

## Laboratory Reporting of Tuberculosis Test Results and Patient Treatment Initiation in California

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**Prompt laboratory reporting of tuberculosis (TB) test results is necessary for TB control. To understand the extent of and factors contributing to laboratory reporting delays and the impact of reporting delays on initiation of treatment of TB patients, we analyzed data from 300 consecutive culture-positive TB cases reported in four California counties in 1998. Laboratory reporting to the specimen submitter was delayed for 26.9% of smear-positive patients and 46.8% of smear-negative patients. Delays were associated with the type of laboratory that performed the testing and with delayed transport of specimens. Referral laboratories (public health and commercial) had longer median reporting time frames than hospital and health maintenance organization laboratories. Among patients whose treatment was not started until specimens were collected, those with delayed laboratory reporting were more likely to have delayed treatment than patients with no laboratory reporting delays (odds ratio [OR] of 3.9 and 95% confidence interval [CI] of 1.6 to 9.7 for smear-positive patients and OR of 13.1 and CI of 5.3 to 32.2 for smear-negative patients). This relation remained after adjustment in a multivariate model for other factors associated with treatment delays (adjusted OR of 25.64 and CI of 7.81 to 83.33 for smear-negative patients). These findings emphasize the need to reduce times of specimen transfer between institutions and to ensure rapid communication among laboratories, health care providers, and health departments serving TB patients.**

Timely laboratory reporting of tuberculosis (TB) is important for prompt initiation of appropriate medical therapy for TB patients and rapid public health response. National guidelines and regulations in 39 states specify that laboratories performing TB diagnostic tests and drug susceptibility tests should report test results to the specimen submitters and to health departments within specific time frames (4, 5). Although national surveys of laboratory practice have documented an increase in the number of laboratories that report TB test results within the time frames recommended by the Centers for Disease Control and Prevention and the Association of Public Health Laboratories (2, 8, 10), previous publications have not documented the analysis of factors associated with delayed reporting. Also, the role that laboratory reporting may play in treatment initiation has not been documented in studies of treatment initiation delays. To describe laboratory reporting time frames and delays and how these delays may impact timely initiation of treatment for TB patients, we performed this study. This patient-based study examines the time frames for laboratory reporting of TB test results from a cohort of culture-positive TB patients from California in 1998, describes factors that contribute to delays in reporting, and analyzes the association between delayed reporting of laboratory findings of TB and delays in the initiation of anti-TB therapy. The study was conducted in a state where private, public, health maintenance

organization (HMO), and hospital-based laboratories are all involved in performing TB tests.

### MATERIALS AND METHODS

**Study population.** The study population and data collection have been described previously (11). For each of 300 culture-confirmed TB cases reported to the TB control programs in San Francisco, Santa Clara, Los Angeles, and Riverside counties in 1998, three to six specimens were subjected to acid-fast bacillus (AFB) smear microscopy, culture growth, *M. tuberculosis* complex identification, and drug susceptibility testing. The earliest reported positive result was recorded for each test. Patient data from the Report of Verified Case of Tuberculosis (RVCT), the national TB surveillance case report, were examined.

**Study variables.** The submitter reporting time frame was defined as the time between the date of specimen collection and the date that the laboratory reported the first evidence of *M. tuberculosis* to the specimen submitter. The transport time frame was defined as the time between the date of specimen collection and the date the specimen was received in the laboratory that performed the applicable TB tests. The local health department (LHD) reporting time frame was defined as the time between the date that the first evidence of *M. tuberculosis* was reported to the specimen submitter and the date that the test result was reported to the LHD. The treatment initiation time frame was defined as the time between the date of specimen collection and the date that anti-TB therapy was initiated.

The first evidence of *M. tuberculosis* in a specimen is the presence of AFB on smear microscopy; for patients with AFB smear-negative specimens, the first evidence of *M. tuberculosis* is the presence of AFB-positive growth in a culture or the identification of *M. tuberculosis* complex in a growing culture.

