Request for Sub-collection Under the
Approved Generic ICR: Formative Research and Tool Development
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Title:

DSTDP Assessment of STD clinic users

Supporting Statement A

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ATTACHMENTS

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Attachment 2: Consent/Assent Form

DSTDP Assessment of STD clinic users

A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) proposes to conduct a formative research study with field testing of a paper-based survey. The survey is a tool that is being developed to monitor characteristics and needs of users of federally-funded sexually transmitted disease (STD) clinics before, and at several time intervals after, implementation of the Patient Protection and Affordable Care Act (ACA) of 2010.[1] The findings of the survey will be used to assure the provision of quality STD care that meets the needs of STD clinic users in the context of a changing U.S. healthcare landscape.

In the United States, 23% of men and 20% of women aged 18-64 years were uninsured in 2011.[2] Ongoing changes in the U.S. healthcare system offer opportunities to improve access to and utilization of clinical services. The ACA expands insurance coverage, consumer protections, and access to primary care and emphasizes prevention in addition to care and treatment.[1] However, the Congressional Budget Office estimates that at least 10% of the nonelderly U.S. population will remain uninsured after full implementation of the ACA.[3] It is important to understand access and utilization patterns of men and women who seek health services in STD clinics. Several important healthcare services are provided at STD clinics that protect the reproductive and sexual health of men and women, prevent STD transmission in the community, and prevent HIV transmission. These services include STD testing and treatment, STD partner services, counseling, HIV testing and linkage to care for those who are HIV-infected, and STD and HIV prevention activities for the community.

Previous studies have found that patients prefer to be treated at STD clinics for several reasons, including confidentiality concerns and the convenience of this venue with its expert STD care. Understanding the characteristics of persons who utilize STD clinics such as their health insurance status, and their reasons for selecting this venue rather than other types of venues, will be useful in understanding and refining the role of STD clinics as part of the healthcare safety net in the United States. It will also provide information to ensure that federally-funded health departments and clinics appropriately serve its clients, by providing clinics with feedback to help them provide the highest quality of services to meet the needs of their clients.

We will field test a brief survey instrument with 4,400 STD clinic users. Data will be gathered over a 2-month period. These data will be used to further develop and refine the survey instrument so it can be used again at future time points to monitor changes in STD clinic users.

A.1.2 Privacy Impact Assessment

Information will be collected on a paper-based survey form, and will not include any personally identifiable information (PII). The implementation of surveys in STD clinics will involve the National Association of County and City Health Officials (NACCHO) contracting a survey vendor. CDC will not receive any PII. Any PII collected by the contractor will be removed from data to be delivered to CDC. No surveys will be directed at children younger than aged 13 years. All completed surveys will be stored in separate locked file cabinets in locked offices in a secured facility. At the completion of the data collection period, all survey forms will be delivered to CDC via FedEx. All survey forms will be accessible only to fully authorized personnel, and maintained and protected to the extent allowable by law.

A.1.3 Overview of the Data Collection System

NACCHO will implement all phases of this study. The type of information collection activities included in this sub-collection request is field testing of a brief paper-based survey (N=4,400). Data will be collected over a 2-month period.

A.1.4 Items of Information to be Collected

The proposed study will collect information from users of STD clinic on the following: reasons for choosing care at the STD clinic, options for STD care if the clinic did not exist, access to other healthcare venues, and willingness/ability to use health insurance to pay for STD care at the clinic. Additionally, information will be collected on STD clinic users' sociodemographic characteristics and sexual orientation. A copy of the survey instrument is in **Attachment 1**.

A.1.5 Identification of Web Site(s) and Web Site Content Directed at Children Under 13 Years of Age

This information collection does not involve Web sites or Web content directed at children younger than aged 13 years.

