appropriate per dataset or data type) which metadata will be created to make the data easier to find and reuse.

- Yes

In REDCap* (Datasets 2+5-8) , Qualtrics (Datasets 1+3+9) and Nvivo (Datasets 4 + 10) metadata are automatically captured.
We will provide a general README.txt file for each dataset, explaining briefly the content of the data, the context in which the data were collected, sharing the (pseudonymised) fieldnotes, information about file formats. Also steps taken to remove direct identifiers in the data will be described. In general, for each study meta-data will be available and stored on the shared drive (Teams) of KU Leuven.
*When extracting data (without identifiers) from REDCap, the codebook will also be extracted to link the variable names with the ‘field labels’ and ‘choice labels’.

3. Data storage & back-up during the research project

Where will the data be stored?

During the research, all data and documents will be stored in a Microsoft Teams environment at KU Leuven (Team COMINANDO). The advantages are that data are accessible from different devices, are synchronised and it enables collaboration. The KU Leuven researchers involved will have access to all data after multi-factor authentication. The master's thesis students will only have access to the data they will collect and analyze in WP2 (interviews pharmacists, physicians, nurses and healthcare professionals). They will send data with the Belnet filesender to Indira Coenen.
The coding of the documents with identifiable results will be done by the doctoral researcher; the code key will be kept on the supervisor's individual OneDrive for Business account. In this way, only pseudonymized data will be worked with during the data analysis.
The antibiotic consumption data will be collected via REDCap and are secondary pseudomised data. This platform meets KU Leuven's data security standards and requires a multi-factor authentication procedure to gain access. Only authorized users with user rights have access to the database; only Indira Coenen and Veerle Foulon have full access to the database. Access to REDCap records is automatically logged and changes to the recorded data are stored in independent audit trails. REDCap's security measures for identifiable data are applied: "tags" are applied to variables that collect identifiable data, and only pseudonymized data are extracted from the database.
The results of the questionnaires, will be collected within the researchers' personal Qualtrics account (access via login and password).
Once the interviews from WP2 have been transcribed ad verbatim, the recordings will be removed from the Teams environment, and completely deleted.

How will the data be backed up?

A digital back-up of the data will be made weekly on the personal OneDrive of Indira Coenen (access KU Leuven laptop via password) and on an external disk.

Is there currently sufficient storage & backup capacity during the project? If yes, specify concisely.
If no or insufficient storage or backup capacities are available, then explain how this will be taken care of.

- Yes

The total estimated volume of the datasets (203,5 GB) will be less than the maximum storage size of Microsoft Teams (5TB).

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

During the research, all data and documents will be stored in a Microsoft Teams environment at KU Leuven (Team COMINANDO). The KU Leuven researchers involved will have access to all data after multi-factor authentication.

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

Microsoft Teams and OneDrive is Free for KU Leuven staff. The cost for the external disk (+/- 50 euros) will be covered with the bench fee of Indira Coenen.

4. Data preservation after the end of the research project

Which data will be retained for at least five 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...).

Datasets 1-10 will be retained for at least 10 years.

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

Data (including final datasets and/or metadata) will be finally stored in KU Leuven's Research Data Repository to ensure safe, secure and sustainable storage. Only the doctoral researcher and supervisors have access to the data and are responsible for its management. Data will never be deleted. If it is necessary to delete data (e.g. at the request of a participant), this will be documented. (Personal) data will be deleted after 10 years (KU Leuven RDM guideline).
Final manuscripts will be published in Open Access journals and available through Lirias and Flanders Research Information Space.
Participants who indicated in the informed consent to receive the study results will receive insight into the overall study results (at group level) after the study is completed, through a scientific report or publication. This information will be delivered via email to the email address provided by participants in the informed consent.

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

SharePoint online-site is free.

5. Data sharing and reuse

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

- Yes, in an Open Access repository
- Yes, in a restricted access repository (after approval, institutional access only, …)

After the research project the data will be made available in:
Open Access repository: Datasets 1+2+3+5-8 (quantitative data)
Restricted acces repository: Datasets 3+4+9+10 (qualitative data) in a Shared J Drive of the research group Clinical Pharmacology and Pharmacotherapy

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

Upon permisson of the involved researchers (Indira Coenen and Veerle Foulon), researchers can request access.

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 in the comment section per dataset or data type where appropriate.

- Yes, Privacy aspects
- Yes, Ethical aspects

All datasets contain personal and sensitive information of a vulnerable group, so we have an ethical and legal obligation to protect (and not share) some of the data, e.g. not-pseudonymised transcripts and audio recordings.

Where will the data be made available? If already known, please provide a repository per dataset or data type.

Via KU Leuven Research Data Repository – RDR, an online infrastructure for data storing, publishing and sharing, these data will be automatically be registered in Lirias.

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.

CC-BY-NC-ND-4.0
• Free to share.
• Give appropriate credit, indicate if changes were made.
• Do not distribute modified material (remix, transform, build upon).
• Do not use the material for commercial purposes.

Do you intend to add a PID/DOI/accession number to your dataset(s)? If already available, you have the option to provide it in the comment section.

- Yes

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?

Because the repositories are for free, no cost is expected for data sharing.

6. Responsibilities

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

Indira Coenen

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

Indira Coenen

Who will manage data preservation and sharing?

Veerle Foulon

Who will update and implement this DMP?

Indira Coenen