Information Collection for Tuberculosis Data from Panel Physicians

Request for a Revision

OMB No. 0920-1102
(Exp. 2/28/2019)

July 24, 2018
Statement A

Program Contact

Lee Samuel
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta, Georgia 30333
Phone: (404) 718-1616
Email: llj3@cdc.gov

TABLE OF CONTENTS

- Goal of data collection
  - To determine TB rates in immigrant and refugee populations migrating to the U.S.
- Intended use of the resulting data
  - To improve the quality of TB screening overseas and evaluate the impact of CDC's *Culture and Directly Observed Therapy Tuberculosis Technical Instructions*
- Methods to be used to collect
  - Descriptive review of medical exams performed under existing U.S. regulations
- The subpopulation to be studied
  - Immigrant and refugee applicants being examined overseas under existing U.S. regulations
- How data will be analyzed
  - Descriptive summaries of TB rates by panel site

PART A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Background

The Centers for Disease Control and Prevention's (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Global Migration and Quarantine (DGMQ), Immigrant, Refugee, and Migrant Health Branch (IRMH), requests approval for revision to an approved information collection. CDC requests this data collection approval for three years. This revision include a decrease in the requested number of burden hours from 2,648 hours to 1,008, and a decrease in respondents from 353 to 336.

The respondents are U.S. panel physicians. Panel physicians are medically trained, licensed, and experienced medical doctors practicing overseas who are appointed by the local U.S. Embassy or Consulate General to perform medical examinations for prospective immigrants to the United States. More than 760 panel physicians perform overseas pre-departure medical examinations at 336 panel sites, in accordance with requirements, referred to as *Technical Instructions*, provided by the Centers for Disease Control and Prevention's Division of Global Migration and Quarantine, Quality Assessment Program (QAP). The QAP program is housed in the Immigrant, Refugee, and Migrant Health Branch (IRMH). The role of QAP is to assist and guide panel physicians in the implementation of the *Technical Instructions*; evaluate the quality of the overseas medical examination for U.S.-bound immigrants and refugees; assess potential panel physician sites; and provide recommendations to the U.S. Department of State in matters of immigrant medical screening.

To achieve DGMQ's mission, IRMH works with domestic and international programs to improve the health of U.S.-bound immigrants and refugees to protect the U.S. public by preventing the importation of infectious disease. These goals are accomplished through IRMH's oversight of medical exams required for all U.S. - bound immigrants and refugees who seek permanent residence in the U.S. IRMH is responsible for assisting and training the international panel physicians with the implementation of medical exam *Technical Instructions*. CDC's

Technical Instructions are detailed requirements and national policies regarding the medical screening and treatment of all U.S.-bound immigrants and refugees.

Screening for tuberculosis (TB) is a particularly important component of the immigration medical exam and allows panel physicians to diagnose active TB disease prior to arrival in the United States. As part of the *Technical Instructions* requirements, panel physicians perform chest x-rays and laboratory tests that aid in the identification of tuberculosis infection (Class B1 applicants) and diagnosis of active tuberculosis disease (Class A, inadmissible applicants). CDC uses these classifications to report new immigrant and refugee arrivals with a higher risk of developing TB disease to U.S. state and local health departments for further follow-up. Some information that panel physicians collect as part of the medical exam is not reported on the standard Department of State forms (DS-forms), thereby preventing CDC from evaluating TB trends in globally mobile populations and monitoring program effectiveness.

In 2007, CDC revised the *Tuberculosis Technical Instructions* to include several new requirements for *Mycobacteria tuberculosis* (MTB) testing and treatment. Important changes included the requirements for: 1) sputum cultures in addition to sputum smears; 2) tuberculin skin tests or interferon gamma release assays (beginning in 2009) for certain children aged 2–14 years examined in countries where the World Health Organization estimated TB incidence is ≥20 per 100,000 persons; 3) drug-susceptibility testing of positive isolates; and 4) treatment being delivered as directly observed therapy (DOT) throughout the entire course.

Since implementation of these new *Culture and Directly Observed Therapy TB Technical Instructions* (CDOT TB TI), overseas TB case detection has increased by an estimated 60% and allowed U.S. public health programs to save millions of dollars annually. Overseas TB screening data (referred to by DGMQ as 'TB Indicator data') is critical to support the continued analysis of these trends and the monitoring of TB control efforts in the U.S.

The information collection for which approval is sought is in accordance with DGMQ's mission to reduce morbidity and mortality among immigrants, refugees, travelers, expatriates, and other globally mobile populations, and to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the U.S. This mission is supported by delegated legal authorities.

The Secretary of Health and Human Services has the legal authority to establish regulations outlining the requirements for the medical examination of aliens before they may be admitted into the United States. This authority is provided under Section 212(a)(1)(A) of the Immigration and Nationality Act (8 U.S.C. § 1182(a)(1)(A)) (Attachment A1) and Section 325 of the Public Health Service Act (Attachment A2). These regulations are codified in 42 CFR Part 34, which establish requirements that determine whether aliens can be admitted into the U.S (Attachment A3).