The LHD reporting time frame was calculated for only those patients served by non-public health laboratories, because public health laboratories are considered to be part of the LHD. Patients excluded from LHD reporting time frame calculations were those for whom laboratory reporting to the LHD occurred before laboratory reporting to the submitter, those with missing dates, and those with no evidence of laboratory reporting to the LHD (79 AFB smear-positive patients and 59 AFB smear-negative patients).

Delayed reporting and treatment initiation time frames were defined as time

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frames that exceeded the median (13). Overall, the medians for submitter reporting time frames met the Centers for Disease Control and Prevention recommendations (5). Existing guidelines do not recommend a particular time frame for treatment initiation but state that treatment should be initiated promptly when suspicion of tuberculosis is high or the patient is seriously ill with a disorder that may possibly be tuberculosis (6). Thus, delayed treatment initiation was defined as a time frame that exceeded the median based on the precedent set by a surveillance study on delays in diagnosis and treatment (13). Delayed transport occurred if the time between specimen collection and receipt in the laboratory performing the testing exceeded one day (2). Delayed LHD reporting time frames were greater than one working day (15).

Participating laboratories were categorized into four types: public health laboratories, hospital laboratories, HMO laboratories (the state's two regional laboratories that served patients from multiple hospitals of a staff-model HMO health care plan), and commercial laboratories (private laboratories that were not directly associated with hospitals, public health institutions, or HMOs).

**Analyses.** Medians, means, and ranges of the above-described time frames were calculated separately for AFB smear-positive and AFB smear-negative patients and stratified by laboratory type. Comparisons were made using non-parametric methods. The odds ratios (ORs) and relative risks of delays in treatment for those with and without reporting delays were determined. For concise presentation, the ORs are shown in tabular form (see Table 2), but the relative risks are stated in the text only.

Pearson's chi-square or Fisher's exact test was used to determine the association of disease and demographic characteristics with treatment initiation delays. Multivariate analyses were performed with selected variables using forward logistic regression. Variables were included if, when adjusting for them, Cochran-Mantel-Haenszel statistics showed an association of submitter reporting delays and treatment initiation delays and if the variables were associated with treatment delay in previous studies.

All statistical analyses were performed using SAS (version 8.2; SAS Institute, Cary, N.C.).

## RESULTS

**Study population and laboratories.** Fifty-five laboratories were involved in TB testing for the patient population, including seven public health laboratories, two HMO laboratories, eleven commercial laboratories, and thirty-five hospital laboratories. Fifty-four laboratories participated in the study; one laboratory declined to participate (11).

Of the 300 patients in the study sample, 32 (10.7%) were excluded from the analyses because they had unknown AFB smear microscopy results, leaving 268 patients with known AFB smear results. The characteristics of these 268 patients were as follows: 163 (60.8%) were male, 69 (25.7%) were  $\geq 65$  years old, 130 (48.5%) were reported as being of the Asian or Pacific Islander race, 195 (72.8%) were foreign born, and 13 (4.9%) were homeless during the year previous to diagnosis. Disease characteristics for this population included the following: 225 (84%) had pulmonary TB, 135 (50.4%) had AFB smear-positive specimens, 224 (83.6%) had abnormal chest radiographs, 59 (26.3%) had cavitation on chest radiographs, 28 (10.4%) had *M. tuberculosis* strains that were resistant to isoniazid, rifampin, or ethambutol, and 6 (2.2%) had strains that were multidrug-resistant (i.e., resistant to at least isoniazid and rifampin). Fourteen (5.2%) patients in this population had AIDS. Excluded patients with unknown AFB smear results did not differ from the study population by demographic or clinical characteristics (data not shown).

Among the 135 AFB smear-positive and 133 AFB smear-negative patients, 31 AFB smear-positive and 22 AFB smear-negative patients were excluded from further analyses because TB treatment was initiated prior to specimen collection or because of missing dates. These excluded patients had demographic and clinical characteristics similar to those of the pa-

TABLE 1. Time frames for reporting to specimen submitter and initiating treatment

