

Plan Overview

A Data Management Plan created using DMPTool

Title: Optimizing implementation of long-acting injectable PrEP

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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.

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Optimizing implementation of long-acting injectable PrEP

Data Type

Types and amount of scientific data expected to be generated in the project: *Summarize the types and estimated amount of scientific data expected to be generated in the project.*

Describe data in general terms that address the type and amount/size of scientific data expected to be collected and used in the project (e.g., 256-channel EEG data and fMRI images from ~50 research participants). Descriptions may indicate the data modality (e.g., imaging, genomic, mobile, survey), level of aggregation (e.g., individual, aggregated, summarized), and/or the degree of data processing that has occurred (i.e., how raw or processed the data will be)

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.

Scientific data that will be preserved and shared, and the rationale for doing so: *Describe which scientific data from the project will be preserved and shared and provide the rationale for this decision.*

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.

Metadata, other relevant data, and associated documentation: Briefly list the metadata, other relevant data, and any associated documentation (e.g., study protocols and data collection instruments) that will be made accessible to facilitate interpretation of the scientific data.

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.

Related Tools, Software and/or Code

State whether specialized tools, software, and/or code are needed to access or manipulate shared scientific data, and if so, provide the name(s) of the needed tool(s) and software and specify how they can be accessed.

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.

Standards

State what common data standards will be applied to the scientific data and associated metadata to enable interoperability of datasets and resources, and provide the name(s) of the data standards that will be applied and describe how these data standards will be applied to the scientific data generated by the research proposed in this project. If applicable, indicate that no consensus standards exist

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.

Data Preservation, Access, and Associated Timelines

Repository where scientific data and metadata will be archived: Provide the name of the repository(ies) where scientific data and metadata arising from the project will be archived; see [Selecting a Data Repository](#))

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.

How scientific data will be findable and identifiable: Describe how the scientific data will be findable and identifiable, i.e., via a persistent unique identifier or other standard indexing tools.

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.

When and how long the scientific data will be made available: Describe when the scientific data will be made available to other users (i.e., no later than time of an associated publication or end of the performance period, whichever comes first) and for how long data will be available.

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.

Access, Distribution, or Reuse Considerations

Factors affecting subsequent access, distribution, or reuse of scientific data: NIH expects that in drafting Plans, researchers maximize the appropriate sharing of scientific data. Describe and justify any applicable factors or data use limitations affecting subsequent access, distribution, or reuse of scientific data related to informed consent, privacy and confidentiality protections, and any other considerations that may limit the extent of data sharing. See [Frequently Asked Questions](#) for examples of justifiable reasons for limiting sharing of data.

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

Whether access to scientific data will be controlled: State whether access to the scientific data will be controlled (i.e., made available by a data repository only after approval).

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

Protections for privacy, rights, and confidentiality of human research participants: If generating scientific data derived from humans, describe how the privacy, rights, and confidentiality of human research participants will be protected (e.g., through de-identification, Certificates of Confidentiality, and other protective measures).

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.

Oversight of Data Management and Sharing

Describe how compliance with this Plan will be monitored and managed, frequency of oversight, and by whom at your institution (e.g., titles, roles).

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.
