Community-Based Organizations' Changes in Preparedness and Resources for Support of Biomedical HIV Prevention

0920-New

Section A: Supporting Statement

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EXHIBITS

LIST OF ATTACHMENTS

- **Goals of the study:** To assess community-based organizations' (CBOs) awareness of,

intentions to provide, and provision of Treatment as Prevention (TasP), non-occupational post-exposure prophylaxis (nPEP), or pre-exposure prophylaxis (PrEP). To assess changes in awareness and provision of biomedical HIV prevention interventions among these organizations by comparing responses from a newer survey to those of a previous survey conducted by the Centers for Disease Control and Prevention (CDC) Division of HIV/AIDS Prevention's (DHAP) HIV prevention with negatives team.

- **Intended use:** This information will be used to inform CDC/DHAP staff on the needs of CBOs to scale-up biomedical HIV prevention interventions and identify targets for capacity building within these organizations. Results from the survey will be presented to DHAP staff via internal presentations and to external partners through HIV and public health conferences. Results will also be used to develop manuscripts for publication.
- **Methods to be used to collect data:** Data will be collected through web-based surveys using CDC's Survey Monkey license.
- **Subpopulations to be studied:** Respondents will include executive level staff members or direct client service providers who will complete the survey on behalf of organizations engaged in HIV prevention and outreach. Up to 330 respondents (N=330; 175 DHAP funded CBOs and 155 unfunded CBOs) will be recruited to complete the survey.
- **How data will be analyzed:** Data analysis will include descriptive statistics (e.g., frequencies, counts, means, range, standard deviation) using SAS statistical computing software. Frequency and differences in item responses will be analyzed for relationship to CBO characteristics (e.g., clinic CBOs vs. non-clinical). We will perform multivariable analysis as needed (to assess interactions between time and type of CBO). All information will contain no identifiers.

Supporting Statement

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention's (CDC) Division of HIV/AIDS Prevention (DHAP), requests OMB approval for two years on an assessment entitled, "Community-Based Organizations' Changes in Preparedness and Resources for Support of Biomedical HIV Prevention". Data collection will be carried out by an epidemiologist from DHAP who will lead the survey design, data collection, analysis, and dissemination of results.

In persons without HIV infection, ARVs can be given as either: 1) for 28 days following a potential HIV exposure through sexual or injection behaviors as nonoccupational postexposure prophylaxis (nPEP) or 2) begun before potential sexual HIV exposures and taken daily for months to years as preexposure prophylaxis (PrEP).[1-5] In persons with HIV infection, beginning treating with ARVs early in their infection (e.g., with high CD4 cell counts) can greatly lower their risk of transmitting infection to uninfected sexual partners; this is also called treatment as prevention or TasP.[6-9] PrEP is 99% effective at reducing the risk of HIV through sexual contact when taken daily.[10-14] PrEP is also 74%-84% effective at reducing the risk of HIV infection through injection drug use when taken daily.[4, 15] Persons living with HIV who are taking ARVs as prescribed as well as achieving viral suppression effectively have no risk for transmitting the virus to an HIV-negative partner through sexual contact.[6-9] CDC is working with various jurisdictions with high HIV prevalence to increase capacity of ARV provision, build collaborative efforts between health departments and community-based organizations, and engage multi-

sector provider systems to reach individuals with high risk of HIV infection as part of the End the HIV Epidemic Initiative.[16]

Because these prevention methods all involve prescribing ARVs to people and monitoring for side effects and safety, they can only be done by clinicians licensed to prescribe medication. Non-clinical CBOs are critical to educating communities about these biomedical prevention methods and working with men and women to provide support for the use of ARVs for prevention. This can include identifying clients who might benefit from biomedical interventions and referring/linking them to clinical care sites, supporting medication adherence, and supporting behavioral risk reduction activities. In addition, some non-clinical CBOs may want to add clinical staff or formally collaborate with clinical providers for the delivery of biomedical HIV prevention services.

DHAP funds community-based organizations (CBOs) to deliver HIV prevention services; some are directly funded and some indirectly through state and local health departments. Most are funded to provide non-clinical prevention services (e.g., counseling, HIV testing, HIV education). Some are clinical care sites funded to provide HIV testing and services to increase linkage to, and retention in, HIV treatment.

A previous survey of community-based organizations (CBO) assessed the interest, current capacity, and anticipated needs for engagement with biomedical HIV prevention interventions as part of their HIV prevention services.

With the advent of the Ending the HIV Epidemic initiative, there is a need to assess changes in awareness and provision of biomedical HIV prevention interventions by these organizations. We are conducting a survey to assess differences in awareness, intentions to provide, and provision of TasP, nPEP, or PrEP between the original survey and the newer survey. The results from this assessment will lead to publication of a report on a CDC website or in a journal.

