Evaluation Models to Assess Patient Perspectives on Opt-out HIV testing in Clinical Settings

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A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests approval for a term of 1 year for a new project that will pilot test a questionnaire and protocol to assess patient perspectives and satisfaction with routine HIV screening in health-care settings. The purpose of the survey is to collect information to develop a model patient questionnaire for inclusion in an evaluation toolkit of patient satisfaction.

In September of 2006, CDC issued its *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings*[1]. In order to increase the number of patients being screened for HIV infection in health-care settings, detect HIV infection earlier, and to link those with unrecognized HIV infection to clinical and prevention services, the CDC recommends routine HIV screening in health-care settings to persons 13-64 years of age. According to the new recommendations, patients should be offered routine HIV screening on an opt-out basis (that is, they will be routinely offered testing and are asked if they would like to decline, rather than accept). High risk patients should be screened annually, separate written consent should not be required, and prevention counseling should not be required with diagnostic testing or screening programs.

Currently there are few resources available to health-care providers to assist them in implementing routine HIV testing in their clinical settings. To support the development and dissemination of administrative tools and other educational and training materials needed to implement the revised guidelines, CDC published Program Announcement PS07-764 "*National Organizations Working to Eliminate Perinatal HIV Transmission and to Implement CDC's Revised Recommendations for HIV Testing of Adults, Adolescents and Pregnant Women in U.S. Health Care Settings*" in 2007. One aim of the program is to foster the exchange of information and experiences of routine HIV testing in health-care settings by assessing attitudes, reactions and acceptance of HIV screening by patients.

The goal of this project is to develop evaluation models as part of PS07-764 to assist health-care providers in a variety of clinical settings to independently assess the effect that expanded HIV screening activities have on patient attitudes toward and acceptance of HIV testing. The evaluation models developed in this project will be packaged into a toolkit containing educational materials, administrative tools and a model questionnaire to measure patients' perceptions of their ability to decline testing, the sufficiency and effectiveness of methods used to impart information prior to testing, and satisfaction with the testing process.

As part of the development of a model questionnaire for inclusion in the toolkit, three health-care settings (a hospital emergency department, a private primary care practice and a public primary care practice) will be selected to pilot test the patient questionnaire. Pilot testing activities will ensure survey questions disseminated in the model toolkit have undergone psychometric evaluation to ensure validity and reliability across a variety of health-care settings and patient populations. CDC will approach patients in each clinic setting until the recruitment goal of 150 respondents per setting has been reached. Persons 18 years or older will be offered participation

in the study. If a patient accepts participation, they will be taken to a private area of the clinic where the interview will take place. Patients will first be read a brief consent form and will provide verbal consent to participate. A verbal consent process is being used since it is not necessary to collect names or any other personally identifying information from the patient. Once the patient has consented, they will then begin the survey. It is estimated that 85% of patients approached will accept participation in the survey, which means we will approach approximately 177 patients in each setting in order to reach our recruitment goal of 150 patients per setting. The average duration of the survey is estimated to be 20 minutes. Participation is voluntary. Data collection will be used to improve the model patient questionnaire included in the toolkit. The survey will not collect any identifying information and there is no cost to the respondents other than their time.

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 data collection system

In each health-care site, trained evaluators will ask patients to voluntarily complete a brief computer assisted self interview (in either English or Spanish) regarding their experience with the HIV testing process during their health-care visit (Attachment 3). Up to 450 patients ages 18 years and above will be enrolled over the one year time period. No identifying information will be collected from any of the patients. All electronic data on the laptop will be kept secure through the use of a password. Data will be uploaded to a secure computer server and only analytic staff will have access to the data files. At the end of the analytic phase, all electronic Audio Computer Assisted Self Interview (ACASI) data will be destroyed. Data collected through the survey are stored and accessed by a survey identification number. Other data collected through the patient survey, while sensitive, are not personally identifying; these survey questions are described in Section 11.

Items of information to be collected

The survey will include a series of questions related to demographic variables, experiences surrounding informed consent, confidentiality and pre-test information, knowledge related to HIV testing including advantages of testing, potential risks, linkage to care, and right of refusal, fears related to stigma, discrimination and violence related to testing, HIV risk perceptions, risky sexual practices, social support, access to health care, HIV stigma, and relationships with and trust of medical providers. The questionnaire also collects information on reasons for refusing testing, among those persons who refused testing during their health care visit. The patient survey will not collect any identifying information.

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

The information collection system will not involve a web-based data collection method or refer respondents to websites. This system does not host a website.

