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## Evaluation of the national tuberculosis surveillance program in Haiti

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### Abstract

**OBJECTIVE**—To assess the quality of tuberculosis (TB) surveillance in Haiti, including whether underreporting from facilities to the national level contributes to low national case registration.

**METHODS**—We collected 2010 and 2012 TB case totals, reviewed laboratory registries, and abstracted individual TB case reports from 32 of 263 anti-tuberculosis treatment facilities randomly selected after stratification/weighting toward higher-volume facilities. We compared site results to national databases maintained by a non-governmental organization partner (International Child Care [ICC]) for 2010 and 2012, and the National TB Program (*Programme National de Lutte contre la Tuberculose*, PNLT) for 2012 only.

**RESULTS**—Case registries were available at 30/32 facilities for 2010 and all 32 for 2012. Totals of 3711 (2010) and 4143 (2012) cases were reported at the facilities. Case totals per site were higher in site registries than in the national databases by 361 (9.7%) (ICC 2010), 28 (0.8%) (ICC 2012), and 31 (0.8%) cases (PNLT 2012). Of abstracted individual cases, respectively 11.8% and 6.8% were not recorded in national databases for 2010 ( $n = 323$ ) and 2012 ( $n = 351$ ).

**CONCLUSIONS**—The evaluation demonstrated an improvement in reporting registered TB cases to the PNLT in Haiti between 2010 and 2012. Further improvement in case notification will require enhanced case detection and diagnosis.

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## Keywords

TB; tuberculosis; surveillance; PNLT; Haiti

TUBERCULOSIS (TB) is a serious public health problem in Haiti; disease rates are the highest in the Western hemisphere,<sup>1</sup> and TB has been reported among the leading causes of death.<sup>2</sup> Between 2005 and 2011, the Haitian National TB Program (*Programme National de Lutte contre la Tuberculose*, PNLT) consistently reported approximately 14 000 cases each year. Case detection coverage was thought to be incomplete, however, as during this time the World Health Organization (WHO) estimates of the annual numbers of incident cases ranged from 22 000 to 27 200.<sup>1</sup> The true prevalence and potential causes of under-detection are poorly understood. Prevalence surveys, capture/recapture studies, and review of vital records can inform estimates of case-detection rates, but these have not been implemented in Haiti.

The PNLT has conducted TB surveillance since the late 1980s. As of mid-2013, there were 233 diagnostic and treatment centers (*Centres de Diagnostique et de Traitement*, CDT) and 30 treatment centers (*Centres de Traitement*, CT) registering patients for treatment across Haiti's 10 administrative departments.<sup>3</sup> Several paper-based registries are used for data collection at the site level, including TB case, laboratory, contact tracing, and respiratory symptomatic registries. In 1997, International Child Care (ICC), a local non-governmental organization (NGO) partnering with the PNLT, established a national level surveillance database containing individual case report data. In 2011, the PNLT established a separate case-based database, and both databases are currently being maintained during a period of transition from ICC to the PNLT. Data collection methods vary by region and by database. While ICC manually duplicates case registries to collect data at the site level, PNLT staff obtain photocopies of TB case registers during quarterly departmental meetings. Data entry and cleaning for both databases are performed at the central level, in Port-au-Prince, Haiti. During the quarterly department meetings, program and site-level data are reviewed and aggregate data reports are generated.

To evaluate accuracy and completeness of reporting, and to determine if underreporting from facilities to the national level contributes to low national case registration, we evaluated TB surveillance in Haiti using a nationally representative sample of TB cases reported by the PNLT.

## METHODS

From February to May 2013, we conducted an evaluation of the TB surveillance system in Haiti. We used adapted versions of WHO and Global Fund (Geneva, Switzerland) tools, including the TB Information System Assessment Tool (TISAT), the 'Assessment of Surveillance Data Workbook', and the Routine Data Quality Assessment (RDQA) tool<sup>4-6</sup> to assess TB data abstracted from program-associated registries, patient cards, reports, and centralized databases. Data from year 2010 and 2012 were evaluated to allow both an examination of recent data and an assessment of reporting over time.

### Sample size and facility selection

We estimated the sample size required to assess the proportion of cases identified at either CDT or CT facilities that were included in 2011 national TB case databases ( $n = 276$ ). Based on a conservative estimate that 50% of cases registered at facilities would be reported centrally, a precision estimate of  $\pm 4\%$  and a design effect of 4, we calculated a target sample size of 2056 cases per year. Thirty facilities (Figure) were chosen at random after stratifying facilities by the number of annual cases seen and weighting toward larger facilities to ensure capture of the potential impact large facilities might have on reporting quality. The initial sample included facilities from eight of Haiti's 10 departments; two additional larger facilities were randomly selected from the departments of Grande-Anse and Nippes so that at least one facility was assessed in each department.

### Data collection and abstraction

At each facility, we obtained both aggregate tallies and patient-level data from the four available TB registries (TB case, laboratory, respiratory symptomatic, and contact tracing) for 2010 and 2012.

