



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
PUBLIC HEALTH SERVICE  
CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)  
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Subject: Site Visit to South Carolina for Evaluation of Current and Proposed Surveillance of Latent Tuberculosis Infection (LTBI) — August 31–September 2, 2015

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As part of an EIS surveillance evaluation project, Jorge Salinas and Maryam Haddad visited the South Carolina Department of Health and Environmental Control (DHEC) from 8/31/15 through 9/2/15. During this site visit, we met with the following DHEC staff:

Tammy McKenna, RN, MSN, TB Nurse Consultant  
Debra Ray, RN, BSN, MPH, TB Nurse Consultant  
Roscia Hardee, RN, BSN, MPH, TB Nurse Consultant  
Priscilla McCormick, RN, BSN, TB Nurse Liaison  
Victoria (Tori) Bethay, MPH, CHES, TB Health Educator  
Yolanda (Yogi) Jacobs, TB Surveillance Coordinator  
Denise Atkinson, TB Section Administrator  
Nelís Soto-Ramírez, MS, MPH, PhD, Biostatistician, Division of Acute Disease Epidemiology (DADE)  
Dana Giurgiutiu, PhD, MPH, Director, DADE  
Linda Bell, MD, State Epidemiologist

We performed the following activities during our evaluation of South Carolina's current and proposed LTBI surveillance:

### **Gathered information about current and proposed LTBI surveillance in South Carolina**

#### *Current surveillance*

Reporting of LTBI in South Carolina is not currently mandatory. Screening for TB infection occurs in private provider offices as well as in healthcare facilities, colleges, military bases, and DHEC clinics; either a tuberculin skin test (TST) or interferon-gamma release assay (IGRA) is used. The state public health lab is able to do IGRAs in-house. DHEC typically retests persons referred from provider offices, particularly if their TSTs reportedly measured between 5 and 10 mm. One reason is that DHEC has been encouraging use of IGRAs in foreign-born persons (e.g., the refugee resettlement programs) and thus feels its overall LTBI treatment caseload might be decreasing but they are treating more "true positives."

What remains unknown is how many persons in the community are tested for TB infection (i.e., the denominator) or are found to have a positive test result but do not follow up with DHEC for further evaluation or treatment. However, because DHEC offers free treatment for LTBI, most persons with a positive TST or IGRA who wish to receive treatment are referred to a DHEC clinic, suggesting that measuring the number of LTBI cases reaching DHEC for treatment would be a fair estimate of the total number of patients being treated in South Carolina. The 12-dose isoniazid/rifapentine (3HP) regimen is increasingly popular in South Carolina, which previously primarily used isoniazid (either 6 or 9 months). The 4-month rifampin regimen is rarely used in South Carolina.

DHEC is divided in four regions: Lowcountry, Midlands, Pee Dee, and Upstate. Beginning in 2013, each region's program manager has compiled data on each county's weekly TB workload for submission via an Excel spreadsheet on a secure DHEC share drive. Originally created with the intent to give situational awareness about the distribution of TB-related work in the state's public health sector, this spreadsheet has since undergone several revisions to expand (and then reduce) the number of variables. Another emphasis, as recently as 1 week before our visit, was to clarify the definitions used so that all four public health regions are applying the same definitions as they complete the spreadsheet.

Currently, the following aggregate numbers are being reported for each county each week:

1. Number of **new evaluations** for suspected LTBI,  
either initiated within DHEC or referred to DHEC by an outside provider
2. Number of patients **beginning treatment** for LTBI (counted just the first week)
3. Number of patients **currently receiving** LTBI treatment (counted every week following)
4. Number of patients receiving LTBI treatment with **Directly Observed Therapy (DOT)**
5. Number of patients receiving **self-administered** LTBI therapy
6. Number of patients that **refused** therapy
7. Number of patients that **did not complete** therapy

This spreadsheet does not include any patient names or patient-level information (just aggregate numbers), nor does it contain LTBI regimen information. The county-based DHEC clinics typically maintain the detailed case management information about LTBI evaluation and treatment on standard DHEC paper forms.

