Request for Sub-collection Under the
Approved Generic ICR: Formative Research and Tool Development
OMB No. 0920-0840

Assessment of STD Service Needs and Provisions

Supporting Statement A

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The goal of this generic information collection request is to conduct field testing of a new quality assessment tool, also referred to as pilot testing. The purpose of the patient portion of the survey is to assess STD service needs of persons attending STD clinics. The purpose of the administrative portion of the survey is to field test a tool for clinic staff that will assess clinic operations and clinic capacity. The use of this survey tool will help determine the feasibility of using clinic surveys that identify gaps in STD care needs experienced by STD patients.

- The data collected in this project will be used to determine needs of patients attending STD clinics and the services provided by the STD clinics so as to enhance customer service for STD patients.

- The methods used to collect data for this surveys entails the use of two survey instruments. We will conduct field testing of two survey collection instruments. The first instrument is a five minute, paper-based questionnaire provided to patients attending STD clinics. The second instrument is a 10-minute, paper based questionnaire provided to STD clinic administrators. Data gathered from these two instruments will be tabulated.

- Respondents to this survey include 5,000 men and women who utilize STD clinics. At each of 25 STD clinics in U.S. cities across the United States, 100 men and 100 women will be asked to complete the survey while waiting to see a clinician. Additionally, the survey takers will administer a 10-minute in-person survey to administrators at each of the clinics to assess the types of STD services provided at the clinic.

- Data will be analyzed through simple tabulations of responses producing frequencies that can be cross-tabulated with other descriptive information collected in the survey.

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 entitled, “DSTDP Assessment of STD Clinic Users”, under the OMB approved Generic Clearance, “Formative Research and Tool Development” (OMB #0920-0840 exp. 1/31/2019). 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, the implementation of the Patient Protection and Affordable Care Act (ACA) of 2010. 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.

The Patient Protection and Affordable Care Act (ACA) was passed into law in 2010, but

not fully enacted until 2014. The original survey was conducted in 2013. This new survey will be able to measure healthcare access, use of services and needs of patients after the full implementation of the ACA. Furthermore, the healthcare landscape has continued to evolve beyond 2014, especially in terms of Medicaid expansion and the rising costs of care. Additionally, STD surveillance reports demonstrate that there is an increase in the number of diagnosed STDs across the country indicating higher demand for STD services. Therefore, it is important to conduct this survey now in order to determine how the needs of patients seeking STD care have changed since 2013, and to ensure that STD clinics are able to meet those needs. However, any comparisons cannot be generalized to the broader population utilizing the services of STD clinics and should be carefully characterized as formative.

This request is authorized by Title III – General Powers and Duties of the Public Health Service, Section 301 (241.)a. Research and investigations generally (**Attachment 1**).

It is estimated that in 2016, nearly 28 million people under the age of 65 remained uninsured in the United States and one main barrier for not having insurance was cost.[1] Ongoing changes in the U.S. healthcare system offer opportunities to improve access to and utilization of clinical services through the ACA expanding insurance coverage, consumer protections, and access to primary care and emphasizing prevention in addition to care and treatment.[2] However, the CBO estimates that by 2027, an additional 2 million people in the US will be uninsured [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.[4-6] Furthermore, recent research suggests that nearly half of patients attending STD clinics who are insured, are willing to use their health insurance for their visit, but barriers to using this insurance still exist at both the patient level as well as the clinic level.[7] 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. This information also provides insight into best methods to ensure that federally-funded health departments and clinics appropriately serve their clients, by providing clinics with feedback to help them provide the highest quality of services to meet the needs of their clients.

Previous surveys of STD clinic patients have made apparent the need to also collect data at the same time as the patient survey from the administrators of the clinics that the patients visit to understand any associations between clinic characteristics and patient preferences and needs.

We will field test a brief survey instrument with 5,000 STD clinic users and 25 STD clinic administrators. These data will be used to further develop and refine the survey instruments so they can be used again at future time points to monitor changes in STD clinic users and how STD health services are provided at clinics.