Patient group	No. of patients	Time frame median (range) <sup>c</sup>	
		Submitter reporting	Treatment initiation
<b>AFB smear positive</b>			
All	104	1.0 (0–35)	1.0 (0–70)
With delays <sup>a</sup>		2.0 (2–35)	4.0 (2–70)
Tested in hospital lab	63	1.0 (0–14)	1.0 (0–16)
Tested in public health lab	17	2.0 (0–35)	2.0 (0–48)
Tested in commercial lab	10	2.0 (1–3)	4.0 (0–70)
Tested in HMO lab	14	1.0 (0–5)	2.5 (0–20)
<b>AFB smear negative</b>			
All	111	21.0 (9–143)	22.0 (0–145)
With delays <sup>b</sup>		28.5 (22–143)	33.5 (23–145)
Tested in hospital lab	49	20.0 (9–143)	20.0 (0–145)
Tested in public health lab	19	22.0 (11–64)	20.0 (0–78)
Tested in commercial lab	23	28.0 (18–60)	31.0 (0–75)
Tested in HMO lab	20	18.5 (10–29)	21.0 (1–62)

<sup>a</sup> Number of AFB smear-positive patients with delays in submitter reporting, 28; number with delays in treatment initiation, 42.

<sup>b</sup> Number of AFB smear-negative patients with delays in submitter reporting, 52; number with delays in treatment initiation, 52.

<sup>c</sup> Values are numbers of days.

tient population included in the study (data not shown). The remaining 104 AFB smear-positive and 111 AFB smear-negative patients were included in the final analyses.

**Submitter reporting time frames and factors contributing to delayed reporting for AFB smear-positive patients.** The majority of patients with AFB smear-positive specimens had smear microscopy performed in hospital laboratories (60.6%). A much lower percentage of patients had smear microscopy performed by public health, HMO, and commercial laboratories (23.7, 11.9, and 8.9%, respectively).

The median time from the date of specimen collection to the date that the laboratory reported results to the specimen submitter (submitter reporting time frame) was 1.0 day (mean, 1.88 days; range, 0 to 35 days) for AFB smear-positive patients but was longer for specimens tested in public health and commercial laboratories than that for specimens tested in hospital and HMO laboratories ( $P < 0.0001$ ) (Table 1). Overall, the 28 patients with delayed submitter reporting (26.9%) had a median reporting time frame of 2.0 days (mean, 5.0 days).

To determine whether the time between specimen collection and specimen receipt in the laboratory (transport time frame) was associated with delays in reporting positive AFB smear results, these time frames were calculated for patients tested at each laboratory type. Transport time frames were longer for AFB smear-positive specimens tested in public health and commercial laboratories than for specimens tested in hospital and HMO laboratories (median times: for public health laboratories, 1.0 day; for commercial laboratories, 1.5 days; for hospital and HMO laboratories, 0 days;  $P = 0.0002$ ). In addition, patients having AFB smear-positive specimens that took longer than 1 day to arrive in the laboratory that performed the AFB smear microscopy were 5.9 times more likely to have delayed laboratory reporting to the specimen submitter than patients with specimens that arrived in the laboratory within 1 day of collection ( $P < 0.0001$ ). Delayed transport was only one

of potentially many factors contributing to submitter reporting delays; 14 of 27 (51.9%) specimens having reporting delays were received in the testing laboratory within 1 day of specimen collection. Additional factors contributing to submitter reporting delays for AFB smear-positive patients were not explored in this study.

**Submitter reporting time frames and factors contributing to delayed reporting for AFB smear-negative patients.** Laboratories reported the first indication of the presence of *M. tuberculosis* in AFB smear-negative patients as either the presence of AFB in a growing culture (60.4%) or the positive identification of *M. tuberculosis* complex in a culture (39.6%). Hospital, commercial, HMO, and public health laboratories reported the first indications of *M. tuberculosis* to specimen submitters for 44.1, 20.7, 18.0, and 17.1%, respectively, of AFB smear-negative patients.

The median submitter reporting time frame was 21.0 days (mean, 25.35 days; range, 9 to 143 days) for AFB smear-negative patients, but specimens and cultures tested in commercial laboratories had longer reporting time frames than specimens and cultures tested in public health, HMO, and hospital laboratories ( $P = 0.0005$ ) (Table 1). The 52 patients with delayed reporting (46.8%) had a median submitter reporting time frame of 28.5 days (mean, 35.3 days).

