THE SONOGRAPHIC ASSESSMENT OF LABOR PROGRESS, FETAL WELLBEING AND THE PELVIC FLOOR IN THE CONTEXT OF CHILDBIRTH: DEVELOPING NEW APPLICATIONS TO IMPROVE LABOR OUTCOME AND IDENTIFY HIGH-RISK PATIENTS FOR RELATED MORBIDITIES.

A Data Management Plan created using DMPonline.be

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Funder: Fonds voor Wetenschappelijk Onderzoek - Research Foundation Flanders (FWO)

Template: FWO DMP (Flemish Standard DMP)

ID: 199253

Last modified: 02-05-2023

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FWO DMP (Flemish Standard DMP)

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1. Research Data Summary

List and describe all datasets or research materials that you plan to generate/collect or reuse during your research project. For each dataset or data type (observational, experimental etc.), provide a short name & description (sufficient for yourself to know what data it is about), indicate whether the data are newly generated/collected or reused, digital or physical, also indicate the type of the data (the kind of content), its technical format (file extension), and an estimate of the upper limit of the volume of the data.

Execution of our research projects will result in the collection of the following data types (**all new data, no reuse of existing data**):

- **2D B-mode ultrasound images (jpg file format, observational data)** :
  - **For WP1.1**: Measurement of the AoP and plane of minimal hiatal dimensions at the onset of the active second stage (rest + maximal Valsalva), and identical images after 20 minutes of pushing (both in the intervention and the control group, necessary for straightforward comparison). Two additional images at the onset of the 2nd stage for measurement of the MLA and OSA/CCA (in both groups). Total of 12 2D images/participant, multiplied by 550 participants (total sample size): 6600 images. One image (2D, B mode, 10 cm depth, 60° angle, adequate for measurement of AoP, MLA and OSA/CCA) is approximately 1 Mb, translating into 6-7 Gb for the entire sample size.
  - **For WP2.1**: 100 2D images (B-mode + Power doppler, with calculations PI/RI/PSV) for both MCA and VA. Total of 200 images for the entire cohort. One image is approximately 2Mb (2D, B mode + Power doppler, 10 cm depth, 60° angle, adequate for measurement PI/RI/PSV), translating into 400 Mb for the entire sample size.
  - **For WP 2.2**: identical to WP 2.1, but wide variety in the number of observations to be expected depending on the duration of labor (median duration of the active first stage 5 hours for nullipara, 4 hours for multipara). Estimation of 5-7 images/participant (1-2 latent phase, 2-3 active phase, full dilatation, and 30 minutes into the 2nd stage): multiplied by 300 participants and 2Mb per image: 3-4Gb for the entire sample size.
  - **For WP3**: One image (2D, B mode, 10 cm depth, 60° angle) for measurement of AoP, MLA and OSA/CCA in every subject. The aim is to have a full dataset in 200 individuals. Every image is approximately 1 Mb, translating into almost 200 Mb for the entire cohort.
- **3D/4D ultrasound volumes (volume document, .vol, observational data)** :
  - **1:** Pelvic floor ultrasound during labor: 4D ultrasound volume at the onset of the active second stage and after 20 minutes of pushing (measured both in the intervention & control group). Clip with estimated duration of 5 seconds (from rest to maximal Valsalva). Total of 2 volumes/participant x 550 participants: 1100 volumes. Size of a 5 sec 4D pelvic floor ultrasound volume is +/- 30 Mb, translating into 33 Gb for the entire cohort.
  - **WP 1.2**: Pelvic floor ultrasound at the time of postpartum follow up: one 4D volume of the pelvic floor at rest, maximal pelvic floor muscle contraction and Valsalva respectively (approximately 30 Mb each). One static 3D volume of the anal sphincter (6Mb), one render 4D volume of anal sphincter contraction (approximately 5 seconds, 30 Mb). Total of 70 Gb for the entire cohort.
  - **WP3:** similar volumes required as in WP 1.2; aim is a full dataset in 360 subjects, translating into 45 Gb for the entire cohort.
- **Clinical data** (Demographics, Labor or delivery related clinical data - specified in the scientific project outline, **observational data**):
  - Source data is encoded into KWS (“KlinischWerkStation”, electronic medical notes system, hosted at UZ Leuven) at the time of delivery by the relevant caregivers (encoding is standardized with pre-set options).
  - CTG traces are stored on “Intellispace” (hosted at UZ Leuven, archived for at least 25 years in accordance with Belgian legislation requirements).
  - Trial data will be retrieved from the medical notes by the PhD student and transcribed into the REDcap data management tool (eCRF).
- **Questionnaires (observational data)**: BSS-R questionnaire (10 items, every item scored on a 5-point Likert scale). The clinical trial data capturing tool (REDcap, hosted at UZ Leuven) allows sending out electronic surveys to study participants (in accordance with the General Data Protection Regulation GDPR), encoding the questionnaire answers immediately into the eCRF.

