

Information Collection for Tuberculosis Data from Referring Entities to CureTB

Request for OMB approval of a Revision Information Collection (OMB Control No. 0920-1186)

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Supporting Statement B

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B. Collections of Information Employing Statistical Methods

This information collection does not involve statistical methods.

1. Respondent Universe and Sampling Methods

The respondents are local health departments (LHD) and federal Immigration and Customs Enforcement (ICE) detention centers within the United States and physicians in healthcare facilities or public health departments in other countries who provide diagnostic and treatment services to individuals affected by TB. Individual TB patients may also be respondents if critical clinical or contact information is missing from their referral and CureTB follows-up with them to fill-in gaps to complete the referral service. All 50 US states and territories may refer TB patients to the CureTB program. There are no sampling methods.

2. Procedures for the Collection of Information

Information will be collected from local health departments and federal ICE detention centers, whenever these referring entities provide clinical services to an individual with TB who has imminent plans to relocate and needs continuity of care in their new location. The local health departments and federal ICE detention centers shares the information with CDC CureTB via fax, encrypted email, or phone so CDC CureTB can help coordinate care in the new location. TB patients may also be a respondent if critical clinical or contact data is missing and requires follow-up by CureTB to complete a patient's referral information set. The information collected is as follows:

- patient name, date of birth, sex
- contact information for patient
- expected location where patient will be moving to (e.g. country, state, municipality)
- tuberculosis laboratory results and other relevant clinical data
- tuberculosis treatment start date, medications
- contact information for referring entity

The request for CDC CureTB services comes from the referring entities and they supply the information around the time the patient is likely to leave their jurisdiction. The local health departments or ICE detention centers may update information only if relevant information to the patient's care becomes available to them after their first communication with CDC CureTB. Therefore, information is already largely collected by CDC CureTB only at one point in time, with subsequent information only collected if departure is delayed or when initially pending information becomes available and this is beyond the control of CDC.

CDC is notified of the date the patient will leave and sends the information they received to public health authorities in the new country via fax or encrypted email. That information is shared with the local physician that would provide care to the TB patient after they arrive.

Post relocation of the TB patient, data is also collected from the receiving physicians to determine patient outcomes via phone or encrypted email. CDC Cure TB contacts the physician an average of every two months during the standard TB treatment process. The following data is collected:

- 1) Is patient still on treatment? Yes or No
- 2) If yes, what medications?
- 3) What is anticipated date of treatment completion?
- 4) If not, what is the final outcome?

Standard international outcomes:

- Lost
- Abandoned
- Died
- Stopped for medical reasons
- Completed treatment

3. Methods to Maximize Response Rates and Deal with No Response

Reports to CureTB are not mandatory, however health departments are required to provide outcome information for each patient diagnosed in their jurisdiction. Health departments are aware that CureTB can provide outcome information for patients who move outside of the US, which is otherwise extremely difficult for individual health departments to collect. Respondents voluntarily connect with CureTB for continuity of care services, not only to assure they get outcome information, but also to assure that their patients are connected to curative services because health department TB programs are in the business of patient-centered care and maximizing successful outcomes.

4. Tests of Procedures or Methods to be Undertaken

Based on efforts in TB referral services over the last year, CureTB receives about 1,160 referrals for continuity of care per year. Each referral is entered into an internal password protected spreadsheet for tracking. The process is that information is shared with health authorities in the location where the patient will be returning to so that they can be prepared to continue the patient's care. The patient is contacted by CureTB to assure they understand the arrangements

being made on their behalf and the importance of continuity of care, and to collect any missing information in their referral file. Once the patient moves, CureTB checks in with the patient to provide any support or additional help. Similarly, CureTB follows up with the new provider on average every two months to understand the outcomes of the treatment for each referred patient.

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

No statistical methods are employed in this information collection.