Aggregate Reports for Tuberculosis Program Evaluation
0920-0457
(1) Follow-up and Treatment of Contacts to Tuberculosis Cases

(2) Targeted Testing and Treatment for Latent Tuberculosis Infection

Supporting Statement A

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Table of Contents

A. Justification

1. Circumstances Making the Collection of Information Necessary

Background

This is a request for reinstatement with change of an approved data collection, OMB Control No. 0920-0457, which is in active use by tuberculosis (TB) control programs in health departments throughout the United States. Changes within this information collection request (ICR) reflect an increase in the annual cost to the government (see Table B.12.1). The increased cost is due to increases in salaries of personnel conducting data collection and analysis since the last ICR approval.

The Division of Tuberculosis Elimination (DTBE), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC), maintains cooperative agreements with the health departments of the 50 states, 10 large cities, and 8 trust territories and protectorates who submit tuberculosis program management reports. Since 2000, the "Aggregate Reports for Tuberculosis Program Evaluation", replaced several outdated reports and are used nationwide. The changes in these reports corresponded to the evolving national tuberculosis control strategy and the new data-systems technology. CDC also provides ongoing technical consultation about tuberculosis control for these health departments.

The two reports submitted here (Attachments 3a and 3b), measure the extent, the efficiency, and the yield of these activities. For tuberculosis control, 68 federal cooperative agreement sites encompass the United States, and they are the respondents for the reports. These sites have adopted the Aggregate Reports for Tuberculosis Program Evaluation as their generic tool for assessing their tuberculosis prevention activities. They use the reports for generating the indicators used in program evaluation as stipulated in the 2010 cooperative agreement, for monitoring the workload of tuberculosis prevention, and for estimating the epidemiological status of tuberculosis in their jurisdictions.

This data collection is authorized under Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment 1).

Privacy Impact Assessment

Overview of the Data Collection System

Data are collected by state and local health departments as part of routine contact investigation activities for providing information on cases of tuberculosis disease or infection. Data aggregation varies by site, with computerized methods becoming the norm at large jurisdictions. Respondents provide the data following the format as outlined on the Aggregate Reports for Tuberculosis Program Evaluation. The respondents have a

choice of submitting their aggregated data to CDC by encrypted computer transmission, by facsimile copy, by email, or by US Postal service. There is no current plan for data retirement as the data is used for monitoring trends over an indefinite period of time.

Items of Information to be Collected

No individually identifiable information is being collected. The two reports submitted here (Attachments 3a and 3b) identify the types of non-individually identifiable information that will be collected. The source data for the Aggregate Reports for Tuberculosis Program Evaluation are gathered as part of standard public health practice for tuberculosis control under the authority of state and local health departments. No respondents submit these data with individual patient records to CDC. Although health departments may collect identifiable information for local tuberculosis control purposes, consistent with state and local laws, this information is retained at those level, and health departments do not transmit person-level data or identifiable data to CDC. The data associated with this OMB clearance are submitted to CDC only in an aggregate format (refer to Section A.10).

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

The instructions for reporting and completing the aggregate reports are available on-line (http://www.cdc.gov/tb/publications/PDF/ARPEs_manualsm1.pdf) information collection does not involve web-based data collection methods and does not refer respondents to websites

The website is available only to the health departments with a secured password.

2. Purpose and Use of Information Collection

CDC uses the data from these reports for monitoring local, state, and national tuberculosis control programs, for planning national tuberculosis control strategy, and in estimating funding needs. The results in these reports are compared to the national performance goals, and they indicate progress toward achieving tuberculosis elimination. These data address Government Performance Results Act (GPRA) section IIH, Tuberculosis Performance Goal 1 Item 3 (“Increase the percentage of contacts of infectious AFB smear positive cases who are placed on treatment for latent tuberculosis infection and complete a treatment regimen”) and Item 4 (“Increase the percentage of other high risk infected persons who are placed on treatment for latent tuberculosis infection and complete a treatment regimen”). The Aggregate Reports for Tuberculosis Program Evaluation show that approximately 65% of contacts of infectious tuberculosis cases start and finish a treatment regimen, which informs CDC and the respondents that the current prevention activities are not at their full potential. This informs strategy and resource allocation.

