**National Survey of HIV Testing in Hospitals**
**Supporting Statement A**

**0920-NEW**

## Contact Information

Drew Voetsch, PhD

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Division of HIV/AIDS Prevention
Behavioral and Clinical Surveillance Branch
Centers for Disease Control and Prevention
1600 Clifton Road NE, Mailstop
Atlanta, GA 30333.

Voice: (404) 639-8088
Fax: (404) 639-8640
Email: aav6@cdc.gov

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**National Survey of HIV Testing in Hospitals**

**Table of Contents**

**LIST OF ATTACHMENTS**

| | |
|---|---|
| **Attachment 1** | Authorizing Legislation |
| **Attachment 2** | 60 Day Federal Register Notice |
| **Attachment 3** | Data collection instrument |
| **Attachment 4** | List of consultants |
| **Attachment 5** | Assurance of Confidentiality for HIV/AIDS Surveillance Data |
| **Attachment 6** | IRB approval |

**Supporting Statement**

**Section**
**A. Justification**

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

The Centers for Disease Control and Prevention (CDC) requests approval for a new data collection called "National Survey of HIV Testing in Hospitals" for 2 years. This project will evaluate the impact of CDC's recommendations for HIV testing in health-care settings.

CDC's HIV Prevention Strategic Plan establishes four goals to reduce the annual number of new HIV infections in the United States. One of these goals is to increase the proportion of HIV-infected people in the United States who know they are infected. Of the more than one million persons estimated to be infected with HIV in the United States, 24-27% were unaware of their infection (Glynn 2005). Routine rapid HIV testing programs in emergency departments and urgent care centers have great potential to identify a large number of previously undiagnosed individuals. However, prior to the release of the revised recommendations, few such programs existed in the United States. CDC is committed to increasing the number of such programs in the US, and is currently working with partners to achieve these goals (Janssen 2007).

In September 2006, CDC released revised recommendations for HIV testing of adults, adolescents, and pregnant women in healthcare settings as a measure to address the high number of HIV-infected individuals who are unaware of their HIV status (CDC 2006). Changes from the previous CDC recommendations include HIV screening of all persons in health-care setting aged 13 – 64 years unless the HIV prevalence is below 0.1%, notification of patients that HIV testing will occur unless they decline (opt-out testing), elimination of written consent for HIV testing, and elimination of the requirement for pre-test counseling. The extent to which hospitals have adopted these recommendations and their potential impact on HIV testing policies and practices in hospitals is currently unknown.

A previous report of HIV testing in US hospitals showed that although one-quarter of hospitals provided routine HIV screening, predominantly in the labor and delivery setting,

routine screening in other hospital settings was very low (Torres 2005). Previous studies of HIV screening in hospital emergency departments have shown that routine, opt-out testing is feasible (Lyons 2005; Brown 2007; CDC 2007) and acceptable to patients (Haukoos 2008). However, a survey of 128 emergency departments with training programs showed that less than half expected to implement CDC HIV testing recommendations within the next few years (Ehrenkranz 2008). In a review of barriers to implementation, Burke and colleagues identified 8 common barriers to implementing HIV testing in labor and delivery, emergency department, and other health-care settings (insufficient time, consent process, lack of knowledge/training, language, lack of patient acceptance, pre-test counseling requirements, competing priorities, inadequate reimbursement) (Burke 2007). Because of logistical complications, some facilities may partially implement the CDC recommendations (Lyons 2007). For example, elimination of the requirement for written consent alone at the San Francisco Department of Health Medical Care System increased the monthly rate of HIV testing and the mean number of positive tests per month (Zetola 2007).

To determine uptake and assess the impact of the CDC's revised recommendations on HIV testing practices and policies in hospitals, the CDC will conduct a nationwide survey of U.S. hospitals.

This study will be conducted under Title III – General Powers and Duties of Public Health Service, Section 301 (241.)a.(Attachment 1).

Privacy Impact Assessment

Overview of the data collection system

The National Survey of HIV Testing in Hospitals will be administered to a random sample of 1,000 non-federal, short-term hospitals in the United States that provide general medical and surgical services as well as general children's services. 2006 American Hospital Association (AHA) Annual Survey data will be used to identify hospitals that meet these criteria.

A hardcopy of the survey instrument and cover letter will be mailed to each sampled hospital's chief executive officer (CEO). The cover letter to the CEO will include a description of the study and will address the importance of their hospital's participation, as well as clear

instructions as to who in the hospital should complete the survey. Specifically, hospital infection control nurses will be requested to complete the survey on behalf of the hospital. The infection control nurse will potentially need to obtain the information from emergency department personnel, inpatient unit personnel, and hospital administration. This will require approximately one hour per location.

