

**Project PrIDE**

OMB No. 0920-NEW

Supporting Statement A

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### **Abstract**

- **Goal of the study:** The purpose of this project is to support 12 health departments in the United States to implement PrEP and Data to Care demonstration projects, prioritizing MSM and transgender persons at high risk of HIV infection and living with HIV infection.
- **Intended use of the resulting data:** To assist health departments in monitoring and evaluating their activities to help them develop, deliver, and refine successful HIV prevention and care interventions for MSM and transgender persons. These data are also used to report key program performance indicators to CDC to show whether the funded programs are efficient and effective in achieving their stated goals.
- **Methods:** CDC has established guidelines for monitoring and evaluation content. The funded health departments will determine how data are to be collected. Many grantees will use their own data system; however, data will be reported to CDC in a standardized format.
- **Subpopulation:** The population targeted for this project are MSM and transgender persons at risk for and living with HIV infection in the funded health departments.
- **How data will be analyzed:** Descriptive analyses will be conducted using appropriate statistical software (i.e. SAS) on data variables related to HIV prevention and care services (qualitative and quantitative) in attachments 3-5. Monitoring and Evaluation variables will be reported to CDC twice a year by all PrIDE grantees.

## **Section A. Justification**

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

The Centers for Disease Control and Prevention (CDC) requests a 3 year approval for a new information collection entitled "Project PrIDE" (PrEP Implementation, Data to Care & Evaluation). The project is intended to support 12 health departments in the United States to implement PrEP and Data to Care demonstration projects, prioritizing MSM and transgender

persons at high risk of HIV infection and living with HIV infection.

### **Background**

In August 2015, 12 health departments were funded to implement PrEP demonstration projects (Baltimore Department of Health, California Department of Public Health, Chicago Department of Public Health, Colorado Department of Health, Houston Department of Health and Human Services, Los Angeles County Public Health Department, Louisiana Department of Health, Michigan Department of Community Health, New York City Department of Health and Mental Hygiene, San Francisco Department of Public Health, Tennessee Department of Health, and Virginia State Department of Health). Five of the 12 were also awarded additional funds to implement Data to Care projects (Baltimore Department of Health, Chicago Department of Public Health, Houston Department of Health and Human Services, Los Angeles County Public Health Department, Louisiana Department of Health, and San Francisco Department of Public Health). Health departments that are funded under this cooperative agreement will be required to prioritize their services to MSM and transgender persons at high risk of HIV infection, particularly persons of color. PrEP services may also be provided to HIV-negative persons at substantial risk for HIV who are not MSM or transgender. Additionally, Data to Care services may be provided to persons

diagnosed with HIV infection and out of care, those who are in care but not virally suppressed, or those who have ongoing risk behavior who are not MSM or transgender.

The goals of PrIDE are consistent with the long-term goals of the National HIV/AIDS Strategy (NHAS) including reducing HIV incidence, increasing access to HIV care and optimizing health outcomes, and reducing HIV-related health disparities.

To evaluate the impact of PrIDE in the 12 jurisdictions, data will be collected from both existing CDC data sources and through new data collection activities. Existing CDC data sources that may be used for the evaluation are listed below, along with relevant OMB control numbers and expiration dates. Each of these data collection activities has received OMB approval.

**Table A-1-1: OMB Control Number and Expiration Date of Existing CDC Data Sources for PrIDE Evaluation**

System	OMB Control No.	OMB Expiration Date
National HIV Prevention Program Monitoring and Evaluation System Data (NHM&E)	0920-0696	02/28/2019
National HIV Surveillance System (NHSS)	0920-0573	06/30/2019
National HIV Behavioral Surveillance System (NHBS)	0920-0770	03/31/2017
Medical Monitoring Project (MMP)	0920-0740	06/30/2018

In addition to the above OMB approved information collections, this new information collection request (ICR) is requested to assist with the PrIDE evaluation. This new data collection activity will occur in all 12 PrIDE jurisdictions and is designed to monitor process and outcome indicators and supplement existing HIV surveillance data already being collected via CDC data systems in these cities. Information about client demographics and services provided will be collected. These quantitative data will be collected semiannually for PrIDE program monitoring and evaluation (M&E) (**Attachment 3 and Attachment 4**).