CDC is authorized to conduct the information collection under Section 301 of the Public Health Services Act [42 U.S.C.A.2.] (**Attachment 1**).

2. Purpose and Use of the Information Collection

The purpose of this information collection is to assess current capacity and provision of nPEP, PrEP, and TasP among CBOs providing HIV services to populations with increased risk for HIV acquisition. In addition, the results of this survey will be compared to the results of the 2015 survey to assess differences in awareness, capacity, and provision of biomedical HIV prevention interventions. This project will employ a cross-sectional survey design.

Respondents will include executive level staff members or direct client service providers who will complete the survey on behalf of organizations engaged in HIV prevention and outreach. Up to 330 respondents (N=330; 175 funded CBOs and 155 unfunded CBOs) will be recruited to complete the survey.

Selection, inclusion or sampling of participants:

Two sampling strata will be created:

A. Clinical and non-clinical CBOs directly funded by CDC

B. Unfunded CBO applications for CDC funding

This project will employ a cross-sectional survey design. Executive level staff members of all CBOs within each of the two strata (mentioned above) will receive phone calls, using publicly available

information to elicit interest in participating in the survey (**attachment 3**). If the executive level staff member is not interested or is unable to complete the survey, he or she may nominate a direct client service provider and provide this person's email address to study staff. Potential respondents will be contacted from a list of CBOs that completed the 2015 survey. In addition, potential respondents from CBOs that received DHAP funding through PS15-1502 and PS17-1704 will also be contacted to determine their interest in participating in the data collection effort. Each organization's representative will be sent an email (**attachment 4**) with a link to the survey website (created with Survey Monkey). One link will be used for CBOs directly funded by CDC and a separate link will be used for unfunded CBOs. The email will instruct the recipient on how to complete the survey. Three email reminders will be sent to organizations for those that do not complete the survey. Email reminders will be sent two weeks, one month, and two months after the initial email if the potential respondent does not compete the survey.

Where possible, data from the 2015 survey will be combined with data from the 2020 survey. Analyses will include completeness (non-response rates per item) as well as frequency of item responses for awareness, intentions, and provision of PrEP, nPEP, and TasP will be assessed for all respondents combined. Frequency and differences in item responses will be analyzed for relationship to CBO characteristics (e.g., clinic CBOs vs non-clinical). Frequency and differences in item responses will be analyzed across survey years. We will perform multivariable analysis as needed (to assess interactions between time and type of CBO).

Electronic data will be immediately downloaded and stored in a CDC CSV file that is password protected and encrypted (even at rest). Any changes to the electronic database are audited by systems controls to identify who made the change, when, and what change was made.

Exhibit 2.1: Overview of Key Variables

CBO Survey (Att. 3)
• Awareness of PrEP, nPEP, and TasP • Intentions to prescribed PrEP, nPEP, and TasP • Provision of PrEP, nPEP, and TasP • Type of CBO (i.e., clinical or non-clinical) • Whether CBO has been designated as a Federally Qualified Health Center by the Health Resources and Services Administration • Whether CBO has received funding from CDC • Anticipated needs of the organization to support scale-up of PrEP, nPEP, and TasP • Client demographics • Barriers and facilitators to support the scale-up of biomedical HIV prevention interventions • Impact of novel coronavirus pandemic on services-

3. Use of Improved Information Technology and Burden Reduction

The survey will be created using a Survey Monkey platform, which is extremely user friendly. Participants will be sent a link to the web-based survey via email. Users will be able to move quickly through the survey on their computer. Most of the questions are closed ended questions and require little effort to answer- often just a simple mouse click. When participants are finished with the survey, they simply click "submit" and they are finished. Since it is electronic, they do not have to mail in a hard copy of their survey.

4. Efforts to Identify Duplication and Use of Similar Information

Literature searches were conducted to identify duplicate information collections. A previous version of this survey was conducted in 2015 by staff in the Division of HIV/AIDS Prevention. However, no other similar information is currently available for the purposes of this study. As far as we know, this information collection does not duplicate any existing efforts or surveillance activities. With the expansion of effective clinically-delivered HIV prevention methods (PrEP, nPEP, and TasP) and the advent of the Ending the HIV Epidemic initiative, CDC Division of HIV/AIDS Prevention needs to assess changes in interest, current capacity, and anticipated needs of community-based organizations for engagement with these interventions as part of their HIV prevention services. Although research exists on the provision of PrEP, nPEP and TasP, there is not any information on changes in the willingness and capacity of CBOs to provide these or related services. There is no information on whether previously identified obstacles continue to hinder CBOs' ability to provide these services. Also, there is limited research on what tools and resources CBOs would need to help assist clients to effectively access and use these new HIV prevention methods to end the HIV epidemic.

