Plan Overview

A Data Management Plan created using DMPonline

Title: Prospective evaluation of early urological diagnostic of neurogenic bladder patients (after 12-20 year follow up)

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Prospective evaluation of early urological diagnostic of neurogenic bladder patients (after 12-20 year follow up)

1. General features

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

DMP template version	29 (don't change)
ABR number *(only for human-related research)*	N/A
METC number *(only for human-related research)*	TBD
DEC number *(only for animal-related research)*	N/A
Acronym/short study title	PEDNB
Name Research Folder	xx-xxx_PEDNB
Name Division	Surgical Specialities
Name Department	Peadiatric Urology
Partner Organization	UMC Utrecht
Start date study	
End date study	
Name of datamanager consulted*	Dax Steins
Check date by datamanager	20-05-2021

1.2 Select the specifics that are applicable for your research.

- Clinical study
- Non-WMO
- Monocenter study
- Prospective study

2. Data Collection

2.1 Give a short description of the research data.

To evaluate early diagnostics in patients with 'neurogenic bladder' we intend to compare data from a pre-existing database with prospective patient data. Eligible patients suspected of a 'neurogenic bladder' were examined in the Sylvia-Tóth-outpatient clinic at the Wilhelmina Children Hospital (part of University Medical Center Utrecht) between 1st January 2000 and 31st December 2008. Medical data from the outpatient clinic was then extracted from the electronic patient record and combined into a database (e.g. physical examination, MRI of the sacrum, urodynamic examination, etc.). We intend to reuse this database.
To collect follow-up data we aim to contact patients by phone and ask a single question ('Can you void spontaneously?').

For the use of the pre-existing database and the follow-up data by phonecall we will ask written informed consent dirst. Only data from the database of the patients that provided informed consent will be kept. It will be then be merged with the newly collected follow-up data. The final database will be frozen for analysis and pseudonymized by the main investigator/staff member with a key-linking table for patient re-identification. Only researchers directly involved in the study are allowed to access the key-linking table.

Subjects	Volume	Data Source	Data Capture	File Type	Format	Storage space
Human	176	HiX	SPSS	Database	.sav	66 kB
Human	176	Phone call	SPSS	Quantitative	.sav	unknown

2.2 Do you reuse existing data?

- Yes, please specify

We shall reuse clinical data originating from a pre-existing database from the department of urology at the UMC Utrecht, the Netherlands. This data was collected from the electronic patient record. Furthermore, we intend to collect follow-up data. After informed consent, we intend to merge the data and analyze it. For further details see 2.1

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

Type of data	**Who has access**
Direct identifying personal data	Research team, Datamanager
Key table linking study specific IDs to Patient IDs	PI, Datamanager
Pseudonymized data	Research team, Datamanager

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

Data from included patients will be extracted from an existing SPSS database by the division datamanager en collected in a new database.

#	**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		

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

#	**Type of costs**	**Division** ("overhead")	**Funder**	**Other** (specify)	
1.	Time of datamanager	X			
2.	Design of eCRF	X			
3.	Data Capture Tool license fee	X			
4.	Questionnaire license fee	X			
5.	Storage	X			
	Archiving	X			

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.

UMC Utrecht is and remains the owner of all collected data for this study. The data is collected in a relatively large patient group and is very valuable for further, broader studies in Europe. It may for example be used to find study subjects for future treatment studies. 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

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

Which personal data?	Why?
All data originating from the assesment at the 'Sylvia-Toth'-outpatient clinc including anamnesis, physical examination, MRI and urodynamic testing	It is the baseline which we try to analyze.
Data originating from the phone call (single question)	This is the result by which we want to evaluate the initial results.

See study protcol for detailed list of personal data.

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.

The data are pseudonymized and the linking table to personal data is saved. An authorized person manages the linking table, can re-identify study participants when necessary and deliver, correct or delete the data. The procedure can be found: L drive

Right	Example answers
Right of Access	Research data are coded/pseudonymised, 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.

All data originating from the SPSS database will be stored in a secured researchfolder (L:... provide pathname as soon as the research folder is created) of the UMC. Only authorized personnel has access to personal data, including the key table that links personal data to the pseudoID.

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.

SPSS data and documantion will be secured on secured datamap of the UMC Utrecht
(L: \\ds\DATA\HS\Onderzoek\Kinderchirurgie\xx-xxx_PEDNB)

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

All data originating from the SPSS database is stored on UMC Utrecht networked drives from which backups are made automatically twice a day by the division IT (dIT).
Furthermore we will only work in copies of the original SPSS database. The unchanged version of raw data wil serve as backup.

5. Metadata and Documentation

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

SPSS creates a log which will be combined to one document so all changes and calculations will be retrievable. A data-dictionary will serve as a guide guide for the database (see 6.).
Additional metadata originating from SPSS will not be registered in a Word document.
If applicable, a more in depth description shall be added later on.

5.2 Describe your version control and file naming standards.

We will distinguish versions by indicating the version and date (YYYYMMDD) 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).
Initials of the editor of the file will be added to the file name in case multiple persons are editing the same file.
File naming is descriptive, they reflect the content of the file.

6. Data Analysis

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

Our preliminary analysis plan is described in the study protocol. Once we have our raw dataset we will generate a data dictionary and a more detailed analysis plan.
Data analyses will be conducted in IBM SPSS Statistics (25.0). The entire analysis will be documented using syntax. Comments will be added in the script to give insight into
decisions making

7. Data Preservation and Archiving

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

The research folder will work as a data package containing the necessary data and protocols to showcase and explain all steps leading to the final result.
The data package will contain raw data, the study protocol describing the methods and materials, the script to process the data and the scripts leading to tables and figures in the publication.

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

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.

As UMCU we are not yet connected to a public repository. We are currently dealing with this matter and hopefully by september we can make use of DataverseNL.
For now the L:Drive serves as an archive.

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

We do not have yet a PID available. If there will be publication, we will provide the DOI number and as pointed out in 7.3: if we will use repository we will also provide persistent indentifier for that.

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.

The raw data can be of interest for other researchers in our field.

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)

To be determined.

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

To be determined.

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

- Other (please specify)

To be determined.

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

To be determined.