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# Use of Recommended Laboratory Testing Methods among Patients with Tuberculosis in California

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**This study assessed the extent to which laboratory methods recommended by the Centers for Disease Control and Prevention were used in tuberculosis testing of patients in California in 1998. While recommended methods were used for most patients, there was room for improvement by hospital and independent non-health maintenance organization laboratories.**

The resurgence of drug-susceptible and multidrug-resistant tuberculosis (MDR-TB) in the United States between 1985 and 1992 led to new recommendations that urged laboratories to use more rapid and accurate testing methods for diagnosing TB (2, 4). Studies assessing the use of recommended testing methods for TB have consistently shown increases in the proportion of laboratories adopting rapid methods (1, 3, 5, 6). However, the extent to which laboratory-level improvements correlate with improvements at the patient level is unknown. TB testing services are gradually being consolidated in a smaller number of laboratories; consequently, a few laboratories using less rapid testing procedures now have the potential to disproportionately affect the quality of testing for a large proportion of TB patients.

In 1998, TB cases in California represented approximately 20% of all the TB cases in the United States (Centers for Disease Control and Prevention [CDC], www.cdc.gov/nchstp/tb/surv/surv.htm). That year, we conducted a study to assess the use of recommended testing methods for California patients with culture-confirmed TB and to evaluate the testing procedures of the mycobacteriology laboratories that performed the tests for those patients.

**Study population.** The study population comprised 300 culture-confirmed cases of TB reported to the TB control programs in Los Angeles, Riverside, San Francisco, and Santa Clara counties between 1 January and 31 December 1998. In 1998, 48% of California's TB cases were reported in these counties. We selected the first 75 culture-confirmed cases reported in each county during the study period. Because only 68 cases were reported in Riverside County during 1998, 7 additional cases were selected from Los Angeles County. These two counties are adjacent to each other and have similar populations.

**TB testing laboratories.** Fifty-five separate laboratories were identified through patient records as having performed primary TB testing for one or more of the study patients. If a patient had many specimens tested for TB, the specimen with the earliest test result was selected for this evaluation. The laboratories that served the patient sample included 7 (13%) public health laboratories, 2 (4%) health maintenance organization (HMO) laboratories, 11 (20%) independent non-HMO laboratories, and 35 (64%) hospital laboratories. Laboratory-specific calculations are based on 54 laboratories because one hospital laboratory declined to participate in the study. In addition to patient-specific data, each laboratory was asked to complete a questionnaire concerning laboratory practices, including the range of testing services performed and monthly volume of specimens processed in that laboratory.

**Completeness of data.** Information on the testing method used was available for 268 (89%) of the 300 patients for smear microscopy, 265 (88%) of the 300 patients for mycobacterial

TABLE 1. Proportion of laboratories performing TB testing, compared with the proportion of TB patients tested by these laboratories, by laboratory type

| Test and group | Total no. | No. (%) tested in different laboratory types | | | |
|---|---|---|---|---|---|
| | | Public health | Independent non-HMO | HMO | Hospital |
| Smear microscopy | | | | | |
| Laboratories | 44 | 3 (7) | 8 (18) | 2 (5) | 31 (70) |
| Patients | 268 | 54 (20) | 39 (15) | 39 (15) | 136 (51) |
| Mycobacterial culture | | | | | |
| Laboratories | 43 | 4 (9) | 8 (19) | 2 (5) | 29 (67) |
| Patients | 265 | 58 (22) | 38 (14) | 39 (15) | 130 (49) |
| Identification of *M. tuberculosis* | | | | | |
| Laboratories | 27 | 5 (19) | 9 (33) | 2 (7) | 11 (41) |
| Patients | 272 | 83 (31) | 61 (22) | 40 (15) | 88 (32) |
| Drug susceptibility testing | | | | | |
| Laboratories | 19 | 6 (32) | 8 (42) | 1 (5) | 4 (21) |
| Patients | 266 | 99 (37) | 82 (31) | 23 (9) | 62 (23) |

