Plan Overview

A Data Management Plan created using DMPonline

Title: TeamBirth - an intervention to improve patient safety and person-centered care during childbirth

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Affiliation: Karolinska Institutet

Funder: Swedish Research Council

Template: Swedish Research Council Template

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Project abstract:

Most adverse events within maternity care stem from communication and teamwork failures. Despite national
and international recommendations, few interventions include person-centered care as means for safe care. The
aim of this project is to evaluate the effectiveness and implementation of TeamBirth (TB); designed to enhance
teamwork and person-centered intrapartum care.
TB will be evaluated at nine labor wards, covering 26% of all births in Sweden. During this four year project
outcomes, processes, and implementation will be addressed in four work packages (WPs).
WP1. Patient safety and person-centered care: Interrupted time series design using data from the Swedish
Pregnancy Register & Questionnaire.
WP2. Patient reported experiences: TBs contribution to person-centered care will be explored by a questionnaire sent to women one month after birth, including validated scales.
WP3. Process measures: Patient safety climate and interprofessional teamwork will be investigated using a
longitudinal cross-sectional design with validated scales to staff working with intrapartum care at the participating study sites.
WP4. Process evaluation: A mixed method design using data from questionnaires and interviews.

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TeamBirth - an intervention to improve patient safety and person-centered care during childbirth

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General Information

Project Title

TeamBirth - an intervention to improve patient safety and person-centered care during childbirth

Project Leader

Malin Edqvist

Registration number/corresponding

2024-02476

Version

Version 1.0

Date

2025-03-03

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

How will data be collected, created or reused?

Data collected in this project include:

- Register data from the Swedish Pregnancy Register and the National Pregnancy Survey
- Questionnaires
- Recording of interviews

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

- Register data from the Swedish Pregnancy Register will be recieved in CSV format from the register. The data will then be further imported to a statistical sofware program (STATA, R or SPSS).
- Survey data will be collected via REDCap and the exported format will be in CSV.
- Recording of clinical interviews will be saved in m4a or WMA format. Transcription of interviews will be saved in docx files.
- Volume of data will be <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.?

To ensure that the metadata is compatible and usable, we will use the metadata standard prescribed by Karolinska Institutet, incorporating the Data Documentation Initiative (DDI) standard where applicable. This will ensure that the data is managed and documented in a consistent and standardized manner.

Data will be organized into specific databases with a structured folder system for version control and easy access. Each dataset will be stored in clearly labeled folders reflecting the data type and version. A consistent naming convention will be used, including project identifiers, version numbers, and dates to track data evolution. Version control will be maintained through regular updates and backups, ensuring proper documentation. Additionally, a log will be created for each work package to track changes and versions. KI ELN will be used to document project details. We will use templates when applicable.

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

- The register holder assures data quality in terms of completeness and correctness of registration. Data will further be checked for outliers and unresanable values
- Survey data is collected via REDCap and will after export to data file be checked for duplicate responses and unreasonable values.

Storage and backup

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

We will follow Karolinska Institutets rules and regulations regarding storage and backup for data. At KI specific project folders for storage of research is used as well as ELN.

- KI ELN, KI server, and REDCap will be used for storage and backup of data.
- Working datasets and metadata will be stored on a folder at KI:s server.
- Both ELN and KI servers are considered safe and are backed up.
- KI ELN will be used for the documentation of all analyses and results.

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

We will follow KI rules and regulations.

- Access to data in KI ELN, KI servers and REDCap will be restricted to researchers in the research team.
- For KI ELN and REDCap a two factor authentication is required. KI ELN is considered very safe, with security monitoring and risk assessments performed regularly by an external partner.
- ELN allows for audit trails for tracking data changes and versions.
- We will only work with pseudonymized data.

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?

We will ensure full compliance with all applicable laws and regulations, including GDPR (https://staff.ki.se/gdpr) in the management of personal data in the project. The project has received ethical approval from the Swedish Ethical Review Authority.

How is correct data handling according to ethical aspects safeguarded?

All participant data is pseudonymized before any handling, and the ethical aspects will be safeguarded by the principal investigator.

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?

Aggreagated results will be shared in publications. Data from registers contains sensitive personal data and cannot be shared openly. Survey data and qualitative data are considered as personal data according to GDPR and cannot be shared openly. We will be able to share data with other researchers only upon drafting appropriate data sharing contracts. We will share analyses scripts, and the associated developed code openly. For the qualitative data, quotes to support data will be published, and audit trails will be shared.

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 follow KI rules and regulations, and KI ELN and the KI server will be used for the purpose. Data, including raw data and the final data analysis file will be stored at least 10 years after publication.

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?

Quantitative participant data in the project will be in CSV format which can be read by any statistical software compatible with CSV. Qualitative participant data can be opened by any software compatible with M4A or MP4 files. The transcribed interviews will be in docx format.

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

As the registerdata and the data collected via surveys contains sensitive personal information, the use of uploading datasets to a repository will not be possible due to GDPR. We will create meta data records to describe the dataset that contains personal information to be uploaded, while the actual dataset will be stored on KI server and ELN. KIs central storage for publishing datasets is under developement, and we will update the DMP when it is functioning.

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?

- Data management is performed by a dedicated postdoc and PhD students in the project who are supervised by the PI Malin Edqvist.

- The PI Malin Edqvist is responsible for the data management and the archive function will be responsible for long-term storage.

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?

Salaries for those managing data are partly funded by this project.