Plan Overview

A Data Management Plan created using DMPonline

Title: National implementation of the Manchester Procedure as a surgical treatment for women with uterine prolapse

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Affiliation: Radboud University Medical Center (Radboudumc)

Funder: ZonMw (Nederlands)

Template: Radboudumc Data Management Plan

Project abstract:

Recent evidence suggests that the Manchester procedure should be the preferred method for the vast majority of women with apical prolapse who require an initial surgical intervention. However, this technique is currently the least utilized in the Netherlands. Active implementation is therefore essential.

The primary objective of this study is to evaluate the impact of the implementation strategy on the proportion of Manchester procedures relative to the total number of uterus-preserving prolapse surgeries among patients indicated for an initial surgical intervention for uterine prolapse. The goal of the implementation is for at least 50% of uterus-preserving procedures to involve the Manchester procedure within two years.

We will start this study with a nationwide benchmark measurement to analyse what percentage of patients eligible for MP does indeed receive this surgery. Next, a problem analysis will be conducted among stakeholders. With this information, we will develop and execute a multifaceted implementation strategy. After the integration of these changes, we will repeat the benchmark measurement to determine a possible change in MP use. For the analysisi of the effectiveness of our implementation strategy, we will use an observational design with a before-after comparison and process evaluation.

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Copyright information:

National implementation of the Manchester Procedure as a surgical treatment for women with uterine prolapse

1. Project info

1.1 DMP version and date

Version 0.3 / 18-10-2024: plan revised by local data steward, feedback incorperated into the file

1.2 Name of data management support staff consulted during the preparation of this plan and date of consultation.

Expert: Mirjam Brullemans-Spansier (central data steward from RTC Data stewardship)
Date: 17-10-2024

1.3 Does the project consist of multiple (sub)projects?

- Yes (please specify which (sub)projects)

This implementation study consist of multiple subprojects (phases of the implementation process):

1. Pre-implementation measurement in all Dutch hospitals
2. Stakeholders analysis: interviews with patients and gynecologists
3. Development and execution of implementation strategy
4. Post-implementation measurement, an effect- and process evaluation

1.4 Project number(s)

Funder project number: 10390172310015

1.5 Project leader (PI); provide contact information (Name, email address, phone number)

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1.6 Science department
(and if applicable, also add the research programme and research group(s) involved in the

project)

Department of Obstetrics & Gynecology, Radboudumc

1.7 Will non-human research (i.e. research NOT performed on human subject data) be performed in this project?

- No

1.8 Will the research conducted in this project involve human participants (WMO compliant / non-WMO)?

- Yes, non-WMO research (please specify which (sub)projects)

Subprojects:

1. Stakeholder analysis: for the patient interviews, a non-WMO compliance has already been received
2. Pre- and post-implementation measurement: a non-WMO compliance is necessary and already requested

1.9 Is review of this DMP needed in order to obtain approval by the Executive Board (Local Feasibility procedure ('Lokale Uitvoerbaarheid))?

- No, this is not needed.

2. Planning and design

2.1 Will this research project involve collaboration with other parties? (E.g. in collecting, processing, analyzing and/or publishing the data).

- Yes

This is a multicenter study for which Radboudumc is the sponsor.

2.2 If yes, which parties will be involved, and what will be their contribution with regard to collection, processing, analysis and/or publishing of project(s) data?

All Dutch hospitals will be approached for contribution to data collection regarding number of executed

prolapse surgeries. These hospitals will not be involved in the processing, analysis or publishing of the data.

2.3 If yes, describe which agreements (have been made / will have to be made) with these parties regarding data management and intellectual property?

Agreements with participating sites will be laid down in a data transfer agreement.

2.4 Who are the persons involved in data management? Mention all persons that have access to the data, and in which role they will participate.

Institute	Name	Role
Radboudumc	Lisa Stoter, PhD candidate	DMP writer, data collection and analysis
Radboudumc	Kirsten Kluivers, Principal investigator	Data analysis, data preservation, key file preservator
Radboudumc	Eva Verkerk, Postdoc Implementation research	Data analysis
Radboudumc	Lieke Hubers, Medical student	Data collection and analysis

2.5 For human-related research, describe the informed consent procedure. Will consent be obtained from the participants to collect and process their data? Multiple options can be selected, specify the informed consent procedure for the applicable project(s).

- Yes (please specify)

Subproject: patient interviews
Written or oral informed consent is obtained from research participants prior to the study.

2.6 If yes, will consent be obtained from the participants to share and re-use their data for future research, according to the FAIR principles?

- Yes

In the informed consent form, research participants are informed about the possible reuse of their data for future projects. Participants can indicate in the consent form whether they agree with future reuse or not.

3. Collect and Create

3.1 Will existing data be used for this project?

- Yes (specify which data sources)

Care data registered in the Electronic Health Record (Epic).

