Plan Overview

A Data Management Plan created using DMPonline

Title: Vacuum Assisted Delivery Training Phantom Validation

Creator: Haochen WANG

Principal Investigator: Haochen WANG

Data Manager: Haochen WANG

Affiliation: Delft University of Technology

Template: TU Delft Data Management Plan template (2021)

Project abstract:

This research aims to validate a new vacuum-assisted delivery (VAD) training phantom through a two-phase study. In the first phase, the phantom's effectiveness will be assessed via a static display and simulated delivery performed by participants, followed by a questionnaire. In the second phase, quantitative data on pulling force and angle will be captured using an LSB200 sensor and video recordings, respectively. These objective measurements will be compared with existing VAD data to validate the phantom’s effectiveness.

ID: 161619

Start date: 18-12-2023

End date: 15-11-2024

Last modified: 25-10-2024

Copyright information:

Vacuum Assisted Delivery Training Phantom Validation

0. Administrative questions

1. Name of data management support staff consulted during the preparation of this plan.

My faculty data steward,

2. Date of consultation with support staff.

2024-10-18

I. Data description and collection or re-use of existing data

3. Provide a general description of the type of data you will be working with, including any re-used data:

Type of data	File format(s)	How will data be collected (for re-used data: source and terms of use)?	Purpose of processing	Storage location	Who will have access to the data
Traction Force Data	.txt	The data will be collected using a TU Delft ME Faculty Workshop calibrated LSB200 force sensor along with a corresponding LabVIEW program.	This data will be compared with the existing traction force data to validate the effectiveness of the phantom.	Local disk + OneDrive +Google Drive	Corresponding Responsible Researcher: Haochen WANG and Responsible Researcher: Jenny Dankelman
Attitudes on the Newly Developed Phantom	.xlsx	The data will be collected Anonymisly in physical paper, then input into the MS Excel by the responsible researcher.	To prevent the potential disclosure of personally identifiable information (PII), such as identifying participants through handwriting. These data will also be used to validate the effectiveness of the phantom.	Local disk + OneDrive +Google Drive	Corresponding Responsible Researcher: Haochen WANG and Responsible Researcher: Jenny Dankelman
Traction Angle Video	.mp4	The video will be recorded using an iPhone 12 mini, and DaVinci Resolve 18 will be used for video stabilization and blurring any individuals who are accidentally captured in the footage.	Personally identifiable research data (PIRD) will be anonymized to ensure privacy. The anonymized data will be compared with existing data to validate the effectiveness of the phantom.	Local disk + OneDrive +Google Drive	Corresponding Responsible Researcher: Haochen WANG and Responsible Researcher: Jenny Dankelman

4. How much data storage will you require during the project lifetime?

- < 250 GB

II. Documentation and data quality

5. What documentation will accompany data?

- Methodology of data collection

III. Storage and backup during research process

6. Where will the data (and code, if applicable) be stored and backed-up during the project lifetime?

- OneDrive

IV. Legal and ethical requirements, codes of conduct

7. Does your research involve human subjects or 3rd party datasets collected from human participants?

- Yes

8A. Will you work with personal data? (information about an identified or identifiable natural person)

If you are not sure which option to select, first ask your Faculty Data Steward for advice. You can also check with the privacy website . If you would like to contact the privacy team: privacy-tud@tudelft.nl, please bring your DMP.

- Yes

- Level of satisfaction with the examined vacuum delivery training phantom of participants, including the original handwritten physical questionnaires, and any of their image backups will be destroyed by the end of the project, specifically before November 15, 2024.
- Video recordings of traction angle, which will be anonymized after collection, and the original videos will also be destroyed by the end of the project, specifically before November 15, 2024.
- Signed informed consent forms.

8B. Will you work with any other types of confidential or classified data or code as listed below? (tick all that apply)

If you are not sure which option to select, ask your Faculty Data Steward for advice.

