
Plan Overview

A Data Management Plan created using DMPOnline

Title: Risk factors for suicide among psychiatric patients that have experienced compulsory mental care

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Project abstract:

Suicide is the leading cause of death among young adults in both Sweden and the world. Psychiatric inpatients in general present with an excess risk of suicide yet the risk is rarely studied in the subgroup admitted by force to compulsory mental care (CMC). A CMC decision is often used to prevent suicide but its effect is rather unclear. Today, we lack information on both the underlying risk and risk factors for suicide among CMC treated patients. The core purpose of this project is to apply epidemiological methods with a national 40-year cohort (1973-2013) of registry data to investigate both the suicide risk itself and associated risk factors for CMC patients. This knowledge base will thereafter inform better clinical decision making (e.g. discharge risk assessment) to reduce the suicide rate in these patients.

Aim 1 will investigate the risk of suicide among CMC patients, both in absolute terms and relative to other clinical populations and a representative total population sample. Aim 2 will study risk factors for suicide with a broad focus on sociodemographic, hereditary, and clinical variables, including CMC-unique variables (e.g. interventions during CMC).

This cross-disciplinary project fills a critical gap in our knowledge through straightforward Precision Medicine for a very ill yet still understudied group of psychiatric patients – in line with both VR's specific Call and VR's general focus on Precision Medicine.

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Risk factors for suicide among psychiatric patients that have experienced compulsory mental care

General Information

Project Title

Risk factors for suicide among psychiatric patients that have experienced compulsory mental care

Project Leader

John Wallert

Registration number/corresponding, date and version of the data management plan

Version

1

Date

20221101

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

How will data be collected, created or reused?

The project will exclusively use data from nationwide registries containing data on the individual level. Using the Swedish personal identification numbers, several nationwide population-based registers have been linked and pseudonymised by personnel at the Department of Medical Epidemiology and Biostatistics (MEB) at KI. The registers range from:

SOURCES	EXAMPLES OF POTENTIAL RISK FACTORS
Total Population Register	Place of birth, migration, and place of residence
National Patient Register	All diagnoses given in inpatient care since 1973, specialist outpatient care since 2001, duration of compulsory care, interventions during compulsory care, previous suicide attempts
Multi-generation Register	Identity of first- and second- degree biological and social relatives as well as maternal/paternal age at birth. Family history of suicide, alcohol use, etc.
Social Insurance Registers	Sickness-absence, disability pension, parental leave
Longitudinal integrated database for health insurance and labor market studies (LISA)	Employment status, income, education
School Register	School grades in year 9 and high school
Military Conscription Register, males only	Psychometrics including cognitive ability, stress resilience, substance use, anthropometry, erythrocyte sedimentation rates, hematocrit, hand grip strength, eye sight
Prescribed Drug Register	Prescribed medications, duration of medication treatment
Medical Birth Register	Perinatal variables such as parity, gestational age, fetal growth, mode of delivery, pre- eclampsia, Apgar score, mothers' alcohol consumption and tobacco use

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

We will not collect any new data nor create any new individual data. Register data will be received in large quantities of gigabyte-size. It will be analysed and stored in SAS/R format.

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 (MEB) at KI. 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.

Every authority has their own detailed description of the specific register data. A general description of all gathered registers can be found on the research group's server.

The usage of the data will be documented with the Karolinska Institutet's (KI) Electronic Lab Notebook (ELN). Every researcher is required to give detailed documentation of how and what the data is used for, additionally also write a detailed description plan before the start of every research question within the project.

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

Extraction of register data has been done by the relevant agency (e.g., Statistics Sweden extracts, merges, quality checks, and handles the Swedish Labor Market Data (LISA)), the Swedish data registration, storage and its validation of input and quality is documented.

At the merging and management of different register data in the research group, detailed forms are filled in by each researcher who then work closely with a statistician or data manager to get the required variables. Further management of data is documented by the relevant researcher in KI's ELN.

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 the PI's approval. The Department's research data and other storage are backed up every day with snapshots of different versions available to recall.

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

The present study will exclusively use already gathered data from nationwide registries which is extensively used at MEB. These data will only be handled in pseudonymized form (individuals will not be identifiable) and kept on the safe server at MEB at KI protected by double authentication and other modern research standards to ensure participants safety and integrity. All archived data in the project will be held strictly confidential with pseudonymized data, and stored in the security server at the department.

Everyone working with the data is required to attend a course "Good Data Management Practice".

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 can be found at <https://medarbetare.ki.se/gdpr>

All identifying information such as name and personal identity number have been removed before data sets are made available

to personnel for analysis; we only work with pseudonymised data.

How is correct data handling according to ethical aspects safeguarded?

Ethical permit for the project has been granted by the Regional Ethical Committee in Stockholm (protocol number: 2013/862-31/5;2020-06540). The present study will exclusively use already gathered data from nationwide registries which is extensively used at KI. These data will only be handled in pseudonymised form and kept on the safe server at MEB at KI protected by double authentication and other modern research standards to ensure participants safety and integrity. The key for breaking pseudonymisation is not and will not be available to the researchers as it is kept by the appropriate government agency (Socialstyrelsen) which routinely performs this safekeeping for Swedish registry research.

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?

Since data is subject to GDPR, only metadata from registers can be accessible by anyone, due to the open metadata information on each authority's webpage. The register data that we have gathered can only be used by the research group at KI with the purpose that the group has been granted the ethical approval for.

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

When the project is completed, data archiving will be done according to KI's rules and policies. 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.

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?

Materials that are used for data management, analysis and results are stored in a readable format, in order to understand, partake in or use/analyse data in the long term, as according to Departmental documentation guidelines.

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

Karolinska Institutet has a central database with DOIs of all the published articles, which is backed up 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?

The people from the group assigned to a specific project have a shared responsibility for the data management of the research project, both statisticians and researchers alike. The project PI is responsible for the storage and management after the end of the project.

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?

Resources required: Computers, software/licenses, server storage, back-up is handled by Department-IT. Because of the sensitive nature of data, the FAIR principles will be addressed on a case by case basis.