

**Expanding PrEP in Communities of Color (EPICC)
(PS21-003) Data Use Plan**

This plan describes the anticipated use and release by CDC of the dataset(s) named below. All CDC data use plans are required to be in compliance with the CDC/ATSDR Policy on releasing and sharing data, available at: [policy385.pdf \(cdc.gov\)](https://www.cdc.gov/policy/385.pdf).. This plan is modifiable and does not represent a legal contract between CDC and any other entity.

Dataset Name: Expanding PrEP in Communities of Color (EPICC), Grant# U01PS005236

Data in this dataset were collected by the EPICC research team, supported by PS21-003, “PrEP Choice: Increasing the Use of HIV Pre-exposure Prophylaxis in an Era of Choices.” This Notice of Funding Opportunity (NOFO) was designed to: a) implement evidence-based provider and patient education and support tools in clinical settings to increase PrEP screening, counseling, initiation, adherence, and persistence by MSM and b) to understand reasons for selection of a PrEP formulation and switching patterns associated with the use of daily, 2-1-1, and injectable PrEP. Additionally, data collect data to describe real-world PrEP use among MSM in an era of multiple PrEP options. Accessing data from clinic settings about PrEP use among MSM in an era of multiple PrEP options is essential to developing future guidelines and tools.

Custodial Unit/Contact Information:

NCHHSTP/DHAP/PRB: Mary Tanner, MD (klt6@cdc.gov), Project Officer, U01PS005236

Study / Program Description:

The purpose of this research is to evaluate the use of evidence-based provider and patient education and support tools (EBT) in clinical settings to increase preexposure prophylaxis (PrEP) screening, counseling, initiation, adherence, and persistence by young men who have sex with men (YMSM) and to understand reasons for selection of a PrEP formulation and switching patterns associated with the use of daily, 2-1-1, and injectable PrEP. This project will involve interaction with human participants and intends to collect new individually identifiable data and biospecimens from the participants.

The Expanding PrEP in Communities of Color (EPICC) project proposes to adapt and implement existing EBT to facilitate PrEP shared decision making (SDM), train providers on the use of evidence-based provider and patient education and support tools (EBT) and evaluate the impact within a longitudinal cohort of racially and geographically diverse YMSM (cisgender males, ages 18-39). We refer to this combination of interventions as the EPICC+ intervention package, which includes provider training, EBT for providers, and a mobile app-based platform to support ongoing participant engagement and monitoring, as well as to provide additional adherence support.

This study will consist of two distinct aims to adapt and implement the EBT and materials:

Aim 1: Train providers on the use of newly developed EBT and updated PrEP clinical guidance. The training will focus on implementation of the EBT to ensure providers’ ability to engage in PrEP screening, counseling, initiation and to provide support for adherence and persistence.

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Aim 2a: Test the newly adapted EBT materials through a hybrid type 2 effectiveness implementation clinical trial to assess PrEP uptake and adherence to PrEP amongst 400 YMSM (effectiveness outcomes) and provider provision of PrEP and competence with EBT to increase PrEP services (implementation outcomes). Aim 2a also includes exit interviews with a subset of patients (45) to understand factors that influence participants' selection of PrEP regimens, changes and/or discontinuations as well as perceptions of the counselling they received by providers at PrEP initiation and follow, receipt of tools or materials that influenced choice and feasibility/acceptability of the HMP app.

Aim 2b: Host six post-trial virtual focus groups with 48 PrEP providers and clinical staff to gather feedback on overall perceptions of the barriers and facilitators to EBT implementation at their clinical sites. Clinic-level assessments on implementation of PrEP support services will also be conducted every six months during Aims 1 and 2.

Memoranda of Understanding (MOU) Pertaining to Datasets: Persons who request data are required to provide an approved copy of the Publication Guidelines Concept Proposal and signed copy of the Data Sharing Agreement before data will be transferred. The agreement must be signed by all individuals who will have access to the data or participate in preparing materials for publication before engaging in research activities with these data.

