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OPTIMISE PARTNERSHIP PROJECT:

Data Management Plan

Version Control

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| Name | Affiliation/Role | Version | Date Last reviewed | Summary of changes |
| Katrina Long | Monash University | 1.0 | 10/12/2020 |  |

Document Purpose

To describe the protocol for collection, cleaning, storage, and sharing of qualitative and quantitative data generated through the OPTIMISE project.

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1. Project Governance

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| Name | Affiliation/ Role |
| Start date | 01st February 2016 |
| End date | 31st May 2020 |
| Funding source | NHMRC Partnerships for Better Health Scheme (2015, Round 2) |
| Grant number | 1106372 |
| Investigators | Prof. Grant Russell  Prof. Mark Harris  A/Prof. Virginia Lewis  Prof. Helena Teede  Prof. William Hogg  Prof. Kevin Pottie  Prof. Graham Meadows  Dr Joanne Enticott  Dr. Jenny Advocat  Dr. I-Hao Cheng |
| Collaborators | Monash Health  Cohealth  Victorian Department of Health and Human Services  Victorian Refugee Health Network  NSW Refugee Health Service  enliven (trading name for South Eastern Health Care Partnership)  North Western Melbourne Primary Health Network  South Western Sydney Primary Health Network  AMES Australia  Settlement Services International  the Royal Australian College of General Practitioners  the Refugee Health Network of Australia |

1. Data organisation, documentation and storage

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| Data types and description  (See Appendix A for specific details) | **Quantitative**  Survey data from practices (Practice Description Survey), individual practitioners (Practitioner Survey) and practice QI team (Refugee healthcare survey) Data is entered into Qualtrics, which can be download as Excel or SPSS files.  Patient data from PENCS CAT4. Extracted in de-identified format from patient medical records and exported to Excel. Converted into SPSS for cleaning and into STATA for analysis.  Service provision data from TIS National. Provided in de-identified Excel format by TIS National. Converted into SPSS for cleaning and analysis.  **Qualitative**  Transcriptsfrom interviews with practice staff (GPs, nurses, receptionists and practice managers), practice facilitators, regional research officers and regional refugee service managers. Audio files provided in a range of formats. Transcripts stored in Word and uploaded to NVivo for analysis.  Documentary sourcesincluding facilitator and research officer diaries, contact summary sheets and practice action plans. Raw data files stored as .pdf, .docx or .xlsx and uploaded to NVivo for analysis. |
| Use of existing or 3rd party data | **Patient data** from PENCS CAT4. Extracted in de-identified format from patient medical records and exported to Excel.  **Service provision data** from TIS National. Provided in de-identified Excel format. Converted into SPSS for cleaning and analysis. |
| Tools or applications using to create, process or visualise the data | **Quantitative**  Survey data entry using Qualtrics.  Data processing and analysis via SPSS, STATA, Excel (some researchers will use other programs).  **Qualitative**  Qualitative interviews –Word, Acrobat, any JPEG viewer, any audio player, NVivo  Documentary sources – Word, Excel, Acrobat, NVivo. |
| Data checking and verification | All data that is to be shared with investigators, staff, and students not listed on the Monash University ethics will be deidentified. |
| Expected file formats | **Quantitative**  SPSS - Statistical Package for the Social Sciences (.sav)  Stata (.dta)  Microsoft Excel (.cvs, .xlsx, .xls)  **Qualitative**  NVivo (.nvp)  Word (.doc, .docx)  PDF (.pdf)  Audio (.mp3, .wma, .m4a) |
| Size/amount of data | < 1 TB |
| Data storage location | Identifiable data will be stored locally (Monash University, LaTrobe University and UNSW) with filing and naming conventions to be determined locally.  Complete datasets of identifiable aggregated data will be stored on the Monash University S Drive.  Transborder flow of de-identified data has received ethical approval. |
| Data retention and destructions | Data will be kept in in secure storage for at least five years for ongoing research purposes.  At the end of this period, paper records will be shredded and electronic records deleted in accordance with the appropriate university data destruction procedures. |