Once surveys have been mailed to potential participating hospitals, a representative from the contractor will work with AHA and state hospital associations to increase awareness of the survey and its importance among member hospitals. Surveys can be completed using either the paper copy of the questionnaire or using an internet-based data entry screen. During the course of data collection, the CDC contractor will contact by telephone hospitals which have not yet responded to maximize the overall response rate. Survey data will be entered into an electronic database and maintained indefinitely at CDC.

Items of Information to be collected

The information to be collected includes current HIV practices and policies for the hospital; HIV services provided by different hospital departments; HIV testing practices in the hospital and in specific departments, including use of rapid tests; types of HIV tests used at hospitals; types of staff conducting HIV testing; nature of HIV testing protocols including informed consent process, pre-test counseling, and linkage to care and treatment services; and funding and reimbursement for testing programs. Hospital-level characteristics such as bed size, census region, ownership, metropolitan statistical area, and teaching status are part of the AHA database of hospitals. No patient-level data will be collected as a part of this study. All data collected will be at the hospital or department level. No identifiers which would uniquely identify a particular hospital or department within the hospital will be kept at CDC.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

The information collection system will involve a web-based data collection method that is password protected. The website will be accessed by hospital personnel to complete

the survey. No person under 13 years old will access the website.

## 2. Purpose of Use of the Information Collection

Findings from this study will be used to provide an improved understanding of the integration of CDC's revised recommendations by hospitals, nationally. Findings will further inform CDC about the prevailing policies and practices that hospitals have utilized for incorporating HIV testing into their services (including information on the provision of pre-test information, post-test information, and linkage of newly-identified HIV-positive persons to health and preventive care services). Study findings will also be used as the basis to refine recommendations for offering HIV testing on a routine basis in hospital settings in a manner which causes minimal impact on and disruption of their other clinical activities. Because the hospitals selected are a simple random sample of all U.S. hospitals, the results can be generalized to the approximately 4500 non-federal, short-term hospitals in the United States that provide general medical and surgical services as well as general children's services.

Privacy Impact Assessment Information

Information is being collected to monitor the diffusion of revised CDC recommendations for HIV testing in health-care settings (CDC 2006). The information from the proposed data collection will be used to determine the proportion of health-care settings (i.e., hospitals) that have policies for routine HIV testing that are in concurrence with CDC recommendations. There are no other sources of information that describe the changes in hospital policy and procedures as a result of the revised CDC HIV testing guideline.

There are no Privacy Act issues. No patient data will be collected as a part of this study. No information in identifiable form (IIF) is being collected. There is no sensitive information being collected. Therefore, the proposed data collection will have no effect on the respondent's privacy.

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

This study will use a web-based system for data collection. However, to accommodate hospital respondents, the option of completing a paper version of the survey will be available. Surveys which are completed on paper and mailed to the contractor will be entered into the web-based system by contractor staff. A 10% sample of surveys will be randomly checked by data entry staff, for data entry errors. The web-based survey and the supporting database will be designed by the contractor. No personally identifiable information will be transmitted to CDC.

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

There are no sources or agencies who are collecting similar information. We conducted literature searches, HIV conference abstracts searches, and consultations with experts in HIV testing, including the CDC guideline authors, to assist in determining that a similar data collection is not being conducted by another institution. CDC program reviews were conducted to identify potential areas of duplication; however, none were found to exist. We reviewed currently-funded programs and did not identify potential areas of duplication. No known department or agency maintains data regarding HIV testing policies and practices in health-care settings.

Monitoring changes in HIV testing practices in health-care settings can be conducted in several ways. First, the prevalence of persons tested can be monitored through population surveys, such as the Behavioral Risk Factor Surveillance System (BRFSS), the National Health Interview Survey, and the National Survey of Family Growth (Anderson 2000; CDC 2004). Second, health-care providers can be surveyed to determine changes in HIV testing practices (Fincher-Mergi 2002; Burke, Sepkowitz et al. 2007). Third, health-care system level data can be used (Ehrenkranz, Ahn et al. 2008).

There is no known Department or Agency which maintains the necessary information, nor is it available for other sources within our Department.

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

The burden of participation on hospitals and private clinics involved in this survey will not affect the normal functioning of these entities. There is no other cost associated with their participation.

## 6. Consequences of Collecting the Information Less Frequently

Data collection activities will occur in 2009. The survey is a one-time study and respondents will provide the information only once. Participating hospitals are only eligible for selection once.

There are no legal obstacles to reduce the burden.

## 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 on May 16, 2008, page numbers 28478-28479). A copy of this publication is attached (Attachment 2). We did not receive public comments. A 30-day notice is also attached (Attachment 2a).

Several consultations were conducted with various scientists and public health practitioners outside the agency. All names, affiliations, and contact information are included in Attachment 3.

