Plan Overview

A Data Management Plan created using DMPonline

Title: HEARER study- HomE-testing in Asthma foR hEalthcare pRofessionals

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Template: University of Manchester Generic Template

Project abstract:

Asthma is common but the misdiagnosis is substantial. It is a disease characterised by variability over time. However the current diagnostic strategy rely on one-off clinic-based testing, regardless if patients are experiencing their typical symptoms. Furthermore, limited access to lung functions and other key tests may also form barriers for accurate asthma diagnosis in the community. Longitudinal testing using home diagnostics may help to improve asthma diagnosis by capturing asthma variability. However, its feasibility, potential benefit and barriers for primary care healthcare professionals to use this diagnostic strategy is unclear. We aim to explore the views of primary care HCPs on asthma home diagnostic strategy through a focused group and a national survey. The findings will inform the design and delivery of the future study in investigating the utility of home-diagnostics in asthma.

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Manchester Data Management Outline

1. Will this project be reviewed by any of the following bodies (please select all that apply)?

- Ethics
- Funder

2. Is The University of Manchester collaborating with other institutions on this project?

- Yes - Part of a collaboration and owning or handling data

Collaborating with Wythenshawe Hospital staff employed by respiratory research department

3. What data will you use in this project (please select all that apply)?

- Acquire new data

4. Where will the data be stored and backed-up during the project lifetime?

- University of Manchester Research Data Storage Service (Isilon)

University of Manchester research data storage service Isilon

5. If you will be using Research Data Storage, how much storage will you require?

- < 1 TB

6. Are you going to be receiving data from, or sharing data with an external third party?

- No

7. How long do you intend to keep your data for after the end of your project (in years)?

- 5 - 10 years

Guidance for questions 8 to 13

Highly restricted information defined in the Information security classification, ownership and secure information handling SOP is information that requires enhanced security as unauthorised disclosure could cause significant harm to individuals or to the University and its ambitions in respect of its purpose, vision and values. This could be: information that is subject to export controls; valuable intellectual property; security sensitive material or research in

key industrial fields at particular risk of being targeted by foreign states. See more examples of highly restricted information.

If you are using 'Very Sensitive' information as defined by the Information Security Classification, Ownerships and Secure Information Handling SOP, please consult the Information Governance Office for guidance.

Personal information, also known as personal data, relates to identifiable living individuals. Personal data is classed as special category personal data if it includes any of the following types of information about an identifiable living individual: racial or ethnic origin; political opinions; religious or similar philosophical beliefs; trade union membership; genetic data; biometric data; health data; sexual life; sexual orientation.

Please note that in line with data protection law (the UK General Data Protection Regulation and Data Protection Act 2018), personal information should only be stored in an identifiable form for as long as is necessary for the project; it should be pseudonymised (partially de-identified) and/or anonymised (completely de—identified) as soon as practically possible. You must obtain the appropriate ethical approval in order to use identifiable personal data.

8. What type of information will you be processing (please select all that apply)?

- Personal information, including signed consent forms
- Audio and/or video recordings

9. How do you plan to store, protect and ensure confidentiality of any highly restricted data or personal data (please select all that apply)?

- Store data in encrypted files, folders, computers or devices
- Where needed, follow University of Manchester guidelines for disposing of personal data
- Anonymise data

10. If you are storing personal information (including contact details) will you need to keep it beyond the end of the project?

- Yes – Other

It will be stored for 5 years and then destroyed.

11. Will the participants' information (personal and/or sensitive) be shared with or accessed by anyone outside of the University of Manchester?

- No

12. If you will be sharing personal information outside of the University of Manchester will the individual or organisation you are sharing with be outside the EEA?

- Not applicable

13. Are you planning to use the personal information for future purposes such as research?

- No

14. Will this project use innovative technologies to collect or process data?

- No

15. Who will act as the data custodian for this study, and so be responsible for the information involved?

Professor Clare Murray

16. Please provide the date on which this plan was last reviewed (dd/mm/yyyy).

2023-08-01

Project details

What is the purpose of your research project?

As majority of asthma diagnosis is made within primary care, we aimed to identify the views of Healthcare Professionals (HCP) in the community on the potential benefits, barriers and facilitators of providing such devices in the community for asthma diagnosis. This will be achieved by carrying out a focus group with a range of primary care practitioners. The discussions will be transcribed and analysed using framework analysis.
We hope the insight gained from this activity will help us design a national survey on the topic, and will help the design of future research studies to improve asthma diagnosis in the community.