5. Impact on Small Businesses or Other Small Entities

Some of the community health centers or other CBOs may be considered small businesses or entities. One identified respondent from each organization (community health centers and other CBOs) will receive an e-mail (**attachment 4**) with a link to the survey website (created with the CDC Survey Monkey license). The email will instruct the respondent (one executive level staff member or one client service provider) to complete the survey. Participation in the survey will have minimal impact on the CBO as we are requesting one staff member from the organization to complete the survey. All responses will be aggregated to estimate frequencies, means, and counts of responses to survey questions. The survey will take approximately 30 minutes to complete, thus participation in the survey will not have a major impact on the normal operations of the CBO and limited burden on the individual completing the survey on behalf of the organization (**attachment 5a, 5b**).

6. Consequences of Collecting the Information Less Frequently

The activities involve a one-time collection of data. There are no legal obstacles to reducing the burden. Participants will complete the web-based survey one time.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A 60-day federal register notice to solicit public comments was published in the Federal Register on Monday, March 9, 2020, Vol. 85, No. 46, page #13656 (**attachment 2)**. CDC received no comments.

There were no consultations outside of the agency.

9. Explanation of Any Payment or Gift to Respondents

Survey participants will not receive token of appreciation funds. No incentives will be provided.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The CDC Privacy Office has determined that the information collected under this request will include personally identifiable information (PII) covered by the Privacy Act such as the name and email address (**attachment 7**). This collection of PII is covered under a CDC System of Records (SORN) # 09-20-0161 Records of Health Professionals in Disease Prevention and Control Training Programs. This is an organizational assessment and does not involve confidentiality issues for respondents. CDC will collect data via web survey using Survey Monkey. Phone calls will be made to each CBO to elicit interest in participating in the survey. If interested, one respondent will be identified per CBO, one executive level staff member or one line staff client service provider. Since the focus of the survey is on the characteristics of the organizations, respondents will not be asked about their personal demographic variables (e.g., age, gender, race, ethnicity, etc.). Respondents will be asked questions on client demographics (e.g., client populations served such as men who have sex with men). However, we will not collect identifying information on client populations served. An email with the survey link will be sent to each of these respondents for completion. In the database, individuals responding for organizations will only be entered by codes. Contact information for organizational respondents will be destroyed when the sample is complete, and any data queries have been addressed.

Contact information of nominated staff members will be destroyed after the survey is closed. All PII will be destroyed upon survey completion.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

This data collection request was determined to be exempt from IRB review and approval because the information collected is of the organization and not the individual. Participants will imply their consent by clicking the survey link and completing the survey. The survey does not contain PII and we will remove all potential identifiers from the data.

Sensitive Questions

The questions to be asked include no sexual orientation or gender identity questions and no especially sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

This data collection will include 330 individuals completing the survey on behalf of their organization (175 staff from funded CBOs and 155 staff from unfunded CBOs). The staff and supervisor interviews **(Attachment 5a, 5b)** will take 30 minutes to complete and will be administered once.

Exhibits 12.1 and 12.2 provide further details about how the estimates of burden hours and costs were calculated. The estimated annualized burden is 165 hours.

12A. **Estimated Annualized Burden Hours**

Exhibit 12.2: Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden Per Response (hours)	Total Burden Hours
Direct client service providers or executive-level staff member	Community Based Organization HIV Prevention Needs Assessment Survey (Att 5a, 5b)	330	1	30/60	165
				Total	**165**

12B. **Estimated Annualized Burden Costs**

The annualized costs to the participants are described in Exhibit 12.2. The United States Bureau of Labor Statistics' employment and wages estimates from May 2018 https://www.bls.gov/oes/current/oes_nat.htm#21-0000) were used to estimate the hourly wage rate for the "Community and Social Service Occupations" for the purpose of this GenIC request. The figure of $23.69 per hour was used as an estimate of average hourly wage for adults. Thus, the total anticipated annual cost to participants for collection of information in this project will be $3,908.85.

Exhibit 12.3: Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Community-based organization - Staff	Community Based Organization HIV Prevention Needs Assessment Survey (Att 5a, 5b)	165	$23.69	$3,908.85
				Total $3,908.85

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no other costs to participants for participating in this survey. There are no additional costs for record keepers as the principal investigator will keep records stored on a CDC network drive that is only accessible by the principal investigator.

14. Annualized Cost to the Federal Government

Exhibit 14.1 provides the annualized cost to the government, which totals $ 18,115.20 using the 2019 Atlanta locality salary schedule. Managing the project, collecting and analyzing the data, and generating assorted reports will require the expertise of one CDC staff member.

