Plan Overview

A Data Management Plan created using DMPTool

Title: Optimizing implementation of long-acting injectable PrEP

Creator: Steven John - **ORCID:** 0000-0002-1316-3920

Affiliation: Medical College of Wisconsin (mcw.edu)

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Project abstract:

The study of HIV pre-exposure prophylaxis (PrEP) implementation is a moving target as new and forthcoming methods of PrEP dosing become available with very different implications for clinical practice. Implementation research is needed to support further roll-out of PrEP as an umbrella HIV prevention strategy, yet long-acting injectable PrEP (LAI-PrEP) via intramuscular cabotegravir has unique implications for clinical practice that will not easily fit within implementation strategies for oral PrEP. In this study, we aim to *identify* determinants to LAI-PrEP roll-out, conduct consensus building with stakeholders to *plan* optimal strategies to support LAI-PrEP implementation, and pilot a cyclical *Plan-Do-Study-Act* implementation strategy within two outpatient clinics serving priority populations for HIV prevention.

Start date: 12-01-2023

End date: 11-30-2026

Last modified: 04-07-2023

Optimizing implementation of long-acting injectable PrEP

This project will produce qualitative and quantitative generated from formative semi-structured interviews, surveys, and electronic health records. Qualitative data will be collected from 75 participants in the formative phase and 20 participants during exit interviews, generating two datasets. Quantitative survey data will be collected from 38 participants in the modified Delphi consensus building and 20 participants in the longitudinal survey of clinic providers and staff, generating two datasets. Electronic health record data will be collected from clinic patients to generate a single dataset.

Raw data will be de-identified and transferred to MAXQDA, SPSS, STATA, and/or Mplus for analysis. To protect research participant identities, de-identified individual qualitative and quantitative data will be made available for sharing. Summarized electronic health record data will only be made available for sharing. In circumstances where small sample sizes may easily allow re-identification of research participants, only summarized data will be made available for sharing.

We expect to generate the following data file types and formats during this project: text (.docx, .txt), and quantitative data (.dat, .sav, .csv). The total size of the data collected is projected not to exceed 1 GB.

The final datasets will include qualitative and quantitative datasets from interviews and surveys of research participants. We will share de-identified individual-participant level (IPD) data. Appropriate measures such as removing "safe harbor" personal identifiers (e.g., name, contact information, and IP addresses) per MCW policy AD.AP.090 will be used for data de-identification and sharing, and informed consent forms will reflect those plans. In circumstances where small sample sizes may easily allow re-identification of research participants, only summarized data will be made available for sharing.

To facilitate interpretation of the data, interview guides, survey measures, and questionnaire files will be created, shared, and associated with the relevant datasets. Documentation and support materials will be compatible with ClinicalTrials.gov Protocol Registration Data Elements.

Qualitative data will be made available in .docx and .txt formats and will not require the use of specialized tools to be accessed or manipulated. Quantitative data will be made available in .csv and not require the use of specialized tools to be accessed or manipulated.

Data will be stored in common and open formats, such as .txt for our qualitative data and .csv for quantitative data. Information need to make use of this data along with references to the sources of those standardized names and metadata items will be included wherever applicable.

All datasets that can be shared will be deposited in openICPSR. openICPSR is a self-publishing repository for social, behavioral, and health sciences research data.

The openICPSR provides metadata, persistent identifiers using ICPSR ID numbers and DOI, and long-term access. The repository is supported by the Inter-university Consortium for Political and Social Research (ICPSR) and datasets are available under a Creative Commons Attribution 4.0 International (CC BY 4.0) License. Data will be discoverable online through standard web search of the study-level metadata as well as the persistent pointer from the ICPSR ID and DOI to the dataset.

All scientific data generated from this project will be made available as soon as possible, and no later than the time of publication or the end of the funding period, whichever comes first. The duration of preservation and sharing of

the data will be a minimum of 10 years after the funding period.

There are no anticipated factors or limitations that will affect the access, distribution or reuse of the scientific data generated by the proposal.

Controlled access will not be used. The data that is shared will be shared by unrestricted download.

In order to ensure participant consent for data sharing, IRB paperwork and informed consent documents will include language describing plans for data management and sharing of data, describing the motivation for sharing, and explaining that personal identifying information will be removed.

To protect participant privacy and confidentiality, shared data will be de-identified by removing personal identifiers (e.g., name, contact information, and IP addresses) per MCW policy AD.AP.090. In circumstances where small sample sizes may easily allow re-identification of research participants, only summarized data will be made available for sharing.

The PI will be responsible for the day-to-day oversight of data management activities and data sharing for this project. Broader issues of DMS Plan compliance oversight and reporting will be handled by the PI and Co-I team as part of stewardship, reporting, and compliance processes.

The PI will be responsible for monitoring compliance no less frequently than annually at the time of RPPR submission.

Any changes to the DMS plan will be communicated to NIH by the PI, through the Office of Grants and Contracts as required by NIH.