2. Purpose and Use of Information Collection

DGMQ's TB Indicator data provides valuable epidemiologic data on globally mobile populations and allows CDC to monitor the effectiveness and impact of CDC's *Technical Instructions* in diagnosing applicants with TB disease. This data will be used to:

- Improve quality assurance efforts and monitor proficiency of TB screening programs overseas
- Estimate the impact of the CDOT TB TI on the immigrant screening program by analyzing the number of smear negative/culture positive TB cases. These cases represent the number of TB cases that would have been missed under the old screening program.
- Compare TB Indicator incidence rates to WHO country-specific TB incidence rates for internal quality assessment purposes only.
- Detect and resolve problems at panel sites demonstrating lower than expected TB detection rates.

Data will primarily be used internally to monitor program impact, but may also be shared with state and local health authorities involved in TB control. Information dissemination may include abstract submission to scientific conferences, including the Union World Conference on Lung Health, the National TB Controllers Association and the Panel Physician Training Summits.

3. Use of Improved Information Technology and Burden Reduction

DGMQ staff will employ electronic technology to collect and process data in order to reduce respondent burden and aid in data processing and reporting efficiency. Particular emphasis will be placed on compliance with the Government Paperwork Elimination Act (GPEA), Public Law 105-277, title XVII.

The primary method of information collection will include an electronic TB Indicator Reporting Form spreadsheet (Attachment C) that panel physicians can use to send aggregate TB data to CDC. The number of questions posed are the minimum required in order to elicit the necessary TB-related data.

4. Efforts to Identify Duplication and Use of Similar Information

Because DGMQ's public heath mission is supported by regulatory responsibilities related to immigrant medical screening, as outlined in Section A1, it is not expected that any of the information collected under this proposed new clearance is duplicative or is already in the possession of the federal government. By collecting information on the total number of applicants screened at each panel site, the TB Indicator data provides an accurate denominator of immigrants and refugees screened overseas, which is not available through any existing CDC system. The TB Indicator data also provides the number of applicants with abnormal radiology findings suggestive of TB disease, the number with active TB disease and the drug-susceptibility results of those with culture positive TB disease. Currently, CDC lacks any data system that collects this information for all applicants screened by a panel physician.

5. Impact on Small Businesses or Other Small Entities

While panel physicians may be considered small businesses, they have each been chosen by the Department of State to be the sole medical provider of pre-departure medical screening to U.S.-bound immigrants and refugees. They are therefore the most reliable source of TB data in these specific populations. CDC has endeavored to lessen the burden to extent possible while still collecting the necessary data.

6. Consequences of Collecting the Information Less Frequently

This request is for a new information collection. There are no legal obstacles to reduce the burden. Currently, CDC is requesting this data to be sent by panel physicians once per year. The consequences of reducing this frequency would be the loss of monitoring program impact and TB burdens in mobile populations on an annual basis.

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

This request fully complies with the regulation 5 CFR 1320.5.

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

A. This is a request for a revision. A 60-day Federal Register Notice was published in the Federal Register on May 29, 2018, Vol. 83, No. 103, pp. 24476-24478 (Attachment B). Three non-substantive public comments were received (Attachments B1-B3).

B. Consultation

The following individuals were consulted on the collection of TB indicator data from Panel Physicians.

Individuals	**Title**	**Role**	**Contact Information**
Dr. Angel Contreras, MD	U. S. Panel Physician, Dominican Republic	Consulted on the need for data collection, approved necessity of project	abcontreras@codetel.net.do
Dr. Ali Jawa	President, International Panel Physicians' Association	Consulted on the need for data collection, approved necessity of project	alijawa@gmail.com
Dr. Akeza Teame	U.S. Panel Physician, Ethiopia	Consulted on the need for data collection, approved necessity of project	ateame@yahoo.com

Dr. Funmi Alakija	U.S. Panel Physician, Nigeria	Consulted on the need for data collection, approved necessity of project	qlifecare@hotmail.com
Dr. Daniel Baume	U.S. Panel Physician, Congo	Consulted on the need for data collection, approved necessity of project	daniel.baume@gmail.com

9. Explanation of Any Payment or Gift to Respondents

DGMQ will not provide remuneration or incentives to participants.

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

No PII is being collected under this control number. The National Center for Emerging and Zoonotic Infectious diseases has reviewed this proposed collection and determined that the Privacy Act does not apply. No PII is being collected as part of this project. TB Indicator data will be stored electronically on secure CDC servers, with a limited number of relevant employees having access.

Information will be collected from each Panel Physician site using a Microsoft Excel spreadsheet on an annual basis. The TB-related information that is sent to CDC is aggregate in nature, and no personal identifying information (PII) from any applicant for U.S. immigration is included.