CDC has disseminated the results from these reports in the following ways:

- An annual “dear-colleague” letter from the director of DTBE, for data years 2000–2006, to the respondents, who are the 68 state, territorial, and big city tuberculosis control officials. This letter reiterates the purposes of the data collection and provides a national interpretation of the results for the year.
- A journal publication of the baseline data that some of the respondents submitted to CDC during the first year of the reporting cycle (Jereb J, Etkind S, Joglar O, Moore M, Taylor Z. Tuberculosis contact investigations: outcomes in selected areas of the United States, 1999. The International Journal of Tuberculosis and Lung Disease 2003;7:S384-S390).
- CDC poster presentations of the national summary results and interpretation at the annual conference of the National Tuberculosis Controllers Association (NTCA, i.e., the official organization representing the report respondents). Presentations in this forum will continue annually.
- Results from the reports will also be incorporated into the National Tuberculosis Indicators Project (NTIP). NTIP is a secure web-based monitoring system that allows state and local health authorities to access reports and review data. The NTIP system will provide TB programs with reports to describe their progress, based on data already reported to the Centers for Disease Control and Prevention (CDC), and facilitate the use of existing data to help programs prioritize activities and focus program evaluation efforts.

CDC uses the reports for assessing the effective use of federal tuberculosis cooperative agreement funds. Reports for program evaluation are stipulated in the cooperative agreements. The CDC tuberculosis program consultants, who use the reports as the standard measurement of workload and performance, visit the 68 cooperative agreement sites at least annually to review local progress toward tuberculosis elimination.

All state health departments have adapted the Aggregate Reports for Tuberculosis Program Evaluation for their own tuberculosis control programs. Most health departments use the identical reports that they submit to CDC, while a few, such as the health departments in California and Florida, have elaborated on the reports to meet their specialized needs. Health departments that have their own comprehensive data management systems for tuberculosis control, such as in New York State and Illinois, have designed their systems so that information for the Aggregate Reports for Tuberculosis Program Evaluation are generated automatically and thus at no added burden for the respondents, who already were collecting the data for their own use.

There are no revisions to the Aggregate Reports for Tuberculosis Program Evaluation. The majority of technical-support questions about the reports have been related to data definitions. CDC has addressed these questions by preparing extended on-line instructions that are linked to the DTBE web page (http://www.cdc.gov/nchstp/tb/pubs/PDF/ARPEs_manual.pdf). The on-line instructions include guidance about how the respondents (i.e., the state and local public health departments) can use the reports for monitoring the results of their own tuberculosis

control programs.

Difficulties have been reported anecdotally for specific complex large tuberculosis outbreaks in institutional settings (e.g., prisons or homeless shelters) two or three times per year. The data structure required by these outbreaks is too complex for the Aggregate Reports for Tuberculosis Program Evaluation. These issues have been resolved collaboratively between the respondents and the CDC tuberculosis program consultants by collapsing the data into simpler formats that were compatible with the reports. CDC is not proposing revisions to the reports to accommodate more complex data because the current reports are sufficient for most data. If the reports were expanded for rare instances of complex data, this would increase the burden to the respondents without sufficient compensatory benefit to the respondents or to CDC.

State and local public health officials have cited improved convenience and usefulness of the current reports in comparison to the older CDC reports. The reports document that the scope of prevention activities is large: according to the most recent final reports, at least 130,000 persons in the United States were listed as exposed to tuberculosis in 2003, and more than one-quarter of the persons who underwent diagnostic testing were found to have tuberculosis infection. The reports also have shown that approximately 10% of contagious tuberculosis patients in the United States do not have contacts listed, which demonstrates a particular need for improvements in tuberculosis prevention.

These data from the Aggregate Reports for Tuberculosis Program Evaluation continue to demonstrate the scope of the public health problem and the prevention activities for which CDC is jointly accountable, in collaboration with U.S. state and local health departments. Without the Aggregate Reports for Tuberculosis Program Evaluation reports, CDC does not have a standard measurement of workload, yield, efficiency, and effectiveness of the prevention activities carried out by state and local tuberculosis control programs. National data about the transmission of tuberculosis infection and the prevention of tuberculosis cases will not be available. CDC needs a fair, standard assessment of the utilization of the funding disbursed through the federal tuberculosis cooperative agreements. Even if CDC could not collect the reports, state health departments would continue using them for monitoring the efforts of their own tuberculosis programs, because they have found the reports to be feasible and useful.

Privacy Impact Assessment Information

The information relates to the two priority areas of TB prevention and control (1) evaluating all contacts to contagious tuberculosis and treating the contacts who are infected, and (2) carrying out targeted testing for latent tuberculosis infection in selected populations and treating the persons who are infected.

