Supporting Statement
Evaluating Channels for Dissemination and Influencing Factors for Implementation of CDC's Dental Infection Control Guidelines

Submitted by:

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A. JUSTIFICATION

A1. Circumstances Making the Collection of Information Necessary

The publication of the *Guidelines for Infection Control in Dental Health-Care Settings – 2003* in December 2003 by the Centers for Disease Control and Prevention (CDC), represents a consolidation of previous recommendations, revisions and updates to previous recommendations, as well as new recommendations, for preventing and controlling the spread of infectious diseases, as well as managing the health and safety of patients and employees in dental care settings. While the Occupational Safety and Health Administration (OSHA) in the U.S. Department of Labor has responsibility for setting standards (making regulations) to protect the health and safety of persons employed in dental care settings, it has been the CDC's Division of Oral Health (DOH), working in collaboration with other authorities in infection control, that has taken the broader responsibility of developing guidelines (recommendations) that are intended to protect both patients receiving care and dental health care personnel (DHCP) – dentists, dental hygienists, dental assistants, and dental laboratory technicians – from the spread of infectious diseases in the dental care setting. These latest recommendations are intended to prevent or reduce disease transmission from patient to DHCP, DHCP to patient, and patient to patient. They replace the previous *Recommended Infection Control Practices* issued by CDC in 1993 that followed the OSHA publication of its blood borne pathogen standards in 1991. These older recommendations were more than a decade old, and the technology and issues in dental infection control had changed and issuance of new and updated guidelines was warranted.

Copies of the *Guidelines* were mailed to DHCPs, dental and allied dental educational programs, state boards of dental examiners, and dental laboratories soon after publication. This dissemination was intended to make DHCPs aware of the presence of the new guidelines from CDC. In addition, publication of the *Guidelines* served to alert state licensing boards of the new standard of infection control being promoted for dental practice. While CDC can only recommend adoption of these new infection control guidelines for dental care settings, the state licensing boards can make them their standard and require their implementation as a condition of licensure to practice in the state. We have found that about half of the states have done so in one way or another. At this time, however, no one knows how many dentists have fully implemented the recommendations. The proposed study will help fill that gap in knowledge as well as assist CDC to develop the next strategic steps in its campaign to have dental settings implement its newest guidelines. This data collection activity is authorized under Section 301 of the Public Health Service Act (42 U.S.C. 241) **(Attachment C1)**.

A2. Purpose and Use of the Information Collection

The purpose of this project is to develop the information that CDC needs to assess the existing level of infection control guideline implementation resulting from its dissemination efforts and those of others, so that it can develop its future research agenda and strategic plan to target available resources in ways that will foster and promote further awareness and adoption of the guidelines. The study will evaluate the extent to which these guidelines have been implemented in private non-institutionally based dental facilities, and assess how implementation of the

guidelines (in full or only in part) is related to: (1) characteristics of the dentists (demographic and educational but also including their knowledge of the guidelines and attitudes regarding their importance), (2) characteristics of the way care delivery is organized in their offices or clinics (with particular attention to the business, staffing, and physical facility aspects), and (3) factors in the larger environment including regional practice standards, state's licensing requirements, and available opportunities for continuing dental education.

The study will consist of a mail survey of 6,500 active dentists working in private practices in the U.S. to whom the *2007 Survey on CDC's 2003 Infection Control Guidelines* **(Attachment C4)** questionnaire will be mailed. Despite recognition that a dental hygienist or assistant may be the infection control manager for the dental practice, we have chosen to only mail the study questionnaire to dentists for two reasons. These reasons include the limited funds available for this study, and the fact it is dentists who own and operate the practices and are the persons responsible for the infection control recommendations that get adopted and implemented in their practices everywhere.