What policies and guidelines on data management, data sharing, and data security are relevant to your research project?

NIHR are funding the project. They have guidelines which we will be adhering to which can be found here:
https://openresearch.nihr.ac.uk/for-authors/data-guidelines

The University of Manchester policies that apply to this project include:

- The University of Manchester Research Data Management Policy
  http://documents.manchester.ac.uk/DocuInfo.aspx?DocID=33802%20
- The University of Manchester Records Management Policy
  http://documents.manchester.ac.uk/display.aspx?DocID=14916
- The University of Manchester Publications Policy
  http://documents.manchester.ac.uk/display.aspx?DocID=28526
- The University of Manchester IT policies and guidelines
  http://www.itservices.manchester.ac.uk/aboutus/policy/
- The University of Manchester Intellectual Property Policy http://documents.manchester.ac.uk/display.aspx?DocID=24420
- The University of Manchester Data Protection Policy
  http://documents.manchester.ac.uk/display.aspx?DocID=14914.

Responsibilities and Resources

Who will be responsible for data management?

Dr Katie Lawton- Responsible for designing the data plan, collecting the data, anonymising the data
Dr Ran Wang- Responsible for storage of the audio recording device, repsonsible for the longer-term storage of the data using the Ipsilon system
Binish Khatoon- Research associate- Responsible for transferring the data from the audio recording device to the university laptop and deletion of the data from the audio recording device.
Professor Clare Murray- Overall supervisor role for data management

What resources will you require to deliver your plan?

Audio recording equipment, university- accredited transcription service- Lawson Hardwick t/a 1st Class Secreterial Services

Data Collection

What data will you collect or create?

Qualitative data on what the primary care staff feel are the advantages, disadvantages, barriers and enablers for home-testing in asthma. This will be stored as an audio file on a dictaphone which will be transferred immediately onto a password-protected university of manchester laptop and then removed from the dictaphone. The data will then be transferred from the university laptop to the university of Manchester research storage system Isilon. We estimate there will be two focus groups of 6-8 people, and 3-4 hours will be the culmulative duration of the interview recordings (estimated at 1.5-2 hours per focus group). These will be FLAC files.

The audiofiles will then be transcribed using the university of manchester's approved transcription service, and these transcribed files will be stored on the Isilon system. These will be MS Word files.

Personal data- i.e. Name, email address and job role will be stored on an excel spreadsheet on the password-protected university of manchester laptop and then transferred onto the Isilon system. These will be MS Excel files.

How will the data be collected or created?

We are collecting and storing personal identifiable information in accordance with UK data protection law which protects a participant's rights. The legal basis for collecting this data is that it is "a public interest task" and "a process necessary for research purposes".
Specifically we will need to collect:

- Name
- Job role,
- Contact details
- Record of consent.

We will be using a nominal technique to collect our data, whereby the individuals come up with their own ideas for the four themes (advantages, disadvantages, barriers and enablers) and then work together to discuss which the most important ideas are. We will be using this technique in both focus groups and also aim to do a pilot run in order to standardise the data collection as much as possible. The plan for this is included in our ethics submission.
The focus groups will be audio-recorded. Prior to the audio recording we will check recording equipment and sound environment to ensure the quality of the focus group recordings. The data will be anonymised on transcription. Therefore, any direct quotes used in the final report will be anonymous. A university approved transcription service will be utilised. When the data returns to us from the transcription service we will use tracked changes to log any changes made to the transcriptions, and a copy of these tracked changes will be stored.
Audio recordings will be stored for a maximum of five years and then destroyed. The research laptop will be password protected and research data will be stored on the Isilon service.
Every time a file is updated a new version number will be created that includes the individuals initials and version number.
All personal data will be confidential and will be kept separately from the interview transcriptions.
Confidentiality will only be broken if we have concerns that the participant or anyone else is at significant risk of harm. If possible we will tell the participant that we are having to break confidentiality. For example, if any information is disclosed about misconduct, we would have a professional obligation to report this to a relevant professional body.
Participants will be able to request a copy of the information we hold about them, including audio recordings.
We aim to report the data collected back to the participants prior to any publication, to allow them to give any feedback and also to ensure continued consent.
At the end of the project we will deposit a fully anonymised dataset in an open data repository such as figshare where it will be permanently stored. Researchers at other institutions and others can access the anonymised data directly from the repository and use it for further research or to check our analysis and results.

