

**OMB Clearance Package
Supporting Statement A**

**Assessment of Occupational
Exposure Management**

Contact:

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A. Justification

1. Circumstances Making the Collection of Information Necessary

The Division of Healthcare Quality Promotion (DHQP), Centers for Disease Control and Prevention (CDC), has as its primary mission, the protection of patients and healthcare personnel through the promotion of safety, quality, and value in the healthcare delivery system. One of its primary areas of interest is preventing transmission of bloodborne pathogens to healthcare personnel during delivery of medical care. In 1996, the U.S. Public Health Service (USPHS) first recommended use of postexposure prophylaxis (PEP) as part of occupational HIV exposure management. (See <http://www.cdc.gov/mmwr/preview/mmwrhtml/00042200.htm>) PEP is a type of preventive treatment designed to reduce the possibility of infection after an exposure to an infectious agent, such as human immunodeficiency virus (HIV) or hepatitis B virus (HBV). Currently, PEP is recommended for the prevention of infection in cases where there has been a known risk of infection after work-related exposure to HIV or HBV. (See <http://www.cdc.gov/mmwr/PDF/rr/rr5011.pdf> and <http://www.cdc.gov/mmwr/PDF/rr/rr5409.pdf>)

These 2001 guidelines were disseminated to all US hospitals in 2002. The 2005 updated guidelines have not been similarly disseminated; they are available by subscription to the MMWR and on the CDC website. While the USPHS PEP recommendations are widely distributed, the awareness and extent of implementation of these recommendations by healthcare providers are unknown.

DHQP has unpublished data showing that in a sample of less than 100 U.S. hospitals, there have been improvements over time in testing of source patients for HBV, hepatitis C virus, and HIV and in duration of taking HIV PEP after exposure to an HIV-infected source. However, it is not clear to what extent these observed trends apply to a larger sample of US hospitals or to other healthcare settings where occupational exposures take can occur.

The purpose of this project is to conduct an assessment of personnel safety in healthcare settings in the United States, specifically occupational exposure management as part of a larger plan to address prevention of transmission of bloodborne pathogens. CDC data collections are authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241, Attachment C).

2. Purpose and Use of Information Collection

CDC has undertaken the task of conducting a survey to assess occupational exposure management programs in a sample of different types of healthcare settings, namely acute-care facilities (hospitals), ambulatory surgery facilities, long-term care facilities, and hemodialysis facilities. The purpose of the survey is to assess general policies on managing exposures, surveillance and reporting of occupational exposures, laboratory diagnostic capacity, staffing of occupational health services, staff training about occupational bloodborne exposure management and prevention, and, and provision of counseling for exposed workers. The survey also is intended to assess the extent that occupational exposures management policies and practices are consistent with national guidelines. The results of this survey may inform updates of guidelines and educational materials on management of occupational exposures to bloodborne viruses. Depending upon the findings of the survey, DHQP may modify its methods of disseminating

information on management of occupational exposures, including working with HHS partner agencies such as HRSA.

3. Use of Improved Information Technology and Burden Reduction

This survey will be conducted by a contract research organization, NRC + Picker. NRC+Picker is a market research and performance measurement firm that focuses on the health and human service survey research field. The company has 24 years of healthcare-specific research experience.

The survey methodology consists of a pre-notification letter inviting the facility contact person to participate in the survey (Attachment B); a mailed questionnaire (Attachments C-F) and cover letter (Attachment G); and a subsequent mailed questionnaire (Attachments C-F) and cover letter (Attachment H) for those who do not respond within 2 weeks to the first mailing. In the cover letters (Attachments G and H), the recipient is given the option to complete the questionnaire (Attachments C-F) on the Web. Screen shots of the ambulatory surgery center questionnaire survey are found in Attachment I. The letter provides a URL to a secured site and a personal password to use in accessing the electronic version of the questionnaire/survey. A postage-paid business return envelope is enclosed for recipients who choose to complete the hardcopy of the questionnaire. Because the survey participants are healthcare professionals with access to the Internet but with limited time, a Web option is provided in an effort to increase response rates for the survey. All correspondence will be addressed to the contact person provided in the sample frame data file. When no contact name is provided, the correspondence will be addressed to "Facility Administrator." Additional directions in the letters and on the questionnaires ask that the questionnaire be completed by the person most familiar with the facility's policies and procedures regarding occupational exposure management.

Follow-up reminders will be sent only to non-respondents to the initial invitation (Attachment H).

