



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

Name:	Prof. Dr. Lee Ping Yein
Project Title:	Klang Asthma Cohort: Developing and evaluating interventions at patient and practice level to improve asthma care- "HEAL ASTHMA UPM"
Institute:	UNIVERSITI PUTRA MALAYSIA
Start Date:	01 AUGUST 2017
End Date:	31 MARCH 2021
DMP version number and date:	1.0 (3 December 2020)
<p><u>Responsibilities & Resources (applicable across the sections below)</u></p> <p><i>Who will be involved in the data management of this research?</i></p> <p>Principal Investigator: Professor Dr. Lee Ping Yein Co-Investigator: Professor Dr. Sazlina Shariff Ghazali Co-Investigator: Associate Professor Dr. Cheong Ai Theng Research Assistant: Roshan Nur Anand, Jasmine Wong Enumerator: Kathiaini Alegesan, Amin Rasihidi</p> <p>The SPSS Software The NVIVO12 SOFTWARE Microsoft Word Microsoft Excel</p>	
<p>1. Data Capture</p> <p><i>What data will be generated or reused in this research?</i></p> <p>1. Phase 1a (Qualitative Study) Data. The purpose of this study is to explore healthcare professionals' views and experiences on delivering asthma self-management and asthma care to patients. This research is necessary to provide information to develop an intervention for improving asthma self-management. A total of 26 participants from various other healthcare facilities in the Klang district participated in this study. The whole study lasted about one year and participation in each session was about 1–2 hours. Data was analysed using the NVIVO12 SOFTWARE.</p>	

Data was also collected and stored in the form of audio recordings of each respective focus group discussion (FGD) which were then transcribed verbatim and stored as a word file.

2. Phase 1b (Quasi-Experimental Pre-Post Study) Data.

The purpose of this study is to discover the effectiveness of a pictorial asthma action plan to improve asthma control in adults with asthma. This research is necessary to provide information in developing an intervention to improve asthma self-management. A total of 70 participants from the Botanik District Health Clinic is participating in this study. The whole study will last about 18 months and the patient's participation will require about 5 sessions over a period of 12 months: the first session is a visit to the Botanik District Health Clinic and the subsequent four encounters will be through telephone calls. (for 1st, 3rd, 6th, 12th months). The quantitative information of the Health Literacy Survey, Follow-Up Questionnaire and KAC baseline data will be inputted into the SPSS Software.

Focus group discussions will also be conducted to explore the acceptability, usability and feasibility of the pictorial asthma action plan from the patients' (20 patients), doctors' and other healthcare professionals (20 health care providers) perspectives. Data will be analysed using the NVIVO12 SOFTWARE. Data will also be collected and stored in the form of audio recordings of each respective focus group discussion (FGD) which will then be transcribed verbatim and stored as a word file.

How much data will be generated?

0-50GB of data.

2. Data Management

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

1. Phase 1a (Qualitative Study) Data.

The data gathered in Phase 1a was transcribed and checked by researchers for accuracy, then entered onto the NVIVO12 Software for qualitative analysis of the data, and subsequently, data was saved in QSR on NVIVO12 Software. The audio recordings were then erased.

2. Phase 1b (Quasi-experimental Pre-Post Study) data.

The quantitative data gathered for Phase 1b was entered into the SPSS Software, saved in .sav on SPSS Software. Contained within this codebook was the Klang Asthma Cohort Baseline Data, the Health Literacy Survey responses, and the Follow-Up Questionnaire responses.

The qualitative data gathered in Phase 1b (focused group discussions) will be transcribed and checked by researchers for accuracy, then entered onto the NVIVO12 Software for qualitative analysis of the data. Data will be saved in QSR on NVIVO12 Software. The audio recordings will then be erased.

Where will the data be stored and backed-up?

The information we have collected in paper copies will be stored under lock and key in Universiti Putra Malaysia, while the electronic data will be anonymised and can only be accessed with a secure password in the laptop for this research encrypted in the 7zip format. Data will be backed-up and encrypted on an external hard disk drive and online on University of Edinburgh's data storage service "DataStore." The external hard disk will be stored in a locked file cabinet in Universiti Putra Malaysia.

1. Phase 1a (Qualitative Study) Data.

Data will be stored in the NVIVO12 Software and paper copies of transcripts will be kept under lock and key at Universiti Putra Malaysia.