Documentation and Metadata

What documentation and metadata will accompany the data?

The title, the date created and the people who created the date will accompany the data- both the original audio data and the transcripted anonymised data. We will also include a README file i.e. a basic text file which gives more detailed information about the data that can be read alongside your dataset, for example interview schedules, a log of any changes made to transcriptions/notes, abbreviations used and methodology and research context.

Ethics and Legal Compliance

How will you manage any ethical issues?

Participant Information sheets (PIS) will be distributed to all eligible and interested HCPs. With their consent they will be contacted a week after they received the PIS to ascertain agreement to participate and answer any questions. Written or verbal consent will be taken before the nominal group meeting starts in a private room. This consent will ensure that the anonymised data collected can be shared and re-used.

Data will be anonymised upon transcription.

Participants will be informed that they are free to withdraw at any time without giving a reason and without detriment to themselves, including during the recording process. However, it will not be possible to remove a participant's data from the project once it has been anonymised as we will not be able to identify a specific individual's data. This will not affect a participant's data protection rights.

Confidentiality will only be broken if we have concerns that the participant or anyone else is at significant risk of harm. If possible we will tell the participant that we are having to break confidentiality. For example, if any information is disclosed about misconduct, we would have a professional obligation to report this to a relevant professional body.

Participants will be able to request a copy of the information we hold about them, including audio recordings.

The transferring of data from dictaphone to a password-protected university of manchester laptop will occur directly after the focus groups, and the audio recordings will then be deleted from the dictaphone. The sensitive data (personal data) will only be kept on the password-protected university of Manchester laptop until the point of transferring for the 5 year storage period.

How will you manage copyright and Intellectual Property Rights (IPR) issues?

At the end of the project we will deposit a fully anonymised dataset in an open data repository where it will be permanently stored. Researchers at other institutions and others can access the anonymised data directly from the repository and use it for further research or to check our analysis and results.

NIHR has the following stance:

NIHR has a responsibility to ensure that the NIHR, NHS and broader public sector have the best chance of realising benefits and achieving impact.

We use standard contracts developed with the Department of Health and Social Care to ensure that the IP generated from NIHR funding is secured within an appropriate legal, contractual environment to facilitate benefit realisation for patients.

The contracts outline a clear position on ownership and management of IP created using NIHR funding. They ensure, as far as is reasonably possible, that the IP on which a researcher wishes to base their NIHR-funded research is able to be used in research and delivery of improved health and care.

Storage and backup

How will the data be stored and backed up?

The data will be stored with the university of manchester *Research Data Storage Service for the five years following the study.*

How will you manage access and security?

The name and job role are not confidential data as they are in the public domain. However the contact details are confidential. We will use the university's Research Data Storage service to help us manage the risk to data security, which only the four researchers will be granted access to via a password. If data needs to be stored during creation out in the field, this will be stored on a password-protected university of Manchester laptop which will be transferred onto the RDM as soon as possible and then deleted off the mobile device.

The personal data will be stored directly onto the RDM .

Selection and Preservation

Which data should be retained, shared, and/or preserved?

We hope to publish the data, which will be in an anonymised format. At the end of the project we will deposit a fully anonymised dataset in an open data repository where it will be permanently stored, such as Figshare. Researchers at other institutions and others can access the anonymised data directly from the repository and use it for further research or to check our analysis and results. We will also share materials such as the thematic analysis codes in this same repository.

What is the long-term preservation plan for the dataset?

At the end of the project we will deposit a fully anonymised dataset in an open data repository where it will be permanently stored. Researchers at other institutions and others can access the anonymised data directly from the repository and use it for further research or to check our analysis and results.

Data Sharing

How will you share the data?

At the end of the project we will deposit a fully anonymised dataset in an open data repository where it will be permanently stored. This will be via figshare. Researchers at other institutions and others can access the anonymised data directly from the repository and use it for further research or to check our analysis and results.

Are any restrictions on data sharing required?

Participants will be informed that they are free to withdraw at any time without giving a reason and without detriment to themselves, including during the recording process.

The consent form will explicitly detail what data will be shared and how this will be made available, i.e. the anonymised transcripts will be shared via an open data respository accessible to the public.

However, it will not be possible to remove a participant’s data from the project once it has been anonymised as we will not be able to identify a specific individual’s data. This will be explained to participants at the time of consent.

Data will be anonymised at the point of transcription. Therefore the only confidential data will be the participant contact details which will only be accessible by the four members of the research team.