

Assessment of the 2011 CDC Protocol Change for Flight-Related Tuberculosis Contact Investigations

OSTLTS Generic Information Collection Request
OMB No. 0920-0879

Supporting Statement – Section A

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Program Official/Project Officer

Vanessa Fong, MPH

Public Health Advisor

National Center for Emerging and Zoonotic Infectious Disease

Division of Global Migration and Quarantine

Quarantine Border Health Services Branch

San Francisco International Airport, P.O. Box 280548, San Francisco, CA 94128

Phone: 650-876-2872

Fax: 404-471-8585

Email: ici6@cdc.gov

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- **Goals of the study:** This data collection will assess the level of satisfaction of state and local health department Tuberculosis (TB) programs with the updated Tuberculosis Contact Investigation (TBCI) protocol and to ascertain their perceptions regarding the overall change, resource utilization and allocation, adverse effects, and suggestions for future modifications.
- **Intended uses of the resulting data:** Information collected will be used by DGMQ to better understand the importance of flight-related TBCIs for state and local health departments' TB control efforts, assess stakeholder knowledge or awareness of the change in the TBCI protocol, determine impact of the protocol revisions on health department TB-related resources, determine if the protocol change resulted in missed opportunities to prevent TB disease, and assess and implement improvements to the TBCI process and the outcomes reporting form.
- **Method to be used to collect:** Data will be collected using a web-based instrument created in collaboration with the National Tuberculosis Controllers Association (NTCA) using SurveyGizmo®.
- **The subpopulation to be studied:** The respondent universe includes 125 tuberculosis controllers, or their designees, across 125 (50 states, 57 counties, 10 cities, and 8 territories) state, local, and territorial public health departments.
- **How data will be analyzed:** Data will be analyzed using Microsoft Excel and EpiInfo to create summary reports showing the frequency and counts of responses for each question of the online assessment. Descriptive statistical analyses will be conducted on responses to multiple-choice questions and qualitative analyses on response to open-ended questions.

Section A – Justification

1. Circumstances Making the Collection of Information Necessary

Background

This information collection is being conducted using the Generic Information Collection mechanism of the OSTLTS OMB Clearance Center (O2C2) – OMB No. 0920-0879. The respondent universe for this information collection aligns with that of the O2C2. Data will be collected from 125 tuberculosis controllers or their designees across 125 (50 states, 57 counties, 10 cities, and 8 territories) state, local, and territorial health departments acting in their official capacities (**see Attachment A – Tuberculosis Controller Jurisdictions**). The tuberculosis controllers were chosen to participate in the assessment because of their role as leaders of tuberculosis control programs in state, local, and territorial public health departments and are therefore the most knowledgeable about the information being requested in this data collection.

This information collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241). This information collection falls under the essential public health service(s) of:

- 1. Monitoring health status to identify community health problems
- 2. Diagnosing and investigating health problems and health hazards in the community
- 3. Informing, educating, and empowering people about health issues
- 4. Mobilizing community partnerships to identify and solve health problems
- 5. Development of policies and plans that support individual and community health efforts
- 6. Enforcement of laws and regulations that protect health and ensure safety
- 7. Linking people to needed personal health services and assure the provision of health care when otherwise unavailable
- 8. Assuring a competent public health and personal health care workforce
- 9. Evaluating effectiveness, accessibility, and quality of personal and population-based health services
- 10. Research for new insights and innovative solutions to health problems¹

Transmission of *Mycobacterium tuberculosis* during air travel is uncommon but has been documented. A review of 13 studies that assessed risks of in-flight transmission found two studies reporting reliable evidence of transmission on long-haul flights.² Both index patients were considered highly infectious at the time of the flights, as they were sputum smear-positive for acid-fast bacilli (AFB) and had cavitation on chest radiograph (CXR).^{3,4} Other studies found no evidence of transmission among passengers or were inconclusive.^{2,5,6}

CDC's Division of Global Migration and Quarantine (DGMQ) conducted a comprehensive review and analysis of the epidemiology of flight-related TB contact investigations (TBCIs) in the United States and found that the risk of transmission appeared to be low.⁵ The authors concluded that precise determination of in-flight transmission risk of *M. tuberculosis* was not feasible despite the use of significant resources on the part of international, federal, state, and local health authorities. Additionally, the contribution of flight-related TBCIs to domestic TB control was also low.