A.2 Purpose and Use of the Information Collection

The purpose of this data collection is to conduct field testing of a new assessment tool, also referred to as pilot testing. The objective of field testing is to evaluate the ability of this survey instrument to assess a potentially changing population of STD clinic users over time. The data collected will serve as a test of the feasibility of administering surveys to clinic users in STD clinic waiting rooms and be used to refine and revise the survey for future data collections to monitor STD clinic use after full implementation of the ACA. It will also be used to inform the development of additional assessments of client needs, and interventions to assure access to STD clinics and quality of services at these clinics. A copy of the field testing survey instrument is provided in **Attachment 1**.

CDC and NACCHO will disseminate the study results to each clinic site, and to the public through reports prepared by CDC and peer-reviewed journal articles where appropriate. All releases of information will be reviewed and approved by CDC.

A.3 Use of Improved Information Technology and Burden Reduction

Field testing will utilize paper-based surveys to be self-administered in STD waiting rooms. The use of improved information technology, such as portable computing devices, is not feasible or affordable because the survey will likely be completed by multiple clients simultaneously in the STD clinic waiting room. Completion of the paper-based survey will require 10 minutes or less during one sitting, thus minimizing participant burden. The use of a paper-based survey for data collection will also help to reduce interviewer biases and minimize social desirability.

A.4 Efforts to Identify Duplication and Use of Similar Information

The National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) has verified that there are no other information collections that duplicate the study types included in this request.

A.5 Impact on Small Businesses or Other Small Entities

This collection request does not involve burden to small businesses or other small entities.

A.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.

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

This data collection request fully complies with the regulation 5 CFR 1320.5.

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

The Federal Register notice was published for the Generic Clearance 0920-0840 on August 2, 2012 (Vol. 77, No. 149, pp. 4604-46095. There were no comments received from the public.

A.9 Explanation of Any Payment or Gift to Respondents

Because the survey will require minimal time to complete, and will be administered while clients are waiting in the STD clinic waiting room for their clinical encounter, no incentive will be provided.

A.10 Assurance of Confidentiality Provided to Respondents

CDC and NACCHO will receive the paper-based surveys for data entry and analysis, and these survey instruments will not contain any PII.

Survey vendors contracted by NACCHO will approach participants in the waiting area of the STD clinic after they have registered for care, and invite them to participate in the survey. The vendor will read an informed consent script to a potential participant (see **Attachment 2**), and verbal informed consent will obtained. Only participants who provide verbal informed consent will be given the survey to complete. An information sheet that contains the same content as the informed consent script will also be given to each participant (**Attachment 2**). The vendor will track those who were approached and those who provided verbal informed consent using non-identifiable designations (i.e., S001, S002, S003, etc.).

Participants will be assured that their answers to survey questions (see **Attachment 1**) will not be shared with anyone outside the research team and that their names will not be included on the survey instrument (see **Attachment 2**). Participants will be told that the information obtained from all of the surveys will be combined into a summary report so that details of individual questionnaires cannot be linked to a specific participant.

The survey vendor will collect completed surveys from participants and place them in a locked cabinet in a secure location for storage until completion of the data collection period at that site. The contracted survey vendor will take the following security measures to ensure separation between a participant's identity and their survey data: no participant name, address, e-mail address, telephone number, or any other kind of PII will appear on the survey. No photocopies will be made of any survey.

The vendor will maintain a worksheet of persons approached (designated as S001, S002, S003, etc.), those who provided verbal consent, and those who completed the survey, all stratified by sex. The survey vendor will retain study records for the duration of the study, and after final delivery of paper surveys to CDC, the vendor will destroy all study records upon request. Once this information is destroyed, the survey vendor will be unable to supply or access it for any reason, even at the request of CDC.

Surveys with no PII from all 22 collection sites will be delivered to CDC by FedEX. CDC maintains restricted access to all data preparation areas (i.e., receipt, data entry, and analyses). Data files will be accessible to designated CDC staff on a "need-to-know" basis only. Data from surveys will be entered in a proprietary database by CDC, and individual surveys will be assigned an identification number upon data entry by CDC. Although these data are not encrypted, once inside the firewall, they will be stored in a relational database protected by several layers of intrusion detection and access control.

A.11 Justification for Sensitive Questions

The survey (see **Attachment 1**) asks questions of a sensitive nature including questions related to reasons for visiting the STD. This measurement of sensitive STD healthcare seeking questions is necessary to adequately assess the topic area.