1. Data sharing and access policy

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| Data types and description | **Publicly available data**  Public access will be provided for deidentified metadata that underlie the results reported in study publications (e.g. text, tables, figures, and appendices). We will also make available the statistical analysis plan and relevant statistical code. Availability will begin 6 months after and end 36 months following article publication and will be for proposals that have been approved by an independent review committee.  Cleaned, de-identified copies of the following datasets will be made available to other researchers on request (see request protocol below). Data requests will be considered from June 1, 2021.  Note that this dataset excludes data from participants who did not consent to future data use. The data will be provided with a data dictionary (quantitative data).   * Survey data from practices (Practice Description Survey), individual practitioners (Practitioner Survey) and practice QI team (Refugee healthcare survey). Provided as Excel or SPSS files. * A node summary of qualitative data including node definitions and representative quotes.   **Complete dataset**  The complete cleaned dataset will be made available to the current research team (i.e. researchers listed on the Monash University ethics). The data will be provided with a data dictionary (quantitative data) and/or coding summary description (qualitative data).  The dataset includes:   * Survey data from practices (Practice Description Survey), individual practitioners (Practitioner Survey) and practice QI team (Refugee healthcare survey). Provided as Excel or SPSS files. * Patient data from PENCS CAT4. Provided as SPSS files. * Service provision data from TIS National. Provided as Excel or SPSS file. * Transcripts from interviews with practice staff (GPs, nurses, receptionists and practice managers), practice facilitators, regional research officers and regional refugee service managers, coded according to the published protocol. Provided as an NVivo file. * Documentary sources including facilitator and research officer diaries, contact summary sheets and practice action plans, coded according to the published protocol. Provided as an NVivo file. |
| Terms and conditions of data access | Data will be shared only for the purpose of health research and within the constraints of the consent under which the data were originally collected.  **Data version control**  A master version of the qualitative and quantitative datasets (henceforth the original datasets), will be stored on bridges.monash.edu. This version should not be edited or modified.  Approved users who wish to make changes to the original datasets for the purposes of analysis should create a copy of the original dataset. A copy of any edited dataset should be stored on the Bridges server and clearly labelled (e.g. OPTIMISE\_qualitativedata\_LaTrobe).  Approved users must try to minimize the number of data copies that are created.  **Data access and sharing**  Current project investigators, staff and students will receive default “approved user” status and access to the data.  Student users must be supervised by an investigator or project staff member.  Data may not be transferred to any individual who is not an “approved user”.  Data must be returned or destroyed in the event of a current project investigator, staff or student leaving the project without having an approved request for ongoing access.  **Data ethics**  The approved user must not attempt to identify any individual from the data provided.  Approved users must not use the data in a way that is unlawful, harmful, or misleading.  Supplied data must only be used for the proposed purpose.  Supplied data should not be re-shared with external parties.  Any links used to grant access to the data should not be re-shared with external parties.  Approved users must not have a conflict of interest that may potentially influence their interpretation of any analyses.  Approved users must have Ethics Committee approval. Ethics Committee approval is the responsibility of the requestor.  In accordance with Monash University’s Health Privacy Principle HPP 9 for trans-border data flow, any data from this project sent to investigators outside of Monash University will display equivalent privacy laws to that of Monash University.  The ethics, security, and privacy guidelines outlined in this protocol also apply to any copies of the original dataset. |
| Terms and conditions of shared data publication | **Publication of Papers**  Any papers resulting from the secondary analysis of OPTIMISE data must be submitted to OPTIMISE investigators at least 30 days before it is submitted for publication.  **Authorship**  Where possible, those using data collected by OPTIMISE authors should seek collaboration with those who collected the data.  OPTIMISE researchers who collected the data should be invited to participate in secondary analyses and the development of the resulting manuscript, with appropriate authorship.  It is expected that OPTIMISE investigators will be involved as collaborators on studies resulting from shared data and be offered co‐authorship on resulting publications or presentations. It may also be appropriate to acknowledge members of the original study staff who contributed directly to the original study.  **Acknowledgements**  Authors of secondary analyses must reference the source data to provide appropriate credit to those who generated it and allow searching for the studies it supported.  Please provide a link to the original dataset whenever possible. Please cite the dataset following the applicable citation norms.  In addition to a description of OPTIMISE data in the methods and citation of the appropriate published results, studies using OPTIMISE data should include the following acknowledgement sections in their manuscripts. Additional acknowledgements of OPTIMISE researchers and staff may also be appropriate.  *Research contribution acknowledgement statement:*  The scientific results reported in this article are based on data obtained as part of the OPTIMISE research program.  *Funding acknowledgement statement:*  The OPTIMISE project- implementing and evaluating a practice facilitation intervention in general practice settings is funded by the National Health and Medical Research Council (APP1106372). The information and opinions contained in this paper do not necessarily reflect the views or policy of these funding agencies. |
| Hierarchy of access to complete dataset | The ability to access and request data will be prioritized as follows:   1. OPTIMISE investigators 2. Past, present and future OPTIMISE staff 3. Past, present and future OPTIMISE students 4. Researchers affiliated with OPTIMISE partner organisations 5. Other researchers |
| How requests should be made | Data requests from Researchers affiliated with OPTIMISE partner organisations and other researchers will only be considered from June 1, 2021.  Researchers desiring access to the publicly available data and supplementary project documents (e.g. statistical analysis plan, statistical code, qualitative coding structure) are strongly encouraged to first informally approach the study investigators to discuss the feasibility of data sharing.  A data sharing request is to be submitted by email to Prof Grant Russell ([grant.russell@monash.edu](mailto:grant.russell@monash.edu)) for consideration. The request (2 pages max) should include the following:   * Name(s) of the requestor   + Multiple individuals may be listed as the requestor, provided that they are eligible to submit a data request, as outlined above.   + One individual should be assigned as the primary requestor. The primary requestor is responsible for submitting any data and analysis requests, and any associated correspondence. * Objectives   + Why the requestor would like the data   + What research question the requestor hopes to answer using the data * Proposed Methodology   + How the requestor proposes to answer their research question   + Data outputs the analyses are expected to generate * Relevant references * Funding sources * Any potential conflicts of interest * Peer reviewed publications demonstrating the requestor’s ability to carry out the proposed analyses * Evidence of Ethics Committee approval where appropriate. * A data security plan   The request for data sharing will be reviewed by Grant Russell, Mark Harris and Virginia Lewis, and determined based on available resources and competing priorities. |
| Tools or applications used to share data | Bridges  Quantitative and qualitative data will be stored on bridges.monash.edu. This is a cloud-based storage system that uses the secure servers at Monash University to store files. It can be accessed remotely by investigators and staff at Monash University and at external organizations. |

