Plan Overview

*A Data Management Plan created using DMPTool*

**Title:** Understanding the Effectiveness of PEN-Plus clinics in Salima and Karonga, Malawi

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**Affiliation:** Harvard Medical School (hms.harvard.edu)

**Principal Investigator:** Emily Wroe

**Data Manager:** Bright Mailosi

**Project Administrator:** Bright Mailosi

**Contributor:** Bright Mailosi

**Funder:** Department Of Global Health And Social Medicine

**Template:** Digital Curation Centre

**Project abstract:**

The PEN-Plus model successfully diagnoses and manages complex chronic non-communicable diseases (NCDs) elsewhere. However, its performance in Malawi's Ministry of Health-owned (MOH-owned) hospitals has yet to be studied. Through longitudinal mixed-methods learning, we seek to understand the performance of two new MOH-run PEN-Plus clinics in Malawi. We will review patient charts retrospectively, and conduct focus group discussions with patients, in-depth interviews with providers, and patient clinic-encounter observations to assess fidelity to PEN-Plus protocols among Healthcare workers (HCWs). We will enroll HCWs, and patients with type one diabetes and heart failure registered in the clinics before 31st January 2023.

**Start date:** 05-31-2023

**End date:** 05-30-2024

**Last modified:** 04-16-2023
Copyright information:

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Understanding the Effectiveness of PEN-Plus clinics in Salima and Karonga, Malawi

Data Collection

What data will you collect or create?

1. Patient clinical information
   - In Excel spreadsheet format
   - This data contains routine patient clinical information
   - Encrypted with Microsoft password encryption
2. Patient-provider encounter observations
   - Excel Dataset
   - This data will use a checklist, and the student PI will shadow a clinical consultation and observe conformity to clinical protocols
   - Data will use Microsoft encryption
3. Health Care Worker Post-test Scores
   - Excel spreadsheet
   - The Health Care Workers will take a test administered by the student PI and the test scores will be aggregated on an Excel sheet.
   - Data will use Microsoft encryption
4. Health care worker in-depth interviews
   - Data will be in the form of Microsoft Word transcripts
5. Patient Focus Group Discussions
   - Data will be in the form of Microsoft Word transcripts

How will the data be collected or created?

1. Patient Clinical Information
   - Retrospective patient chart review
   - Any missing information will be discussed with the providers on-site for clarification.
   - We will review a specific quantity of charts in a given day to ensure quality.
2. Patient-provider encounter observations
   - Prospective observation during clinical consultations
   - Data will be organized using a checklist
   - We will observe a specific volume of encounters to ensure quality.
3. Health Care Worker Post Test score
   - The Health Care workers will take a test that they took during initial training.
   - The scores will be enlisted on an Excel spreadsheet
4. Health Care Worker In-depth Interview transcripts
   - Interviews will be translated and transcribed verbatim.
5. Patient Focus Group Discussion
   - FGDs will be translated and transcribed verbatim
Documentation and Metadata

What documentation and metadata will accompany the data?

1. All data on the Excel spreadsheet will be de-identified and analyzed using Stata
   • We will label, and define all variables and values
   • A de-identified Stata file format dataset will be stored
2. The word files will be de-identified and stored in word format

Ethics and Legal Compliance

How will you manage any ethical issues?

• Consent is obtained before data collection
• For retrospective routine clinical data, consent will be waived by the Malawi IRB.
• Identifiable information is stored separately from the rest of the data

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

Data from this study will be owned by the student PI

Storage and Backup

How will the data be stored and backed up during the research?

• Data will be stored using a secure Harvard Office365 one drive
• We will back up the data in a password protected external hard drive
• Harvard IT team will be responsible for data recovery in terms of any incident

How will you manage access and security?

All data will be accessed by individuals who have a Harvard Key or password to the external hard drive

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

All data will be kept for at least seven years and destroyed after.

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

The data is stored in a password-protected hard drive used only to store research data.
The student PI will be responsible for data curation during this period.

**Data Sharing**

**How will you share the data?**

Only the study team with Harvard Key or password to the secure external hard drive will have access to the data.

**Are any restrictions on data sharing required?**

Only the study team with Harvard Key or password to the secure external hard drive will have access to the data.

**Responsibilities and Resources**

**Who will be responsible for data management?**

The student PI is responsible for Data Management

- Data capture
- Metadata production
- data quality assurance
- Storage and backup
- archiving
- Secure data sharing

**What resources will you require to deliver your plan?**

No additional resources will be required. This study and plan will be conducted alongside my mentor and the PI, Dr. Emily Wroe. I do not need any additional required hardware software and I am not going to use a data repository.
Planned Research Outputs

**Dataset - "Retrospective routine patient clinical data - Salima [2022-2023]"**
Salima PEN-Plus routine patient clinical data for 08-2022 to 07-2023

**Dataset - "Retrospective routine patient clinical data - Karonga [2022-2023]"**
Karonga PEN-Plus routine patient clinical data from 08-2022 to 07-2023

**Dataset - "Patient-provider encounter data - Salima 2023"**
Checklist data documenting patient-provider encounter observations at PEN-Plus in Salima, 2023

**Dataset - "Patient-provider encounter data - Karonga 2023"**
Checklist data documenting patient-provider encounter observations at PEN-Plus in Karonga, 2023

**Dataset - "Health Care Worker in-depth Interviews - Salima 2023"**
Transcripts from interviews with PEN-Plus Health care workers at Salima district hospital, Malawi, 2023

**Dataset - "Health Care Worker in-depth Interviews - Karonga 2023"**
Transcripts from Interviews with PEN-Plus HCWs from Karonga district hospital, Malawi, 2023

**Dataset - "Patient Focus Group Discussion Dataset - Salima 2023"**
Transcripts from PEN-Plus patient and caregiver focus group discussion for Salima district hospital, Malawi, 2023.

**Dataset - "Patient Focus Group Discussion Dataset - Karonga 2023"**
Transcripts from PEN-Plus patient and caregiver focus group discussion for Karonga district hospital, Malawi, 2023.

**Dataset - "Health Care worker Post-Test scores - Salima 2023"**
Test scores from PEN-Plus HCWs were taken during data collection. The test is the same as during their initial training in 2022.

**Dataset - "Health Care worker Post-Test scores - Karonga 2023"**
Test scores from PEN-Plus HCWs were taken during data collection. The test is the same as during their initial training in 2022.
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