Under CDC direction, RTI (the prime contractor on this task order) is responsible for the development of the survey questionnaire, preparation of sampling specifications for the population of actively practicing dentists, analysis of the outcomes, and overall management of the study. The American Dental Association (ADA) has been subcontracted by RTI to use the ADA Dentists Master File as the frame from which to actually select the sample, disseminate the survey, monitor returns, conduct follow-up activities, key the responses, and prepare an electronic data base from the survey and additional selected items of data from the Master File. After receipt of OMB clearance, RTI will conduct a small pilot study with a random sample of no more than nine dentists in private practices who are not included in the larger study to test the instrument and planned survey procedures.

A3. Use of Improved Information Technology and Burden Reduction

Information will be collected through a mail survey of a stratified random sample of dentists to assess by self-administered questionnaire adoption of CDC's infection control guidelines. Respondents will be asked questions that relate only to the most current recommendations issued in 2003 and will not address recommendations issued prior to 2003.

After two follow-up mailings are conducted, attempts to call non-respondents will be made. The use of Internet searches to obtain current phone numbers will reduce the number of calls made to incorrect phone numbers. If the response rate is 50 percent or higher, the interviewer calls will merely prompt non-respondents to complete and return their questionnaires. In the event the response rate is below 50 percent, the interviewer caller will seek to complete the questionnaire over the phone by reading the questions and recording the responses on a questionnaire form for the respondent.

A4. Efforts to Identify Duplication and Use of Similar Information

The ADA's Survey Center will conduct data collection of information from a representative sample of U.S. dentists. The ADA's Survey Center is responsible for collecting, compiling,

analyzing and disseminating practice, economic, scientific, and statistical information of concern to the dental profession. Since the 1950s the Survey Center has conducted large-scale surveys of practicing dentists including the “1995 Survey of Dental Practices”, the “Survey of Current Issues in Dentistry, 1994", and the “Survey of Advanced Dental Education”.

Similar information was gathered from dentists for the CDC after the release of the infection control guidelines in 1993. However, since the publication of the 2003 infection control guidelines, no studies have been done to assess their implementation or how they might be further disseminated and implemented. The guidelines issued in 2003 were expanded beyond the 1993 guidelines to include topics such as hand hygiene products, dental radiology, oral surgical procedures, dental unit water standards, and infection control program evaluation.

A5. Impact on Small Businesses or Other Small Entities

Data will be collected from dentists who are currently practicing in private, outpatient facilities. The questions have been held to the absolute minimum required for the intended use of the survey data. The instrument will be presented in a clear and easy to read format based on previous ADA surveys. The respondents will be able to complete the survey at their leisure and will answer questions only about themselves and the practice in which they practiced most in previous 12 months. The questionnaire does not require respondents to look up information or consult records; therefore the time burden will be minimal.

A6. Consequences of Collecting the Information Less Frequently

This request is for a one-time study. There are no legal obstacles to reduce the burden.

A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for the study. The study fully complies with the regulations stated in 5 CFR 1320.5.

A8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

A. The 60 Day Federal Register Notice was published on April 5, 2006 (vol. 71, no.65, pg. 17102). One public comment was received. The comment and the response are attached (**Attachment C2**). No changes to the utility and scope of the proposed project were necessary after the review of the comment received.

B. At CDC’s request, Harold Edelman, D.D.S. has been consulted by RTI to review the questionnaire for comprehension and appropriateness. Dr. Edelman is an infection control expert, lecturer, and for 32 years a practicing dentist, who now travels around the nation lecturing to and consulting with dental care providers on how to implement the CDC infection control guidelines in their practices. Staff within the ADA and RTI have produced and reviewed the instrument at CDC’s request. ADA and RTI created the

questionnaire utilizing relevant items from previous surveys and adding newer items using the ADA format.

A9. Explanation of Any Payment or Gift to Respondents

No payments or gifts will be provided to respondents.