Performance Progress Reports are required for all CDC-funded cooperative agreements. Qualitative information on program implementation, successes, challenges, anticipated changes, lessons learned, and best practices will be collected (**Attachment 5**).

Synthesizing data collected through this new data collection activity with data collected through existing CDC data sources will allow CDC staff to evaluate PrIDE and make a broad statement about its success. The standardized variables will assist Health Departments in monitoring and evaluating their activities to help them develop, deliver, and refine successful HIV prevention interventions. These data are also used to report key program performance indicators to CDC to show whether the programs

implemented or supported are efficient and effective in achieving their stated goals. These data will supply program managers with service-level information regarding intervention processes (e.g., who delivered what to whom, how many, where, and when) and aggregate-level information (e.g., client demographics, behavioral risk factors, exposure to services, verified referrals into other services, and changes in risk-behaviors for selected interventions) for monitoring and enhancing local HIV prevention programs. Much of these data are collected by community-based organizations and health departments using locally developed forms as part of their usual business process. Furthermore, data collected and reported will be used to inform progress toward meeting goals and objectives of the National HIV/AIDS Strategy.

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

The purpose of this project is to support state and local health departments to develop and implement demonstration projects for provision of comprehensive HIV prevention and care services for MSM and transgender persons of within their jurisdiction.

The M&E data variables provide a comprehensive, yet parsimonious, standardized set of program data variables essential to monitoring and evaluating HIV prevention programs in funded jurisdictions. When used for assessing outcomes associated with CDC-funded HIV prevention program activities, the



results of analyses of M&E data will enable CDC to track program activity, identify best practices, and assist grantees in redesigning interventions that do not accomplish stated goals. CDC will use the M&E data with surveillance and research data, for the following purposes:

- Disseminate rapid feedback reports to the grantees showing progress toward NHAS goals and grantee comparison to other grantees
- Assess CDC HIV budget allocations with respect to prioritized risk populations at the jurisdiction level and allocations to key program areas
- Identify gaps in HIV prevention service provision
- Respond to data requests from Congress, the administration, and other interested parties
- Assess the extent to which HIV prevention programs have reached their target population
- Assess the annual performance of CDC and its grantees in meeting priority goals and objectives

The M&E data variables have been developed with extensive input from representatives of health jurisdictions (see **Attachment 8**) and the partner branches the Division of HIV/AIDS Prevention (NCHHSTP/CDC). The data variables are based on HIV prevention business processes and sound scientific approaches to

HIV prevention. The M&E data variables will cover the activities required for the project.

Collection of the M&E data will supply program managers with service-level information regarding intervention processes (e.g., who delivered what to whom, how many, where, and when) and aggregate-level information (e.g., client demographics, utilization of services, and verified referrals to other services) for monitoring and enhancing local HIV prevention programs. See **Attachment 3** for the list of PrIDE data elements.

Without these data, CDC would be unable to determine what is being done with the funding it provides, what populations are being served, what services are being provided, or which programs are having the most effect in preventing HIV and supporting HIV care. It would be unable to account to the administration, Congress, or other stakeholders for the proper use of public money or provide transparency for the programs it funds.

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

Each of the 12 PrIDE health department representatives/respondents will determine how data are to be collected. There are no required format, forms or other data collection instruments.

All PrIDE data are to be submitted to CDC electronically. While grantees may collect the data by whatever means they

choose, data must be submitted to CDC electronically using CDC provided Microsoft Excel templates or EvaluationWeb as appropriate.

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

Within CDC, there are some complementary systems already in place that contain similar data elements to the PrIDE evaluation:

- National HIV Prevention Program Monitoring and Evaluation System Data (NHM&E) (OMB # 0920-0770, exp. 2/28/2019)
- National HIV Surveillance System (NHSS) (OMB #0920-0740, exp. 6/30/2019)

Although data collected through NHM&E and NHSS are similar to the data that will be collected through PrIDE, there is additional information to be collected through the PrIDE data collection activity such as Pre-exposure prophylaxis and data-to-care services that is necessary for conducting the PrIDE evaluation. Furthermore, the existing NHM&E and NHSS data collections cannot be modified to satisfy the needs of the proposed project.

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

No small businesses will be involved in this activity.