A 2. Purpose and Use of the Information Collection

The purpose of this data collection is to conduct field testing of a new quality assessment tool, also referred to as pilot testing. We will conduct field testing of this survey by using 5-minute paper-based surveys of 5,000 men and women who utilize STD clinics and a 10 minute survey of STD clinic administrators that will be conducted via interview. At each of 25 STD clinics in U.S. cities across the United States, 100 men and 100 women will be asked to complete the patient survey and one clinic administrator will be asked to complete the administrative survey.

The objective of field testing is to evaluate the feasibility of this assessment tool in order to evaluate 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 and any future changes to the US healthcare system. 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 patient survey instrument is provided in **Attachment 3a**.

The purpose of the administrative/staff portion of the survey (**Attachment 3b**) is to field test a tool for clinic staff that will assess clinic operations and clinic capacity. The use of this survey instrument will help determine the feasibility of using clinic surveys to identify gaps in STD care needs experienced by STD patients. A copy of the field testing survey instrument that will be completed during the 10-minute interview is provided in **Attachment 3b**.

The administrative staff portion of the survey will assess clinic quality by determining the scope of services available at the clinic and the capacity of the clinic to offer on-site same-day treatment for different STDs. Having this clinical information together with the data on patient characteristics will provide important and essential components for the goals of this formative work. We anticipate that this data collection will determine whether these instruments are optimal for repeated data collections in the future.

CDC and NACCHO will disseminate the study results to the public through reports prepared by CDC and through 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. Because of the setting and because the survey may be completed by multiple clients simultaneously as they wait to be seen by a clinician, use of improved information technology (such as portable computing devices) is not feasible or affordable. Completion of the survey on paper will require up to 5 minutes in 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 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 for data collection.

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 60-Day federal register notice was published for this collection on Thursday, June 25, 2015, Vol. 80, No. 122, pp. 36540 (See Att2). No comments were received.

A.9 Explanation of Any Payment or Gift to Respondents

No incentive will be provided.

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

The CDC Privacy Review Officer has assessed this package for applicability of 5 U.S.C. § 552a, and has determined that the Privacy Act applies to the information collection. CDC will receive the paper-based surveys for data entry and analysis, and these survey

instruments will not contain any PII. The administrator instrument contains no data on the person providing the information, and the patient instrument asks only sex, age in years, race, ethnicity, sexual orientation, and five-digit ZIP code.

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 and provide the informed consent form (see **Attachment 4**). After reading the informed consent, each participant must state "YES, I agree to participate" or "NO, I do not wish to participate." Only participants who state "YES" will be given the survey to complete. Survey vendors will sit down with the clinic administrator to complete the administrative portion of the survey.

Participants will be assured that their answers to survey questions (see **Attachment (3a & 3b)** will not be shared with anyone outside the research team and that their names will not be included on the survey instrument. 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 survey vendor will review completed surveys to determine if each participant met inclusion criteria, and whether exclusion criteria apply. The vendor will keep a running tally of the number of completed surveys that met enrollment criteria, 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 25 collection sites will be delivered to CDC by FedEX. Individual surveys will be assigned an identification number upon data entry by CDC. 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. Finally, data from surveys will be entered in a proprietary database. 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 Institutional Review Board (IRB) and Justification for Sensitive Questions

The materials and methods for this project have received IRB approval through NORC at the University of Chicago. The NORC IRB Registration Number is IRB00000967 and the expiration date for this approval is March 23, 2019.

The patient instrument asks questions of a sensitive nature including questions related to reasons for visiting the STD clinic. This measurement of sensitive STD healthcare seeking questions is essential to adequately assess the topic area. Further, the questions in this data collection, when compiled in aggregate form, are necessary to assess patient expectations and needs regarding key STD services and strategies.

The patient survey (see **Attachment 3a**) also includes questions about sexual orientation. These questions are necessary to determine the characteristics of the STD clinic patient population and to inform the development of patient-focused care that meets the needs of patients.

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.12.1 Estimated Annualized Burden Hours

We anticipate reaching 5000 patient participants providing 1 response each. The survey (3a) is expected to take 5 minutes for a total of 417 burden hours. We anticipate reaching 25 clinic staff participants providing 1 response each. The administrative survey (3b) is expected to take 10 minutes for a total of 4 burden hours. Exhibit A1 provides details of how this estimated was calculated.