If you reuse existing data, please specify the source, preferably by using a persistent identifier (e.g. DOI, Handle, URL etc.) per dataset or data type:

No planned reuse of existing data.

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? Describe these issues in the comment section. Please refer to specific datasets or data types when appropriate.

- Yes, human subject data

We will be collecting sensitive personal data (observational source data from the medical notes or measurements/findings from ultrasound images and volumes) that will require pseudonymization.

The personal (patient) data that will be collected can differ slightly according to the different aims of every work package. In general, it will consist of demographical variables and data related to labor and/or delivery characteristics.

All personal data shall always be treated as confidential, including during collection, handling and use or processing, and the personal data (including in any electronic format) shall always be stored securely and with all technical and organizational security measures that would be necessary for compliance with EU and national data protection legislation.

The following project have already been approved by the Ethics Committee for research at UZ/KU Leuven:

-- **S66425 (WP3)**: B3222022000789

-- **S66995 (WP2)**: B3222022000971

Similarly, ethical approval will be sought prior to the commencement of every research project. No research project (i.e., data collection) will start before ethical approval has been obtained.

Will you process personal data? If so, briefly describe the kind of personal data you will use in the comment section. Please refer to specific datasets or data types when appropriate.

- Yes

- The eCRFs will under no circumstances contain personal data that allows for direct identification of a study participant, such as but not limited to, the participant or their relative(s) name, home address, contact details, full date of birth or medical record number (e.g. UZ Leuven EAD number), social security number etc.

- Other personal data (specific for every project) will undergo pseudonimization prior to encoding in the eCRF (REDcap), or being stored in the dedicated data storage means or repositories (ultrasound images/volumes).

Does your work have potential for commercial valorization (e.g. tech transfer, for example spin-offs, commercial exploitation, …)? If so, please comment per dataset or data type where appropriate.

- No

Do existing 3rd party agreements restrict exploitation or dissemination of the data you (re)use (e.g. Material/Data transfer agreements/ research collaboration agreements)? If so, please explain in the comment section to what data they relate and what restrictions are in place.

- No

Are there any other legal issues, such as intellectual property rights and ownership, to be managed related to the data you (re)use? If so, please explain in the comment section to what data they relate and which restrictions will be asserted.

- No

2. Documentation and Metadata

Clearly describe what approach will be followed to capture the accompanying information necessary to keep data understandable and usable, for yourself and others, now and in the future (e.g., in terms of documentation levels and types required, procedures used, Electronic Lab Notebooks, README.txt files, Codebook.tsv etc. where this information is recorded).

We will be working with highly sensitive personal data (observational data from labor/delivery or measurements/findings from ultrasound images and volumes) that will require pseudonymization.

Upon enrollment of a study participant, the REDcap data capturing tool allocates a unique study-specific-identifier number to every trial participant. A separate Excel spreadsheet will be kept in a login restricted file (accessible only by research personnel) on the UZ Leuven server, linking this participant number to the patient-identification number in KWS.

The (observational) source data is kept in the medical notes (KWS, Klinisch Werk Station, Hosted at UZ Leuven). Only data relevant for the trials (as specified in the study protocols), will be transferred in the case report forms in REDcap. This will be done in a timely manner and by always ensuring confidentiality and privacy.

Prior to the acquisitioning of ultrasound volumes and images (= sonographic source data), a unique identifier code will be entered as “patient identification” during the scan. This identifier code will ensure pseudonymization of volumes and images immediately at the time of acquisitioning. The REDcap identifier number will be incorporated in this code, linking the images and volumes to the observational source data.

Will a metadata standard be used to make it easier to find and reuse the data? If so, please specify (where appropriate per dataset or data type) which metadata standard will be used. If not, please specify (where appropriate per dataset or data type) which metadata will be created to make the data easier to find and reuse.