After being tested by AFB microscopy, specimens from the 111 AFB smear-negative patients were processed in one of three ways: 92 patients (82.9%) had reports of the first evidence of TB made by the same laboratory that performed the AFB smear microscopy, 15 patients (13.5%) had specimens referred to another laboratory before reports were made, and 4 patients (3.6%) had specimens that were inoculated into culture before they were referred to another laboratory for identification of *M. tuberculosis* complex. Specimens that were first inoculated into culture before referral had longer reporting time frames (mean, 31.5 days; median, 28.5 days) than specimens that were directly referred (mean, 23.9 days; median, 21.0 days) and nonreferred specimens (mean, 25.3 days; median, 21.0 days) ( $P = 0.48$ ). There was not enough power in this study to determine the extent to which referral practices may have contributed to delays. However, transport times for patient specimens and cultures that were referred from one laboratory to another were longer (mean, 5.7 days; median, 0.5 day) than for patient specimens that were not referred between laboratories (mean, 1.27 days; median, 0.0 days) ( $P = 0.047$ ). In addition, patients with AFB smear-negative specimens that took longer than 1 day to reach the laboratory that performed the culture and/or identification of *M. tuberculosis* complex were 2.5 times more likely to have delayed laboratory reporting than patients with specimens or cultures that arrived in the laboratory within 1 day of collection ( $P = 0.001$ ). Again, delayed transport was only one of potentially many factors contributing to submitter reporting delays for AFB smear-negative patients: 38 of 46 (83%) specimens having reporting delays arrived in the laboratory within 1 day of the specimen collection.

Another factor that contributed to submitter reporting delays for AFB smear-negative patients was the practice of reporting the first indication of TB as positive identification of *M. tuberculosis* complex in a culture, rather than as the presence of AFB in a growing culture. Reporting positive identification of

*M. tuberculosis* complex as the first indication of TB (mean, 32.8 days; median, 27.0 days) was 2.9 times more likely to be delayed than reporting a growing culture as the first indication of TB for AFB smear-negative patients (mean, 20.5 days; median, 19.0 days) ( $P < 0.0001$ ).

**Laboratory reporting to LHD.** Reporting TB test results to the specimen submitter is not the only reporting requirement of laboratories. In California and many other states, laboratories are required to report TB test results to the appropriate LHD within 1 working day of reporting to the specimen submitter.

Public health laboratories are part of LHDs, and their patients were not included in the following analyses. Non-public health laboratories tested 87 AFB smear-positive patients; 79 of these fit the inclusion criteria for calculating medians, means, and ranges of LHD reporting times (see Materials and Methods). The median LHD reporting time frame for these 79 AFB smear-positive patients was 0 working days (mean, 1.6 days; range, 0 to 35 days). Laboratory reports to the LHD for 12 of 87 (13.8%) AFB smear-positive patients were delayed, i.e., the reporting time frame was greater than the legal requirement of 1 working day from notification of the specimen submitter. Of these delayed reports, 66.7% ( $n = 8$ ) were made by hospital laboratories.

Non-public health laboratories tested 92 AFB smear-negative patients; 59 of these fit the inclusion criteria for calculating medians, means, and ranges of LHD reporting times. The median LHD reporting time frame for these 59 AFB smear-negative patients was 0 days (mean, 1.1 days; range, 0 to 34 days); six (6.5%) reports were delayed. Of these delayed reports, 83.3% ( $n = 5$ ) were made by HMO laboratories. Eighteen AFB smear-negative patients served by non-public health laboratories (19.6%) had no evidence of laboratory reporting to the LHD; hospital, HMO, and commercial laboratories performed the TB testing for seven, six, and five of these AFB smear-negative patients, respectively.