3.2 Do restrictions apply to the use of these existing data? Describe how the use of these data will be arranged with the owners of the data.

No, there is no restriction on this data.

3.3 Will human patient data be used from Radboudumc's clinical archives, like Epic, GLIMS, PACS , Dentium, etc.?

- Yes, Epic data will be used (see next question for further details)

3.4 If Epic data is used, how will these data be obtained?

- Data will be manually copied from Epic (please specify in 3.5)

3.5 If applicable, describe which other method will be used to obtain data from Epic, and how patient privacy is safeguarded:

Data on performed prolapse surgeries will be retrospectively extracted from patient electronic records by local researchers in each participating hospital. For each surgery, information on the surgical technique used and the pre-operative Pelvic Organ Prolapse Quantification (POP-Q) score will be collected. No additional data regarding patient characteristics will be collected. The data will be anonymized at the local hospital level before being shared with the study sponsor.

3.6 How will privacy of the human participants be safeguarded?

- The data will be anonymized

3.7 How will pseudonymization/ anonymization/other be arranged?

- The data will be pseudonymized / anonymized by using a tool or system different from PIMS (explain in next question)

3.8 Please specify how pseudonymization or anonymization will take place. How is the subject ID composed, will identifying elements be omitted, where (and/or in which system) will the Subject Identification Log be saved?

Each study number will be composed as follows: CENTERABBREVIATION_001, CENTERABBREVIATION_002.
In this study, the local researcher will maintain a confidential list that links each surgery to its corresponding study number. This list will be securely stored and used exclusively for matching surgical data to the study identifiers, ensuring accurate data management and patient confidentiality throughout the research process. There is data collection regarding patient characteristics. The data will be anonymized at the local hospital level before being shared with the study sponsor.

3.9 Provide the details from the Identification Log data in PIMS.

Not applicable

3.10 Describe the data that will be collected / created:
(optional: the data can be described per (sub)project, for instance workpackages or chapters)

(Sub)Project *(optional)*	**Volume, N=**	**Existing / new data**	**Data source**	**Data collection tool / system**	**Data Type**	**File Format**	**Storage space**
Pre- and post implementation measurements	Estimated N=1000	Existing data	EPD	Excel	Quantative data, patient data from health records	.xlsx	<1 GB
Patient interviews	N=6	New data	Interviews	Atlas.ti	Qualitative data	Atlas.ti	<1 GB
Gynecologists interviews	N=8	New data	Interviews	Atlas.ti	Qualitative data	Atlas.ti	<1 GB

3.11 Are study participants randomly allocated to groups? Select which option applies to the randomization (if any) of the participants.

- No randomization will take place.

4. Store and analyze

4.1 Where will the data be stored during the data collection (e.g. for combining, processing, and/or analyzing data)? Check the boxes for both digital and paper data storage.

- Data will be stored in a paper archive
- Data will be stored on a department server

When the department server is migrated to SharePoint/Teams in the future, we will evaluate the possibility of transferring our data to the Radboud Data Repository.

4.2 Give a short description of all the options that will be used for data storage, during the data collection. Provide the locations for digital and paper data.

Digital storage:
Research data is stored at the departmental shared network folder: Raboudumc server, H-schijf/afdelingsmappen/obstetrie en gynaecologie/onderzoek/ gyn-SAM-studie/implementatie
Paper storage:
Signed paper Informed Consent forms are stored in a cabinet: Department of obstetrics & gynaecology, route number 623, room number 4.22, cabinet number 0 and 1.

4.3 How will data security be ensured during the data collection?

Not applicable, since standard Radboudumc facilities are used.

4.4 How often, where and by whom will backups be made of the data?

Not applicable, since standard Radboudumc facilities are used.

4.5 How will access to the data be arranged for all parties, internal and external (if applicable); which restrictions will be applied to data access during the data collection?

Access to the departmental shared network folder is only granted by the PI to individual members of

the research team.

4.6 Which software or tools will be needed to process or analyze the data?

- Atlas.ti
- Microsoft Excel
- SPSS

4.7 Will standard facilities, (like Zero Clients "werkplek 2.0", Fat clients provided by Radboudumc ICT or DRE), be sufficient to process and analyze the data or will extra computing power and memory be required ?

- The Radboudumc standard facilities will suffice for processing and analyzing the data (virtual 'werkplek 2.0', standard fat clients, standard DRE work space)

4.8 What will be the estimated costs for managing the data during the study, and how will these be covered?

All costs for data management during the study (the use of Castor EDC and the departmental server) are covered by the department (overhead) or by the Radboudumc.

4.9 How will you structure your data? Briefly elaborate on the naming conventions and the structure of the files and directories.

Files will be structured in folders using the following naming scheme:
namefolder_namefile_date_version number

4.10 How will version control be applied, with clear version numbers, to maintain all changes that will be made to the data?