In light of these findings, DGMQ compared the risk and cost-benefit of more restrictive protocols for conducting flight-related TBCIs with the protocol in existence in 2008. Analyses suggested that the more restrictive criteria adopted in the 2011 modified CDC protocol would be more cost-effective than the criteria in the 2008 CDC protocol and would not increase public health risk.⁷ Both DGMQ and the Division of TB Elimination (DTBE), with the endorsement of the National Tuberculosis Controllers Association (NTCA), approved the 2011 Modified CDC Protocol for flight-related TBCIs on June 24, 2011 (hereafter referred to as the TBCI protocol). It was implemented in July 2011.

The updated guidelines have more restrictive criteria for initiating a TBCI based on the low risk of in-flight TB transmission for flights at least 8 hours in duration (gate-to-gate time). This protocol change has not yet been systematically assessed for stakeholder opinion. DGMQ recognized the need for a stakeholder assessment and subsequently partnered with NTCA for support in the development and dissemination of the assessment.

Through the support of NTCA, this data collection will assess the level of satisfaction of state and local health department TB programs with the updated TBCI protocol and to ascertain their perceptions regarding the overall change, resource utilization and allocation, adverse effects, and suggestions for future modifications.

Findings from this data collection will be used by DGMQ to:

- Better understand the importance of flight-related TBCIs for state and local health departments' TB control efforts
- Assess stakeholder knowledge or awareness of the change in the TBCI protocol
- Determine impact of the protocol revisions on health department TB-related resources
- Determine if the protocol change resulted in missed opportunities to prevent TB disease
- Assess and implement improvements to the TBCI process and the outcomes reporting form.

Overview of the Information Collection System

Data will be collected from 125 tuberculosis controllers, or their designees, across 125 (50 states, 57 counties, 10 cities, and 8 territories) state, local, and territorial health departments (**see Attachment A – Tuberculosis Controller Jurisdictions**) via a web-based questionnaire (**see Attachment B –Instrument: Word version and Attachment C –Instrument: Web version**). The web-based data collection instrument will be used to gather information from public health TB controllers or their designees at state, local, and territorial health departments regarding their perceptions of the overall change in the TBCI protocol, including resource utilization and allocation and negative outcomes. Additionally, the instrument will ask respondents for suggestions for improving the protocol. The instrument was created in collaboration with the National Tuberculosis Controllers Association (NTCA) using SurveyGizmo®. This method of data collection was chosen to allow respondents to complete and submit their responses electronically, reducing the overall burden on respondents. The data collection instrument was pilot tested by eight public health professionals. Feedback from this group was used to refine questions as needed, ensure accurate programming and skip patterns, and to establish the estimated time required to complete the data collection instrument.

Items of Information to be Collected

The web-based data collection instrument (**see Attachment B –Instrument: Word version and Attachment C –Instrument: Web version**) consists of 29 questions. Question types include dichotomous (yes/no), multiple response, and open-ended. In an effort to minimize response burden, the instrument was designed with particular focus on streamlining questions to allow for skipping questions based on responses to previous questions. Also, an effort was made to limit questions requiring narrative responses from respondents whenever possible.

The instrument will collect information on the following:

- Respondent demographic information related to official role (6 questions)
 - Jurisdiction type

- Jurisdiction's TB incidence rate (high/medium/low)
- Respondent's primary role at health department
- Time with jurisdiction and
- Percentage of time spent on TB control
- Respondent and jurisdiction name
- Flight-related TBCI Protocol and the 2011 Protocol change (9 questions)
 - Awareness of the change in the protocol
 - Change in the number of TBCIs conducted (more/less/remained the same)
 - Importance of TBCIs in jurisdiction's TB control efforts
 - Having adequate funding and human resources to conduct TBCIs
 - Change in resources available for TB control efforts (increased/decreased/remained the same)
 - Awareness of TB cases that could have been prevented if the TBCI protocol had not been put into place
- Flight-related TBCI passenger contact follow-up and outcomes reporting (10 questions)
 - Number of notifications received in past year
 - Frequency of attempts to reach passenger contacts provided by DGMQ
 - Frequency of reported TBCI outcomes to DGMQ in past year
 - Check items that could be done to improve outcomes reporting of health departments to DGMQ
 - Awareness of and feedback regarding TBCI outcome summary reports created by DGMQ
- Suggestions for potential flight-related TBCI protocol revisions (4 questions)
 - Questions or concerns about the TBCI protocol implemented in 2011
 - Opinion on current European criteria for doing TBCIs
 - Recommendations on TBCIs for situations involving multidrug-resistant (MDR)/extensively drug-resistant (XTR) TB cases
 - Any other recommended changes