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TABLE 2. Testing methods for smear microscopy, mycobacterial culture, identification of *M. tuberculosis* and drug susceptibility testing of patient specimens

| Procedure[a] | No. (%) of patient specimens tested using indicated method |
|---|---|
| Smear microscopy | |
| Fluorochrome* | 243 (91) |
| Carbol fuchsin | 25 (9) |
| Mycobacterial culture medium | |
| Liquid* | 73 (28) |
| Solid | 17 (6) |
| Both* | 175 (66) |
| Identification of *M. tuberculosis* | |
| Nucleic acid probes* | 213 (78) |
| BACTEC NAP* | 4 (1) |
| HPLC* | 43 (16) |
| Biochemical tests | 0 (0) |
| Nucleic acid amplification* | 12 (4) |
| Drug susceptibility | |
| BACTEC* | 190 (71) |
| Agar proportion | 31 (12) |
| Both* | 45 (17) |

[a] Methods recommended by the CDC are indicated with an asterisk. BACTEC was from Becton Dickinson, Sparks, Md. HPLC, high-performance liquid chromatography; NAP, *p*-nitro-α-acetylamino-β-hydroxypropiophenone.

culture, 272 (91%) of the 300 patients for identification of *M. tuberculosis*, and 266 (89%) of the 300 patients for drug susceptibility testing. Unless otherwise noted, patient-specific analyses are based on these denominators. Analyses were performed using SAS 6.12 (SAS Institute, Cary, N.C.). If information on a specific variable was missing for a laboratory or a patient, the laboratory or patient was excluded from analyses relating to that variable; for this reason, denominators for different analyses may vary.

**Comparison of laboratories performing TB testing and patient specimens tested by those laboratories.** In some cases, a small proportion of the laboratories was responsible for testing a relatively large proportion of patient specimens for TB (Table 1). Public health and HMO laboratories accounted for <15% of the laboratories performing smear microscopy and mycobacterial culture, but they tested more than one-third of the patient specimens in our study population. Although most (60 to 90%) laboratories performing TB testing were either hospital or independent non-HMO laboratories, they performed a relatively smaller proportion of testing. Even so, these laboratories performed more than half of all TB testing.

**Use of recommended testing methods.** Most of the study patients were tested using CDC recommended methods (Table 2). In general, the proportion of laboratories that performed TB testing using recommended methods correlated closely with the proportion of patients tested using those methods (Table 3). However, differences in these proportions were noted for smear microscopy, mycobacterial culture, and drug susceptibility testing. With regard to smear microscopy and culture testing, hospital laboratories largely accounted for these discrepancies. For drug susceptibility testing in independent non-HMO laboratories, the proportion of patients tested using BACTEC was lower than the proportion of laboratories that used this method. These differences suggest that laboratory-level surveys may yield inaccurate estimates of the proportion of patients tested using recommended methods.

Hospital laboratories that did not use recommended methods for TB testing generally processed a lower volume of specimens (Table 4). Public health and HMO laboratories were most likely to adhere to all of the recommended methods for TB testing. These laboratories generally processed large volumes of specimens for TB testing (>300 specimens per month in most cases) and performed the full range of TB testing in house.

**Areas for improvement.** Our results suggest that efforts to further expand the use of recommended methods for smear

TABLE 3. Proportion of laboratories using recommended methods for TB testing compared with the proportion of patients tested using recommended methods by laboratory type

