Plan Overview

A Data Management Plan created using DMPonline

Title: Survey on pedicle screw repositioning

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Funder: UMC Utrecht

Template: UMC Utrecht DMP

Project abstract:

Survey among spine surgeons.

The survey contains pseudonymized radiologic images from patients that underwent spinal fixation.

Survey participants assess the radiologic images and, based on the provided images, determine if they would reposition the marked pedicle screw.

The survey will be conducted online using VQuest.

ID: 102441

Start date: 01-11-2022

End date: 28-04-2023

Last modified: 25-11-2022

Survey on pedicle screw repositioning

1. General features

1.1. Please fill in the table below. When not applicable (yet), please fill in N/A.

DMP template version	30 (don't change)
ABR number *(only for human-related research)*	
METC number *(only for human-related research)*	
DEC number *(only for animal-related research)*	
Acronym/short study title	Survey on pedicle screw repositioning (S2D3D)
Name Research Folder	22-961_S2D3D
Name Division	Surgical Specialty
Name Department	Orthopaedics
Partner Organization	
Start date study	01-11-2022
Planned end date study	28-04-2023
Name of datamanager consulted*	Nivard Koning
Check date by datamanager	28-10-2022

1.2 Select the specifics that are applicable for your research.

- Non-WMO
- Retrospective study
- Use of Questionnaires

Survey among spine surgeons with retrospective radiologic images from patients who underwent spinal fixation in the UMCU

2. Data Collection

2.1 Give a short description of the research data.

No.	Subjects	Volume	Data Source	Data Capture Tool	File Type	Format	Storage space
1.	Human	8	PACS/MRI/CT scanner	PACS	Imaging	.dcm	4 GB
2.	Human	8	Pseudonymized images from PACS	VQUEST	Imaging	.dcm	4 GB
3.	Participants in the survey	18-40	Outcome data of survey	VQUEST	Quantitative	.csv	<1 GB
4.	Participants in the survey	18-40	Outcome data of survey	R statistical software	Quantitative	.csv	<1 GB

1. Imaging data will be retrieved through PACS by the treating physician.
2. The pseudonymized images will be cropped and added to the questions in VQUEST.
3. The outcome data of the survey (thus, the answers from participants) will be exported as an .csv file once the survey has finished.
4. Statistical analysis will be performed using R statistical software

2.2 Do you reuse existing data?

- Yes, please specify

The treating physician will download pseudonymized radiologic images from eight patients who underwent spinal fixation in the UMCU through PACS.

2.3 Describe who will have access to which data during your study.

Type of data	Who has access
Direct identifying personal data	PI with care relationship to patient
Key table linking study specific IDs to Patient IDs	PI with care relationship to patient, Datamanager
Pseudonymized imaging data	Research team, Datamanager

The treating orthpedic surgeon (in this case the PI) will select the patients from which pseudonymized images will be used for the survey

2.4 Describe how you will take care of good data quality.

#	Question	Yes	No	N/A
1.	Do you use a certified Data Capture Tool or Electronic Lab Notebook?	X		
2.	Have you built in skips and validation checks?			X
3.	Do you perform repeated measurements?			X
4.	Are your devices calibrated?			X
5.	Are your data (partially) checked by others (4 eyes principle)?			X
6.	Are your data fully up to date?			X
7.	Do you lock your raw data (frozen dataset)			X
8.	Do you keep a logging (audit trail) of all changes?			X
9.	Do you have a policy for handling missing data?			X
10.	Do you have a policy for handling outliers?			X

1. The pseudonymized images are uploaded to VQUEST. For the rest, no measurements will be done with any of the images. All other questions are not applicable for obtaining the imaging data.

2.5 Specify data management costs and how you plan to cover these costs.

#	Type of costs	Division ("overhead")	Funder	Other (specify)
1.	Usage of VQuest			X
2.	Time of datamanager	X		
3.	Storage	X		
4.	Archiving			X

1. The usage of VQuest is for free.

4. Where data will be archived and how these costs will be covered has yet to be determined. This answer will be updated later.

2.6 State how ownership of the data and intellectual property rights (IPR) to the data will be managed, and which agreements will be or are made.

1. UMC Utrecht is and remains the owner of all collected data for this study. Our data cannot be protected with IPR, but its value will be taken into account when making our data available to others, when setting up Research Collaborations and when drawing up Data Transfer Agreement(s).

3. Personal data (Data Protection Impact Assessment (DPIA) light)

Will you be using personal data (direct or indirect identifying) from the Electronic Patient Dossier (EPD), DNA, body material, images or any other form of personal data?

- Yes, go to next question

Imaging will be downloaded from PACS by the treating physician. The images will be downloaded pseudonymized.