The intended use of the information is to continue dialogue between CDC and public

No IIF is being collected nor reported. The proposed data collection will have little or no effect on the respondent's privacy.

3. Use of Improved Information Technology and Burden Reduction

The federal tuberculosis cooperative agreements include funds for computer equipment and support. From 1997 through 2008, all the project areas were using the Tuberculosis Information Management System (TIMS), a software package developed at CDC for the electronic collection, storage, collation, and transmission of tuberculosis data. Tuberculosis cases (OMB Control No. 0920-0026) were first reported through TIMS in 1998. In 2000, CDC added the Aggregate Reports for Tuberculosis Program Evaluation to TIMS. During the discontinuation of TIMS in 2009, CDC accepted facsimile transmissions and paper copies for the reports, particularly from low-burden respondents who report so few data that the electronic format was not advantageous. CDC continues to work with the respondents in adopting new technology. Some jurisdictions are transferring to the CDC-led National Electronic Disease Surveillance System (NEDSS) (OMB Control No. 0920-0728), but the future of the tuberculosis-specific module for NEDSS is uncertain. In 2009, jurisdictional health authorities submitted data by the electronic media of their choice. During 2010, a module in the National Tuberculosis Indicators Project (NTIP) is being developed for providing a new, secure web-based option for direct data entry and submission to CDC. Overall 73.5% of the responses will be electronic and the remainder (26.5%) will be manual.

4. Efforts to Identify Duplication and Use of Similar Information

The Aggregate Reports for Tuberculosis Program Evaluation is a comprehensive standard summary of priority tasks for controlling and eliminating tuberculosis in the United States. Some state health departments (e.g., in California, New York, Illinois, and Florida) subsequently have designed their own similar reports for program evaluation, in accordance with their specific programmatic needs. Their reports are compatible with the national reports, but those reports are either too specific or too complex for national adoption. No federal agency besides CDC collects uniform data on tuberculosis prevention nationwide. Through literature searches, attendance at national tuberculosis meetings and conferences, and ongoing consultations with tuberculosis experts nationwide, CDC has determined that the Aggregate Reports for Tuberculosis Program Evaluation are unique and that no other similar data are available within or outside the federal government.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection. Data are requested from state, local, and territorial health departments. Data are collected only once a year and are kept to an absolute minimum to lessen the reporting burden.

6. Consequences of Collecting the Information Less Frequently

Annual reporting is linked to the annual funding cycle and program evaluation of the tuberculosis cooperative agreements. Less frequent reporting would delay feedback and technical consultation to the respondents and would leave CDC without current data for monitoring the national tuberculosis situation. The reporting frequency is once a year. The respondents collect the data for these reports continuously as part of standard public health practice. There are no legal obstacles to reducing the burden to the respondents.

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

This request fully complies with the guidelines in 5 CFR 1320.5, and no special circumstances require the information to be collected in any other manner.

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

A. A 60-day Federal Register Notice was published in the *Federal Register* on April 8, 2010, vol. 75, No. 67, pp.17922 (see Attachment 2). There were no public comments.

B. In 2009, TB control officials from New York State, Colorado, Tennessee, Texas, and California reviewed the indicators that are in the Aggregate Reports for Tuberculosis Program Evaluation and recommended their inclusion in the National Tuberculosis Indicators Project (NTIP).

In 2009, CDC launched a new web-based user interface, the National Tuberculosis Indicator Project (NTIP), for returning data and reports in a convenient format to state and local public health authorities. The cumulative Aggregate Reports for Tuberculosis Program Evaluation are being integrated into NTIP. During the design and the implementation of NTIP, CDC sought consultation from public health authorities from four state health departments and with representatives the National Tuberculosis Controllers Association, which advocates for the respondents for the Aggregate Reports. In these consultations, CDC was advised to continue the Aggregate Reports for Tuberculosis Evaluation in their current form and to make them accessible through NTIP.

9. Explanation of Any Payment or Gift to Respondents

The respondents do not receive payments or gifts for providing the Aggregate Reports for Tuberculosis Program Evaluation.

10. Assurance of Confidentiality Provided to Respondents

<u>Privacy Impact Assessment Information</u>

A. This project has been determined not to involve human subjects and IRB approval is not needed (Attachment 4). The Privacy Act is not applicable. Respondents are state and local health departments that provide CDC with aggregate information on cases of tuberculosis disease or infection. Although health departments may collect

identifiable information for local tuberculosis control purposes, consistent with state and local laws, this information is retained at those level, and health departments do not transmit person-level data or identifiable data to CDC.