2. Phase 1b (Quasi-experimental Pre-Post Study) Data.

Data for Phase 1b is also stored in the form of Excel for reference, and then inputted into the SPSS format. Data is stored on a RESPIRE-HEAL ASTHMA dedicated laptop managed by the Principal Investigator.

KAC baseline data will be accessed by travelling to University of Malaya where the data is stored to extract Heal Asthma relevant data. No data will ever leave its designated university storage.

Data for focus group discussions will be stored in the NVIVO12 Software and paper copies of transcripts will be kept under lock and key at Universiti Putra Malaysia.

3. Integrity

How will you quality assure your data?

1. Phase 1a (Qualitative Study) Data.

Data will be transcribed from audio recordings using as reference the FGD meeting minutes. All transcribed data will then be checked and uploaded to the NVIVO12 Software after being reviewed by the Co-Investigator.

2. Phase 1b (Quasi-experimental Pre-Post Study) Data.

Quantitative data will be taken from the questionnaires (Health Literacy Surveys and Follow-Up Questionnaires) to be uploaded to the SPSS Software. Data will then be checked and cleaned prior to analysis.

Qualitative data will be transcribed from audio recordings using as reference the FGD meeting minutes. All transcribed data will then checked and uploaded to the NVIVO12 Software after being reviewed by the Co-Investigator.

4. Confidentiality

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

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 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 has been obtained for the disclosure of any said confidential information to other parties.

5. Retention and Preservation

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

All data will be stored for 5 years.

How will the data be preserved?

All investigators and study site staff involved with this study must comply with the requirements of the appropriate data protection legislation (including the General Data Protection Regulation and Data Protection Act 2018 with regard to the collection, storage, processing, and disclosure of personal information and will uphold the Act's core principles. Access to collated identifiable participant data will be restricted to individuals from the research team treating the participants, representatives of the sponsor(s) and representatives of regulatory authorities. For qualitative studies, once the transcripts have been completed and checked by the researchers for accuracy, the audio recordings will be erased. The information we have collected in paper copies will be stored under lock and key in Universiti Putra Malaysia, while the electronic data will be anonymised and can only be accessed with a secure password in laptops for RESPIRE research and external hard disk drive encrypted in the 7zip format, and online on "DataStore." Only quantitative anonymised data will be published on Edinburgh's open source platform "Edinburgh DataShare" and made accessible and available to all. Qualitative data will not be shared in any open source platform as it is identifiable to the participant. All physical copies of data, the research laptop, and external hard disk drive will be archived in a locked cabinet in Universiti Putra Malaysia. Data saved on "DataStore" will be archived in "DataVault." Published results will not contain any personal data that could allow identification of individual participants.

6. Sharing and Publication

Which data will be shared and how?

Published results will not contain any personal data that could allow identification of individual participants.

Only quantitative anonymised data will be published on Edinburgh's open source platform "DataShare" and made accessible to all. Qualitative data will only be shared among the research team, representatives of the sponsor(s) and representatives of regulatory authorities. Qualitative data is not be shared in any open source platform as it is identifiable to the participant.

The investigators and study site staff involved in this study will not disclose any data, or other unpublished, confidential information other than to analyse performance of the study.

Hard copy data from the study will be archived in a locked cabinet at Universiti Putra Malaysia and may be transmitted outside the country for the purpose of analysis, but the patient's identity will not be revealed at any time.

Individuals involved in this study and in medical care, qualified monitors and auditors, the sponsor or its affiliates and governmental or regulatory authorities may inspect and copy the participants information and study data, where appropriate and necessary.

Are any restrictions on data sharing required?

When publishing or presenting the study results, the participants identity will not be revealed without his/her expressed consent.

Data from the qualitative study will not be shared as it contains sensitive elements (for example, participant quotes may be identifiable to the individual);

1. Both verbal and written consents will be obtained from the eligible participants before conduct of this study.
2. Confidentiality of the participants will be ensured. The participants will be assigned non-identifiable identification codes for data entry and data analysis.
3. All consent forms and questionnaires will be stored in a locked filing cabinet accessible only to the research team for 5 years. After this time, information will be shredded and disposed in secure bins.
4. The participants will be anonymised before publications or report writing.