

Justification for the modification of 0920-1178, Comprehensive HIV Prevention and Care for Men Who Have Sex with Men of Color

The Centers for Disease Control and Prevention (CDC) requests to make non-substantive changes to the currently approved Project titled **Comprehensive HIV Prevention and Care for Men Who Have Sex with Men of Color also known as project THRIVE** (OMB No. 0920-1178; expiration date 4/20/2020). The proposed changes are for the Monitoring and Evaluation (M&E) data elements on HIV Prevention and Care Services and the Collaborative Assessment Tool (CAT). All other project activities and methods remain the same as in the previously approved information collection request. The proposed changes do not change the burden shown in the current inventory.

This submission includes “redlined” and “original” versions of the M&E data elements and the CAT.

Please see the following attachments for additional detail as needed:

1. Original M&E variables (Att4)
2. Revised M&E variables with changes in “red” (Att4)
3. Original CAT survey questions (Annual Collaboration Assessment Tool (CAT) Att6)
4. Revised CAT online survey questions (Annual Collaboration Assessment Tool (CAT) Att6)
5. THRIVE CAT screenshots

Overview of THRIVE

THRIVE data collection is for the purposes of evaluation of the 7 state and city health departments and their 80 community-based organizations, clinics and other health providers, behavioral health and social health providers in their jurisdiction that form a collaborative. The sites and their 80 collaborative members will be required to provide thirteen HIV prevention services for MSM of color at substantial risk for HIV infection and eleven HIV care services for MSM of color living with HIV infection. Data will be collected from all grantees for the required 24 prevention and care services.

Data collection utilizes mixed methods. The modifications are reflection of the following data collection:

Monitoring and Evaluation (M&E) data elements on HIV Prevention and Care Services. These data describe steps in the continuums of HIV prevention services and HIV care services. Client level data will be transmitted electronically to CDC twice a year. If client level data is not feasible, then aggregate data will be electronically transmitted, stratified by race/ethnicity, current gender, age group, and HIV transmission group. Attachment 4 represents guidance for transmitting data and is not a data collection form.

Collaborative Assessment Tool (CAT) will be used to assess how successful grantees have been in creating, engaging, and sustaining collaborative partnerships and to understand how these partnerships contributed to achieving the goals of the project, open-ended questions and a survey will be used to evaluate. The CAT will be disseminated annually to health department and collaborative partner staff (e.g., CBOs, healthcare providers, social service providers) as an online survey (see attached survey screenshots).

Proposed Changes and Justification

The estimated burden of the data collection for the M&E (9 hours for THRIVE partners and 1 hour for THRIVE awardees) and CAT (20/60 hours for THRIVE partners and awardees) is expected to be the same.

We propose the following changes:

There were 11 variables that were added to the M&E data (see attachment 4):

- Added question on facilitators for adhering to PrEP(2M.1 & 2M.2)
- Added questions on SBIRT variables to section 12 (12S1-12S4)
- Added question on whether same day ART was offered (4A.1)
- Added question on whether same day ART was accepted (4A.2)
- Added question on whether financial incentives were provided (4A.3)
- Added question on was creatinine testing conducted (1k)
- Added question on date of creatinine test (1L)

There were 6 variables that were deleted from the list of variables previously approved by the OMB (see 5B.2-5H in Table 1)

In addition, we made the following clarifications to the list of variables previously approved by the OMB (see Table 1):

- Given the complexity of sex and gender and the focus of this project on a specific target population (men who have sex with men), we added to “section A. Demographics” (i.e., added an “othergender” and “sex at birth” variable; revised transgender labels, added a variable to assess the sex/gender of sexual partners, and a “year at birth” variable)
- To be conclusive of all types of HIV tests funded sites might use, we expanded the previously approved options for “types of HIV tests” (1A.2) to include “Western Blot” and “Geenius”
- In response to some funded sites’ difficulty in tracking client initiation of some medications, we separated out “prescription” and “initiation” for PrEP (2G.1 & 2), nPEP (3G.1 & 2), and ARVs (4B.1 & 2)
- Corrected an error: Replaced “early infection” with “recent infection” throughout the assessment
- Listed all types of STD infections for the previously approved variable “Screened positive for one or more STDs” (section 8B.)
- Included a missing step of the HIV prevention and treatment continuum – linkage. “Linkage” was included for previously approved variables in this continuum (i.e., yes/no questions for linkage to HIV testing [1A.1 & 2], medication adherence support [6A.1 & 2], retention intervention [7A.1 & 2] and evidence-based behavior risk-reduction counseling [10A. 1 & 2])
- Included a missing step of the HIV treatment continuum – identification of HIV positive persons out of care (5A.1)

We created the CAT and included screen shots (see attachments 6 and 8).

The overall net increase of 5 questions and clarifications are not expected to change the estimated average time it takes for respondents on data collection because respondents are already collecting this information and it will be part of routine data submission for the approved variable. All proposed changes are consistent with the purpose and use of the information collection as stated in the OMB-approved project and do not change the burden to respondents.

The proposed changes are based on: 1) interactions with awardees on what and how variables are collected; 2) the need to provide information to monitor CDC's Division of HIV/AIDS Prevention's Strategic Plan's goals and objectives related to the HIV care and prevention continuum; and 3) recommendations from subject matter experts and CDC programs.

Impact of Changes on the Estimated Burden

The proposed non-substantive changes to the data collection will not change the overall estimated burden of this project.