

# **Preexposure Prophylaxis (PrEP): Local Health Department Assessment**

OSTLTS Generic Information Collection Request  
OMB No. 0920-0879

## **Supporting Statement – Section A**

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- **Goal of the study:** Assess 1) the current level of engagement of local health departments (LHDs) in preexposure prophylaxis (PrEP) implementation, 2) the perceived role that LHDs have in PrEP implementation, and 3) the resource and support needs for potential future engagement in PrEP.
- **Intended use of the resulting information:** Inform CDC's activities to support the roles of LHDs in PrEP implementation to help achieve maximal impact in reducing new human immunodeficiency virus (HIV) infections.
- **Methods to be used to collect information:** Data will be collected using a web-based assessment tool.
- **The subpopulation to be studied:** 500 HIV/ sexually transmitted infections (STI) program managers located within 500 city/county LHDs, across 47 states and the District of Columbia.
- **How information will be analyzed:** Descriptive statistics such as frequency, percentage, and mean/median will be conducted for all participants and/or subgroups. Multivariable analysis methods (e.g., logistic regression) will be applied to assess correlates of current and planned engagement in PrEP implementation.

## Section A – Justification

### 1. Circumstances Making the Collection of Information Necessary

#### Background

This information collection is being conducted using the Generic Information Collection mechanism of the OSTLTS OMB Clearance Center (O2C2) – OMB No. 0920-0879. The respondent universe for this information collection aligns with that of the O2C2. Data will be collected from 500 HIV/STI program managers in 500 city/county health departments across 47 states in the US and the District of Columbia acting in their official capacities (see Attachment A).

The estimated number of new HIV infections has not declined in the US in more than 15 years, remaining at about 50,000 per year<sup>1</sup>. In specific subgroups, new infections are increasing, including young men who have sex with men nationally<sup>2</sup>, and in local communities among injection drug users<sup>3</sup> and heterosexuals demonstrating a need for additional effective HIV prevention methods. Preexposure prophylaxis (PrEP) is a new and highly effective HIV prevention method that involves the daily oral use of specific antiretroviral medications by HIV-negative individuals to reduce their risk of HIV infection. In clinical trials<sup>4-7</sup> and open-label studies<sup>8</sup> conducted by CDC, the National Institutes of Health, and research foundations, for both sexual and injection exposures, adherence to daily dosing reduces the risk of acquiring HIV infection by more than 90%. The U.S. Food and Drug Administration approved PrEP as an indicated use for the fixed-dose combination of tenofovir disoproxil fumarate and emtricitabine (brand name Truvada) in July 2012.<sup>9</sup> Based on FDA approval and the effectiveness demonstrated in trials and other research in preventing HIV infection, CDC

and the US Public Health Service issued the first comprehensive clinical practice guidelines for PrEP use with daily oral Truvada in May 2014<sup>10</sup>.

Communities across the United States are at varying stages of PrEP awareness and implementation, and many local health departments (LHDs) are considering what they could be doing to support PrEP implementation and how to go about doing it. There are a number of potential roles that LHDs could play in supporting PrEP delivery including raising community and provider awareness of PrEP as a supported intervention; working with community partners to identify persons who would benefit from its use and linking them to care sites trained to provide it; and monitoring access, utilization, and its impact on new infection rates. However more work is needed to identify, define, support, and advance these roles. PrEP is a new HIV prevention method and while the science from clinical trials and open-label studies demonstrate its effectiveness and potential impact, implementation science to guide real world activities is lacking.

The purpose of this assessment activity aims to help fill this void assessing 1) LHD's current HIV/STI prevention program structure and services; 2) the current level of engagement of LHDs in PrEP implementation, 3) the perceived role that LHDs have in PrEP implementation, and 4) the resource and support needs for potential future engagement in PrEP. The findings are critical to identifying opportunities, strategies, and mechanisms for supporting LHDs to incorporate PrEP into their HIV prevention efforts and advancing PrEP implementation. The information collected through this assessment will be used to support and promote LHD engagement in PrEP implementation, as well as overall HIV prevention practice, and to inform our federal and state programmatic activities.