A 'revision' numbering system is used (v01, v02 etc), if necessary, initials are added to version numbers to show who has made the amendments.

4.11 Which documentation will be added to the data to (further) describe the data collection?

- I will make use of a codebook, that describes all data items in the data collection
- I will include syntaxes that will be used to process and/or analyze the data
- I will document the research process (data cleanings, methodology of data collection, quality

controls, statistics)

5. Archive and share

5.1 Describe the data that will be archived for the predetermined legal retention period.

All (source) data and other study essential documents (research file) that are required for verification purposes will be archived within the Radboudumc for 10 years.

5.2 Where will the data (described in question 5.1) be archived for the predetermined legal retention period after the research? Provide the locations for digital and paper data.

Digital argive:

eCRF Data is archived in Castor EDC.

Research data is archived at the departmental shared network folder:

H-schijf/afdelingsmappen/obstetrie en gynaecologie/onderzoek/ gyn-SAM-studie/implementatie

Paper archive

Signed paper Informed Consent forms are archived separately from research data by using a different cabinet: department of obstetrics & gynecology, route number 623, room 4.22, cabinet number 0 and 1.

5.3 Will there be any issues that affect the sharing of (parts of) the data collection after the research? If so, briefly describe these issues.

- Yes, there are issues that affect the sharing of (parts of) the data after the publication of the results. (please specify)

Because personal data is collected during patient interviews, there are privacy issues.

5.4 Which (part of the) data will be made findable and shared for reuse and/or verification?
(See also the table from question 3.10 that describes the data collection)

• Final (definitive) versions of data used for analysis, possibly also raw and processed data (depending on privacy issued)
• Documentation/codebooks necessary for understanding the data
• Questionnaires that were developed for this project
• Read me.txt for understanding the structure and contents of the documents

5.5 How will the data be made findable and shared for reuse and/or verification? Select the options that apply, and provide further details the comments field.

- Data will be published in a data repository or other online data archive (e.g. Radboud Data Repository, DANS Data Station, disciplinary repository, data archive) (please specifiy)

The Radboud Data Repository will be used to guarantee long-term accessibility of the research data from this project.

5.6 Will restrictions be applied to access to (parts of) the data?

- Yes, restrictions will be applied to (parts) of the data (please specify, e.g. how restrictions will be applied, how will access to the data be arranged, who will be made responsible for granting access to the data)

The pseudonymized data will be accessible in the Radboud Data Repository under restricted access. Requests for acces will be checked by the PI against the conditions for sharing the data as described in the signed Informed Consent.

Qualitative data for interviews, that cannot be anonimized, will be archived in a Closed Access Data Acquisition Collection (DAC) in the RDR; metadata about the data will be published but the data will not be accessible.

5.7 Will a license be applied to the published data? If yes, what license?

Not applicable

5.8 In case of restricted access, what are the conditions for access to the data? If yes, how are these defined, e.g. in a consortium agreement, data use agreement and/or other terms of use?

The pseudonymized data will be accessible in the Radboud Data Repository under restricted access. Requests for acces will be checked by the PI against the conditions for sharing the data as described in the signed Informed Consent.

5.9 How will metadata be published to describe the data collection, and to enable findability of the data collection? And which metadata will be shared, e.g. will standards be used?

- Dublin Core and DataCite Metadata about the data collection will be registered in RIS
- Metadata about the data collection will be published via the data repository/repositories (see above, please specify which metadata standard(s))

5.10 Will the dataset be made findable by means of linkage to a persistent identifier (PID) like a DOI, a Handle or other PID? Please provide the PID here as soon as it is available!

A DOI will be assigned to the published data collections in Radboud Data Repository. *Example DOI: https://doi.org/10.34973/t96x-8f34*, and also for the closed access DAC.

5.11 Which documentation will be added to the published data collection to enable reuse? (see also 4.6 and 4.11 for examples of data documentation)

SPSS scripts/syntax that were used to transform, restruct and analyze the data
Documentation/codebooks necessary for understanding the data
ABOUT.txt for understanding the structure and content of the documents

5.12 What will be the estimated costs for data archiving and/or publication after the study, and how will these be covered?

Costs for data management have not been budgeted for this project. These costs are covered by the department (overhead) or by the Radboudumc.

5.13 Which (bio)medical or other discipline specific terminology (vocabularies, classifications, ontologies or other standards) will be used within the data collection?

Not applicable

5.14 Which data formats will the data collection contain? See also 3.10, is there a need to migrate the data to (a) preferred data format(s)?

For this project, the following preferred data format are used which will be usable in the long term:
- Word and other text documents are saved as .PDF files.
- Excel files are saved as .CSV files.
- SPSS files (incl Castor export) are saved as .DAT/.SPS (syntax) files.
- Full study structure form Castor EDC is saved as .XML file.

5.15 If applicable, describe your strategy for publishing the analysis software that will be generated in this project.

Not applicable