The aggregate data are not stratified by age, sex, or specific medical conditions except for tuberculosis, and therefore the accidental identification of any patient who is counted in the reports is extremely unlikely. All data which are submitted electronically through NTIP are encrypted and files are password protected. Any reports that are transmitted by telephone facsimile are sent unencrypted, to the CDC office where the data are collected, under the privacy-statement cover sheet of the submitting agency as guided by state or local law. Any printed records from specific jurisdictions are kept in a locked file cabinet. The summary national reports contain no sensitive or private information.

CDC previously has not made any assurance of confidentiality to the respondents. Data from specific respondents will be treated in a confidential manner and will not be disclosed unless otherwise compelled by law. The respondents requested in 1999, and CDC agreed, that local public health authorities will be notified before locality-specific data is published or shared outside CDC. CDC publishes the national data and shares the national summaries with the respondents routinely after aggregating the reports. This surveillance activity does not require IRB review and approval.

B. The information submitted by respondents will be secured with the appropriate safeguards currently in place to minimize the possibility of unauthorized access, use, or dissemination of the information being collected. Technical controls include user identification, passwords, firewall, virtual private network (VPN), and encryption. All data which are submitted electronically through NTIP are encrypted and files are password protected. Any reports that are transmitted by telephone facsimile are sent unencrypted, to the CDC office where the data are collected, under the privacy-statement cover sheet of the submitting agency as guided by state or local law.

Physical controls include security guards, identification badges, key cards, and locked file cabinets. Any printed records from specific jurisdictions are kept in a locked file cabinet. Administrative controls include training manual and user guides for information collection, completion of required security training for computer access and data collection annually by all CDC personnel, and role-based access to data.

C. As the primary users of the data, the respondents are informed about the intended uses of the information collection through the cooperative agreement and are able to access the results of the aggregate reports through NTIP. Local public health authorities will be notified before locality-specific data is published or shared outside CDC. CDC publishes the national data and shares the national summaries with the respondents at least annually after aggregating the reports.

D. Through the federal cooperative agreement respondents are informed about the voluntary or mandatory nature of their response.

11. Justification for Sensitive Questions

As a part their routine public health practices, health department officials (i.e., the respondents) collect sensitive information (e.g., address, occupation, country of origin, infection with the human immunodeficiency virus and risk factors for it, and the use of alcohol or illegal drugs) from persons who have tuberculosis infection or who have been exposed to tuberculosis. For preparing the reports, the respondents interpret some of this sensitive information, but the sensitive information is not recorded per se in the reports, and it is not extractable from the reports. The aggregate format of the reports precludes linking any sensitive information to any persons who are counted in the reports.

12. Estimates of Annualized Burden Hours and Costs

A. The data that the respondents need to prepare the Aggregate Reports for Tuberculosis Program Evaluation are accrued during the normal operations of a tuberculosis control program following standard accountability practices. Therefore the annualized burden-hour estimates are based on the time for studying the report instructions, searching the existing data sources, and tabulating and reviewing the results. The reports are submitted annually. The annualized burden is estimated partly from the experience with older reports, the Tuberculosis Program Management Reports (formerly, portions of OMB No. 0920-0026). A series of pretests of the current report forms was done in 1999 with four volunteer respondents who tabulated their data for the report manually.

The respondents are the tuberculosis control officials of the 68 U.S. jurisdictions receiving federal tuberculosis funding. The officials ideally assign the responsibilities for preparing and submitting these reports to administrative personnel, such as data clerks and program managers. CDC does not request data on who prepares or submits the reports.

The estimates for annualized burden hours are variable because some respondents use custom automated data management systems for tabulating results while other tabulate results manually and then either enter the results into computer spreadsheets or maintain paper files. The tuberculosis incidence at a site also influences the annualized burden hours, because greater numbers of cases generate greater amounts of data. The maximum estimate for annualized burden hours is shown in the table.

Table A.12.1: Estimated annualized burden hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Data clerks	Follow-up and Treatment of Contacts to Tuberculosis Cases	50	1 (electronic)	30/60	25
		18	1 (manual)	3	54
Program Mangers	Follow-up and Treatment of Contacts to Tuberculosis Cases	50	1 (electronic)	30/60	25
		18	1 (manual)	30/60	9
Data clerks	Targeted Testing and Treatment for Latent Tuberculosis Infection	50	1 (electronic)	30/60	25
		18	1 (manual)	3	54
Program Mangers	Targeted Testing and Treatment for Latent Tuberculosis Infection	50	1 (electronic)	30/60	25
		18	1 (manual)	30/60	9
Total					**226**

B. The annualized costs to the respondents are estimated here based on estimated savings from using electronic storage and transmission of reports. The entire costs are labor. Part of the reporting is be done by (1) the 43 CDC field-staff employees who are assigned to the TB control programs of state and local health departments and (2) the health department personnel who work in positions funded by the federal tuberculosis cooperative agreements, which reduce direct costs to the correspondents, and therefore the costs that are shown probably represent an overestimation.