The potential respondent universe will be comprised of four sample frames: acute-care facilities, ambulatory surgery centers, long-term care facilities, and dialysis centers. Data files containing facility contact information have been obtained from Medical Marketing Service (MMS) for the acute care, ambulatory surgery, and long-term care sample frames. A file containing facility contact information for hemodialysis centers was provided to the Contractor by CDC. The purchased data files only contain contact information. Additional fields of demographic information and other data are not included in these files. Therefore, random sampling will be conducted within each frame but the samples will not be further stratified. The number of responses required is the number necessary for statistical accuracy at a 95% confidence level (details of this calculation are provided in Section B.1, below) or 10% of the sample frame for each facility type, whichever is larger.

There are no plans to provide results of this survey to the respondents.

4. Efforts to Identify Duplication and Use of Similar Information

There exists no known national source of data on the extent of knowledge about or implementation of occupational exposure management guidelines. There is no identical or similar data collection effort underway within the CDC or elsewhere in the government.

Literature searches for papers, books, or journal articles on this subject were conducted using PubMed, Google, and Yahoo as well as the online search engine for the University of Nebraska Medical Center Library. There were no similar studies or questionnaires found in the preceding 5 years.

5. Impact on Small Businesses or Other Small Entities

The survey tool for this project will contain the minimum number of questions necessary to facilitate the evaluation of current practices for managing occupational exposures to bloodborne pathogens among healthcare personnel in a variety of healthcare settings. It is estimated to take less than 20 minutes to complete and should not pose an undue burden on the healthcare professionals who are the intended recipients. One or two questions of the questionnaire will be applicable only to certain facility types and will not appear on questionnaires to other facilities/practices. Examples of this include one or two questions specific to hemodialysis centers or questions specific to long-term care facilities.

6. Consequences of Collecting the Information Less Frequently

This request is for a one time study. 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 regulation cited herein.

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

Pursuant to the requirements of 5CFR 1320.8(d), a 60-day public notice for public comments on this request was published in the *Federal Register* on July 3, 2006 Vol. 71, No.127, pp. 37939-37940. A PDF of the notice is included here as Attachment J.

(a) Responses to the Federal Register Notice: No comments were received during the Public Notice period.

(b) Efforts to Consult Outside the Agency: Consultation regarding the development and administration of this study has been provided by the following associates of the contractor response for conducting the survey:

- A. Kevin Horne, Director of Research and Standards, NRC+Picker (a division of National Research Corporation). Phone: 800-388-4264. KHorne@nrpicker.com
- Carson Simões, Manager of Measurement and Improvement Analysts, NRC+Picker. Phone: 800-388-4264. CSimoes@nrpicker.com
- Cynthia Hobbs, Senior Project Manager, NRC+Picker. Phone: 800-388-4264. CHobbs@nrpicker.com

9. Explanation of Any Payment or Gift to Respondents

No payments, gifts, or other incentives will be provided to respondents of this survey.

10. Assurance of Confidentiality Provided to Respondents

This submission has been reviewed by CDC's Privacy Officer who determined that the Privacy Act does not apply. Surveys collect information about policies and practices related to

occupational exposure management at respondent organizations. All correspondence will be addressed to the contact person provided in the sample frame data file. When no contact name is provided, the correspondence will be addressed to “Facility Administrator.” Although the pre-notification letter and the initial questionnaire will usually be mailed to a named contact person, the name of the person who completes the survey will not be collected. Additional directions in the letters and on the questionnaires ask that the questionnaire be completed by the person most familiar with the facility’s policies and procedures regarding occupational exposure management. Surveys do not collect any personal information about the individual who completes the survey on behalf of the respondent organization.

Data collection will be conducted for CDC by a contract research organization, NRC + Picker. NRC+Picker is a market research and performance measurement firm that focuses on the health and human service survey research field. The company has 24 years of healthcare-specific research experience.

The contractor will assign a unique identification code (“lithocode”) to each organization invited to participate in the survey. Each organization has the option of completing a paper survey or an on-line survey, and the name of the respondent organization will not appear on either type of data collection instrument. Paper survey instruments will be bar-coded with the unique identifier to facilitate data processing and follow-up reminders. A postage-paid business return envelope is provided to recipients who choose to complete the hardcopy questionnaire. Alternatively, the introductory letter to respondents will include a URL to a secured site, and an organization-specific passcode (also linked to the lithocode in the contractor’s database), for organizations that prefer to respond electronically. The contractor retains the ability to re-link response data to organization name throughout the project. The contractor will provide the raw data to CDC, stripped of identifiers.

No assurance of confidentiality will be provided to respondents of this survey nor to the facilities, however, respondents will be advised that CDC does not plan to disclose respondents’ identities. The following statement will appear in the cover letter and on the survey questionnaire: *Data will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law.*

This project is not research involving human subjects.

11. Justification for Sensitive Questions

Persons completing the questionnaires are supposed to be knowledgeable about the policies and practices regarding management of occupational exposures. The only information collected about the persons completing the questionnaires is their job category. Because the respondents are healthcare facilities, race and ethnicity will not be collected as it is not applicable.