Exhibit 14.4: Annualized Cost to the Government (2019 scale)

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs	CDC, Principal Investigator (GS-11, 56.61 hr /320 hrs)	$18,115.20
	Subtotal, Direct Costs	**$18,115.20**
	TOTAL COST TO THE GOVERNMENT	**$18,115.20**

15. Explanation for Program Changes or Adjustments

This is a new information collection request (ICR).

16. Plans for Tabulation and Publication and Project Time Schedule

Data collection will occur between October 2020 – May 2021, analyses will be carried out in June-July 2021, and the final dataset and report will be submitted in October 2021. The project timeline is detailed in exhibit 16.1.

Exhibit 16.5: Project Time Schedule

Activity	Time Schedule
Develop data collection tools, sampling and data plans, study protocol	November 2019 – February 2020; CDC project determination and protocol approval
OMB Submission	February 2020 – August 2020; OMB approval
Recruitment	1 month after OMB Approval (September 2020)
Data Collection	2–8 months after OMB Approval (October 2020 – May 2021)
Data analysis finalized	9–10 months after OMB Approval (June–July 2021)
Draft report and final report written	11–12 months after OMB approval (August–September 2021)
Final report disseminated	13–15 months after OMB Approval (October–November 2021)

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We do not seek approval to eliminate the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exemptions to the certification.

References

1. Dominguez, KL, Smith DK, Thomas V, Crepaz N, Lang KS, et al. Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposures to HIV—United States, 2016. 1-91.

2. Thigpen MC, Kebaabetswe PM, Paxton LA, et al; TDF2 Study Group. Antiretroviral preexposure prophylaxis for heterosexual HIV transmission in Botswana. N Engl J Med. 2012;367(5):423-434.

3. Baeten JM, Donnell D, Ndase P, et al; Partners PrEP Study Team. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. N Engl J Med. 2012;367(5):399-410.

4. Choopanya K, Martin M, Suntharasamai P, et al; Bangkok Tenofovir Study Group. Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial. Lancet. 2013;381(9883):2083-2090.

5. Grant RM, Lama JR, Anderson PL, et al; iPrEx Study Team. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. N Engl J Med. 2010;363(27):2587-99.

6. Cohen MS, Chen YQ, McCauley M, et al. Antiretroviral therapy for the prevention of HIV-1 transmission. N Engl J Med 2016;375:830-839.

7. Rodger AJ, Cambiano V, Bruun T, et al. Sexual activity without condoms and risk of HIV transmission in serodifferent couples when the HIV-positive partner is using suppressive antiretroviral therapy. JAMA 2016;316(2):171-81.

8. Bavinton BR, Pinto AN, Phanuphak N, et al. Viral suppression and HIV transmission in serodiscordant male couples: an inter¬national, prospective, observational, cohort study. Lancet 2018 Jul 16.

9. Rodger AJ, Cambiano V, Bruun T, et al. Risk of HIV transmission through condomless sex in serodifferent gay couples with the HIV-positive partner taking suppressive antiretroviral therapy (PARTNER): final results of a multicentre, prospective, observational study. [published online May 2, 2019]. Lancet http://dx.doi.org/10.1016/S0140-6736(19)30418-0.

10. Grant RM, Anderson PL, McMahan V, et al. Uptake of pre-exposure prophylaxis, sexual practices, and HIV incidence in men and transgender women who have sex with men: a cohort study. Lancet 2014;14:820-829.

11. Liu AY, Cohen SE, Vittinghoff E, et al. Preexposure prophylaxis for HIV infection integrated with municipal- and community-based sexual health services. [published online Nov 16, 2015]. JAMA Intern Med. doi:10.1001/jamainternmed.2015.4683.

12. McCormack S, Dunn DT, Desai M, et al. Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomised trial.[published online Sept 10, 2015] Lancet. http://dx.doi.org/10.1016/S0140-6736(15)00056-2.

13. Volk JE, Marcus JL, Phengrasamy T, et al. No new HIV infections with increasing use of HIV preexposure prophylaxis in a clinical practice setting. Clin Infect Dis 2015;61(10):1601-3.

14. Marcus JL, Hurley LB, Nguyen DP, et al. Redefining Human Immunodeficiency Virus (HIV) preexposure prophylaxis failures. Clin Infect Dis 2017;65(10):1768-1769.

15. Martin M, Vanichseni S, Suntharasamai P, et al. The impact of adherence to preexposure prophylaxis on the risk of HIV infection among people who inject drugs. AIDS 2015;29:819-24.

16. Department of Health and Human Services. Ending the HIV Epidemic: Counties, Territories, and States. https://files.hiv.gov/s3fs-public/Ending-the-HIV-Epidemic-Counties-and-Territories.pdf. Accessed July 25, 2019.