Exhibit A.1 Annualized Burden Hours

Type of Respon-dent	Form Name	No. of Respon-dents	No. of Responses per Respon-dent	Average Burden Per Response (in Hours)	Total Response Burden Hours
General public	Patient Survey	5,000	1	5/60	417
Clinic Staff	Administrative Survey	25	1	10/60	4
Total					**421**

A.12.2 Estimated Annualized Burden Costs

We do not know what the wage rate category will be for the selected participants (or even whether they will be employed). We used $23.86 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 January 2018, (http://www.bls.gov/oes/current/oes_nat.htm#00-0000). The estimated annualized total cost to participants for the collection of information will be $10,331.38.

Exhibit A.2 Annualized Cost to Respondents

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Patient Survey	417	$23.86	$9949.62
Administrative Survey	4	$23.86	$95.44
Total	**421**		**$10,045.06**

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

CDC does not anticipate providing start-up or other related costs to private entities. There are no costs to respondents or record keepers.

A.14 Annualized Costs to the Federal Government

One CDC Technical Monitor will be responsible for obtaining CDC approvals, providing project oversight, and participating in analysis 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 under a CDC Cooperative Agreement #PS13-1302. With the expected period of performance, the annual cost to the federal government is estimated to be $463,000 (**Exhibit A.3**). This is the cost estimated by the NACCHO, and includes the estimated cost of coordination with CDC and data collection.

Exhibit A.3 Estimates of Annualized Cost to the Government

Expense Type	Expense Explanation	Annual Costs
CDC oversight of collaborator (NACCHO) and project	10% of FTE: GS-14 Health Scientist	$13,000
Data collection	Labor hours and ODCs	$550,000
Total cost		$563,000

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

A.15 Explanation for Program Changes or Adjustments

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**. Data collection is anticipated to begin approximately July 1, 2018 Once data is collected using the paper-based forms, the data will be keyed into an Excel spreadsheet by NORC at the University of Chicago. This data will then be analyzed by CDC using SAS to produce tables of frequencies for each question. The information that is tabulated will then be shared with the participating STD clinics with an overall report, and when requested, a more detailed clinic specific report. This information will also be communicated to the broader STD community through peer-reviewed publications.

Exhibit A.4 `Project Time Schedule`

Activity	Time Schedule
Conduct paper-based surveys	1 month after OMB approval
Submit report	6 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. Key Facts about the Uninsured Population. The Henry J. Kaiser Family Foundation. (Accessed January 31, 2017, 2018, at: https://www.kff.org/uninsured/fact-sheet/key-facts-about-the-uninsured-population/)
2. Patient Protection and Affordable Care Act Health-Related Portion of the Health Care and Educcation Reeoncilliation Act of 2010. 2010. (Accessed on January 31, 2017, at: https://www.hhs.gov/sites/default/files/ppacacon.pdf)
3. Federal Subsidies for Health Insurance Coverage for People Under Age 65: 2017-2027. Accessed on January 31, 2018, at: https://www.cbo.gov/system/files/115th-congress-2017-2018/reports/53091-fshic.pdf)
4. Felsenstein D. A universal health insurance mandate does not equate to universal coverage for STI clinic patients (C3.3). In: National STD Prevention conference; 2012 March 14, 2012; Minneapolis; 2012.
5. Celum CL, Bolan G, Krone M, et al. Patients attending STD clinics in an evolving health care environment. Demographics, insurance, coverage, preferences for STD services, and STD morbidity. Sex Transm Dis. 1997; 24:599-605.
6. Hoover K, Parsell BW, Leichliter JS, et al. Continuing need for sexually transmitted disease clinics after the Affordable Care Act. Am J Public Health. 2015; 105 Suppl 5:S690-5.
7. Pearson WS, Cramer R, Tao G, et al. Willingness to use health insurance at and STD clinic: A survey of patients at 21 US Clinics. Am J Public Health. 2016; 106(8):1511-3