Data Source(s): All data collected and provided to CDC under RFA-PS-21-003: Grant# U01PS005236, PrEP Choice: Increasing the Use of HIV Pre-exposure Prophylaxis in an Era of Choices

Population Represented by Datasets: (See individual protocols for complete eligibility requirements.) Populations will include but are not limited to young men who have sex with men (YMSM ages 18-39); racial/ethnic minorities; and healthcare providers.

Type of Data: In-depth interviews, observational data, structured surveys, medical record abstractions, data from biological markers including dried blood spots, and HIV and other STI test results. All data shared with and by CDC will be stripped of participant names and contact information.

Process for Omitting Identifying Information: Prior to transferring data to CDC, the PS21-003 awardee, University of North Carolina, Chapel Hill, will electronically delete all directly identifiable information including study participant names and contact information (addresses, phone numbers, and email addresses), from all data. Therefore, data provided by CDC for public release will not contain participant names or contact information. All quotations by intervention participants used in publications where the research population contains 40 or fewer participants will only be identified using gender identity, age category (not specific age), and race/ethnicity (if more than one race is provided, use 'multi-race'). For example, quotes will follow this format:

“Lorem ipsum dolor sit amet, duo ei dicta theophrastus intellegebat. Est meliore liberavisse cu. An duo populo laboramus, eam iusto appareat no. Eum

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*probatus evertitur in. Ad ius feugiat consectetur, eu liber maiorum mea. Nec
an alia iriure.” Hispanic/Latina Transgender Woman, 18-24 years old.*

Quotations by clinic/agency staff used in publications where the research population contains 40 or fewer participants will only be identified by using the title “staff” and the name of the social service agency. For example, quotes will follow this format:

*“Elit fuit ipsum super decennium. Habemus consilia ad expand nostra
proiectione progressio annum.” Staff at TransLife Center.*

Data Quality Protocol: The EPICC research team will conduct data cleaning on all data sets prior to delivery to the CDC. This process will ensure that all direct identifiers are deleted from the data. All data will be coded with identification numbers. The document that links participant names and identification numbers will be maintained by the EPICC research team using security measures described in the project protocol. The linking document will never be shared with CDC or other entities seeking to use project data through this agreement.

Data Retention/Disposal Plan: Study data will be retained by the EPICC Research Team until analyses are complete and for up to three years following study closure. At that time, users must delete all data stored on their servers. The de-identified public access dataset will be hosted by CDC and will be stored on a secure server that is accessible through the Division of HIV Prevention, HIV Research Branch for 6 years; after which time, the data will be archived according to guidance set forth by CDC Records Management Policy, Policy # CDC-GA-2005-07 (updated 9/14/2021).

Data Analysis Plan:

Applicants requesting access to specific datasets created from datasets provided by the EPICC research team at the termination of its CDC-funded study, and after the EPICC research team, its study partners, and CDC have agreed that all required study analyses have been completed and presented, will submit a plan for analysis of the data requested from CDC. The data analysis plan will include a description of the topic(s), expectations or hypotheses that will be assessed based on analysis of the requested dataset, and a description of planned steps for analyzing and presenting the results of the planned data analysis.

Dataset Release Type*: (**BOLD all that apply**) 1) public-access 2) **restricted access** /
***special-use data sharing agreement**, 3) no public access

*Special-use data sharing agreement:

- Proposed activities involving the use of the data are reviewed and approved by CDC
- The special use dataset will be generated from a subset of the EPICC public-access dataset hosted by CDC, with specific data elements to be determined with each individual request

Dataset Release Site: __ CDC/NCHHSTP/DHAP/HRB _____

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Dataset Release Timeline: The EPICC research team will submit project data to CDC after the data have been cleansed of directly identifying information. CDC project staff, the grantee, and its project partners will collaboratively review all data and analyze data relative to dissemination topics agreed to by all project partners. It is anticipated that the restricted use dataset will be available approximately September 2028, after CDC, the grantee, and its partners have agreed that all key study analyses have been completed and cleared by CDC for publication.

