Plan Overview

A Data Management Plan created using DMPonline

Title: Data and the 'Healthcare Revolution' (DARE)

Creator: Catherine Montgomery

Principal Investigator: Catherine Montgomery

Affiliation: University of Edinburgh

Funder: UK Research and Innovation (UKRI)

Template: UKRI Future Leaders Fellowships Template for a Data Management Plan

ORCID iD: 0000-0002-5829-6137

Project abstract:
Data is changing healthcare. But how and to what effect? DARE is the first study to comprehensively address these questions through comparison across multiple data technologies, fields of medicine, and contexts of use. The research will provide a novel comparative and context-specific framework for understanding how informatics and medicine are re-shaping each other and how data-driven healthcare is changing conceptions of health, illness and personhood. In doing so, it will make a major sociological contribution to our understanding of healthcare in the era of digital transformation. Four ethnographic work packages will trace developments in the use of biomedical AI, clinical trials and registries to inform care: (1) 'Home' will investigate the changing relations between data and care that take place when wearables are designed for real-time data capture in home-based clinical trials; (2) 'Hospital' will analyse the shifting boundaries between research and care in the intensive care unit; (3) 'Nation' will examine how citizenship is being re-forged through health data nationalism in the field of dementia and (4) 'Policy' will interrogate the values and assumptions produced in government blueprints for the digital transformation of health systems. Through these work packages, we will investigate and compare the kinds of *work* taking place at the data/care nexus; the forms of *care* that this work enacts; and the style of *learning* that healthcare professionals, data scientists, patients, caregivers and policy-makers are engaged in. A transecting work stream, 'Synergy', is dedicated to producing a synoptic and theoretically-rich understanding of data, care and learning in relation to health. Together, these empirical and theoretical ventures will deliver a body of work which re-defines our understanding of the data-driven 'revolution' in health and provides new theoretical repertoires with which to conceptualise healthcare in the twenty-first century.

ID: 130939

Start date: 01-09-2023

End date: 31-08-2028

Last modified: 26-07-2023

Grant number / URL: EP/Y027620/1 (awaiting award letter)

Created using DMPonline. Last modified 26 July 2023

2 of 7

Data and the 'Healthcare Revolution' (DARE)

0. Proposal name

0. Enter the proposal name

Data and the 'Healthcare Revolution' (DARE)

1. Description of the data

1.1 Type of study

Multi-scale team ethnography using qualitative methods: participant observation, interviews, document analysis

1.2 Types of data

Qualitative data:
Ethnographic field notes
Images from ethnographic fieldwork
Interview recordings and transcripts
Documents

1.3 Format and scale of the data

- Documents (Word, rtf, pdf)
- Field notebooks/diaries/observations (paper and/or Word)
- Transcripts (word/rtf)
- Excel files (xls)
- encrypted audio-recordings (.ds2)
- photographs (jpeg)
- Collections of leaflets, flyers, paperwork

The size of the data will be negligible for storage purposes.

2. Data collection / generation

2.1 Methodologies for data collection / generation

The main methods, and the standard in ethnography, are participant-observation (hand written and typed notes), interviews, and document collection in ongoing conversation with, and observation of, the research participants during naturally occurring behaviour.
The project will be driven by state of the art approaches to team ethnography, in which the PI is highly experienced. Data collection will follow relevant guidelines produced by the British Sociological Association.
Encrypted interview audio files will be saved to a password protected folder on the network drive at the University of Edinburgh. They will then be securely uploaded to 1st Class Secretarial's web portal for transcription. Once the transcript has been

received from 1st Class Secretarial, the interviewer will remove identifying details (names, places etc) and save the document to a folder for Final Transcripts. The raw transcript and the audio file will be securely deleted.

2.2 Data quality and standards

Communication between researchers is key to successful team ethnography and sharing practice and findings within the project group will be actively facilitated through fortnightly meetings, workshops, reading retreats and collaborative writing, built around the concept of collaborative reflexive work. To ensure data quality, the team will regularly review and discuss field notes produced by each team member. The PI will review interview transcripts to ensure consistency and quality of data generation. Metadata will be produced and checked on an ongoing basis.

Interviews will be digitally recorded and transcribed by a professional transcription service, 1st Class Secretarial. Once the transcript has been returned to the interviewer, they will QC the document and attempt to resolve any queries raised by the transcriber.

3. Data management, documentation and curation

3.1 Managing, storing and curating data

Data will be organised in clearly labelled folders, with all files following a project-standardised naming convention. Raw and processed data will be clearly differentiated. Data will be stored on the University of Edinburgh DataStore, which provides enterprise-class storage with guaranteed backup and resilience. Data is retained on DataStore until deletion by the data owner. The backups provide resilience in the case of accidental deletion and against incidents affecting the main DataStore storage. The data are automatically replicated to an off-site disaster recovery facility, with 10 days of file history visible online. Off-site tape backups keep 60 days of history of the filesystem. The 60 day rolling snapshots allow important data to be recovered to a prior state, by request if beyond the visible period. Sensitive data stored on DataStore will be further protected by the use of 256 bit encryption as required by University policy.

3.2 Metadata standards and data documentation

The project will implement a naming and version convention and this will be consistently applied. Interview transcripts will be accompanied by the following metadata: study title and abstract, keywords, data creators, funder, method used to generate the data, data type (text), publisher (e.g. UoE, STIS), grant ID. Researchers will draft a README.txt file describing the research data files: file names; what they contain; how they are related; how they were created (e.g. data collection, analysis software, file format); how they should be used.

