# Plan Overview

*A Data Management Plan created using DMP Tool*

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

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**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:** 06-01-2023

**End date:** 05-31-2024

**Last modified:** 07-08-2024

**Copyright information:**

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

**Data Collection**

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**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**

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**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 harddrive
- 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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**Planned research output details**

| Title | Type | Anticipated release date | Initial access level | Intended repository(ies) | Anticipated file size | License | Metadata standard(s) | May contain sensitive data? | May contain PII? |
|---|---|---|---|---|---|---|---|---|---|
| Retrospective routine patient clinical data - Sali ... | Dataset | 2023-12-30 | Restricted | None specified | 3 GB | None specified | None specified | Yes | No |
| Retrospective routine patient clinical data - Karo ... | Dataset | 2023-12-30 | Restricted | None specified | 3 GB | None specified | None specified | Yes | No |
| Patient-provider encounter data - Salima 2023 | Dataset | 2023-12-30 | Restricted | None specified | 2 GB | None specified | None specified | Yes | No |
| Patient-provider encounter data - Karonga 2023 | Dataset | 2023-12-30 | Restricted | None specified | 2 GB | None specified | None specified | Yes | No |
| Health Care Worker in-depth Interviews - Salima 20 ... | Dataset | 2023-12-30 | Restricted | None specified | 2 GB | None specified | None specified | Yes | No |
| Health Care Worker in-depth Interviews - Karonga 2 ... | Dataset | 2023-12-30 | Restricted | None specified | 2 GB | None specified | None specified | Yes | No |
| Patient Focus Group Discussion Dataset - Salima 20 ... | Dataset | 2023-12-30 | Restricted | None specified | 2 GB | None specified | None specified | Yes | No |
| Patient Focus Group Discussion Dataset - Karonga 2 ... | Dataset | 2023-12-30 | Restricted | None specified | 2 GB | None specified | None specified | Yes | No |
| Health Care worker Post-Test scores - Salima 2023 | Dataset | 2023-12-30 | Restricted | None specified | 2 GB | None specified | None specified | Yes | No |
| Health Care worker Post-Test scores - Karonga 2023 | Dataset | 2023-12-30 | Restricted | None specified | 2 GB | None specified | None specified | Yes | No |