Plan Overview

A Data Management Plan created using DMPonline

Title: How long can labor last? Person Centred care during labor to increase safety for women and newborn

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Project abstract:

Purpose:

To increase person-centred care during labor.

Specifically we want to provide updated comprehensive information on labor duration and patient safety for reduction of; unnecessary medical interventions during normal labor;morbidity and mortality in the new-born; maternal complications during delivery and the puerperal period.

Specific aims:

- Identify risk-groups where labor duration means particularly high risks.
- Identify groups where labor duration has little or no influence on serious complications
- Identify upper limits for excessively long labor.

Method:

Cohort studies, Case-control studies and risk-prediction studies.

Plan for project realization:

The project is carried out at Karolinska Institutet at the Clinical Epidemiology Division where ethical permission, data and software are available. The reproductive perinatal research group has the clinical epidemiological and statistical knowledge to adequately formulate, analyze, and answer the research questions.

Importance:

It is known that prolonged labor duration is associated with very serious complications for some women and infants. Which women and featuses that are at increased risk if labor continues and when labor duration becomes dangerous is still unknown. The results from this project will contribute with important knowledge when preventive interventions are important and when expectant management is preferred.

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How long can labor last? Person Centred care during labor to increase safety for women and newborn

General Information

Project Title

How long can labor last? Person Centred care during labor to increase safety for women and newborn

Project Leader

Mia Ahlberg, RN, RM, Docent

Registration number/corresponding

2023-02010

Version

1

Date

20240313

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

How will data be collected, created or reused?

Data for the research in my VR project entitled: "How long can labor last? Person Centred care during labor to increase safety for women and newborn" will use existing register and electronic medical record data already collected. No new information will be collected in the studies.

The subsequent analyses will use data from medical records in the Stockholm-Gotland Obstetric Cohort, including all births from 2008 to 2020. The cohort includes data from antenatal care, the partograph, which includes detailed information on labour initiation, all cervical examinations, clinical interventions, and total duration of labour. Using the unique personal identification number, the

established cohorts will be linked with the National Patient Register, the Swedish Neonatal Quality (SNQ) register to obtain further information on outcomes, matching factors, and covariates.
We collect new research data approximately every second year.

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

Data has been acquired from the Obstetrix , and from the SNQ . Data is in SAS
format and stored at secure servers at the Division of Clinical Epidemiology at Karolinska University Hospital in Solna. Data from each data source has a unique
ID number for each mother and infant in the databases in the two cohorts.
Volume: <100 GB
The 2 cohorts include data of < 100 GB

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.?

Data in the 2 cohorts is stored in secure servers at the Clinical Epidemiology Division, Karolinska University Hospital in Solna. For each cohort we have separate folders including:

- Original data from each data source
- Documentation on applications for data, decisions for data retrieval, ethical permissions, classification of data and variables
- Derived datasets which are cleaned and prepared for research including documentation on the data program code used for setting up the research datasets.
- The research datasets are separated from the original data and renamed according to the research project.
- We use ICD-codes and procedure codes from the National Board of Health and Welfare for categorization of diseases and procedures.
- When updated data is retrieved for research a new folder is created with the same structure as described above.
- The documentation, cleaning, file naming, format and version is handled by a programmer in the research group

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

The 2 cohorts include observational data from EMRs and SNQ. Data from the Obstetrix EMR and SNOQ is quality controlled according to a procedure set up by our research group. Data has been validated with the EMR in the clinic.

Upon arrival of data the programmer in our group perform a quality check including tests for number of women and infants, check for double entry of data, completeness, missing data and linkage between the data sources.

Storage and backup

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

ELN
Original data and research data is stored at the server on the Divison of Clinical Epidemiology, there is a backup system with daily backups. Data is safeguarded during the research process using the ELN system according to the rules and regulations of Karolinska Institutet. Unauthorized access is avoided by the strict regulations and procedures from our IT department which handle the permissions and restrictions in collaboration with the PI for the project.

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

The cohorts include sensitive personal data and may only be accessed at the server at the Clinical Epidemiology Division. Data will be stored according to KI rules and regulations. Only researchers, programmer and biostatistician in the research project have access to the data files on the server. Data is presented on an aggregated level without the possibility to identify individuals. No personal data is stored on local computer discs or usb. There is a safe external VPN-client system using the Cisco AnyConnet Secure Mobility system with two factor authentication. In the server system there is a daily backup and data can thus be recovered. Firewalls are used in the server system.

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?

Sensitive personal data will be handled according to GDPR. (https://staff.ki.se/gdpr).There are no external partners or collaborations for the data in the research project. There are no copyright or intellectual property right issues to consider in the research project. According to the ethical approval we do not need written consent from the individuals in our cohorts.

How is correct data handling according to ethical aspects safeguarded?

Data is pseudominized for the cohorts included in the research. Individuals will not be contacted based on the information in the cohorts. The research has obtained ethical approval and data will be handled according to these ethical aspects. This is safeguarded by the PI for the research project and by the strict access policy for data on the server, the safety of the server system and by not allowing any personal data to be stored on local computers, hard drives or USB. The cohorts include sensitive personal data and code key will be kept at the server at the Clinical Epidemiology Division. Data will be stored according to KI rules and regulations. Only researchers, programmer and biostatistician in the research project have access to the data files on the server. Data is presented on an aggregated level without the possibility to identify individuals. Data will not be shared externally

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?

Information about data and metadata are available from Cerner inc. (provider of the Obstetrix EMR system). Only metadata will be published openly. We will not make the sensitive personal data accessible to other users according to legislation. Data will be stored at least 10 years after publication.

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

Long-term storage will take place at the server at the Clinical Epidemiology Division. Data will be stored at least 10 years after publication. Data will be stored in the SAS format. The data will include raw data and the final data analysis file. Intermediate working files will be deleted.

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?

Data will be stored in the SAS format. Because we will use observational data from the Obstetrix EMR system data will also be stored in other locations that the server at the Clinical Epidemiology Division at Karolinska University hospital, Solna.

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

The personal identifier for the pseudominized data is stored for 3 years , thereafter the personal

identifier can not be linked to the personal identification number (personnummer). Hence, after 3 years the data will be anomynized.The key will be stored at the server at the Clinical Epidemiology Division. Data will be stored according to KI rules and regulations. Data is presented on an aggregated level without the possibility to identify individuals.

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 PI Mia Ahlberg will guarantee that data is managed appropriately by assigning and checking that a programmer will manage data as stipulated. The data manager performs the data validation, cleaning and set up the datasets for analysis. The programmer will also make sure that documentation is stored according to KI:s rules and regulation. The IT department at the Clinical Epidemiology Division will guarantee server safety, log-in, backup and remote function by VPN.

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?

The PI Mia Ahlberg will make sure that the data is stored at least 10 years after publication after the research project has ended. Data will be stored at the Clinical Epidemiology Division server at the Karolinska University Hospital in Solna.