**Aggregate Reports for Tuberculosis Program Evaluation**

OMB Control Number: 0920-0457 Exp. 12/31/2022

**Supporting Statement B**

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**Justification**

The data accumulation is intermittent, it represents continuous public health practice throughout the United States, and the reporting is annual and recurrent. No analytical methods beyond simple tabulation and trend description are applied to the results of the reports. The indices that are used for program evaluation are unadjusted. There are no changes in the study design or methods from what was done in previous study years.

**1.** **Respondent Universe and Sampling Methods**

The “Aggregate Reports for Tuberculosis Program Evaluation” (ARPE) measure the extent, the efficiency, and the yield of tuberculosis (TB) control activities. Respondents for the reports are the 67 federal cooperative agreement sites that perform TB control activities in the United States. In 2018, 98% of respondents submitted reports. No sampling, stratification, or estimation procedures are used in this data collection. The data are entirely in an aggregate format. The data are left unadjusted for summing the U.S. national tuberculosis program statistics.

**2**. **Procedures for the Collection of Information**

The source data for ARPE are gathered annually as part of standard public health practice for TB control under the authority of state and local health departments. Although health departments may collect identifiable information for local TB control purposes, consistent with state and local laws, this information is retained at those levels, and health departments do not transmit person-level data or identifiable data to CDC. Administrative controls to ensure data quality include a training manual and user guide for information collection. The data associated with this OMB clearance are submitted to CDC only in an aggregate format (refer to Supporting Statement A, Section 10). The aggregate data are not stratified by age, sex, or specific medical conditions except for TB, diagnostic tests used, treatment regimen prescribed; therefore, the accidental identification of any patient counted in the reports is extremely unlikely. Data aggregation varies by site, with computerized methods becoming the norm at most jurisdictions.

The respondents submit data to CDC using the format outlined in ARPE (see Attachment 3a -Follow-up and Treatment of Contacts to Tuberculosis Cases and Attachment 3b-Targeted Testing and Treatment for Latent Tuberculosis Infection). Respondents submit their aggregated data annually to CDC by encrypted computer transmission in the National Tuberculosis Indicators Project (NTIP). All data which are submitted electronically through NTIP are encrypted and files are password protected. Reports submitted to CDC office where the data are collected, are protected 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.

CDC publishes the national data and shares the national summaries with the respondents routinely.

**3.** **Methods to Maximize Response Rates and Deal with Nonresponse**

CDC TB program consultants routinely work with the respondents in all types of data reporting. When reports to CDC are delayed, the CDC TB program consultants contact and meet with the respondents to determine the programmatic needs and to assist in the reporting process. Respondents who are unable to submit reports by the designated submission deadline for data analysis will be excluded from the national aggregate report.

**4.** **Tests of Procedures or Methods to be Undertaken**

CDC tested ARPE (OMB Control 0920-0457) as part of the design and implementation strategy in 1999 by visiting four state and local health departments and entering sample data. The computer system (i.e., NTIP) was tested in 2010 for the completion of automated report transmission.

**5.** **Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data**

Consultation on statistical aspects is not applicable. The public health officials who tested the trial reports (see item #4, directly above) were experts in TB control, and they were consulted on the data collection methods in 1999. In 2009, TB control officials from New York State, Colorado, Tennessee, Texas, and California reviewed the indicators that are in ARPE and recommended their inclusion in NTIP. In 2017, ACET recommended collection of nativity, diagnostic tests used, and drug regimen prescribed to allow for increased usability of the data to assess the adoption of new science and technology (i.e., adoption of a better diagnostic test for detecting TB and a shorter course treatment regimen).

CDC will collect and analyze the aggregate data from the 67 reporting TB control jurisdictions. The 67 reporting TB control jurisdictions may collect and analyze identifiable information for local TB control purposes, consistent with state and local laws; however, this information is retained at those levels, and health departments do not transmit person-level data or identifiable data to CDC. These data are submitted to CDC in aggregate form.

In July 2018, in response to ACET’s recommendations to include nativity, diagnostic tests and drug regimen to the ARPE data collection, CDC reached out to the National Tuberculosis Controllers’ Association (NTCA) for feedback. NTCA surveyed and conducted an in-person focus group with members in the 67 jurisdictions to assess uses of data and the feasibility and burden associated with collecting these recommended data elements. According to NTCA, 76% of respondents reported that ARPE data are useful to their programs. While 43% of the respondents recommended no changes to the current form, most programs reported little or no challenges with regard to their ability to collect and report the recommended data elements. More specifically, 59% of respondents reported little or no difficulties in their capability to collect and report nativity; 77% of respondents reported little or no difficulties in collecting and reporting diagnostic tests used; and 73% of respondents reported little or no difficulties in collecting and reporting drug regimen used.