In December 2007, CDC began holding regular conference calls with Ms. Gretchen Torres and Ms. Julie Yonek of the Health Education and Research Trust (HRET) regarding the development of the survey protocol, sampling plan, and questionnaire.

Beginning in January, 2008, CDC consulted with Dr. Chris Johnson, statistician in the Division of HIV/AIDS Prevention, CDC, to obtain advice on the sampling strategy, analytic methods for examining the objectives, and sample size.

In March 2008, HRET consulted with Ms. Judene Bartley a consultant in epidemiology and infection control who often works with the AHA for her input on survey content and appropriateness of infection control nurses as the main institutional contact to complete this survey on behalf of the hospital.

In March, 2008, CDC consulted with Dr. Bernard Branson, Associate Director for Laboratory Diagnostics in the CDC's Division of HIV/AIDS Prevention, CDC, for survey content and to determine if other agencies were planning to conduct similar surveys.

In March 2008, CDC contacted Dr. Laura Bogart of the RAND Corporation to determine if any follow-up surveys were planned to a previous survey of rapid HIV testing in hospitals conducted by RAND in 2004.

In April, 2008, CDC consulted with Dr. David Weber, Associate Chief of Staff, University of North Carolina Hospital, for survey content and survey administration logistics.

In June 2008, CDC consulted with Dr. Devery Howerton, Chief Lab Practice Evaluation and Genomics Branch in the Division of Laboratory Systems, CDC for survey content and to determine if other agencies were planning to conduct similar surveys.

In August 2008, HRET consulted with Peter Kralovec of the Health Forum, which administers the AHA's Annual Survey, on survey administration logistics, including suggestions for minimizing burden.

No major problems arose that could not be resolved during these consultations.

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

No payment or gift will be provided to respondents.

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

National Survey of HIV Testing in Hospitals is covered by an Assurance of Confidentiality under Section 308(d) of the Public Health Act granted for HIV/AIDS surveillance data (Attachment 5). The Assurance of Confidentiality applies to individuals as well as organizations such as hospitals. The Assurance of Confidentiality is enforced with appropriate training and contractual agreements which clarify the responsibilities of all participants in HIV/AIDS surveillance activities who have access to directly identifiable data or to data that are potentially identifiable through indirect means. State and local health department personnel who conduct HIV/AIDS surveillance are subject to the confidentiality obligations described in the CDC guidelines for the security and confidentiality of HIV/AIDS Reporting System (HARS) data (http://www.cdc.gov/hiv/topics/surveillance/index.htm) and are required to undergo security and confidentiality training. National Survey of HIV Testing in Hospitals data managers will undergo the same security and confidentiality training as required for health department staff. CDC's Procurement and Grants Office will require the inclusion of 308(d) clauses in any HIV/AIDS support services work done by contractors (e.g., data analysis, computer programming, LAN support). All CDC permanent employees and their contractors will be required to attend annual confidentiality training, to sign a Nondisclosure Agreement and to update their confidentiality agreements on an annual basis. Contractors must sign a "Contractor's Pledge of Confidentiality." Access to HIV/AIDS surveillance data maintained at CDC is restricted to authorized personnel who have signed the "Agreement to Abide by Restrictions on Release of Data." Contracts to state and local health departments will reference the Assurance of Confidentiality as a condition of award.

Neither the identity of the participating hospital nor that of the person responding on behalf of the hospital will be transmitted to CDC.

**Privacy Impact Assessment Information**

A. The Privacy Act does not apply based on the items of information collected and transmitted to CDC.

B. National Survey of HIV Testing in Hospitals is covered by an Assurance of Confidentiality under Section 308(d) of

the Public Health Act granted for HIV/AIDS surveillance data (Attachment 5). The Assurance provides the highest level of legal confidentiality protections to the individual persons who are the subject of this data collection, and to the individuals and organizations responsible for data collection. The terms of the Assurance of Confidentiality reflect the collective experience of CDC, health departments, and the Council of State and Territorial Epidemiologists with respect to the collection, electronic transmission, and dissemination of HIV/AIDS surveillance data. The Assurance includes established policies and procedures governing all aspects of data collection and de-identification, physical security for paper forms and records, electronic data storage and transmission, and the release of aggregate data in forms that cannot be linked back to individual respondents. The protections afforded by the Assurance of Confidentiality last forever, and endure even after the respondent's death.

All project staff will undergo the same security and confidentiality training as required for health department staff. Data will be transmitted by the contractor (HRET) in aggregate form to CDC. Survey data will be transmitted to CDC using the internet-based system that is used to transmit HIV/AIDS surveillance data to CDC. This system is referred to as the Secure Data Network (SDN). Databases submitted through the SDN must be encrypted before being sent to CDC. Encryption security for all data must meet the current National Institute of Standards and Technology (NIST) Federal Information Processing Standards (FIPS), which meet or exceed Advanced Encryption Standards (AES). See the document "Technical Guidance for HIV/AIDS surveillance Programs, Volume III: Security and Confidentiality Guidelines" for further information (www.cdc.gov/hiv/surveillance.htm).