**Laboratory reporting and treatment initiation.** A total of 40.4% of AFB smear-positive patients and 46.8% of AFB smear-negative patients had treatment initiation delays (Table 1). Patients whose positive smear results were reported to the submitter more than 1 day after specimen collection were twice as likely to have delays initiating therapy than patients whose positive smear results were reported within 1 day (OR = 3.9) (Table 2). Univariate analyses were performed to detect association of treatment delays for AFB smear-positive patients with demographic or disease characteristics; associations with these factors were not found. For AFB smear-negative patients, those whose first evidence of TB was reported to the submitter more than 21 days after specimen collection were 3.8 times more likely to have delays initiating therapy than patients whose first evidence of TB was reported within 21 days, (unadjusted OR = 4.23) (Table 2). The association of delayed laboratory reporting to the specimen submitter and delayed treatment remained, even after adjusting for older age and normal chest radiograph results (adjusted OR = 25.64) (Table 2), factors that were previously shown in some TB patient populations to be associated with treatment initiation delays (9, 12).

Although delayed laboratory reporting to the submitter was a factor contributing to delayed treatment, many patients with

TABLE 2. ORs for factors associated with treatment initiation delays<sup>a</sup>

Patient group and factor	No. of patients (%)	No. of patients with treatment initiation delays (%)	Unadjusted OR (95% CI)	Adjusted OR <sup>b</sup> (95% CI)
AFB smear positive	104	42 (40.4)		
Report to specimen submitter in >1 day	28 (26.9)	18 (64.3)	3.90 (1.57–9.71)	Not applicable
Report to specimen submitter in ≤1 day	76 (73.1)	24 (31.6)	Ref.	
AFB smear negative	111	52 (46.8)		
≥65 yr old	39 (35.1)	27 (69.2)	4.23 (1.83–9.75)	5.88 (1.86–18.52)
<65 yr old	72 (64.9)	25 (34.7)	Ref.	Ref.
Chest radiograph normal <sup>c</sup>	23 (21.1)	14 (60.9)	1.96 (0.77–5.03)	6.71 (1.70–26.3)
Chest radiograph abnormal <sup>c</sup>	86 (78.9)	38 (44.2)	Ref.	Ref.
Report to specimen submitter in >21 days	52 (46.8)	40 (76.9)	13.06 (5.28–32.25)	25.64 (7.81–83.33)
Report to specimen submitter in ≤21 days	59 (53.2)	12 (20.3)	Ref.	

<sup>a</sup> CI, confidence interval; Ref., reference group.

<sup>b</sup> Adjusted model includes age, chest radiograph results, and submitter reporting time frame.

<sup>c</sup> The total number of patients with normal and abnormal chest radiograph was 109, because 2 had missing chest X-ray data.

delayed treatment had timely submitter reporting (31.6% of AFB smear-positive and 20.3% of AFB smear-negative patients). In addition, AFB smear-positive results for 87.5% of these patients with timely submitter reporting but delayed treatment were reported to the LHD within the required 1-day time frame. These findings suggest that further steps could have been taken by the LHD to ensure prompt treatment initiation for these AFB smear-positive patients. On the other hand, only 41.7% of the AFB smear-negative patients with timely submitter reporting and delayed treatment were reported to the LHD within the required 1-day time frame. Thus, LHDs may not have known of the existence of more than half of this subset of AFB smear-negative patients in time to ensure rapid treatment initiation.

## DISCUSSION

Health care providers received delayed laboratory reports of the first evidence of TB for 27% of AFB smear-positive patients, the most infectious patients, in this population. Reporting delays were associated with delays in the transport of specimens from the collection site to the laboratory performing the smear microscopy, and, consequently, were also associated with laboratory type, with public health and commercial laboratories having longer median reporting times than hospital and HMO laboratories. These data suggest that public health interventions aimed at facilitating the rapid transport of specimens to public health and commercial laboratories would reduce the number of nonhospitalized patients with delayed treatment initiation attributable to delayed laboratory reporting. But not all reporting delays were attributable to transport delays. To identify additional public health interventions, the laboratory practices that contribute to delays in reporting positive AFB smear results to the specimen submitter should be further explored.

Delayed laboratory reports for AFB smear-positive patients were associated with delayed treatment initiation, with 64% of AFB smear-positive patients with delayed reporting having

delayed treatment. The potential adverse outcomes of delays in treatment initiation for AFB smear-positive patients include increased probability of death (9), increased risk of transmission to health care workers and others if the patient is hospitalized and not isolated (12), and increased transmission within the community. An estimate based on California data available in 2002 (3) suggests that approximately 268 nonhospitalized AFB smear-positive pulmonary TB patients had delayed treatment initiation (median treatment delay, 3 days) as a result of delayed laboratory reporting, 88 contacts of these patients had to be evaluated by LHDs (0.11 contact exposed per day of delay [1]), 26 of these contacts had become infected and required treatment for latent TB infection, and 1 contact had TB disease.