- No, I will not work with any confidential or classified data/code

9. How will ownership of the data and intellectual property rights to the data be managed?

For projects involving commercially-sensitive research or research involving third parties, seek advice of your Faculty Contract Manager when answering this question. If this is not the case, you can use the example below.

The datasets underlying the published papers will be publicly released following the TU Delft Research Data Framework Policy. During the active phase of research, the project leader from TU Delft will oversee the access rights to data (and other outputs), as well as any requests for access from external parties. They will be released publicly no later than at the time of publication of corresponding research papers.

10. Which personal data will you process? Tick all that apply

- Signed consent forms
- Other types of personal data - please explain below

- Traction Force during Vacuum-Assisted Delivery on the examined phantom.
- Traction Angle, recorded in video format, during Vacuum-Assisted Delivery on the examined phantom.
- Attitudes toward the Newly Developed Phantom.

11. Please list the categories of data subjects

- Obstetricians and gynaecologists
- Other medical experts

12. Will you be sharing personal data with individuals/organisations outside of the EEA (European Economic Area)?

- No

15. What is the legal ground for personal data processing?

- Informed consent

16. Please describe the informed consent procedure you will follow:

All study participants will be asked to provide their written consent for participation in the study and for the processing of their data.

17. Where will you store the signed consent forms?

- Same storage solutions as explained in question 6

18. Does the processing of the personal data result in a high risk to the data subjects?

If the processing of the personal data results in a high risk to the data subjects, it is required to perform a Data Protection Impact Assessment (DPIA). In order to determine if there is a high risk for the data subjects, please check if any of the options below that are applicable to the processing of the personal data during your research (check all that apply).
If two or more of the options listed below apply, you will have to complete the DPIA. Please get in touch with the privacy team: privacy-tud@tudelft.nl to receive support with DPIA.
If only one of the options listed below applies, your project might need a DPIA. Please get in touch with the privacy team: privacy-tud@tudelft.nl to get advice as to whether DPIA is necessary.
If you have any additional comments, please add them in the box below.

- None of the above applies

22. What will happen with personal research data after the end of the research project?

- Anonymised or aggregated data will be shared with others
- Personal research data will be destroyed after the end of the research project

23. How long will (pseudonymised) personal data be stored for?

- 10 years or more, in accordance with the TU Delft Research Data Framework Policy

24. What is the purpose of sharing personal data?

- For research purposes, which are in-line with the original research purpose for which data have been collected

25. Will your study participants be asked for their consent for data sharing?

- Yes, in consent form - please explain below what you will do with data from participants who did not consent to data sharing

In the informed consent form, participants give their consent for the use of the collected anonymized research data in an MSc thesis, a potential publication in a journal and any potential future research.

V. Data sharing and long-term preservation

27. Apart from personal data mentioned in question 22, will any other data be publicly shared?

- All other non-personal data (and code) produced in the project

29. How will you share research data (and code), including the one mentioned in question 22?

- All pseudonymised data will be uploaded to 4TU.ResearchData with restricted access

30. How much of your data will be shared in a research data repository?

- < 100 GB

31. When will the data (or code) be shared?

- At the end of the research project

32. Under what licence will be the data/code released?

- CC BY-SA

VI. Data management responsibilities and resources

33. Is TU Delft the lead institution for this project?

- Yes, leading the collaboration - please provide details of the type of collaboration and the involved parties below

Incision Group B.V.

- Provider of obstetricians and experiment location

34. If you leave TU Delft (or are unavailable), who is going to be responsible for the data resulting from this project?

Jenny Dankelman
j.dankelman@tudelft.nl

35. What resources (for example financial and time) will be dedicated to data management and ensuring that data will be FAIR (Findable, Accessible, Interoperable, Re-usable)?

4TU.ResearchData is able to archive 1TB of data per researcher per year free of charge for all TU Delft researchers. We do not expect to exceed this and therefore there are no additional costs of long term preservation.