Negotiating consent: patient agency and gynaecological surgery (France and the Netherlands, 1890s-1960s)

A Data Management Plan created using DMPonline.be

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Project abstract:

Scholars have often depicted the rise of informed consent as a recent development in which patients have achieved (legal) autonomy since the 1960s. This project challenges the view that patients had (almost) no autonomy before the post-war period. It aims to provide a long-term historical perspective on patient agency in negotiations over consent in France and the Netherlands from the 1890s until the 1960s. Gynaecological surgery will serve as the main focus. This was a type of invasive abdominal surgery that blossomed around 1890 and for which the omission of consent lead to court cases.

This project focuses on practices and conflicts related to surgical consent and disclosure about the risks of operations. Rarely used sources will be consulted such as hospital archives and court records. In addition, medical publications will be analysed by means of digital text-mining and traditional hermeneutical methods. Using this innovative methodology, this project will extend existing histories of informed consent in which the patient voice and the interaction between doctors and patients have been overlooked. It will generate fresh insight into broader shifts in patient agency and into the behaviour of patients in relation to physicians, relatives and other actors.

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FWO DMP (Flemish Standard DMP)

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.

				Only for digital data	Only for digital data	Only for digital data	Only for physical data
Dataset Name	Description	New or reused	Digital or Physical	Digital Data Type	Digital Data format	Digital data volume (MB/GB/TB)	Physical volume
		Please choose from the following options: • Generate new data • Reuse existing data	*Please choose from the following options:* • Digital • Physical	*Please choose from the following options:* • Observational • Experimental • Compiled/aggregated data • Simulation data • Software • Other • NA	*Please choose from the following options:* • .por, .xml, .tab, .cvs,.pdf, .txt, .rtf, .dwg, .gml, … • NA	*Please choose from the following options:* • <100MB • <1GB • <100GB • <1TB • <5TB • <10TB • <50TB • >50TB • NA	
Data from medical publications	The text and metadata of medical publications about gynecological surgery in the period 1890-1969. Medical publications include gynecological journals, medical dissertations and medical textbooks.	both generate new data and reuse existing data	Both digital and physical	Compiled/aggregated data	.txt, .pdf	• <100MB	4 medical journals and about 20 medical dissertations and textbooks
Data from legal archival records	The text from archival documents relating to court cases that patients filed against gynaecologists.	Generate new data	Physical	Compiled/aggregated data	.docx, .xlsx, .jpg, .pdf	• <100MB	Maximum 10 legal dossiers relating to court cases
Data from medical archival records	The text from medical records in hospital archives. The data concern information about the surgical operations that patients underwent in the period 1890-1969.	Generate new data	Physical	Compiled/aggregated data	.docx, .xlsx, .jpg, .pdf	• <100MB	Maximum 1600-2000 medical files relating to gynecological operations

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:

The reused data concern notes I have made in Zotero about the content of Belgian and international gynaecological journals in the period 1890-1914.

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

Yes, a large part of my research entails a historical analysis of medical records and legal records about gynaecological operations performed in the period 1890-1969. These records include sensitive patient information. I have recently submitted a privacy and ethics application by using the digital PRET platform from KU Leuven. My application is now under ethical review by SMEC.

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 medical records that I will analyze contain information about gynecological operations in the period 1890-1969. The medical records also contain patient identifiers such as the names, home addresses and medical record numbers. Similarly, the legal records also contain data that relates to identified individuals. Most persons whose documents I will be studying have passed away, but some of them might still be alive.

As stated in my PRET application, I will take all the necessary administrative steps to protect the privacy of the persons involved in this research. I will, for instance, not write down patient identifiers in my notes. I will record the patient identifiers in a separate Excel spreadsheet, along with a code that I will also use in my notes. In my publications and presentations, I will use fictive names when describing individual cases.

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

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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

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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

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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).

In my notes (.docx), I provide a section in the beginning where I explain the structural components of the historical sources, about things I pay particular attention to and questions I have during the research. This section will be further completed during the duration of the research project.

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.

- No

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

Where will the data be stored?

I will follow current KU Leuven guidelines on the secure management of research data. Throughout the project, I will store data on a KU Leuven-issued PC protected by Bitlocker and on KU Leuven OneDrive for Business, with multifactor authentication enabled.

How will the data be backed up?

The use of KU Leuven OneDrive for Business ensures that the data is adequately secured and backed up regularly.

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

As outlined in the answer to the first question, less than a 100 MB is required, which should not pose any problem whatsoever.

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

I will store data on a KU Leuven-issued PC protected by Bitlocker and on KU Leuven OneDrive for Business, with multifactor authentication enabled. In this way, unauthorized persons will have no access to the data.

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

I do not expect to have costs for data storage.

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...).

All of the data described in this DMP will be stored for at least 10 years in accordance with KU Leuven RDM policy. Those data that are not subject to legal or ethical restrictions will will be preserved for at least 10 years.

There are 2 exceptions. It is possible that the preservation of my notes and/or scans and pictures of the archival records in the selected archival institutions in Paris and Amsterdam (de Archives de l'Assistance Publique – Hôpitaux de Paris, het Stadsarchief Amsterdam, het Academisch Medisch Centrum) is subject to particular legal/ethical restrictions regarding the preservation of personal data after completion of the research project. Restrictions might apply because these archival records contain sensitive information about the surgery that patients have undergone in the period 1890-1969.
The second exception are digital datasets (digitized medical publications) that are the preserved by the Koninklijke Bibliotheek in Den Haag. I am allowed to use their datasets on condition that I remove the datasets from my computer within 30 days following the end date of my project. I will comply to their instructions.

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

In order to ensure safe storage of my research data, they will be archived in central storage facilities with automated backup of my research unit. Given that my data are personal, they will be stored with extra security.

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

The expected costs for data preservation will be less than 100 EUR per year. These costs will be covered by the research group Cultural History since 1750.

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.

- No (closed access)

The only data I create during the project concern notes about medical publications and archival records. The notes are personal and provide answers to my research questions. If, however, another researcher is interested in my notes relating to medical publications, I will be happy to share these. However, I will not provide access to notes relating to the archival records, because they contain sensitive information about patients' health.

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

Prof. Dr. Kaat Wils, the supervisor of my proposed project, will have access to all project backups and data during and after the research.

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

Given the personal and sensitive nature of my archival documents, I will record the data in such a way that the patient identifiers are protected. Regarding medical records, I will record personal data, such as patient name, medical record number and date of surgery, in a separate Excel spreadsheet, along with a code that I will use in my notes. That code consists of a number (e.g. "Patient 1 Paris", "Patient 98 Amsterdam") My notes will be kept in a separate electronic document (a Word document). In my notes, I will note details about the gynaecological operations performed under the code used. These notes will not contain patient identification details. As for legal records, I will adopt a similar approach. I will note the patient's name, date of surgery and date of legal trial in a separate Excel spreadsheet, along with a code. In my notes in a separate electronic document, I will note details about the operations and the legal condlict, but no identifying information.
In my publications and presentations, I will never mention patients' personal data. I will always refer to "a patient" or use a fictitious name

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

I will not make the data available.

When will the data be made available?

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

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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

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

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6. Responsibilities

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

Me.

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

Me.

Who will manage data preservation and sharing?

Me.

Who will update and implement this DMP?

Me.