Data Elements to be Released: The grantee will share with CDC all qualitative and quantitative data collected for this research project in addition to codebooks. All data will be coded. All data will be stripped of directly identifying information. Data elements that may be shared via restricted access / special use data sharing agreement will include focus group and in-depth interview guides and qualitative responses from client and provider participants and structured survey instruments and responses from client and provider participants.

Dataset Release Format: Focus group and in-depth interview data will be available in text format. Data from structured surveys or assessments will be provided in a SAS, SPSS or excel file format.

Data Release Outside of CDC: Data collected and stored by CDC will not contain names, contact information, or other identifiable information. Persons from outside of CDC who request data are required to provide an approved copy of the Publication Guidelines Concept Proposal and signed copy of the Data Sharing Agreement before data will be transferred. The agreement must be signed by all individuals who will have access to the data or participate in preparing materials for publication before engaging in research activities with these data. Persons requesting data will submit a plan for analysis of the data requested from CDC. The data analysis plan will include a description of the topic(s), expectations or hypotheses that will be assessed based on analysis of the requested dataset, and a description of planned steps for analyzing and presenting the results of the planned data analysis.

It is anticipated that the restricted use dataset will be available approximately September 2028, after CDC, the grantee, and its partners have agreed that all key study analyses have been completed and cleared by CDC for publication. The de-identified public access dataset will be hosted by CDC and will be stored on a secure server that is accessible through the Division of HIV Prevention, HIV Research Branch for 6 years; after which time, the data will be archived according to guidance set forth by CDC Records Management Policy, Policy # CDC-GA-2005-07 (updated 9/14/2021).

Date This Form Filled / Last Revised: Jan 26, 2023

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Data Sharing Agreement for CDC PS22-003 Datasets

This data sharing agreement ensures that CDC's guiding principles of accountability, privacy and confidentiality, stewardship, scientific practice, efficiency, and equity are adhered to. This agreement is subject to change. All changes will be retroactive, and applicants provided with a summary notice of changes made. A signed data sharing agreement is a contract between CDC and the signatory data users.

Dataset Contract Number and Name:

Applicants Who Will Have Access to Data:

List all persons (name, job title, research role, affiliation, email, phone) approved to have access to data and identify the principal person responsible for the analysis and maintenance/security of the data.

Period of Approval to Use Data: From [Date]:_____To [Date]:_____

Restrictions on Use of Data:

I will not use these data except for qualitative and/or statistical analysis and reporting as described in the attached Publication Agreement product proposal.

Any effort to determine the identity of any individual, group or organization whose data appears in the dataset is prohibited. I will not link these data files with individually identifiable data from other data files.

Maintaining Confidentiality and Requirements if Individual Identity Discovered:

It is of utmost importance that the identity of data subjects cannot be disclosed. All direct identifiers, as well as characteristics that might lead to identification, are omitted from the dataset. If an individual identity is discovered, I will make no use of the identity and will immediately advise Dr. Mary Tanner, 404.639.6376, and no one else, of this discovery.

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Requirement to Include CDC Disclaimer in Publications:

All written and oral presentations of results of analyses will include the following disclaimer:
"The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention."

Requirement / Request for Copies of Draft and Final Publications:

Copies of draft oral and written presentations will be submitted to the CDC program office at least 2 weeks prior to presentation or submission to a publisher so that CDC and program partners can be informed. CDC and partners may submit comments within this 2-week window. CDC reserves the right to refuse publication.

CDC will be notified upon final publication of a product and provided with a copy and citation information.

Penalties for Violating Agreement:

I understand that if I violate this agreement, penalties may apply in accordance with CDC policies and Federal law.

Compliance with this agreement will be monitored through pre-publication review of presentation products and/or verification of dataset destruction.

Signature of Data User:

All approved users must sign and date application Date: _____

Signature of CIO/Division/Branch Oversight Official:

Signature of approving official Date: _____