A10. Assurance of Confidentiality Provided to Respondents

The CDC Privacy Officer has reviewed this submission and determined that the Privacy Act applies because the survey includes questions relating to knowledge, opinions and beliefs which are considered personal information, and responses will be identifiable to the data collection staff for the duration of the data collection period (up to six months). Although respondents will be dentists in private practice speaking in part from their roles as owners, they will also be asked to answer questions about their knowledge of the 2003 CDC Infection Control Guideline recommendations, to supply information on incorporation of them into their office procedures, and to give opinions and beliefs about why some practices have implemented the Guidelines and others have not. The relevant Privacy System Notice is 0920-0136, Epidemiologic Studies and Surveillance of Disease Problems.

Both the prime contractor for this project, RTI, and the data collection subcontractor, ADA, will have access to identifiable response data throughout the data collection period which includes data entry and data editing. The contractors are committed to maintaining the trust of dentist respondents by keeping the responses private and will take the steps necessary during the data collection period to assure that this commitment is maintained. The steps include having data collection staff with access to identifiable data sign pledges of confidentiality as well as maintaining identifiable data secure, under lock if on paper (returned questionnaires and any completed by telephone) or in password protected directories and files (after keying and made electronic). A unique identification number will be assigned by the ADA to each sample member and affixed to the questionnaire as part of the mailing label. The number will be associated with the name and address of the dentist and be maintained by ADA thus making respondents identifiable to ADA during collection and to RTI as needed for data editing during the data collection period. Thus, only a limited number of staff involved in the data collection part of the project will have access to identifiable data, and then only for a limited time (up to six months).

The ability to identify respondents during this approximately seven month period is necessary to allow tracking of non-respondents for efficient follow-up to assure the highest possible response within the available resources. It will also make it possible to follow back to respondents for needed clarification of open-ended responses. The name and address information will not be made part of the keyed data file created from the questionnaires returned from respondents or completed by telephone. When the data collection period is completed, the identification number will be removed from the data file and be replaced with a serial number that will not be associated in any way with the original identification number or the dentist's name and address. This will result in an identity-free data file and eliminate the possibility of associating response data to the identities of the respondents. The ADA will not maintain any copies of any data files or any material that will enable it to make a link between cases on the file and the respondents'

identification number or name and address. ADA will strip all identifiers off the paper questionnaires and ship them to RTI for secure storage during the remainder of the project and eventual destruction by shredding. CDC will receive copies of the identity-free data file from RTI as project deliverables. RTI will conduct its analysis using the identity-free data file.

Data from the survey will be analyzed by RTI for CDC in aggregate form. No personal identifiers will be included in the data that are analyzed or delivered to CDC. The identity-free data will be maintained in accordance with the security safeguards described above – locked storage for paper documents and password protected accounts for electronic files. Only a limited number of authorized staff involved in the study will have access to the information collected.

This project has been exempted from IRB review by both RTI and CDC (**Attachment C8**.).

A11. Justification for Sensitive Questions

The survey includes some questions that may be considered sensitive by some responding dentists, especially those who practice in states where compliance with some or all of the guidelines have been made a condition of licensure. These questions probe compliance in the previous year in their primary place of practice with selected aspects of the guidelines (items 8 through 23). In addition, some respondents may view items 34 and 35, on the amount of infection control education they have received, as sensitive. It is important to ask the questions about compliance with aspects of the infection control guidelines to assess the level of guideline adoption and compliance nationwide. The items on infection control education are needed to determine whether greater participation in such activities is associated with greater adoption of the guidelines. We expect that having the ADA conduct the survey, telling respondents in the cover letter with the survey that after the survey is completed all personal identifiers will be removed, and that only aggregate analysis will be performed, will reassure dentists enough for them to respond honestly.

Race and ethnicity items are considered sensitive items, but CDC has no reason to believe that adoption of the guidelines is associated with the dentist's race or ethnicity. For this reason, the sample was not designed to consider that a domain of interest and there are no items in the questionnaire related to race and ethnicity.