3.1 Describe which personal data you are collecting and why you need them.

Which personal data?	Why?
CT-scan and X-ray	We need these images to answer our research question

3.2 What legal right do you have to process personal data?

- Study-specific informed consent

3.3 Describe how you manage your data to comply to the rights of study participants.

Right	Example answers
Right of Access	Research data are coded, but can be linked back to personal data, so we can generate a personal record at the moment the person requires that. This needs to be done by an authorized person.
Right of Rectification	The authorized person will give the code for which data have to be rectified.
Right of Objection	We use informed consents.
Right to be Forgotten	In the informed consent we state that the study participant can stop taking part in the research. Removal of collected data from the research database cannot be granted because this would result in a research bias.

3.4 Describe the tools and procedures that you use to ensure that only authorized persons have access to personal data.

1. We use the secured Research Folder Structure that ensures that only authorized personnel has access to personal data, including the key table that links personal data to the pseudoID.
2. We use VQuest to design and conduct the survey. Only authorized personnel has access to the pseudonymized imaging data in a protected personal environment. After the survey has ended, the imaging data will be deleted from VQuest and thus will be only available in the secured Research Folder Sctructure. The outcome data of the survey (thus the responses of participants) will also be exported to the Research Folder Structure and deleted from VQuest. VQuest will not have access to any email addresses or other personal information from participants at any time point during the study.

3.5 Describe how you ensure secure transport of personal data and what contracts are in place for doing that.

We will not transport any personal data outside the UMCU network drives.

4. Data Storage and Backup

4.1 Describe where you will store your data and documentation during the research.

1. The digital files will be stored in the secured Research Folder Structure of the UMC Utrecht (both imaging data and outcome data of the survey).
2. The pseudonymized imaging data will be available in a personal environment in VQuest as long as the survey is online. After the survey has ended, the imaging data will be deleted from VQuest.

4.2 Describe your backup strategy or the automated backup strategy of your storage locations.

1. All (research) data is stored on UMC Utrecht networked drives from which backups are made automatically twice a day by the division IT (dIT).

5. Metadata and Documentation

5.1 Describe the metadata that you will collect and which standards you use.

1. I store the queries of my research in the Research Folder Structure, under my experiments, the PI of my research countersigns all my queries so he knows how the searches were done, and he can find the queries back when my research is over.

5.2 Describe your version control and file naming standards.

1. We will distinguish versions by indicating the version in the filename of the master copy by adding a code after each edit, for example V1.1 (first number for major versions, last for minor versions). The most recent copy at the master location is always used as the source, and before any editing, this file is saved with the new version code in the filename. The file with the highest code number is the most recent version and older versions are moved to a folder OLD. The major versions will be listed in a version document (projxVersDoc.txt), stating the distinguishing elements per listed version.

6. Data Analysis

6 Describe how you will make the data analysis procedure insightful for peers.

1. We will be using R, version 4.0.3, for statistical analysis of the outcome data of the survey in VQUEST. The scripts will contain comments, such that every step in the analysis is documented and peers can read why I made certain decisions during the analysis phase.

7. Data Preservation and Archiving

7.1 Describe which data and documents are needed to reproduce your findings.

1. 1. The data package will contain: the raw data, the study protocol describing the methods and materials, the script to process the data, the scripts leading to tables and figures in the publication, a codebook with explanations on the variable names, and a ‘read_me.txt’ file with an overview of files included and their content and use.

7.2 Describe for how long the data and documents needed for reproducibility will be available.

1. Data and documentation needed to reproduce findings from this non-WMO study will be stored for at least 15 years.

7.3 Describe which archive or repository (include the link!) you will use for long-term archiving of your data and whether the repository is certified.

1. After finishing the project, the data package will be stored at the UMC Utrecht Research Folder Structure and is under the responsibility of the Principal Investigator of the research group.

7.4 Give the Persistent Identifier (PID) that you will use as a permanent link to your published dataset.

1. The data that are used in publication XXX are published with the publication and are to be found under the PID XXX.

8. Data Sharing Statement

8.1 Describe what reuse of your research data you intend or foresee, and what audience will be interested in your data.

1. The pseudonymized imaging data will not be shared with any other researchers
2. The outcome data of the survey can be used to generate new research questions

8.2 Are there any reasons to make part of the data NOT publicly available or to restrict access to the data once made publicly available?

- Yes (please specify)

The pseudonymized imaging data will not be shared with other parties.

8.3 Describe which metadata will be available with the data and what methods or software tools are needed to reuse the data.

1. All data and documents in the data package mentioned in 7.1 will be shared under restrictions.

8.4 Describe when and for how long the (meta)data will be available for reuse

- Other (please specify)

upon request the survey outcome data can be reused. The pseudonymized imaging data cannot be shared or reused.

8.5 Describe where you will make your data findable and available to others.

1. Imaging data is not findable to others, the data will not be shared.
2. The survey outcome data will be available upon request.