The survey also includes questions about sexual orientation. These questions are necessary to assess the needs of clients of federally-funded health department STD clinics, and will help assure that these clinics appropriately serve all their clients.

All participants will be assured that the information will be used only for the purpose of this research and will be kept private to the extent allowable by law.

A.12 Estimates of Annualized Burden Hours and Costs

A.12.A Estimated Annualized Burden Hours

The total annualized response burden is estimated at 733 hours. Field testing will be conducted using a paper-based survey of 4,400 men and women who utilize STD clinics. At each of 22 STD clinics in U.S. cities across the United States, 100 men and 100 women will be asked to complete the survey. The survey is expected to take 10 minutes to complete.

Exhibit A.12.A Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden Per Response (in Hours)	Total Burden Hours
STD Clinic Users	Survey	4,400	1	10/60	733
Total					**733**

A.12.B Estimated Annualized Burden Costs

The annualized costs to the respondents are described in Exhibit A.12.B. We do not know what the wage rate category will be for the selected participants (or even whether they will be employed). We used $21.74 per hour as an estimate of average hourly wage rate across the country for the general public (United States Department of Labor, Bureau of Labor Statistics May 2011, http://www.bls.gov/oes/current/oes_nat.htm#00-0000). The estimated annual cost to participants for the collection of information will be $16,262.

Exhibit A.12.B Estimated Annualized Burden Costs

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost

Survey	733	$21.74	$ 15,935
Total	**733**		**$15,935**

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

There are no costs to respondents or record keepers.

A.14 Annualized Cost to the Federal Government

One CDC Technical Monitor will be responsible for obtaining CDC approvals, providing project oversight, analysis of data, and dissemination of the results. The contractor's costs are based on estimates provided by the contractor who will carry out the data collection activities. With the expected period of performance (**Exhibit A.4**), the annual cost to the federal government is estimated to be $386,114 (**Exhibit A.3**). This is the cost estimated by NACCHO, and includes the estimated cost of coordination with CDC and data collection.

Exhibit A.14 Estimates of Annualized Cost to the Government

Expense Type	Expense Explanation	Annual Costs
CDC oversight of contractor and project	10% of FTE: GS-14 Medical Epidemiologist	$11,114
Data collection	Labor hours and ODCs	$375,000
Total		**$386,114**

CDC: Centers for Disease Control and Prevention; FTE: full-time equivalent; ODC: other direct cost

A.15 Explanation for Program Changes or Adjustments

Not applicable: This request is for a sub-collection under a generic approval.

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

The key events and reports to be prepared for this study are listed in **Exhibit A.4**.

Exhibit A.4 `Project Time Schedule`

Activity	Time Schedule
Conduct paper-based surveys	1 month after OMB approval
Submit report	4 months after OMB approval

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

The OMB expiration date will be displayed.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References

1. Patient Protection and Affordable Care Act Health-Related Portion of the Health Care and Education Reconciliation Act of 2010. 2010. Accessed February 25, 2013, at http://housedocs.house.gov/energycommerce/ppacacon.pdf.

2. Current Population Survey (CPS) Table Creator. 2007. Accessed February 25, 2013, at http://www.census.gov/cps/data/cpstablecreator.html.

3. CBO's February 2013 estimate of the effects of the Affordable Care Act on health insurance coverage. 2013. Accessed February 25, 2013, at http://www.cbo.gov/sites/default/files/cbofiles/attachments/43900_ACAInsuranceCoverageEffects.pdf.

4. Felsenstein D. A universal health insurance mandate does not equate to universal coverage for STI clinic patients (C3.3). At: National STD Prevention conference; 2012 March 14, 2012; Minneapolis; 2012.

5. Celum C. L., Bolan G., Krone M., Code K., Leone P., Spaulding C., et al. Patients attending STD clinics in an evolving health care environment. Demographics, insurance coverage, preferences for STD services, and STD morbidity. Sexually transmitted diseases 1997;24:599-605.