This information collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241). This information collection falls under the essential public health services of development of policies and plans that support individual and community health efforts, and linking people to needed personal health services and assure the provision of health care when otherwise unavailable.<sup>11</sup>

- 1. Monitoring health status to identify community health problems
- 2. Diagnosing and investigating health problems and health hazards in the community
- 3. Informing, educating, and empowering people about health issues
- 4. Mobilizing community partnerships to identify and solve health problems
- 5. Development of policies and plans that support individual and community health efforts
- 6. Enforcement of laws and regulations that protect health and ensure safety
- 7. Linking people to needed personal health services and assure the provision of health care when otherwise unavailable
- 8. Assuring a competent public health and personal health care workforce
- 9. Evaluating effectiveness, accessibility, and quality of personal and population-based health services
- 10. Research for new insights and innovative solutions to health problems

## Overview of the Information Collection System

Data will be collected via a web-based questionnaire (programmed using Qualtrics®) allowing respondents to complete and submit their responses electronically (**see Att. B—Instrument: Word version and Att. C—Instrument: Web version**). The web-based instrument will be used to gather information from HIV/STI program managers at LHDs regarding their role in, and current or future activities supporting, PrEP implementation for HIV prevention. This method was chosen to reduce the overall burden on respondents. The information collection instrument was pilot tested by 6 public health professionals. Feedback from this group was used to refine questions as needed, ensure accurate programming and skip patterns and establish the estimated time required to complete the information collection instrument.

## Items of Information to be Collected

The online data collection instrument consists of 44 main questions of various types, including dichotomous (yes/no), multiple response, and open-ended. An effort was made to limit questions requiring narrative responses from respondents whenever possible. However, respondents will most likely complete a maximum of 30 questions at the most, since the instrument contains skip patterns that depend on whether respondents indicate that their health department is currently engaged in PrEP. The instrument will collect information on the following sections:

All respondents will complete Sections I and V.

- Section I: HIV Prevention Program Structure, Services, and Engagement in PrEP Implementation (9 questions)
- Section V: Concluding Questions (2 questions)

If respondents indicate that their health department is currently engaged in PrEP, they complete:

- Section II: Health Department Engagement in PrEP Implementation (11 questions)
- Section III: Next Steps for PrEP Implementation (3 questions)
- Section IV: Resource and Assistance Needs (5 questions)

If respondents indicate that their health department is currently NOT engaged in PrEP, they complete:

- Section II: PrEP Awareness, Knowledge, and Interest (7 questions)
- Section III: Potential Future Engagement in PrEP Implementation (3 questions)  
The questions in this section focus on what their health department could potentially do to support PrEP implementation. This information will help identify the most likely roles for local health departments in PrEP implementation and inform efforts to support health department decision-making about incorporating PrEP into existing HIV prevention education and services.
- Section IV: Resource and Assistance Needs (4 questions)  
The questions in this section are intended to help identify what resources and assistance their health department might benefit from, if they were to begin considering how to incorporate PrEP into prevention education and services.

## **2. Purpose and Use of the Information Collection**

The purpose of this assessment is to assess 1) LHD's current HIV/STI prevention program structure and services; 2) the current level of engagement of LHDs in PrEP implementation, 3) the perceived role that by LHDs have in PrEP implementation, and 4) the resource and support needs for potential future engagement in PrEP. This data collection will provide current information about the level of engagement by city/county health departments in supporting an HIV prevention method that has only recently been recommended for implementation by CDC and the US Public Health Service<sup>10</sup>. Data collected about current program structure will be used to assess whether differences in current engagement, perceived roles, and needs for future engagement can be categorized by program size, structure, and content.

The findings will be of critical importance to CDC in its efforts to encourage and assist LHDs to implement and scale-up PrEP to reduce the number of new HIV infections occurring each year throughout the US. The information collected through this assessment will be used to support and promote LHD engagement in PrEP implementation, as well as overall HIV prevention practice, and to inform our federal, national, and state programmatic activities.

## **3. Use of Improved Information Technology and Burden Reduction**

Data will be collected via a web-based questionnaire allowing respondents to complete and submit their responses electronically. This method was chosen to reduce the overall burden on respondents. The information collection instrument was designed to collect the minimum information necessary for the purposes of this project (i.e., limited to 44 main questions).

## **4. Efforts to Identify Duplication and Use of Similar Information**

We conducted a literature search using Google Scholar and PubMed to identify any prior published data collections from STI/HIV program managers about LHD PrEP activities or roles and found none. PrEP as an HIV prevention method has only recently been recommended for implementation by CDC and the US Public Health Service. This information collection is the first of its kind.

## **5. Impact on Small Businesses or Other Small Entities**

No small businesses will be involved in this information collection.

## **6. Consequences of Collecting the Information Less Frequently**

This request is for a one time information collection. There are no legal obstacles to reduce the burden. If no data are collected, CDC will be unable to:

- Know the level of engagement, or interest and resources needed for future engagement, in supporting PrEP implementation by local and city health departments.

- More effectively and successfully introduce and scale up of PrEP services to reduce the number of new HIV infections occurring in the US.
- Effectively support city/county health departments in this new HIV prevention effort.

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

There are no special circumstances with this information collection package. This request fully complies with the regulation 5 CFR 1320.5 and will be voluntary.