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

Respondents are asked to submit quantitative data to the CDC on a semiannual basis consistent with all other HIV prevention program data reporting requirements. Less frequent data submission could result in missed opportunities to correct potential issues with program implementation or data collection

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

This request fully complies with the guidelines of 5 CFR 1320.5.

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

A 60-day notice to solicit public comments was published in the *Federal Register Vol. 81, No. 213 / Thursday, November 3, 2016, Page 76592 (Attachment 2)*. CDC has received 2 comments (**Attachment 2a**). CDC's standard response was sent.

CDC developed the PrIDE data variables with feedback from state health departments (**Attachment 8**). Developing the PrIDE data variables has been a collaborative process. There was extensive consultation on revisions to the variables during the grantee orientation meeting, site visits, and a series of conference calls. Additional consultations, workshops, and web-conferences will occur as needed.

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

No payments or gifts will be provided to respondents.

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

The CDC NCHHSTP Associate Director of Science Office reviewed this submission and determined that the Privacy Act is not applicable to this information collection. Health departments may collect identifiers (name, address, etc.) on clients who receive HIV prevention services, including HIV testing. The Privacy Act is not applicable to the client-level data because the information will become a part of the health departments' already established record systems; moreover, its availability and use will be limited to the provision of services at the local level.

CDC will not receive any personally identifiable information from respondents. No personally identifiable information will be collected or stored in the data collection system, including respondent contact information, date of birth.

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

### IRB Approval

The approved Project Determination Form (**Attachment 6**) indicates that this activity is not human subjects research and

that the primary intent is to evaluate a public health program. Data collected through this project will be used for program monitoring and evaluation purposes only. Because this project does not involve human subjects research, the protocol will not be reviewed by CDC's IRB.

### Sensitive Questions

Some of the client-level data to be collected are highly sensitive. HIV can be transmitted from person to person through sexual contact and the sharing of HIV contaminated needles and syringes. These modes of transmission necessitate the collection of sensitive data regarding sexual practices as well as alcohol and drug use. Because collection of these data will be used to provide improved HIV prevention services to high-risk populations, to enhance HIV prevention programs at the local level, and to reduce high-risk behaviors in persons most likely to acquire or transmit HIV, specific information about client demographics and client risk profiles is essential to designing appropriate interventions and programs and to monitoring and evaluating these programs.

This data collection also includes race and ethnicity questions, which may also be viewed as sensitive by some respondents, for use in data analysis (e.g., designing and evaluating programs, as discussed above). The variables are described in **Attachment 3**.

## **12. Estimates of Annualized Burden Hours and Costs**

The total estimated annualized hourly burden anticipated for all data collections would be 1104 hours.

It is estimated that each of the 12 PRIDE health department respondents will target 200 participants per year for a total of 2,400 respondents. The participants will be recruited via agencies in contract with the health departments. The contracted agencies will administer a local screening tool based on variables in **Attachment 3**, with a completion time of 25 minutes. The contracted agencies will then enter the data collected (some may choose to use handheld devices which eliminates data entry) and upload the data to the health department for each of the 200 patients. This is estimated at 5 minutes per respondent). The total annual estimated burden for screening, questionnaire response, and data upload is 1000 hours (**Attachment 3**).

After upload to the health department, the health department will be responsible for aggregating the data received from the individual contract agencies in preparation for data submission to CDC with an estimated data management burden of 20 minutes. The health department grantees will submit M&E data to CDC twice a year using EvaluationWeb® and/or entering into Excel templates as appropriate. The estimated total annual burden is 8 hours (**Attachment 4**). Awardees are expected to electronically

transmit files that conform to NCHHSTP Data security confidentiality guidelines (**Attachment 7**).

Additionally, the 12 PrIDE-funded health departments will also be required to submit annual performance progress reports on their success, challenges and anticipated changes. It is estimated that the 12 health departments will take about 8 hours to enter the data with a total of 96 annualized burden hours (**Attachment 5**).

The calculations for annualized burden are derived from the contracted agencies working with the health department and time needed to search the various local tracking databases or entering into Excel templates as appropriate for existing records, gather and maintain the data, complete the collection of records, and review the information prior to submission to CDC.