2. Purpose of Use of the Information Collection

The purpose of the proposed data collection is to field test the 27-item patient questionnaire to understand issues of feasibility of the model questionnaire and validity of the included items and scales. By pilot testing in a variety of clinical settings in different regions of the U.S., we will also be able to assess differences that may exist by health-care setting type (e.g. between an emergency department setting and a private primary care setting) and by patient population. Pilot testing will allow us to improve the model questionnaire to ensure questions are easy to understand and are valid measures of patient satisfaction as it relates to routine HIV testing.

Once the model questionnaire has been developed using the information collected in this survey, it will be disseminated as part of an evaluation models toolkit to health-care providers interested in independently evaluating their HIV testing programs in order to improve patient outcomes and care.

Privacy Impact Assessment

As this is a pilot evaluation activity, the patient survey will not yield data that can be generalized to a broader population. The data from the evaluation will be used to revise and improve a model questionnaire for dissemination to health-care settings as part of an evaluation models toolkit.

No identifying information will be collected in the survey. Data collected through this evaluation are stored and accessed by a survey identification number. Other data collected through the evaluation, while sensitive, are not personally identifying; these survey questions are described in Section 11. With the safeguards described above to protect the security of the data, the impact on privacy is expected to be minimal and limited.

3. Use of Improved Information Technology and Burden Reduction

Interview data will be collected electronically to minimize the burden to respondents and interviewers. Interview data will be collected on laptops through the use of ACASI methods in each of the three clinic sites similar to a system used by the evaluation partners at the University of California, San Francisco, and the University of Medicine and Dentistry of New Jersey.

Computer-assisted self interviewing can reduce the burden for the respondent because the computer customizes the wording of the question based on the respondent's answers, thus eliminating the need for the respondent to follow skip patterns that would be found in a paper self-administered questionnaire. In addition, previous studies have shown that respondents are more likely to reveal engaging in sensitive behaviors in a computer-assisted self interview without an interviewer than in a face-to-face format.[2]

The evaluation data files will be transferred, or uploaded, from the laptop computers to the project area's secure storage drive on a frequent basis. Data collected in this survey will be

analyzed by the evaluation partners (University of San Francisco and the University of Medicine and Dentistry of New Jersey); therefore, individual interview records will not be transmitted to CDC.

4. Efforts to Identify Duplication and Use of Similar Information

We reviewed currently funded programs and did not identify potential areas of duplication. There is no known department or agency that is currently developing patient evaluation models to assess routine HIV screening in health-care settings.

CDC and the evaluation partners established relationships with other federal stakeholders and consultants during the development of the evaluation protocol. The AIDS Education and Training Centers (AETC), funded by the Health Resources and Services Administration (HRSA) were consulted through the HIV Testing Training Exchange Collaborative. Additionally, health-care providers serving as panelists at the December 2007 Strategic Planning Workshop for HIV Screening in Urgent Care Settings were also consulted in the development of this project. The list of individuals consulted is provided in Attachment 4.

5. Impact on Small Business or Other Small Entities

No small businesses will be involved in this study.

6. Consequences of Collecting the Information Less Frequently

The pilot survey is a one-time study and respondents will be asked to provide information only once. Each person will be asked if they have been interviewed previously for the survey; those who indicate that they have been interviewed already will not be interviewed again.

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 June 13, 2008, Volume 73, pages 33823-33824. A copy of this publication is attached (Attachment 2a). There was one comment received by B. Sachau; the comment is included in Attachment 2b.

Discussions were conducted in 2007-2008 with evaluators, physicians and public health practitioners from CDC, other federal agencies (HRSA) and non-federal agencies. All names, affiliations, and contact information are included in Attachment 4.

9. Explanation of Any Payment or Gift to Respondents

The survey will take approximately 20 minutes to complete. To increase response rates among patients, persons approached will be offered an incentive of $10 to participate. If local regulations prohibit cash incentives, equivalent incentives may be offered in the form of personal gifts or gift certificates. An incentive of $10 was previously used by project collaborators for a Health Resources and Services Administration (HRSA) funded *Enhancing Prevention with Positives Evaluation Center* project assessing prevention interventions with HIV positive patients in 15 U.S. clinics. The survey used in that study was of comparable length to the proposed survey in this pilot project.

10. Assurance of Confidentiality Provided to Respondents

Project data will be covered by the appropriate CDC Assurance of Confidentiality ("Surveillance of Acquired Immunodeficiency Syndrome (AIDS) and Infection with Human Immunodeficiency Virus (HIV) and Surveillance-Related Data," RK-2001-036, Attachment 6). This 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.

<u>IRB Approval</u>

This project has received a non-research determination by the CDC Institutional Review Board. The Non-Research Determination form is located in Attachment 5.

<u>Privacy Impact Assessment</u>

A. This submission has been reviewed by ICRO, who determined that the Privacy Act does not apply. For this data collection, professional evaluators from the project will conduct interviews with patients. No identifying information, including patient's name, will be collected for the survey. Verbal informed consent will be given by participants. No data will be transmitted to CDC.