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

This information collection is being conducted using the Generic Information Collection mechanism of the OSTLTS OMB Clearance Center (O2C2) – OMB No. 0920-0879. A 60-day Federal Register Notice was published in the Federal Register on October 31, 2013, Vol. 78, No. 211; pp. 653 25-26. No comments were received.

CDC partners with professional STLT organizations, such as the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), and the National Association of Local Boards of Health (NALBOH) along with the National Center for Health Statistics (NCHS) to ensure that the collection requests under individual ICs are not in conflict with collections they have or will have in the field within the same timeframe.

**9. Explanation of Any Payment or Gift to Respondents**

CDC will not provide payments or gifts to respondents.

**10. Assurance of Confidentiality Provided to Respondents**

The Privacy Act does not apply to this information collection. Local governmental staff will be speaking from their official roles and will not be asked, nor will they provide individually identifiable information.

This information collection is not research involving human subjects.

**10.1 Privacy Impact Assessment Information**

No individually identifiable information (IIF) will be collected.

**11. Justification for Sensitive Questions**

No information will be collected that are of personal or sensitive nature.

**12.**

**Estimates of Annualized Burden Hours and Costs**

Six public health professionals pilot tested the information collection instrument. In the pilot test, the average time to complete the instrument, including time for reviewing instructions, gathering needed information and completing the instrument, was approximately 22 minutes. Based on these results, the estimated time range for actual respondents to complete the instrument is 14 to 28 minutes. For the purposes of estimating burden hours, the upper limit of this range (i.e., 30 minutes) is used.

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) National Compensation Survey estimate for [job title] (<http://www.bls.gov/ncs/ocs/sp/nctb1349.pdf>). Based on DOL data, an average hourly wage of \$57.11 is estimated for all 500 respondents. Table A-12 shows estimated burden and cost information.

**Table A-12:** Estimated Annualized Burden Hours and Costs to Respondents

<b>Information collection Instrument: Form Name</b>	<b>Type of Respondent</b>	<b>No. of Respondents</b>	<b>No. of Responses per Respondent</b>	<b>Average Burden per Response (in hours)</b>	<b>Total Burden Hours</b>	<b>Hourly Wage Rate</b>	<b>Total Respondent Costs</b>
Preexposure Prophylaxis (PrEP): Local Health Department Assessment Instrument	HIV/STI Program Managers	500	1	30/60	250	57.11	14,278
	<b>TOTALS</b>	<b>500</b>	<b>1</b>		<b>250</b>		<b>14,278</b>

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

There will be no direct costs to the respondents other than their time to participate in each information collection.

**14.**

**Annualized Cost to the Government**

There are no equipment or overhead costs. Contractors, however, are being used to support development of the assessment tool, data collection, and data analysis. The only cost to the federal government would be the salary of CDC staff and contractors. The total estimated cost to the federal government is \$46,304. Table A-14 describes how this cost estimate was calculated.

**Table A-14:** Estimated Annualized Cost to the Federal Government



Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Average Cost
Medical epidemiologist (GS-14, step 10)	80	53.80	4,304
Contractor (NACCHO)	-	-	42,000
<b>Estimated Total Cost of Information Collection</b>			<b>46,304</b>

**15. Explanation for Program Changes or Adjustments**

This is a new information collection.

**16. Plans for Tabulation and Publication and Project Time Schedule**

Descriptive statistics such as frequency, percentage, and mean/median will be conducted for all responses to the web assessment questions. Cross-tabulations will be done for important subgroups (e.g. by region, types of engagement in PrEP). Multivariable analysis methods (e.g., logistic regression) will be applied to assess correlates of current and planned engagement in PrEP implementation. Data analysis will be conducted using STATA 12.1.

It is intended that a manuscript will be developed and submitted to a peer-reviewed journal for consideration for publication. Abstracts will be submitted for presentation of project findings at national conferences and meetings.

Project Time Schedule

- ✓ Design questionnaire ..... (COMPLETE)
- ✓ Develop protocol, instructions, and analysis plan ..... (COMPLETE)
- ✓ Pilot test questionnaire ..... (COMPLETE)
- ✓ Prepare OMB package ..... (COMPLETE)
- ✓ Submit OMB package ..... (COMPLETE)
- ☐ OMB approval ..... (TBD)
- ☐ Conduct assessment ..... (Assessment open 3 weeks)
- ☐ Code, quality control, and analyze data..... (2 weeks)
- ☐ Prepare reports ..... (4 weeks)
- ☐ Disseminate results/reports ..... (2 weeks)

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

We are requesting no exemption.

**18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

## LIST OF ATTACHMENTS – Section A

- Att. A Number of LHDs in sample by state
- Att. B Instrument Word version
- Att. C Instrument Web Version

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