Evaluating Locally-Developed or Adapted (Homegrown) Combination HIV Prevention Interventions for Transgender Persons who have Sex with Men (PS16-003) 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: http://www.cdc.gov/od/foia/policies/sharing.htm. This plan is modifiable and does not represent a legal contract between CDC and any other entity.

Dataset Name: Evaluating Locally-Developed or Adapted (Homegrown) Combination HIV Prevention Interventions for Transgender persons who have Sex with Men (data collected under PS 16-003): Chicago House and Social Service Agency (Chicago House), Grant# 1U01PS005140

Custodial Unit/Contact Information:
NCHHSTP/DHAP/PRB: 1U01PS005140: Damian Denson, PhD (dvd5@cdc.gov)

Study / Program Description: There are approximately 700,000 transgender persons living in the US. The National HIV/AIDS Strategy has identified transgender persons as a priority population for targeting HIV prevention activities and reducing health disparities. A 2008 review of studies found that, on average, 28% of transgender women tested positive for HIV, and rates were highest among African American transgender women (56%); other studies of transgender women have reported similar or higher estimates of HIV infection. In addition, the percentages of transgender women testing positive for HIV infection are comparable to or higher than percentages among men who have sex with men based on multi-city surveys conducted in 2008 and 2011. Many transgender women report high rates of sex and drug use behaviors, engage in sex work activities, may inject hormones and silicone using unclean injection equipment and substances, and prioritize gender reassignment over HIV risks. Transgender persons, including transgender youth, experience social isolation, stigma, gender-related violence and discrimination (transphobia), which can impact access to employment, housing, and education and can lead to mental health and substance use issues. Given the range of social determinants that can affect HIV infection and participation in HIV-related care by transgender women, effective HIV prevention strategies for these populations will need to provide a combination of social services to address both behavioral factors and social and structural determinants of health. The Centers for Disease Control and Prevention's (CDC's) Compendium of Evidence-based Interventions and Best Practices for HIV Prevention has not identified any HIV prevention interventions or best practices for transgender participants that satisfy CDC's evidence-based criteria for efficacy. Several risk reduction interventions have been developed for transgender women; however, four have not been rigorously evaluated and two are currently undergoing randomized controlled trials (RCTs - primary data collection to be completed in 2015 and 2017).
The purpose of the projects funded under PS 16-003 is to evaluate locally-developed or adapted and potentially effective but insufficiently evaluated, interventions that are designed to deliver a combination of HIV prevention, HIV care and treatment, and other support services to transgender persons who have sex with men. Combination HIV prevention interventions are defined as a combination of mutually reinforcing biomedical,

behavioral, and social/structural intervention components that together either reduce participants' risks for acquiring HIV or improve outcomes along the HIV care continuum.

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 PS 16-003:

Grant# 1U01PS005140. Evaluation of TransLife Center (TLC): A Locally-Developed Combination Prevention Intervention for Transgender Women at High Risk of HIV Infection.

Population Represented by Datasets: (See individual protocols for complete eligibility requirements.) Populations will include, but are not limited to: Transgender women who have sex with men; racial/ethnic minorities; and social service providers.

Type of Data: In-depth interviews, observational data, structured surveys, medical record abstractions, and data from biological markers including drug levels (pre-exposure prophylaxis), HIV and STI test results. All data shared by CDC will be stripped of participant names and contact information.

Process for Omitting Identifying Information: Prior to transferring data to CDC, participant names, addresses, phone numbers, email addresses, will be electronically deleted by the awardee (Chicago House). Therefore, data provided by CDC for release will not contain participant names or contact information.

All quotations by intervention participants used in publications from qualitative data where the research population contains 40 or fewer participants can 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 probatus evertitur in. Ad ius feugiat consectetuer, eu liber maiorum mea. Nec an alia iriure." Hispanic/Latina Transgender Woman, 18-24 years old.*

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

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

Data Quality Protocol: Chicago House will conduct data cleaning on all data sets prior to delivery to the CDC. This process will ensure that all participant names and contact information are deleted from the data.

Data Retention/Disposal Plan: All data will be retained until analysis is complete and for up to two years after publication. At that time, users must delete all data stored on their servers. CDC will store complete de-identified data on a secure server that is accessible through the Division of HIV Prevention, Prevention Research Branch.

Data Analysis Plan: All qualitative data will be coded with computer-assisted qualitative data analysis software. Codebooks will be developed and assessed for inter- and intra-coder reliability. Quantitative data will be analyzed in SAS, SPSS or Stata software. Data will be analyzed for outcome publications per agreement with original contract research staff and CDC. No public- or special-use data requests will be approved while CDC directed dissemination efforts are ongoing.

Dataset Release Type*: (**BOLD *all that apply***) 1) public-use dataset, 2) **special-use data sharing agreement,** 3) restricted release, 4) no release

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

Dataset Release Timeline: Data will be made available for release after the data have been cleaned of participant names and contact information and delivered to CDC custodian. CDC staff will review each dataset from each of the projects and analyze and publish primary research questions before the data are made available for public use or restricted use. It is anticipated that the complete dataset will be available approximately June 2025, after CDC has conducted the analyses and prepared papers and other products related to primary findings for publication.

Data Elements to be Released: Interview guides and qualitative responses. Structured survey instruments and responses.

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.

Date This Form Filled / Last Revised: _____ March 20, 2017 _____

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Data Sharing Agreement for CDC PS16-003 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. Damian Denson, 404.639.6125, and no one else, of this discovery.

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.

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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:

_____Date:_____
All approved users must sign and date application

Signature of CIO/Division/Branch Oversight Official:

_____ Date:_____
Signature of approving official