- Yes

Upon encoding the different outcome variables & confounders in the REDcap data capturing tool; a data dictionary is automatically created (a specifically formatted CSV file with the different project fields and variable names). The data dictionary represents and summarizes variable/field names and labels, as well as field attributes (type, Validation, Choices, Calculations, etc.).

The process of pseudonymization guarantees the possibility of retracement of original source data (either in the medical notes (KWS) or images/volumes on the ultrasound machine or university server).

REDcap maintains a comprehensive audit trail within the eCRF demonstrating the validity of collected trial data. This includes historical records of original data entries, by whom the data was entered and when it was entered, as well as detailed records of who, when, which and why corrections to the original data entry were made. This also includes records pertaining to managing user access and data privileges

3. Data storage & back-up during the research project

Where will the data be stored?

We also refer to the section below (data back up).

We will be working with highly sensitive personal data (observational data from labor/delivery or measurements/findings from ultrasound images and volumes) that will require pseudonymization.

Upon enrollment of a study participant, the REDcap data capturing tool allocates a unique study-specific-identifier number to every trial participant. A separate Excel spreadsheet will be kept in a login restricted file (accessible only by research personnel) on the UZ Leuven server, linking this participant number to the patient-identification number in KWS.

The (observational) source data is kept in the medical notes (KWS, Klinisch Werk Station, Hosted at UZ Leuven). Only data relevant for the trials (as specified in the study protocol), will be transferred in the case report forms in REDcap. This will be done in a timely manner and by always ensuring confidentiality and privacy.

Prior to the acquisitioning of ultrasound volumes and images (= sonographic source data), a unique identifier code will be entered as “patient identification” during the scan. This identifier code will ensure pseudonymization of volumes and images immediately at the time of acquisitioning. The REDcap identifier number will be incorporated in this code, linking the images and volumes to the observational source data.

SPSS software will be used for statistical analysis. For this purpose, data exports will be conducted out of REDcap in excel format. These exports will not contain data that allows for identification of a study participant (identifier information). This will ensure compliance with applicable data protection regulations. Results will be represented in Microsoft Office utilities (Word, Powerpoint) or PDF. All necessary precautions will be taken to warrant patient confidentiality. Published results will not contain any personal data that could allow for identification of individual participants.

Any trial related documents (informed consent documents, report forms) will be kept in locked cabinets only accessible by the study investigators. All patient information will be pseudonymized in a manner designed to maintain confidentiality.

All originally signed obtained Informed Consent Forms (ICFs) will be retained/archived in the Investigator Site File (ISF) at the Participating Site and will not be destroyed (even when a scanned copy is available) before expiration of the legal archiving term.

How will the data be backed up?

- Pseudonymized ultrasound images and volumes will be stored on an ultrasound machine dedicated to this research project (*Voluson Swift*). A back-up of all images and volumes will be made on an external hard drive (5TB) that will be stored in a locked cabinet on the labor ward (only accessible by authorized (study related) personnel). Every 24 hours (end of every workday), a second back up of all images and volumes will be made on the university’s central servers in a login restricted file (with additional automated back-up procedures). The data will be stored on the university's central servers for at least 10 years, conforming to the KU Leuven RDM policy.

- Observational data is stored in the REDcap data capturing tool. Automatic back-up procedures are guaranteed by UZ/KU Leuven, with hourly/daily and weekly back-up regimens for the web server, and nightly back-ups of the databases).

Is there currently sufficient storage & backup capacity during the project? If yes, specify concisely.
If no or insufficient storage or backup capacities are available, then explain how this will be taken care of.

- Yes

Sufficient storage is provided for every research project in the REDcap database.

Back-ups of ultrasound images and volumes will be stored on two hard drives (already available) and on the UZ Leuven server (free storage capacity up to 5 TB).

How will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

REDcap is hosted on dedicated KU Leuven data servers at Campus Heverlee. At the clinical database level, only study team members, monitors and auditors/inspectors for whom the coordinating or principal investigator has requested project-specific eCRF access, are granted data access. Upon successful training completion, each user is centrally assigned a user role, associated with predefined system/data privileges. The gatekeeper for UZL REDcap is the Clinical Trial Centre - CTC (ctc.datamanagement@uzleuven.be).

We will be working with sensitive personal data that will require pseudonymization. Upon enrolment of a study participant, the REDcap data capturing tool allocates a unique study-specific-identifier number to every study participant. A separate Excel spreadsheet will be kept in a login restricted file (accessible only by research personnel) on the UZ Leuven server, linking this participant number to the patient-identification number in KWS.