2. Purpose and Use of the Information Collection

The purpose of this data collection is to assess the level of satisfaction of state and local health department TB programs with the updated TBCI protocol and to ascertain their perceptions regarding the overall change, resource utilization and allocation, adverse effects, and suggestions for future modifications. Data will be collected from 125 (50 states, 57 counties, 10 cities, and 8 territories) state, local, and territorial health department TB programs regarding:

- 1) the importance of flight-related TBCIs to state and local health departments' TB control efforts
- 2) knowledge or awareness of the flight-related TBCI protocol change
- 3) the impact of the protocol revisions on health department TB-related resources
- 4) if the 2011 protocol change resulted in missed opportunities to prevent TB disease

- 5) suggestions for improvements to the flight-related TBCI process and outcome reporting form

Findings from this data collection will be used by DGMQ to:

- Better understand the importance of flight-related TBCIs for state and local health departments' TB control efforts
- Assess stakeholder knowledge and/or awareness of the change in the TBCI protocol
- Determine impact of the protocol revisions on health department TB-related resources
- Determine if the protocol change resulted in missed opportunities to prevent TB disease
- Assess and implement improvements to the TBCI process and the outcomes reporting form.

3. Use of Improved Information Technology and Burden Reduction

Data will be collected via a web-based data collection instrument allowing respondents to complete and submit their responses electronically. This method was chosen to reduce the overall burden on respondents. The data collection instrument was designed to collect the minimum information necessary for the purposes of this project (i.e., limited to 29 questions). Further, skip patterns were incorporated to allow for streamlining responses and the reduction of burden on respondents.

4. Efforts to Identify Duplication and Use of Similar Information

This data collection is the first attempt to gather stakeholder feedback regarding the flight-related TB contact investigation protocol changes. Information regarding the satisfaction and/or dissatisfaction with the change, effects the protocol change has/has not had on resource utilization and allocation, and any suggestions for future changes or improvements to the TBCI protocol are lacking. Given these limitations, this data collection will support the need to collect this information.

Additionally, prior to developing this information collection, DGMQ conducted a literature review to confirm no similar reports or assessments of information existed and that this effort is not duplicative.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

This request is for a one-time information collection. There are no legal obstacles to reduce the burden. If no data are collected, CDC will be unable to:

- Collect input from stakeholders regarding knowledge and perceptions of the flight-related TB contact investigation protocol changes and associated impact on TB programs
- Better understand the capacity of TB programs at state, local, and territorial health departments to conduct TBCIs as part of a comprehensive TB control program

- Obtain information that may be used to inform future TB aviation contact investigation protocol changes

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

There are no special circumstances with this information collection package. This request fully complies with the regulation 5 CFR 1320.5 and will be voluntary.

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

This information collection is being conducted using the Generic Information Collection mechanism of the OSTLTS OMB Clearance Center (O2C2) – OMB No. 0920-0879. A 60-day Federal Register Notice was published in the Federal Register on October 31, 2013, Vol. 78, No. 211; pp. 653 25-26. No comments were received.

CDC partners with professional STLT organizations, such as the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), and the National Association of Local Boards of Health (NALBOH) along with the National Center for Health Statistics (NCHS) to ensure that the collection requests under individual ICs are not in conflict with collections they have or will have in the field within the same timeframe.

9. Explanation of Any Payment or Gift to Respondents

CDC will not provide payments or gifts to respondents.

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

The Privacy Act does not apply to this data collection. STLT governmental staff and/or delegates will be speaking from their official roles.

Although NTCA will collect some individually identifiable information (IIF) related to the official roles of respondents, including respondent name and jurisdiction, all information will be kept on secure, password protected NTCA servers accessible only to project team members. NTCA will remove all potential identifiers and share only the de-identified data with CDC. No IIF will be distributed.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

This information collection is not research involving human subjects.

No information will be collected that are of personal or sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

The estimate for burden hours is based on a pilot test of the information collection instrument by eight public health professionals. In the pilot test, the average time to complete the instrument including time for reviewing instructions, gathering needed information and completing the instrument, was approximately 15 minutes (range: 11 to 20 minutes). For the purposes of estimating burden hours, the upper limit of this range (i.e., 20 minutes) is used.

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) Bureau of Labor Statistics for occupational employment for 29-1199 Health Diagnosing and Treating Practitioners (http://www.bls.gov/oes/current/oes_nat.htm). Based on DOL data, an average hourly wage of \$41.86 is estimated for all 125 respondents. Table A-12 shows estimated burden and cost information.