3.3 Data preservation strategy and standards

Interview data in the form of pseudonymised transcripts will be deposited in the UK Data Service for long-term preservation and re-use. Ethnographic data in the form of electronic pseudonyumised field notes and images will be deposited in the University of Edinburgh's DataVault for long-term preservation. Metadata will be stored alongside the data, along with as much contextual data as possible. All data will be preserved for a minimum of 10 years from the end of the project.

4. Data security and confidentiality of potentially disclosive information

4.1 Formal information/data security standards

All digital data will be stored in encrypted folders on the University of Edinburgh's secure server (DataStore) and will be password-protected. Personal data will be stored separately from research data.

Laptops/devices will be encrypted and/or password protected and kept behind lock and key when not in use. Paper notebooks (field notes) will be stored behind lock and key when not in use.

All team members will receive relevant training in data security standards and project-specific processes.

4.2 Main risks to data security

There are two main risks to data security:

1. Data falling into the wrong hands: The main risk to the confidentiality and security of information related to human participants occurs when the researcher is in the field. During this period, fieldnotes are made either with pen and paper in a notebook, or electronically on a tablet/laptop device. The latter will be encrypted and password-protected to manage the risk of unauthorised access to the data. Notebooks will be kept with the researcher at all times and secured behind lock and key when not in use.

2. Accidental loss/deletion: Beyond the risk of data falling into the wrong hands, data loss also has potential implications for the integrity of the research. However, since ethnographic research is not based on the logic of data completeness (all data provides a partial piece of the story and we never have all the pieces), minor data loss - while undesirable - does not jeopardise the success of the overall study.

A Data Protection Impact Assessment (DPIA) will be produced to identify and minimise the data protection risks of the project and ensure all workflows are data security compliant.

5. Data sharing and access

5.1 Suitability for sharing

Psuedonymised interview data will be suitable for sharing once all identifying information has been redacted. This will be done prior to transcripts being deposited with the UK Data Service, along with metadata and relevant contextual information.

Ethnographic data in the form of field notes will not be made available for re-use on the following basis:

1. Anonymity: being deeply intertwined in community and people's lives, these data have enough details to identify others, even with changed names or places.

2. Interpretability: ethnographic data are not typically stored in excel spreadsheets or databases, but in lengthy written texts that span multiple hand-written notebooks and/or digital files (e.g. word docs, photos, audio-recordings). These data require contextualization to be intelligible to other researchers because: a) they reflect a human relationship between researcher and research participants that shapes the context in which the data were generated; b) each notebook/text cannot be easily understood without triangulation across multiple notebooks/devices/personal archives, which cannot all be made available due to the risk of compromising anonymity, and c) without deep knowledge of the research context, of the broader social situation/conversation/physical location in which the notes were made, and of the specific research participants, the data cannot be accurately interpreted.

3. Researcher privacy: Fieldnotes often contain three kinds of information in the same place: observation of research participants/interview notes, the researcher's analytical thoughts, and the researcher's personal experiences and feelings. In ethnographic research, the researcher's thought process, reflections and position are deemed relevant information in order to accurately contextualize and interpret research materials. As such, this information is often written down or typed together with observational field notes and only some of this highly personal and private information is acceptable for wider/public sharing.

We are informed in the above by the Department Cultural Anthropology Development Sociology (CADS) at Leiden University's Data Management Policy (April 2019).

5.2 Discovery by potential users of the research/innovation data

Pseudonymised interview transcripts will be deposited in with the UK Data Service for preservation and re-use. A permanent dataset identifier DOI will be published on the study website, the PI's PURE profile, and in all publications

arising from the project in order to enable discoverability. Interview transcripts will be accompanied by metadata allowing potential new users to identify whether the data are suitable for their research purposes. The UK Data Service will apply a suitable end user license to enable re-use.

Our approach to data sharing will be published on the DARE study website.

5.3 Governance of access

Pseudonymised interview data will be deposited with the UK Data Service ReShare repository as safeguarded data. The PI will grant a non-exclusive, royalty-free licence to UKDS to hold, make copies of, and disseminate copies of the data, in accordance with specified access conditions.

5.4 The study team's exclusive use of the data

The study team will have exclusive use of the data until such time as the intended outputs from the research have been published. As per the grant proposal, these are 4 books and 10 open-access peer-reviewed journal articles.

5.5 Restrictions or delays to sharing, with planned actions to limit such restrictions

Written informed consent for data sharing will be sought from participants taking part in an interview. Access to the data held in the UK Data Service ReShare repository will be restricted to research and learning purposes only, in line with this repository's criteria for safeguarded data.

5.6 Regulation of responsibilities of users

External users will be bound by use terms and conditions for safeguarded data stipulated by the UK Data Service. We will make use of UKDS's processes to regulate the re-use of the data for security reasons.

6. Responsibilities

6. Responsibilities

The primary responsibility for study-wide data management lies with the PI. In addition, each work package lead will be responsible for managing the data generated, creating metadata, quality assurance and data security within their own work package. All members of the project team will receive training from the University of Edinburgh in data protection, information security and working with sensitive data.

7. Relevant policies

7. Relevant institutional, departmental or study policies on data sharing and data security

Policy	URL or Reference
Data Management Policy & Procedures	https://www.ed.ac.uk/information-services/about/policies-and-regulations/research-data-policy
Data Security Policy	https://www.ed.ac.uk/information-services/about/policies-and-regulations/security-policies
Freedom of Information	https://www.ed.ac.uk/records-management/guidance/requests
Data Protection	https://www.ed.ac.uk/data-protection/data-protection-policy
Research Integrity	https://www.edweb.ed.ac.uk/research-office/research-integrity

8. Author and contact details

8. Author of this Data Management Plan (Name) and, if different to that of the Principal Investigator, their telephone & email contact details

Dr Catherine Montgomery