| Test and group | No. with recommended method/total no. (%) | | | | |
|---|---|---|---|---|---|
| | All laboratories | Laboratory type | | | |
| | | Public health | Independent non-HMO | HMO | Hospital |
| Fluorochrome staining | | | | | |
| Laboratories | 35/44 (80) | 3/3 (100) | 8/8 (100) | 2/2 (100) | 22/31 (71) |
| Patients | 243/268 (91) | 51/54 (94) | 39/39 (100) | 39/39 (100) | 114/136 (84) |
| Liquid culture medium | | | | | |
| Laboratories | 37/43 (86) | 4/4 (100) | 8/8 (100) | 2/2 (100) | 23/29 (79) |
| Patients | 248/265 (94) | 58/58 (100) | 38/38 (100) | 39/39 (100) | 113/130 (87) |
| Rapid identification of *M. tuberculosis*[a] | | | | | |
| Laboratories | 27/27 (100) | 5/5 (100) | 9/9 (100) | 2/2 (100) | 11/11 (100) |
| Patients | 272/272 (100) | 83/83 (100) | 61/61 (100) | 40/40 (100) | 88/88 (100) |
| BACTEC drug susceptibilities | | | | | |
| Laboratories | 16/19 (84) | 5/6 (83) | 6/8 (75) | 1/1 (100) | 4/4 (100) |
| Patients | 235/266 (88) | 96/99 (97) | 54/82 (66) | 23/23 (100) | 62/62 (100) |

[a] Nucleic acid probe, BACTEC NAP, HPLC, or nucleic acid amplification test.

TABLE 4. Comparison of hospital laboratories using or not using recommended testing methods for smear microscopy and culture, by average monthly volume of specimens processed for TB testing

| Use of recommended method(s) | Total no. | No. of labs (%) with monthly vol of specimens | | | $\chi^2$ for trend (p) |
|---|---|---|---|---|---|
| | | 0–50 | 51–100 | >100 | |
| Use of fluorochrome staining for smear microscopy | | | | | |
| Yes | 17 | 4 (24) | 5 (29) | 8 (47) | 1.73 (0.19) |
| No | 9 | 4 (44) | 3 (33) | 2 (22) | |
| Use of liquid culture medium | | | | | |
| Yes | 18 | 4 (22) | 5 (28) | 9 (50) | 2.33 (0.13) |
| No | 6 | 3 (50) | 2 (33) | 1 (17) | |

microscopy and mycobacterial culture should focus on hospital laboratories. Whereas other laboratories adhered to the use of recommended methods for these tests, a large proportion of hospital laboratories did not use a fluorochrome method for the initial smear and/or liquid medium for mycobacterial culture.

Efforts to further expand the use of recommended methods for drug susceptibility testing could focus on independent non-HMO laboratories. In our study, a lower proportion of patients in independent non-HMO laboratories was tested using BACTEC compared with patients tested in other laboratories. In California, the task of improving or monitoring the adherence to recommended drug susceptibility testing methods is facilitated by the relatively small number of laboratories involved with this type of testing.

**Study limitations.** First, although the sample included 300 patients, testing for these patients was performed in a small number of public health, HMO, and independent non-HMO laboratories. Therefore, our results may not provide an accurate portrayal of laboratory testing procedures. For example, assessment of the role of specimen volume in the use of recommended testing methods for smear microscopy and culture in hospital labs was limited by the small number of hospital laboratories used in the analysis. However, our results do agree with the results from previous studies showing that hospital laboratories processing fewer specimens were less likely to use recommended testing methods for smear microscopy and culture (6).

Second, data obtained from laboratories that tested a small number of patients may not accurately describe the testing practices in these laboratories. Some laboratories did not always use the same testing method for all specimens tested in those laboratories. Therefore, it may not be appropriate to assume a laboratory did or did not comply with recommended testing practices based on data from a few patients.

**Summary.** Our findings suggest that most patients undergoing evaluation for TB in California are tested using CDC-recommended laboratory methods. These analyses also indicate that results based on surveys at the laboratory level may not accurately reflect results at the patient level. Future efforts to expand the use of recommended methods for smear microscopy and mycobacterial culture should focus on low-volume hospital laboratories, and for drug susceptibility testing the focus should be on independent non-HMO laboratories.

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