However, persons who are found to have LTBI during the course of contact investigations have some patient-level details entered into the state's contact investigation software (TBCIS). Currently the four regions and the TB Section in Columbia enter contact investigation details into TBCIS, which is used to generate the Aggregate Report for Program Evaluation for Follow-up and Treatment for Contacts to TB Cases (ARPE-CI).

In addition, patients prescribed the 3HP regimen also have additional record-level electronic data available on an Excel spreadsheet that is tracked and completed by the TB Nurse Liaison in Columbia as the regional offices request 3HP from the DHEC central pharmacy. 3HP is offered under DOT only. Isoniazid is also supplied by the DHEC pharmacy, but is DOT only under certain circumstances (e.g., pediatric contacts).

#### *Proposed surveillance*

South Carolina currently uses an "eRVCT" in the NEDSS Base System (NBS) to transmit information to CDC about verified cases of TB disease, but DHEC is working with Consilience Software's disease surveillance system (called "MAVEN" in other states) to begin electronically reporting all reportable conditions through this new system (being named SCION for South Carolina). SCION is currently being configured to receive and transmit reportable cases of TB disease (i.e., replace eRVCT) as well as take over the tracking of associated TB contact investigations (i.e., replace TBCIS).

Currently the TB Surveillance Coordinator in Columbia completes all the eRVCT forms for South Carolina, but the vision with SCION is that the RVCT variables will be entered directly at the district level in the future. DADE and TB Section colleagues explained that they would like to incorporate record-level LTBI reporting into SCION, as well. Developing the capacity within SCION for LTBI surveillance means DHEC (a) could start piloting patient-level LTBI surveillance, (b) would be positioned to make LTBI reportable in South Carolina in the future, and (c) be ready to report, if desired, LTBI to CDC in the future.

#### **Identified stakeholders**

- DHEC's DADE, TB Section, four regional offices, and county clinics
- DTBE
- The medical community and other entities that screen persons in South Carolina for LTBI
- S.C. state legislature

#### **Purpose of the surveillance system**

The system aims to measure the workflow of LTBI care in each of the regions as well as burden of disease.

### **Resources used to operate the surveillance system**

The regions aggregate data and report weekly to the DHEC central office via an Excel spreadsheet on a secure DHEC share drive. Then the TB Control staff review reports for accuracy and completeness. They work with the regions to resolve any possible discrepancies. Weekly summaries are compiled into a report that DADE creates for all communicable diseases; this report is distributed back to the regions as well as with DHEC leadership and, as needed, the S.C. state legislature.

### **Design of the surveillance system evaluation**

- We met with several stakeholders to understand the surveillance system, gauge the needs it addressed, and how our evaluation could contribute to those needs.
- We gathered credible evidence assessing the system's usefulness, simplicity, flexibility, data quality, acceptability, sensitivity, predictive value positive, representativeness, timeliness, and stability. We also assessed informatics features (i.e. information quality, system quality, and user experience/service quality).
- After these assessments, we discussed several options for LTBI surveillance going forward, including the building of a comprehensive system that would encompass demographic, epidemiologic, clinical, laboratory, and case management aspects of LTBI care.

### **Gathered credible evidence**

#### *Usefulness*

Current LTBI surveillance is useful to identify the number of individuals being evaluated for LTBI, and starting or continuing LTBI treatment, in each county DHEC clinic during any given week. This information may guide resource allocation to the regions based on LTBI burden.

#### *Simplicity*

The current system is based on Excel spreadsheets. Data is manually entered by the four regional program managers and stored on a secure DHEC share drive. Each file is then reviewed by the TB Control Staff for accuracy and completeness.

#### *Flexibility*

Over the last 2 years that this system has been implemented, multiple changes have occurred based on feedback from users. Definitions for each variable have been refined. Given the simplicity of its electronic format, changes are rapidly implemented without the need for IT support.

#### *Data quality*

The TB Control staff have made a great effort to use standard definitions and train regional staff for uniformity of reporting. Data quality is evaluated at DHEC via manual review of the calculations used for aggregate reporting.

### *Acceptability*

The system has been accepted by the involved stakeholders and subsequent revisions of the reporting requirements have been accepted by the regional program managers.