Table A-12: Estimated Annualized Burden Hours and Costs to Respondents

Information collection Instrument: Form Name	Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Assessing the Impact of the 2011 CDC Protocol Change for Flight-Related Tuberculosis Contact Investigations (TBCI)	Public Health TB Controllers or their designees	125	1	20/60	42	\$41.86	\$1758.12
	TOTALS	125	1		42		\$1758.12

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

There will be no direct costs to the respondents other than their time to participate in each information collection.

14. Annualized Cost to the Government

There are no equipment or overhead costs. The only cost to the federal government would be the salary of CDC staff. Select members of the National Tuberculosis Controller's Association (NTCA)

are being used to support development of the assessment tool, data collection, and data analysis but are doing so in an unfunded, voluntary capacity. The total estimated cost to the federal government is \$10,946.35. Table A-14 describes how this cost estimate was calculated.

Table A-14: Estimated Annualized Cost to the Federal Government

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Average Cost
Epidemiologists (GS-12) Instrument development, pilot testing, OMB package preparation, data collection, data coding and entry, quality control, data analysis, report preparation	30 hours	\$44.23	\$1326.90
Epidemiologists (GS-12) Instrument development, pilot testing, OMB package preparation, data collection, data coding and entry, quality control, data analysis, report preparation	30 hours	\$46.15	\$1384.50
Medical Officer (GS-14) Instrument development, pilot testing, OMB package preparation, report preparation	25 hours	\$72.11	\$1802.75
Medical Officer (GS-13) Instrument development, pilot testing, OMB package preparation, report preparation	25 hours	\$67.30	\$1682.50
Public Health Analyst (GS-13) Instrument development, pilot testing, OMB package preparation, report preparation	25 hours	\$67.30	\$1682.50
Public Health Analyst (GS-14) Instrument development, pilot testing, OMB package preparation, report preparation	25 hours	\$51.92	\$1298.00
Public Health Advisor (GS-12) Instrument development, pilot testing, OMB package preparation, report preparation	40 hours	\$44.23	\$1769.20
National Tuberculosis Controller's Association (NTCA) Survey Committee POC Instrument development, pilot testing	15 hours	\$0	\$0
Estimated Total Cost of Information Collection			\$10,946.35

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Once the 4-week data collection period has closed, respondent data will be downloaded, exported to an Excel spreadsheet, and saved to a secure database maintained by NTCA. NTCA will then remove all potential identifiers and share the de-identified data with CDC. DGMQ will use this de-identified data for analysis. Data will be analyzed using Microsoft Excel and EpiInfo to create summary reports showing the frequency and counts of responses for each question of the online

assessment. Descriptive statistical analyses will be conducted on responses to multiple-choice questions and qualitative analyses on response to open-ended questions. Qualitative analysis of open-ended responses will be achieved by coding responses into categories that can be analyzed quantitatively.

Upon completion of data analysis, CDC will utilize the de-identified data to compile a report summarizing the results and will share this report with DGMQ leadership, NTCA, and respondents. The results will also be used to develop a manuscript for submission to a peer-reviewed journal.

Project Time Schedule

- ✓ Design questionnaire(COMPLETE)
- ✓ Develop protocol, instructions, and analysis plan(COMPLETE)
- ✓ Pilot test questionnaire(COMPLETE)
- ✓ Prepare OMB package(COMPLETE)
- ✓ Submit OMB package(COMPLETE)
- OMB approval (TBD)
- Conduct assessment (Assessment open 4 weeks)
- Code, quality control, and analyze data..... (4 weeks)
- Prepare reports (4 weeks)
- Disseminate results/reports (4 weeks)

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

We are requesting no exemption.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

LIST OF ATTACHMENTS – Section A

Note: Attachments are included as separate files as instructed.

- A. Attachment A – Tuberculosis Controller Jurisdictions**
- B. Attachment B – Instrument: Word version**
- C. Attachment C – Instrument: Web version**

REFERENCE LIST

1. Centers for Disease Control and Prevention (CDC). "National Public Health Performance Standards Program (NPHPSP): 10 Essential Public Health Services." Available at <http://www.cdc.gov/nphpsp/essentialservices.html>. Accessed on 8/14/14.
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7. Marienau KJ, Cramer E, Coleman MS, Marano N, Cetron MS. Risk and economic analyses of flight-related tuberculosis in the United States. *Travel Med Infect Dis* 2014; 1:54-62.