Plan Overview

A Data Management Plan created using DMPonline

Title: Optimizing Medication Use and Treatment Decision-Making for people with Chronic Kidney Disease

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Affiliation: Karolinska Institutet

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Project abstract:

Purpose: One in ten Swedes suffer from Chronic Kidney Disease (CKD), a high-risk condition in need of tailored pharmacological therapy for optimal health outcomes. Ensuring adherence to guideline-recommended care and careful evaluation of risks and benefits of therapies is critical in this population which is prone to adverse drug events. However, there is a lack of evidence, which may be attributed to disease under-recognition, the need of large sample sizes to detect adverse event rates, the need to rely on laboratory tests to evaluate kidney function, and poorly implemented monitoring practices.

This project aims to improve the care of patients with or at risk for CKD. With previous support from Vetenskapsrådet (VR), we have established a dedicated pharmacoepidemiology group and a unique recurrent database enriched with laboratory measurements to identify best clinical practices for effective and safe use of medications across the spectrum of kidney dysfunction.

Aims: We now want to further our work by:

1. Identifying gaps in care among patients with or at risk for CKD, focusing on guideline-recommended medication use, dosing, and monitoring.
2. Addressing risks vs benefits of medications by stages of CKD severity.
3. Applying novel methods to routine care data to detect unknown signals of harm and identify patients most likely to benefit from underutilized treatments.
4. Bringing action to the point of patient care, by evaluating the impact that electronic clinical decision support tools have on the optimization of medical treatments and on the subsequent progression of disease in patients with CKD.

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Optimizing Medication Use and Treatment Decision-Making for people with Chronic Kidney Disease

General Information

Project Title

Optimizing Medication Use and Treatment Decision-Making for people with Chronic Kidney Disease

Project Leader

Juan Jesús Carrero

Registration number/corresponding

2023-01807, Swedish Research Council

Version

1

Date

20 dec 2023

Description of data – reuse of existing data and/or production of new data

How will data be collected, created or reused?

The cohort we have created includes all residents of Stockholm region accessing healthcare in Stockholm County Council (SLL) during 2006-2022, and, during the life of this project we will update to 2025. The cohort is called the Stockholm CREAtinine Measurements (SCREAM) project, and the core dataset of information has been provided by Region Stockholm, the sole healthcare provider of the region.

Within this cohort, there are two disticnt subcohorts, and for each of them we have different granularity of information:

Primary cohort: this cohort is defined by the presence of at least one laboratory measurement of creatinine or albuminuria in routine care during the study period. Information on laboratory measurements was extracted from the laboratory providers of SLL: Aleris, Unilabs/Medilabs and Karolinska University laboratories. If the entry criteria is met, we also extracted other related laboratories. In this cohort we will undertake almost all of the research questions described in our project plan.

Secondary cohort: this cohort is defined as the remaining persons who resided in Stockholm, accessed healthcare during the study period and never had creatinine or albuminuria assessed by the laboratory providers. This secondary cohort is primarily used to evaluate the coverage and representativeness of the primary cohort.

How was the data assembled: Each laboratory provider performed the selection of patients for the primary cohort separately and submitted the patient-identified materials to Region Stockholm. Region Stockholm, via its subsidized company TietoEvry AB, identified Stockholm residents accessing healthcare during the study period and matched this with the information from laboratory providers. TietoEvry AB kept the full dataset for submitting to Socialstyrelsen when required. Thus, the investigators have never had access to patient-identified data.

Socialstyrelsen did the remaining data linkakes with the following:

National registers: Swedish Medicaton register, Swedish cancer and birth registers.

Other national quality registers:

SCB, for information on socioeconomic indicators, country of origin (cluster) and attained education.

Svensk Njurregister, for identification of patients referred to nephrology care, cause of kidney failure, in-hospital provided medications, date of dialysis/transplantation start, etc

SWEDEHEART and SWEDHF, for information on the clinical characterization and severity of the cardiovascular events registered herein.
SVEDEM, for information on cognitive function exploration, diagnoses of dementia, dementia subtypes and other cognitive function information.
SIR, the intensive care registry, and SMiNET, with information on COVID-19 positive tests.
The data will be used to explore a wide range of research questions regarding:
1. Epidemics of chronic kidney disease and quality of nephrology care
2. Risk factors for chronic kidney disease or kidney function decline
3. Health consequences of chronic kidney disease
4. Drug safety and effectiveness in patients with chronic kidney disease
5. Acute and long-term nephrotoxic effect of drugs

What types of data will be created and/or collected, in terms of data format and amount/volume of data?

We will collect data of:

- Laboratory measurements as measured in routine care Healthcare use
- Diagnoses and procedures undertaken during that healthcare use
- Clinical characteristics of specific diseases (as ascertained in the national quality registers)
- Death and immigration/emigration from the region of Stockholm

Collectively, we will create longitudinal healthcare information for more than 3.0 Million people with measurements of creatinine/albuminuria in routine care during a 2006-2022 and beyond
Data is stored in encrypted servers at Karolinska Institutet, with a volume of >1000 gygabites. All datasets are interlinked in a SQL interface. Data includes both numeric and text

Documentation and data quality

How will the material be documented and described, with associated metadata relating to structure, standards and format for descriptions of the content, collection method, etc.?

Documentation of the material follows the approved guidelines of the Department of Medical Epidemiology and Biostatistics. These include a standardized folder structure for documentation comprising of Codebooks (metadata about data), Logbooks (metadata about data processing and cleaning), Analysis plans (including detailed descriptions of the data retrieval and research studies), Manuscripts, syntax scripts and output files from database systems and statistical software (for data management and analysis), Program folders, Data folders and Communications with data providers. The department also has a standard for variable naming and coding for primary data collections.

How will data quality be safeguarded and documented (for example repeated measurements, validation of data input, etc.)?

For primary data collections/generations at the department, the data will be quality checked at collection/generation using standard techniques, such as validation against controls or publically available databases. For secondary data (e.g. data collected originally by another organization than KI), quality documentation will be included by the data provider. Quality controls will be performed at delivery of the data to ensure the delivered data is correct.
A yearly follow-up of the documentation is conducted to safeguard the data quality and improvements are followed based on the feedback given.

Storage and backup

How is storage and backup of data and metadata safeguarded during the research process?

Access to storage of data is guarded strictly by IT-policy at the department with different levels of authorization given to a user (researcher/non-researcher) on PI’s approval.
The department’s research data and other storage is backed up every day with snapshots of different versions available to recall. All data from this project is stored in encrypted servers at MEB, KI

How is data security and controlled access to data safeguarded, in relation to the handling of sensitive data and personal data, for example?

Access to storage of data is guarded strictly by IT-policy at the department with different levels of authorization given to a user (researcher/non-researcher) on PI's approval.

Legal and ethical aspects

How is data handling according to legal requirements safeguarded, e.g. in terms of handling of personal data, confidentiality and intellectual property rights?

KI as an organization complies with GDPR in both legal and ethical aspects.
More information at www. https://medarbetare.ki.se/gdpr
All handling of data is described in the ethical application. Documentation of ethical approvals (applications, amendments and decisions) and informed consent forms for the project are stored in the project folder electronically (and in the paper archive, if relevant). Ethical approvals are registered in the diary (with diarienummer).
Copyright and intellectual property rights will be managed according to Swedish law and KI policies.

How is correct data handling according to ethical aspects safeguarded?

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Accessibility and long-term storage

How, when and where will research data or information about data (metadata) be made accessible? Are there any conditions, embargoes and limitations on the access to and reuse of data to be considered?

The data and all material is archived by the IT section at the department as per the archiving guidelines at the Department of Epidemiology and Biostatistics, and is made accessible whenever required (legally and ethically).
No one is given access to the archived material without legal & ethical permissions which are in general sought through the university's registrar office.

In what way is long-term storage safeguarded, and by whom? How will the selection of data for long-term storage be made?

As described above the data is archived by the IT at the department and safeguarded with no access given to any user unless permitted legally and ethically by registrar's office at the university.
The archiving guidelines include instructions for selection of files necessary to ensure reproducibility of published results, as well as safeguarding the use and readability of valuable data for future research. This includes ensuring that data, metadata and other documentation are saved in stable data file formats over time.

Will specific systems, software, source code or other types of services be necessary in order to understand, partake of or use/analyse data in the long term?

Every material that is used for the data management, analysis and results are stored in a readable format to understand , partake of or use/analyse data in the long term which is a part of the departmental documentation guidelines.

How will the use of unique and persistent identifiers, such as a Digital Object Identifier (DOI), be safeguarded?

The university has a central database with DOIs of all the published articles which is backup regularly.

Responsibility and resources

Who is responsible for data management and (possibly) supports the work with this while the research project is in progress? Who is responsible for data management, ongoing management and long-term storage after the research project has ended?

Database Administrator is responsible for data management, and department's IT is responsible for longterm storageafter the research project has ended following the archiving policies.

What resources (costs, labour input or other) will be required for data management (including storage, back-up, provision of access and processing for long-term storage)? What resources will be needed to ensure that data fulfil the FAIR principles?

A Data Manager and IT infrastructure at the department helps with storage and backup of the data.
Audit personnel, data managers, IT staff, researchers at the department are required to document the work that is done which ensures that the data fulfils the FAIR principles.