Unlike the findings of previous studies on treatment delays that pointed to clinical and social factors that are not amenable to public health intervention (9, 12–14), treatment delays attributable to delays in laboratory reporting of AFB smear-positive results can be addressed by implementing interventions specific to the type of laboratory that is performing the testing. For example, efforts can be directed to ensuring that hospital laboratories report smear-positive results within 24 h of receipt of the specimens.

Health care providers also received delayed laboratory reports of the first evidence of TB for 47% of AFB smear-negative patients in this population. Laboratory reporting delays for AFB smear-negative patients were also associated with transport delays and laboratory type, with laboratories to which specimens and cultures were referred (public health and commercial) having the longest reporting time frames. This study did not have the power to fully assess other aspects of referrals between laboratories that may have affected laboratory reporting times, but these may include batching of specimens and less than 7-days-per-week service. Another factor associated with delays in laboratory reporting to specimen submitters for AFB smear-negative patients was the practice of reporting the first evidence of TB as positive identification of *M. tuberculosis* complex rather than as the presence of AFB in

a growing culture. This finding suggests that all laboratories should report the first evidence of AFB in growing culture to specimen submitters rather than waiting to receive the results of *M. tuberculosis* complex identification tests, when confirmation of TB may be reported.

In this study, 77% of AFB smear-negative patients with laboratory reporting delays had delayed treatment initiation. Treatment delays for these patients were extremely long, measuring in weeks to months, and may have resulted in clinical deterioration and increased transmission of TB in the community, and potentially in the hospitals, as 20.7% (23 of 111) of AFB smear-negative patients with treatment delays were tested in hospitals.

To address delayed reporting for AFB smear-negative patients, public health efforts should focus on commercial laboratories, which had a median reporting time frame of 31 days, 10 days beyond the recommended 21 days. Of course, a recommended reporting time frame of 21 days is not adequate when health care providers are waiting to receive culture results before initiating treatment. The Healthy People 2010 objectives (<http://www.healthypeople.gov/document/html/objectives/14-14.htm>) require that the average time for a laboratory to confirm and report TB cases be reduced to 2 days for 75% of cases. Reaching this objective will decrease the extent of treatment initiation delays attributable to laboratory reporting delays. One way to reach this objective is to implement the use of rapid molecular methods by all laboratories that serve TB patients.

Timely reporting of TB test results to the health care provider is a necessary but not sufficient duty of laboratories. Laboratory reporting of TB test results to LHDs is required because it is often the basis for initiating contact investigations and ensuring that appropriate treatment is begun (7). However, these data showed not only that there was room for improvement in the completeness and timeliness of reporting from all non-public health laboratories to LHDs but also that timely laboratory reporting to LHDs did not always result in prompt treatment initiation. LHDs should evaluate the effectiveness of their interventions to swiftly act on reports of positive AFB smears and cultures.

One strength of this study was that, unlike previous surveys of laboratory practice, it was patient based, allowing the linkage of TB patient data from the RVCT to patient-specific laboratory data. With access to patient data from the RVCT, this study design allowed the analysis of some previously described risk factors for treatment initiation delays (e.g., age and chest radiograph results) in addition to laboratory reporting delays. However, the absence of patient chart data may have prevented the identification of additional factors associated with delays in treatment initiation. Also, because the patients were from California LHDs reporting the largest proportion of TB cases, the results are not representative of all patients in California or the United States. It is likely that these findings underrepresent the extent of the problem of delayed labora-

tory reporting because the laboratories that serve these four urban jurisdictions are more densely concentrated and are likely more proficient in TB testing methods than laboratories that serve less-urban areas with fewer TB cases.

Our findings reveal the crucial role of laboratory reporting of TB test results in TB control. To continue to control and move forward in eliminating TB, it is essential to improve the timeliness and completeness of laboratory reporting of TB test results.

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