Table B.12.1: Estimated Annualized Burden Costs

Type of Respondents	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate*	Total Respondent Costs
Data clerks	50	1 (electronic)	30/60	25	$19	$475
	18	1 (manual)	3	54	$19	$1,026
Program Managers	50	1 (electronic)	30/60	25	$32	$800
	18	1 (manual)	30/60	9	$32	$288
Data clerks	50	1 (electronic)	30/60	25	$19	$475
	18	1 (manual)	3	54	$19	$1,026
Program Managers	50	1 (electronic)	30/60	25	$32	$800
	18	1 (manual)	30/60	9	$32	$288
Total						**$5,178**

*Estimated hourly rates obtained from Department of Labor (www.dol.gov) and U.S. Office of Personnel Management (www.opm.gov).

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

None. The reports do not cause additional capital and maintenance costs to the respondents. The systems that are used for data collection, collation, and storage are already in place for routine public health practice.

14. Annualized Cost to the Government

The reporting is recurrent and ongoing. The costs that are estimated here reflect a public health system that is assumed to be stable. Travel for training in Atlanta no longer is included in the costs because CDC provides comprehensive instructions for reporting on the internet. The upkeep for TIMS is minimal because programming is complete. Routine checks on the functionality of the reporting system are part of routine annual site visits made by CDC tuberculosis program consultants for the federal cooperative agreements, and the costs of these visits are not shown because the visits would be made regardless of the Aggregate Reports for Tuberculosis Program Evaluation.

Annualized Cost to the Government:

NTIP programming @25,000/yr …… $25, 000

Quarter-time medical epidemiologist GS-14 @ $100,000/yr……..$25,000

Quarter-time data clerk GS-12 @ $71,901/yr……..$17,975

Annualized cost – government: $67,975

Total 3 years cost – government: $203,925

This amount reflects an increase of $41,511 since the previous approval. This increase is due to increases in salaries of personnel conducting data collection and analysis since the last ICR approval ($26,464).

15. Explanation for Program Changes or Adjustments

There are no program changes or adjustments

16. Plans for Tabulation and Publication and Project Time Schedule

The data accumulation is intermittent, it represents continuous public health practice throughout the United States, and the reporting is annual and recurrent. A 3-year clearance cycle is requested.

No analytical methods beyond simple tabulation and trend description are applied to the results of the two reports. The indices that are used for program evaluation are unadjusted. The interpretation of the results from each reporting area is discussed between the respondents and their CDC tuberculosis program consultants. Specific data from one respondent are not shared with other respondents by CDC without prior notification because the data ownership (i.e., intellectual property) remains with the respondents as per general agreement between CDC and the Council of State and Territorial Epidemiologists.

The data that are reported to CDC are summed up for the U.S. national tuberculosis program statistics, which are sent to all the respondents annually. At least annually, the program consultants from CDC use the data that are reported by their tuberculosis cooperative agreement project sites for reviewing the effectiveness of existing tuberculosis control programs and for planning new local strategies for tuberculosis control.

A.16-1 Project Time Schedule	
Activity	**Time Schedule**
Notification of Respondents	1 week after OMB approval

Earliest data collection by Respondents	2 months after OMB approval
Earliest reports submitted to CDC	12 months after OMB approval
Data validation	16 months after OMB approval
Data analysis	18 months after OMB approval
Year 1 published summary report by CDC	20 months after OMB approval
Year 2 data collection by Respondents	14 months after OMB approval
Year 2 reports submitted to CDC	25 months after OMB approval
Year 2 data validation	29 months after OMB approval
Year 2 data analysis	31 months after OMB approval
Year 2 published summary report by CDC	33 months after OMB approval
Year 3 data collection by Respondents	24 months after OMB approval
Year 3 reports submitted to CDC	36 months after OMB approval

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

No exemption is sought.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions are included in this request. Paper forms generally are not used for this report, because the respondents either send the report electronically or print the form from TIMS, where CDC can update the form certification easily.