### *Sensitivity/Predictive Value Positive*

The total number of people with LTBI in South Carolina is unknown. There are biological and logistical limitations to understanding the full burden, including neither a gold-standard diagnostic method for LTBI nor a mandate to report positive TSTs or IGRAs to DHEC. Because 3HP in South Carolina is only offered under DOT, we performed a crude estimate of sensitivity by comparing the number of persons reported to be newly starting DOT for treatment of LTBI with the separate DHEC database of persons newly starting 3HP. Our assumption was that 3HP = DOT, but we know that DOT  $\neq$  3HP if regions are choosing to use DOT for other LTBI regimens (e.g., isoniazid in a child under age 2). We used this 3HP database because 3HP initiation must be approved by the TB Section in Columbia and is hence complete. Below are the comparisons.

| Region  | Dates             | Total new DOT starts for LTBI | 3HP | 3HP as a proportion of total DOT |
|---|-------------------|-------------------------------|-----|----------------------------------|
| Lowcountry  | January–June 2015 | 27                            | 13  | 48%                              |
|   |                   |                               |     |                                  |
| Midlands  | January–June 2015 | 74                            | 44  | 59%                              |
|   |                   |                               |     |                                  |
| Pee Dee   | January–June 2015 | 13                            | 47  | 362%*                            |
|   |                   |                               |     |                                  |
| Upstate   | January–June 2015 | 47                            | 16  | 34%                              |
| *This was the only region where the 3HP registry recorded more cases than the LTBI surveillance system, suggesting potential underreporting of the DOT workload in this region. |                   |                               |     |                                  |

There were differences in the reported rates of DOT for LTBI treatment and records of 3HP initiation. Some of the differences likely represent DOT practices for regimens other than 3HP. Interestingly, current LTBI surveillance may be underreporting the DOT caseload in the Pee Dee region; this may reflect difficulties in manual data entering at that region.

Alternative approaches to assess the sensitivity of the current reporting system would be to use DHEC's pharmacy-based records, since all LTBI drugs are centrally dispensed, or the state public health

laboratory's records of testing for IGRAs, although this approach would miss LTBI diagnosed on the basis of TSTs. However, these data were not available at the time of our visit.

The TB Section plans to try these approaches going forward and reevaluate in 6–12 months to compare which of these alternatives may represent a good comparison for reference.

#### *Representativeness*

Current LTBI surveillance is partially representative, as it only captures those individuals evaluated for LTBI at a DHEC clinic, therefore missing those that have not been tested, those testing positive but not referred, or referred to DHEC but not evaluated.

#### *Timeliness*

The results of this LTBI surveillance are reported weekly. With SCION, DHEC is moving towards a more real-time reporting system to capture more information, such as patient-level demographic information, treatment characteristics, and outcomes.

#### *Stability*

The current system works on Microsoft Excel and requires a working Internet connection for updates to the shared folders. No specific IT support is required. The system requires personnel at the regional offices and headquarters for coverage of reporting functions in case the person in charge of reporting is not available; these provisions are in place and there is back up at all regions and headquarters office.

#### *Informatics*

The current system is simple and user friendly. DHEC is moving to a MAVEN/SCION software platform for surveillance purposes. SCION had already developed electronic forms for active TB cases (modeled after the RVCT) and contacts of TB cases (modeled after existing DHEC forms and ARPE requirements).

### **Our recommendations**

On 9/1/15, we met with Tammy McKenna, RN, MSN, Nurse Consultant, TB Section, to share information about SEOIB's identified key variables for states considering a new potential LTBI surveillance system (i.e., the minimal data elements identified for the TB Epidemiologic Studies Consortium "Case Management System"). During that conversation we realized that essentially all of those variables are already elements on standard DHEC forms for case management of LTBI and thus were already incorporated across various "wizards" in SCION.

On 9/2/15, we met with Ms. McKenna and Nelís Soto-Ramírez, MS, MPH, PhD, Biostatistician, DADE, to show which variables could be extracted and rearranged from existing SCION "wizards" to capture LTBI surveillance data within SCION; we followed up with a detailed outline via email.