The following safeguards will be applied to the data on laptop computers used for interviews: 1) laptop computers will be used solely for the evaluation data collection activities; 2) laptop computers will be protected by using a coded password only known by authorized project staff; 3) laptop computers will be kept with the staff at all times when in the field; 4) laptop computers will be collected and secured by the field supervisor after the last interview each day; and 5) when not in use in the field, laptop computers will be locked in a drawer or office.

B. Information will be collected by CDC under Section 306 of the Public Health Service Act (42 U.S.C. 242k) as part of the HIV/AIDS case data that would permit direct or indirect identification of any individual or institution on whom a record is maintained, and any identifiable information collected during the course of an investigation on either persons supplying the information or persons described in it, is collected with a guarantee that it will be held in confidence, will be used only for the purposes stated in this Assurance, and will not otherwise be disclosed or released without the consent of the individual or institution in accordance with Section 308 (d) of the Public Health Service Act (42 U.S.C. 242m(d)). This protection lasts forever, even after death.

C. The informed consent process for respondents will be fulfilled by obtaining verbal consent by respondents. Model informed consent documents are included as Attachment 7. All sites must obtain consent from respondents and interviewers receive training on the importance of safeguarding the identities of respondents and procedures to avoid breaching confidentiality.

D. The consent form will inform respondents that their participation in the survey is voluntary. Respondents will be informed that they have the option to refuse to provide answers to any questions on the survey.

11. Justification for Sensitive Questions

In order to develop a model evaluation tool that provides information to physicians about the HIV risk behaviors of their patient population, specific questions about HIV risk perceptions and sex and drug risk behavior will be asked. All interviews will be conducted by trained project staff in a private location in the clinics where the project is implemented.

12. Estimates of Annualized Burden Hours and Costs

The goal is to interview a convenience sample of 450 persons; 150 in each of three health -care settings (private primary care setting, public primary care setting and emergency department) over a one year period. It will take approximately 20 minutes for the interviewer and respondent to go through the computer program for the survey.

Exhibit 12.A: Estimated Annualized Burden Hours

Type of Respondent		No. of Respondents	No. of Responses per Respondent	Average burden per Response (in hours)	Total Burden hours
Survey		450	1	20/60	150

participant					
TOTAL					150

Exhibit 12.B: Estimated Annualized Burden Costs

Type of Respondent		No. of Respondents	No. of Responses per Respondent	Average burden per Response (in hours)	Total burden (in hours)	Average Hourly Wage Rate	Total Annual Respondent Cost
Survey participant		450	1	20/60	150	$17.75	$2,662.50
TOTAL					150		$2,662.50

In order to estimate the cost to the respondents, we used the seasonally adjusted average hourly wage earnings of total production and non-supervisory workers on private non-farm payrolls proposed for January 2008 by the US Department of Labor. The proposed data collection is estimated to cost $2,662.50 for all respondents listed in Exhibit 12.B

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

There are no other costs to respondents associated with this proposed collection of information.

14. Annualized Cost to the Federal Government

Table 14.A. Estimated Annualized Costs to the Government

Expense Type	**Government Related Expenses**	**Annual Costs (dollars)**
Direct cost to the Federal Government		
	CDC Project Officer (GS-12, .25 FTE)	$35,000
	Travel	$2,000
	Subtotal, direct costs to the government	$37,000
Cooperative Agreement		
	University of California, San Francisco	$397,380
	University of Medicine and Dentistry of New Jersey	$99,127
	TOTAL COST TO THE GOVERNMENT	$533,507

The budget detailed in Table 14.A is for the entire project. Travel mentioned in the table above will be incurred while providing technical assistance and conducting site visits. The University of California, San Francisco and the University of Medicine and Dentistry of New Jersey are funded through a cooperative agreement to serve as the evaluation partners for this project . The cooperative agreement includes salaries, travel, equipment, and supplies and incentives. The cooperative agreement also includes funds for developing the patient questionnaire and survey protocol, as well as data management, validation, and analysis needed to conduct the evaluation

of the patient survey. It also includes funding for dissemination and technical assistance activities.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Table 16.A: Project Time Schedule

Activities	Time Schedule
Begin pilot testing of patient instrument	1 month following OMB approval
Complete pilot testing of patient instrument	7 months following OMB approval
Data management and validation of survey	8-9 months following OMB approval
Revise patient instrument based on pilot	9-11 months following OMB approval

The second year of the project will contain no data collection component. It will consist of disseminating the evaluation models toolkit nationally through the AIDS Education and Training Centers, through collaboration with national organizations such as the Society of General Internal Medicine and through attendance at professional conferences.

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

The OMB Control number and expiration date will be displayed on the laptop computer in the questionnaire program.

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

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