A12. Estimates of Annualized Burden Hours and Costs

A. We have estimated the burden time for respondents to complete the questionnaire to be 15 minutes. Prior to this submission, the questionnaire was completed by ADA, CDC, and RTI staff in order to provide an estimated length of time it will take for respondents to complete the survey. These staff members took an average of 15 minutes to read and answer the questions on the instrument. The instrument consists of 37 questions printed on three legal-sized pages. After receipt of OMB clearance, we plan to conduct a small pilot test of the instrument and survey procedures with nine or fewer dentists not in the study sample. The reasons for the pilot test are to get another estimate of the time needed to complete the survey instrument, and to identify questions or responses that are unclear

or difficult for respondents to answer. The annualized burden is based on the expected number of respondents.

A. 12-1 Estimated Annualized Burden Hours

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden per Respondent (in hours)	Total Annual Burden (in hours)
U.S. dentists	4,550	1	15/60 (15 minutes)	1138 hours

B. We have estimated the cost burden to respondents based on the expected response burden and an estimated hourly wage for U.S. dentists obtained from the ADA for the expected number of respondents.

A.12-2 Annualized Cost to Respondents

Type of Respondent	No. of Respondents	Average Burden per Respondent (in hours)	Estimated Average Hourly Wage Rate	Estimated Total Respondent Costs
U.S. dentists	4,550	15/60 (15 minutes)	$75	$85,313

A13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There will be no respondent capital or maintenance costs associated with this study.

A14. Annualized Cost to the Federal Government

The cost estimates are based on the costs of tasks 3 through 7 of the original RFP bid upon by the RTI. Task 3 includes development of the advance, cover, and follow-up letters and the survey instrument. Task 4 includes preparation of the supporting materials for obtaining IRB and OMB clearance. Task 5 includes selecting the sample, conducting the pilot test, conducting the full survey, and reviewing the data to plan the analysis and incorporates the ADA subcontract. Task 6 involves identifying the factors from the survey that seem to influence adoption of the guidelines by dentists. Task 7 involves preparation of draft and final reports for CDC as well as delivering a verbal briefing. The cost for CDC are based on an estimation for one staff person working 20 percent of full time (defined as 2,000 hours per year.) for the entire survey and reporting period at an average of $75/hour.

A.14-1 Estimated Annual Cost to the Federal Government

Type of Costs	Source	Amount
Salaries	RTI	$89,417

Other Direct Costs	RTI	$75,500
Indirect Costs	RTI	$75,409
Fee	RTI	$16,744
Total Contractor	**RTI**	**$257,070**
Total Fed. Govt. Salary	**CDC**	**$30,000**
Total Combined of Contractor and Government		**$287, 070**

A15. Explanation for Program Changes or Adjustments

This is a new data collection.

A16. Plans for Tabulation and Publication and Project Time Schedule

A.16-1. Project Time Schedule

Task	Time Schedule
Pilot test conducted with sample of 9 dentists not in the study sample of 6500 dentists	Completed within first month after OMB approval
Lead letter mailed out to 6500 dentists	1 month after OMB approval
First mailing comprised of the cover letter and questionnaire sent to respondents	1.5 months after OMB approval
Thank you/reminder postcards sent to respondents/non-respondents	2 months after OMB approval
Second mailing comprised of the cover letter and questionnaire sent to non-respondents	3 months after OMB approval
Thank you/reminder postcards sent to respondents/non-respondents	3.5 months after OMB approval
Telephone reminder for non-respondents if response rate is at least 50%, or telephone interview utilizing the questionnaire if response rate is less than 50%	4.5 months after OMB approval
Begin analysis of data	7 months after OMB approval
Provide survey findings to CDC	9 months after OMB approval
Identify potential influential factors and provide CDC with a brief summary	10 months after OMB approval
Provide draft report to CDC	12 months after OMB approval
CDC provides comments on draft report to RTI	13 months after OMB approval
RTI revises and submits final report to CDC	14 months after OMB approval

A17. Reason(s) Display of OMB Expiration Date is Inappropriate

The expiration date for OMB approval of data collection will be displayed as required.

A18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement.