improving global
R E S P I R E
respiratory health

RESPIRE Data Management Plan (DMP): Template (adapted from the University of Edinburgh)

Name:	Hani Salim
Project Title:	Developing and piloting an ICT-based intervention for adult asthma with limited health literacy to improve asthma self-management
Institute:	Usher Institute, University of Edinburgh
Start Date:	1 April 2018
End Date:	31 March 2021
DMP version number and date:	V.1 28 August 2020

Responsibilities & Resources (applicable across the sections below)

Who will be involved in the data management of this research?

The research team will have direct involvement with the management of the data. They are:

1. Dr Hani Syahida Salim – PhD student
2. Professor Hilary Pinnock – Main Supervisor (Edinburgh)
3. Dr Ingrid Young – Second Supervisor (Edinburgh)
4. Professor Lee Ping Yein – Site Supervisor (Malaysia)
5. Professor Dr Sazlina Shariff Ghazali - Site Supervisor (Malaysia)

My project will be in three phases:
Phase 1 – Systematic review
Phase 2 – Arts-based qualitative study
Phase 3 – Developing, refining and feasibility of an ICT prototype

As the student, I'm involved with data collection, storing and the management of the data. All the data are securely saved within the University of Edinburgh's network, DataStore.

I have received training for Research Data Management Course by IAD and training for RESPIRE students through RESPIRE's Platform III initiatives.

We will only keep unidentifiable data. Access to collated unidentifiable participant data will be restricted to individuals from the research team treating the participants, representatives of the sponsor(s) and representatives of regulatory authorities.

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1. Data Capture

What data will be generated or reused in this research?

Phase 1: Systematic review

Data are in the format of:

- endnotes software (included and excluded papers)
- excel files (data extraction of the)
- word document (data summary and reporting)

For quality assurance, data selection, extraction and analysis were made by two independent reviewers and final decisions we made through consensus or discussion with the supervisory team.

Phase 2: Arts-based qualitative study

The collected data format is as below:

- Audio – interviews of participants
- Photographs – photos which had been shared by patients to narrate the story of their lives
- Nvivo software – data management software which stored analysed transcripts which contained non-identifiable text but potentially identifiable photographs.
- Word document – transcripts and translated transcripts, data summary and report

For quality assurance, data transcribing was rechecked, data translation was done in a back-to-back manner to preserve the semantics of the original language, and data analysis was done in continuous discussion with the supervisory team.

Phase 3: Developing and refining an asthma self-management mobile application

We have completed development and refining phase. We have both quantitative and qualitative. Quantitative data were in the form of participants' demographic and usability & utility data. Qualitative data were in the form of encrypted audio-recorded interviews. These audio data are currently being transcribed and will be exposed securely once the transcripts have been checked.

How much data will be generated?

250 – 500 GB

2. Data Management

How will the data be documented to ensure it can be understood?

Each phase is based on protocols being developed at the start of each phase. I have indexed each phase in a codebook which contained all the details on fieldwork (including notes on deviation from protocol and reasons behind this) and discussion on why individual decisions are made. This documentation is hoped that use of the data in the future can be done effectively and accurately.

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Scientific publications of the data from this project will give more information about each phase.

Where will the data be stored and backed-up?

The data will be stored on the University of Edinburgh's filestore. The storage ensures high-quality storage with guaranteed back-up (automatic data replicate to an off-site disaster facility). If I am outside the university network (doing data collection in Malaysia), I will have access to this facility through VPN network.

The information we have collected in paper copies will be stored under lock and key in Universiti Putra Malaysia.

3. Integrity

How will you quality assure your data?

Phase 1: Systematic review

For quality assurance, data selection, extraction and analysis were made by two independent reviewers and final decisions we made through consensus or discussion with the supervisory team.

The protocol for this systematic review was peer-reviewed and have been published. See; https://www.nature.com/articles/s41533-019-0125-y .The result of this systematic review is currently peer-reviewed.

Phase 2: Arts-based qualitative study

For quality assurance, data transcribing of audio files was rechecked to ensure accuracy. Data translation was done in a back-to-back manner to preserve the semantics of the original language. Data analysis was done in continuous discussion with the supervisory team. We discussed with the participants about captions accompanying their photos. This exercise is to ensure the true meaning of the photographs is captured through the texts. Data immersion through re-reading of transcripts was done to understand the context of the data fully.

Phase 3: Developing, refining and feasibility of an ICT prototype
We have completed development and refining phase. We have both quantitative and qualitative data. Quantitative data were in the form of participants' demographic and usability & utility data. Qualitative data were in the form of encrypted audio-recorded interviews. These audio data are currently being transcribed and will be exposed securely once the transcripts have been checked.

Similarly, as above, transcribed audio files were rechecked for accuracy and discussion between the wider research team ensure the accuracy and meaning of data and analysis.

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4. Confidentiality

How will you manage any ethical and Intellectual Property Rights issues?

I have received ethical approval from Malaysian Medical Research Ethical Committee of the Ministry of Health Malaysia and sponsorship from the Academic and Clinical Central Office for Research & Development (ACCORD) for the University of Edinburgh's Research for all my PhD project. Amendments were made for phase three, where I revised the method of data collection from one-on-one meeting to online meeting, and both Malaysian REC and ACCORD approved this.

In phase 3, I am currently developing a mobile application through an external contractor based in Malaysia. Intellectual property agreement and non-disclosure agreement was a sign between the sponsor and the external contractor. The IP will be shared between the University of Edinburgh and Universiti Putra Malaysia.

All laboratory specimens, evaluation forms, reports, and other records must be identified in a manner designed to maintain participant confidentiality. Clinical information will not be released without the written permission of the participant. The Investigator and study site staff involved with this study may not disclose or use for any purpose other than the performance of the study, any data, record, or other unpublished, confidential information disclosed to those individuals for the study. Prior written agreement from the sponsor or its designee must be obtained for the disclosure of any said confidential information to other parties.

At this point, the Malaysian REC did not approve of any identifiable data sharing of my project on the public domain.

5. Retention and Preservation

Which data do you plan to keep and for how long?

We planned for the product of the final de-identified quantitative data to be available for use by the research and policy community for phase 1 and 3. For qualitative data in phase 2 and 3, we planned to share the overarching themes of the final data in the text version. All audio-files will be destroyed once data analysis is complete.

How will the data be preserved?

For long-term preservation, we planned to deposit de-identified non-sensitive data within the University of Edinburgh (hosted by the Data Library in Information Services), DataShare. As agreed by the Malaysian REC, all data will be disposed of securely at five years, and I do not plan to deposit any data on DataVault.

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6. Sharing and Publication

Which data will be shared and how?

This study is part of a PhD programme of work and will be reported in a publicly available thesis. I have submitted the findings of this study to conferences for presentations and a high impact peer-reviewed journal (listed below) for people who have access to the relevant sites. Other methods of dissemination will include innovative dissemination channels of RESPIRE (websites and Twitter) to raise awareness of our publications.

We will share de-identified quantitative and qualitative data in Edinburgh's DataShare.

Oral:

1. PHASE 1: RESPIRE Annual Scientific Meeting, Porto (May 2018): **Do interventions that address health literacy needs to improve self-management among people with asthma? A systematic review protocol.**

2. Phase 1: 6th IPCRG Scientific Meeting, Romania (May 2019): **Do interventions that address health literacy needs improve self-management among people with asthma? A systematic review.**

3. PHASE 2: RESPIRE Annual Scientific Meeting, KL (September 2019): **The psychosocial influence on asthma self-management and health outcomes among people with limited health literacy in Malaysia: A preliminary analysis of an art-based qualitative study.**

4. PHASE 2: ERS Virtual International Congress (2020): **Negotiating identity: impact on self-management practices in people with asthma and limited health literacy in Malaysia**

Poster:

1. OVERALL PROTOCOL: RESPIRE Annual Scientific Meeting, Porto (May 2018): **Developing and piloting an ICT-based intervention for adult asthma with limited health literacy to improve asthma self-management.**

2. PHASE 2: Global Health Symposium, Edinburgh (August 2018): **Addressing linguistic needs in a multilingual population to improve patient's recruitment and understanding of involvement in asthma research**

3. Phase 1: ERS International Congress (September 2019): **Do interventions that address health literacy needs improve self-management among people with asthma? A systematic review.** https://erj.ersjournals.com/content/54/suppl_63/PA3990

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4. Phase 2: Health literacy UK Conference (Newcastle, 2020): **Health system: How people with asthma and limited health literacy navigate the health system.**

   https://sapc.ac.uk/file/2020-sapc-sig-health-literacy-uk-conference-abstracts-v2-pdf

Publication:

Phase 1: Salim, H., Young, I., Shariff Ghazali, S. *et al.* Protocol for a systematic review of interventions addressing health literacy to improve asthma self-management. *npj Prim. Care Respir. Med.* **29,** 18 (2019). https://doi.org/10.1038/s41533-019-0125-y

Phase 1: Salim H, Ramdzan SN, Ghazali SS, Lee PY, Young I, McClatchey K, Pinnock H; NIHR Global Health Research Unit on Respiratory Health (RESPIRE) collaborations. A systematic review of interventions addressing limited health literacy to improve asthma self-management. J Glob Health. 2020 Jun;10(1):010427. http://www.jogh.org/documents/issue202001/jogh-10-010428.pdf

Are any restrictions on data sharing required?

We will share the data in DataShare with an embargo period until publication or thesis writing has been completed.