The hard drives will be kept in a locked cabinet on the labor ward, only accessible by study personnel.

Any trial related documents (printed IC forms, printed CRFs, copies of other reports) will be kept in locked cabinets only accessible by authorized study personnel.

Computers used to collect and encode the data have limited access measures by usernames and passwords. All necessary precautions will be taken to warrant patient confidentiality as data will be stored exclusively on password-protected domains.

What are the expected costs for data storage and backup during the research project? How will these costs be covered?

A REDcap license costs 80 euros per research project (funds provided for by the project supervisor). Physical means for data storage (i.e., hard drives) will be paid for using the FWO project bench fee (approximately 100 euros/hard drive, 2 drives already bought).

4. Data preservation after the end of the research project

Which data will be retained for at least five years (or longer, in agreement with other retention policies that are applicable) after the end of the project? In case some data cannot be preserved, clearly state the reasons for this (e.g. legal or contractual restrictions, storage/budget issues, institutional policies...).

- The (clinical) source data is stored in the medical notes (KWS). The retention period for medical records of patients in Belgium is at least 30 years (art. 25 'ziekenhuiswet' and art. 6 'KB of 15 December 1987'), the legal responsibility for this storage lies with UZ Leuven.
- The trial data (eCRF, outlined above) will be stored in REDcap and on the University central servers (with automated backup procedures) for at least 25 years (requirement of the ethics committee research UZ/KU Leuven).
- Other trial data (ultrasound volumes/images) will be stored on the UZ Leuven share point (Microsoft Sharepoint online website, restricted access with multifactor authentication using the KU/UZ Leuven Authenticator app).

Where will these data be archived (stored and curated for the long-term)?

See above.

For long term storage (after termination of the research project), the identifier files (linking the study ID numbers to the patient identification numbers in KWS) will be stored on the personal computer of the project supervisor.

What are the expected costs for data preservation during the expected retention period? How will these costs be covered?

Data storage on the Microsoft Sharepoint is free of charge for data volumes smaller than 5 TB, which we expect will be the case for this project.

5. Data sharing and reuse

Will the data (or part of the data) be made available for reuse after/during the project? In the comment section please explain per dataset or data type which data will be made available.

- Yes, in a restricted access repository (after approval, institutional access only, …)

Personal data being archived in the context of this research project may be further processed in pseudonymized form for the better understanding of the condition under investigation, which may be in collaboration with other researchers. Each such new study shall be subject to approval by an ethics committee, which is amongst others responsible for ensuring appropriate protection of the privacy of study participants, and data subjects will be transparently informed of any such secondary use of their personal data in accordance with relevant data protection rules and legislation (including GDPR).

If access is restricted, please specify who will be able to access the data and under what conditions.

Personal data being processed in the context of the present study (and possibly in the context of new studies that consist of secondary use of the personal data being processed for the present study, for which ethical approval has been obtained) may be reviewed by the following people:

- the investigator and his/her research team (which may include –under certain conditions-a master student or a doctoral student);
- study monitors and auditors who will check whether the study is being conducted correctly and whether the information collected about participants is accurate;
- the ethics committee that approved this study and ensures that participants' rights and well-being are guaranteed

Are there any factors that restrict or prevent the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions)? Please explain in the comment section per dataset or data type where appropriate.

- Yes, Privacy aspects
- Yes, Ethical aspects

We will be working with highly sensitive personal data (observational data from labor/delivery or measurements/findings from ultrasound images and volumes) that will require pseudonymization. This process has been outlined above. Secondary use of trial data will only be possible after the necessary ethical approval has been sought.

Where will the data be made available? If already known, please provide a repository per dataset or data type.

Trial data will not be made publicly available, for privacy and ethical considerations.

When will the data be made available?

Non-applicable.

Which data usage licenses are you going to provide? If none, please explain why.

Non-applicable.

Do you intend to add a PID/DOI/accession number to your dataset(s)? If already available, you have the option to provide it in the comment section.

- No

What are the expected costs for data sharing? How will these costs be covered?

Non-applicable.

6. Responsibilities

Who will manage data documentation and metadata during the research project?

Bram Packet (PhD student)

Who will manage data storage and backup during the research project?

Bram Packet (PhD student)

Who will manage data preservation and sharing?

Jute Richter (PhD supervisor)

Who will update and implement this DMP?

Bram Packet (PhD student), the PI (Jute Richter) bears the end responsibility of updating & implementing this DMP