Respondent organizations may view some information about their policies and procedures as sensitive, especially if they are concerned that their procedures could be perceived as deficient. Questions about the number and type of occupational exposures at each facility may also be viewed as sensitive (see #7, 10, and 11). Although potentially sensitive, these questions are necessary for the purposes of the data collection. In recognition of the need to safeguard respondent identity, the contractor utilizes the coding system described above for paper forms and the password system described above for electronic responses.

12. Estimates of Annualized Burden Hours and Costs

(a) Estimated Annualized Burden Hours

The following table of estimates of burden hours summarizes the burden hours for the different types of healthcare settings from which responses are solicited in this survey. The total number of estimated burden hours is 1,773.

Table 1: Estimated Annualized Burden Hours

Type of Respondent (Type of healthcare setting)	Form Name	Number of Respondents	Number of Responses	Average Burden per Response (in hours)	Total Burden Hours
Acute-care Facilities	Survey Questionnaire	865	1	20/60	288
Ambulatory Surgery Centers	Survey Questionnaire	353	1	20/60	118
Long-term Care Facilities	Survey Questionnaire	3634	1	20/60	1211
Dialysis Centers	Survey Questionnaire	468	1	20/60	156
TOTAL HOURS			1		1,773

Although four different questionnaires are attached (Attachments C-F), one for each type of healthcare setting being surveyed, they are identical except for several site-specific questions for characterizing the responding healthcare facility. The burden is estimated to be the same for these four questionnaires.

(b) Estimated Annualized Burden Costs

The estimated annual cost burden is based on the burden hours summarized above. The average salaries of the professional disciplines most likely to be respondents of the survey have been used in the calculations and they are based on data from the Department of Labor, Bureau of Labor Statistics. All costs related to salary are the hourly salary in 2004 by occupation. The disciplines currently most often involved in occupational exposure management are the following along with their average hourly salary in 2004: infection control/occupational health professional \$30.23, staff registered nurse \$26.61, all healthcare providers \$30.62. The last figure, \$30.62 was used as the average salary for the different occupations of those likely to respond to this survey.

Table 2: Est. Annualized Burden Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Acute-care Facilities	288	\$30.62	\$8819
Ambulatory Surgery Centers	118	\$30.62	\$3613
Long-term Care Facilities	1211	\$30.62	\$37,081
Dialysis Centers	156	\$30.62	\$4777
TOTAL COSTS			\$54,289

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

There will be no other cost burden to respondents or record keepers resulting from the collection of information other than the time required to complete the questionnaire.

14. Annualized Cost to the Government

The annualized cost to the Federal government will be approximately \$161,255. This includes \$152,855 (\$141,976 in personnel expenses, \$5,000 for travel, and \$ 5,879 as a fee to GSA) for contracted data collection and analysis and an estimated \$8400 in personnel costs for consultation, oversight, and analysis provided by CDC epidemiologists (total 5% FTE).

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Results of analysis of data from this survey submitted to a peer-reviewed journal and presented at scientific and professional meetings.

Table 3: Project Time Schedule

Activity	Time Schedule
Letter inviting participation mailed to respondents	Approximately 2 weeks after OMB approval
Initial survey and cover letter mailed to respondents	1 week after invitation letters are mailed
Second survey and cover letter mailed to those who did not respond to initial mailing	2 weeks after initial surveys and cover letters mailed
Close data collection period	Approximately 3 – 4 weeks after second survey mailing; Will be determined based on the number of responses received and the rate of returns (i.e., is rate increasing, flat or decreasing).
Complete data analysis and submit draft report	2 – 3 weeks after data collection period closes
Submit final report	Approximately 1 week after draft report is finalized
Publication of peer-reviewed report about survey	Approximately 1.5 years after receipt of report from contractor.

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

The survey instruments will contain the expiration date for OMB approval of the information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

• **LIST OF ATTACHMENTS**

ATTACHMENT A: Section of the Public Health Service Act (42 U.S.C. 241)

ATTACHMENT B: Pre-notification Letter to Respondents

ATTACHMENT C: Questionnaire Survey (for acute-care facilities)

ATTACHMENT D: Questionnaire Survey (for ambulatory surgery facilities)

ATTACHMENT E: Questionnaire Survey (for long-term care facilities)

ATTACHMENT F: Questionnaire Survey (for hemodialysis facilities)

ATTACHMENT G: First Cover Letter to Respondents

ATTACHMENT H: Second Cover Letter to Respondents

ATTACHMENT I: Screen Shots of Questionnaire Survey (for ambulatory surgery facilities)

ATTACHMENT J: *Federal Register* Notice

ATTACHMENT K: Letter of Determination: No IRB Review Required

ATTACHMENT L: NRC+Picker Survey Process