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Appendix A: OPTIMISE datasets

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| Data Type | Specific data | Short term storage1 | Long term storage2 | Available to share3 | Special Use requirements4 | Specific ethical requirements |
| Patient Health Data | | | | | | |
| Raw | PENCS CAT4 extracts – one separate file per practice per extract timepoint; patient level data | Regionally | - | D | N/A |  |
| Cleaned Patient Health Data | PENCS CAT4 extracts deidentified, merged across all regions, practices and timepoints – patient level data | Monash University S Drive | Bridges | D | N/A |  |
| Service provision data | TIS usage data deidentified and aggregated by practice and month – practice level data | Monash University S Drive | Bridges | B - Must be shared on Monash University platforms | A |  |
| Survey data | | | | | | |
| Raw | Practice Description Survey – practice level data  Refugee Healthcare Survey – practice level data  Individual Clinical Staff Survey – clinician level data | Regionally: Qualtrics, Excel, Paper copies | - | D | N/A |  |
| Cleaned | Practice Description Survey – practice level data  Refugee Healthcare Survey – practice level data  Individual Clinical Staff Survey – clinician level data  All de-identified and merged across all regions, practices and timepoints | Monash University S Drive | Bridges | B | A |  |
| Qualitative data | | | | | | |
| Raw | Interview audio recordings transcripts with: Practice staff, Regional research officers, Facilitators, Service Managers  Documents: Facilitator Diaries, Research Officer Diaries, Action Plans | Regionally | - | D | N/A |  |
| Coded | Interview audio recordings transcripts with: Practice staff, Regional research officers, Facilitators, Service Managers  Documents: Facilitator Diaries, Research Officer Diaries, Action Plans | Monash University S Drive | Bridges | B | B |  |

1Short term = for use by researchers during OPTIMISE study

2Long term = to be shared after OPTIMISE study

3Availbility: A: freely available; B: available to reasonable requests; C: availability restricted to OPTIMISE team; D: not available.

4Use requirements: A: no requirements; B: Co-I must be listed as author; N/A: data not available.