Information to be collected using the spreadsheet includes:

- number of applicants screened,
- age categories of applicants,
- number of abnormal chest x-rays,
- acid fast bacilli (AFB) smear results,
- mycobacterium tuberculosis (MTB) cultures,
- drug susceptibility test (DST) results, and
- TB treatment disposition.

This information collection will have no impact on a respondents' privacy. The Panel Physicians are chosen by the Department of State to provide this information and their information is readily available in a number of public venues.

The Panel Physicians will be informed that the data is required as part of their agreement to comply with the CDOT TB Technical Instructions as part of the Quality Assurance Program.

Panel Physicians will be made aware that information collected from the spreadsheet may be shared with CDC partners, become part of presentations, or become part of publications, if

warranted. All sharing of information will be in aggregate and will not identify individual respondents.

A Privacy Impact Assessment is included with this submission (Attachment E).

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

Only aggregate data on TB diagnoses from the Panel Physicians will be collected as part of this project. No information will be collected that are of a personal or sensitive nature.

IRB Approval

This information collection was reviewed by the Associate Director for Science in DGMQ, Dr. Pamela Diaz, who determined that this project does not consist of research involving human subjects (Attachment D).

12. Estimates of Annualized Burden Hours and Costs

A. All Panel physicians will be asked to submit TB Indicator data to CDC once per year. A prior estimate of 7.5 hours has been reduced to 3 hours based on the knowledge that most panel physicians have established electronic tracking systems since the last OMB approval period, thereby reducing the amount of time needed to report this data to CDC.

CDC has also reduced burden by removing four variables related to pending lab results since the last OMB approval period. The reporting deadline for the previous calendar year was moved from January to March which eliminated the need for physicians to report "pending" results. The four removed variables are:

- 5a. AFB Smears Pending
- 5f. Smear+/Culture Pending
- 5g. Smear-/Culture Pending
- 6a. DST Pending

Therefore, based on improved IT capacity at most panel sites and an overall reduction in variables collected since the last OMB approval period, the updated annual burden hours is estimated to be 3 hours per year.

CDC also estimates a decrease in the number of respondents from 353 to 336.

Table 12.A: Estimated Annualized Burden to Respondents

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
International Panel Physicians (All sites)	TB Indicators Excel Spreadsheet	336	1	3	1008

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
TOTAL					1008

B. All of the respondents will be international panel physicians. Table 12.B presents the calculations for cost of respondents' time using one category of mean hourly wages for a physician in the U.S. Hourly mean wage information is from the U.S. Department of Labor's Bureau of Labor Statistics website (https://www.bls.gov/oes/current/oes291069.htm). Based on BLS wage category 29-1069 Physicians and Surgeons, All Other, an average hourly wage of $103.63 is estimated for all 336 respondents. Table A.12-B shows estimated burden and cost information. The total estimated annualized respondent cost is $104,459.04.

Table 12.B: Estimated Annualized Burden Hours

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondents' Costs
International Panel Physicians	TB Indicators Spreadsheet	1008	$103.63	$ 104,459.04
TOTAL				$ 104,459.04

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 complete the TB Indicators Spreadsheet.

14. Annualized Cost to the Government

Describe any cost to the government

The estimated cost for the federal government is calculated to be approximately 30% of the workload of one GS-13 federal government employee salary at the Atlanta, GA locality.

Table 14: Estimated Annualized Cost to the Federal Government

Contract and Personnel	Role	Average Cost
Federal employee costs, per information	1 GS-13 FTE (30%)	$27489.30

collection, (e.g. 30% FTE of one GS-13 at $91,631/year)		
Total Costs		**$27,489.30**

15. Explanation for Program Changes or Adjustments

A prior estimate of 7.5 hours has been reduced to 3 hours based on the knowledge that most panel physicians have established electronic tracking systems since the last OMB approval period, thereby reducing the amount of time needed to report this data to CDC.

CDC has also reduced burden by removing four variables related to pending lab results since the last OMB approval period. Therefore, based on improved IT capacity at most panel sites and an overall reduction in variables collected since the last OMB approval period, the updated annual burden hours is estimated to be 3 hours per year.

16. Plans for Tabulation and Publication and Project Time Schedule

Data will be entered and analyzed March – December of each calendar year and reported at annual TB conferences and meetings, as appropriate. Reports of CDC's findings will also be provided to panel physicians annually. Plans for scheduled or routine peer-review publication are being discussed and may be warranted as DGMQ demonstrates continued impact on domestic and foreign TB-control programs.

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

No exemption is being requested. The display of the expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

Attachment A1: Immigration and Nationality Act 8 U.S.C. § 1182

Attachment A2: Public Health Service Act 42 U.S.C. § 252

Attachment A3: 42 CFR Part 34

Attachment B: 60 day notice

Attachment B1: Public comment

Attachment B2: Public comment

Attachment B3: Public comment

Attachment C: TB Indicator Reporting Form

Attachment D: IRB Determination

Attachment E: Privacy Impact Assessment