**Table A.12-A. Estimated Annualized Burden Hours**

<b>Type of Respondents</b>	<b>Form Name</b>	<b>Number of Respondents</b>	<b>Number of Responses per Respondent</b>	<b>Average Burden per response (in hours)</b>	<b>Total Burden Hours</b>
Clients	Data Elements (att 3)	2400	1	25/60	1000
Health Departments	Data Management Upload (att 4)	12	2	20/60	8
Health Departments	Performance Progress Report (att 5)	12	1	8	96
Total					1104



## B. Annualized Cost to Respondent

Annualized cost to respondents for the burden hours is provided in Exhibit 12.B. The estimate of hourly wages were obtained from the United States Department of Labor's Bureau of Labor Statistics and is based on the May 2015 National Occupational Employment and Wage Estimates for all occupations ([http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm) ). The estimate for health department staff is based on the 2016 OPM general schedule for a GS-10 step 3 (50,302 or \$24.10/hour). (<https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2016/general-schedule/>)

**Table A.12-B. Annualized Cost to Respondents**

Type of Respondents	Number of Respondents	Form Name	Number of Responses per respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Clients	2400	Data Elements	1	1000	23.23	\$23,230
Health Departments	12	Data Management	2	8	24.10	\$192.80
Health Departments	12	Performance Progress Report	1	96	24.10	\$2,313.60
Total						\$25,736.40

**Source:**

<http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2015/ATL.pdf>

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

There are no costs to respondents that are not supported by CDC funding under the program announcement beyond usual and customary business practices that would be carried out even if PrIDE data collection were not required. The conditions of the cooperative agreements that CDC awards for HIV prevention programs require recipients to conduct evaluation of major program activities, interventions, and services, including data collection on interventions and clients served. Program announcements specify that a portion of the funding is to be used for evaluation activities, including data collection. Although

the data previously collected by health jurisdictions varied widely from state to state and program to program, it is the usual and customary business practice of the grantees to gather and maintain HIV prevention program data, complete the collection of records, and review the information prior to submission to CDC. Since the collection of data is a routine and customary practice, grantees that collect PrIDE data should incur little or no net additional costs to respond to this data collection.

#### **14. Annualized Cost to the Federal Government**

The annualized cost to the government is \$77,037.50. The PrIDE data collection is a three-year project. For the purposes of this submission, a three year life expectancy has been used to estimate the annualized cost to the government.

CDC supports costs for HIV prevention program cooperative agreements using funds budgeted for these purposes. Additional expenses will be incurred by CDC for training grantees, providing technical assistance, monitoring and analyzing the submitted PrIDE data, and generating assorted reports. Total costs for these activities, using the Atlanta locality salary schedule, are estimated at \$77,037.50 annually (see table below).

Monitoring, analyzing, and reporting the PrIDE data are projected to require the expertise of one health scientist half time and one data analyst half-time. The health scientist would

be at the pay scale of GS-13 step 5 (\$83,694) and the data analyst would be at the pay scale of GS-12 step 5 (\$70,381).

**Table 14.A Annualized Cost to the Government**

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC Evaluator (Health Scientist, GS-13 (step 5), .50 FTE)	\$41,847.00
Data Management	CDC Data Analyst (Data Analyst, GS-12 (step 5), .50 FTE)	\$35,190.50
	Subtotal - Direct Costs to the Federal Government	\$77,037.50
	TOTAL COST TO THE GOVERNMENT	\$77,037.50

Source:

<https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2016/GS.pdf>

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

This is a new data collection.

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

**Schedule**

Data collection will be conducted during the 3-year period after OMB approval. M&E data will be submitted to CDC on a semiannual basis (once as an M&E report alone and once as part of the larger annual progress report). Data analysis will occur within 12 months of final data collection. A data management and analysis plan will be in place prior to data collection. The plan will be in accordance with the CDC Plan for Increasing Access to

Scientific Publications AND Digital Scientific Data Generated with CDC Funding document.

<b>Activity</b>	<b>Time Schedule</b>
Data collection begins	June, 2017. (within 1 month of OMB approval)
Data submission to CDC	Bi-annually
Initial data analysis	Within 6 months of OMB approval
Data collection ends	33 months after OMB approval
Final Analysis begins	33 months after OMB approval
Dissemination of results	40 months after OMB approval

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

CDC is not seeking approval to not display the expiration date.

**18. Exceptions to Certification for Paperwork Reduction Act (PRA)**

**Submissions 5CFR 1320.3(h)(1)-(10)**

There are no exceptions to the certification.