The process for handling security incidents is defined in the system's Security Plan. Event monitoring and incident response is a shared responsibility between the system's team and the Office of the Chief Information Security Officer (OCISO). Reports of suspicious security or adverse privacy related events should be directed to the component's Information Systems Security Officer, CDC helpdesk, or to the CDC Incident Response Team. The CDC OCISO reports to the HHS Secure One Communications Center, which reports incidents to US-CERT as appropriate.

C. IRB approval is not required for this project (Attachment 6).

D. The voluntary nature of the survey is described to participants in the introductory paragraph of the survey questionnaire (Attachment 3).

**11. Justification for Sensitive Questions**

No sensitive information that would result in liability or competitive disadvantage if disclosed is being collected.

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

**A.** CDC estimates that a total of 1000 respondents would spend one hour in the collection, management, and reporting of information under this project. Data collection will occur over two years with 500 hospitals surveyed each year.

| Type of Respondent | Form Name | No. of Respondents | No. of Responses per Respondent | Avg. Burden per Response (in hours) | Total Annual Burden (in hours) |
|---|---|---|---|---|---|
| Hospital | National Survey of HIV Testing in Hospitals | 500 | 1 | 1 | 500 |
| **Total** | | **500** | | | **500** |

**B**. Annualized cost to respondents for the burden hours is provided in Exhibit A.12.B. The estimates of hourly wages were obtained from the Department of labor. Wages are based on the staff person requested to respond on behalf of the hospital, a registered nurse.

Exhibit A.12. B: Estimated Annualized Burden Costs

| Type of Respondent | Total Burden hours | Hourly Wage Rate | Total Respondent Cost |
|---|---|---|---|
| Hospital | 500 | $30.04 | $15,020.00 |
| **Total** | **500** | | **$15,020.00** |

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

There are no costs to respondents other than their time.

## 14. Annualized Cost to the Federal Government

National Survey of HIV Testing in Hospitals is funded through a 32-month contract with the contractor (HRET) in the amount of $263,916. This contract includes salaries, travel, equipment, and supplies; and incentives. The HRET contract also includes funds for developing the sampling design, survey questionnaire and protocol. It also includes the data collection, management, analysis, and a final report of the survey data. Direct costs to the government include the salary for CDC project officer, principal investigator, and co-investigator and support staff to provide technical assistance and monitor the project contract.

**Exhibit A.14: Estimates of Annualized Costs to the Federal Government.**

The cost of the project for the 32 months is estimated to be $ 354 397.33. The annual cost of $132,899 is summarized in Exhibit A.14.

| Expense Type | Expense Explanation | Annual Costs (dollars) |
|---|---|---|
| Direct Costs to the Federal Government | CDC Project Officer (GS-13, .25 FTE) | $20,124 |
| | CDC Principal Investigator (GS-14, .05 FTE) | $4756 |
| | CDC Co-Principal Investigator (GS-13, .10 FTE) | $8,050 |
| Operational | Equipment, travel, support staff, printing, etc) | $1,000 |
| | Subtotal, Direct Costs to the Government | $33,930 |
| Contractor and Other Expenses | Contract with Health Research Education Trust | $98,969 |
| | | |

| | | |
|---|---|---|
| | Subtotal, Contracted Services | $98,969 |
| | TOTAL COST TO THE GOVERNMENT | $132,899 |

*Salary estimates were obtained from OPM salary scale (http://www.opm.gov/oca/08tables/indexGS.asp).*

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

This is a new data collection.

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

**Exhibit A.16: Project Time Schedule**

| Activity | Time Schedule |
|---|---|
| Distribute surveys to respondents | 1 month after OMB approval |
| Email Reminders (to increase response rate) | 2 months after OMB approval |
| Provide phone support for survey completion | 2 – 3 months after OMB approval |
| Download data from web application | 6 months after OMB approval |
| Data management and validation | 6 – 9 months after OMB approval |
| Initial Tabulation of Results | 9 - 12 months after OMB approval |
| Data validation with hospitals (as needed) | 9 - 12 months after OMB approval |
| Final data analysis | 12 – 18 months after OMB approval |
| Dissemination of results | 18 – 24 months after OMB approval |

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

No such exception is requested. The OMB control number and expiration date will be displayed on the paper questionnaire and on the data collection internet site.

**18. Exceptions to Certification for Paperwork Reduction Act (PRA) Submissions 5CFR 1320.3(h)(1)-(10)**

There are no exceptions to the certification statement identified in Item 13, Paperwork Reduction Act Submission Worksheet, Part I: Information Collection Request.

## References