For the TB case registry, aggregate totals were tallied for all cases, acid-fast bacilli (AFB) smear-positive cases, AFB-negative cases, cases tested for human immunodeficiency virus (HIV) infection, HIV-positive cases, and treatment outcomes (cured, completed treatment, treatment failure, lost to follow-up, or died) for each facility by month. We compared these facility-level aggregate data to the corresponding aggregate facility data from the ICC database for 2010 and 2012, and from the PNL database for 2012.

Patient data for the first TB case of each month were abstracted and compared to data on the same case from the TB laboratory registry, the patient treatment card, and the central databases. At sites where cases were not available each month, additional cases were abstracted to achieve a total of 12 cases.

The TB laboratory registry data were evaluated at each facility for 2012 only. We collected aggregate data on microscopy results from the initial diagnostic sputum specimens evaluated in 2012. During the evaluation, initial defaulters, defined as smear-positive TB patients not confirmed as starting treatment, were recorded from laboratory registers at facilities. After laboratory data had been abstracted at all facilities, the list of initial defaulters was compared with the central databases to determine if the patients were subsequently diagnosed with TB and initiated treatment at another facility.

The respiratory symptomatic registry was evaluated for years 2010 and 2012. Individual case data were aggregated by calendar month. The total number of cases evaluated was recorded, along with total numbers of patients with AFB-positive vs. AFB-negative results. All information from the first AFB-positive case listed each month in the 2012 respiratory symptomatic registry was abstracted and matched to the 2012 TB Case Registry to determine the proportion of individuals that initiated TB treatment at that facility.

## Data storage and analysis

All information was stored on secure databases. To facilitate comparison of individual case data to the national databases, names and other identifying information were used for comparisons between facility registries and the national databases. Weighted proportions were calculated by comparing total cases recorded at facilities to total cases captured within each database and weighting by total cases seen at each facility. These weighted means of the proportions were compared across years for significance ( $P < 0.5$ ) using Student's *t*-test and JMP®10 (SAS, version 9.3; Statistical Analysis System Institute, Cary, NC, USA).

The treatment success rate was defined as the number of cases who were cured or completed treatment divided by the total number of cases. Patients who were transferred, lost to follow-up, or misdiagnosed were excluded from the total number of cases. Treatment success rates were calculated for both aggregate and abstracted individual TB case totals. Treatment success rates were weighted by total cases seen at each facility. For abstracted individual case data, this calculation was restricted to cases who were AFB-positive as described by the WHO calculation.<sup>7</sup> To account for clustering and stratification of facilities, SAS complex survey procedures (SAS version 9.3) were used to calculate the 95% confidence intervals (CIs) and design effect for treatment success rates.

The Centers for Disease Control and Prevention (CDC) and the PNLT determined this project to be a public health program evaluation. Institutional Review Board (IRB) review was not required, as the activity did not constitute human subjects research. Informed consent was not required, as this evaluation of routinely collected surveillance data did not involve contact with human subjects and presented no risk to individuals whose records were reviewed.

## RESULTS

TB case registries were available at 30 of 32 (93.8%) facilities for 2010 and all 32 facilities for 2012 (Table 1). Aggregated facility case totals were 3711 for 2010 and 4143 for 2012 for all available facilities. For 2010, case data had been entered into national databases for all 30 evaluated facilities; for 2012, case data had been entered nationally for 30/32 facilities evaluated (with a facility case total of 3705) (Table 2). Case totals from facilities and the central database were compared for the same facilities. Based on these comparisons, aggregated case totals were higher in facility registries than in the ICC national database by 361 (9.7%) (ICC 2010) and 28 (0.8%) (ICC 2012), and lower by 14 (0.4%) cases for the PNLT 2012 database (Table 2). The weighted means of the proportion of aggregated case data in agreement with central databases was 90.3% (95% CI 85.5–95.0) for the 2010 ICC database, 99.2% (95% CI 95.0–103.5) for the 2012 ICC database, and 99.3% (95% CI 94.74–103.8) for the 2012 PNLT database. The increase in the weighted means of the proportions from 2010 to 2012 was statistically significant ( $P = 0.0058$  for 2010 and 2012 ICC databases;  $P = 0.0046$  for 2010 ICC and 2012 PNLT databases). Treatment success calculated from aggregate facility data was 84% (95% CI 77.1–90.5) for 2010 and 81% (95% CI 75.7–86.9) for 2012.

For the abstracted individual cases, respectively 285/323 (88.2%), 327/351 (93.2%), and 324/351 (92.3%) were recorded in the 2010 ICC, 2012 ICC, and 2012 PNLT national databases. Minimal duplication (0.3–1%) was observed in the databases (Table 3). Case-level data from facilities differed from information in the 2010 ICC, 2012 ICC, and 2012 PNLT national databases for 3.2%, 2.4% and 8.3% of AFB results and 12.3%, 7.3% and 8% of HIV test results, respectively (Table 3). These discrepancies reflected both missing data and the recording of results in the central database that differed from those recorded at the facilities. Final treatment determination for patients expected to have completed treatment was missing from the ICC database in 55.4% (2010) and 33.9% (2012) of cases, and was not available from the PNLT database at the time of the evaluation (Table 3). The weighted treatment success for AFB-positive cases was 88.5% (95%CI 84.1–93.0) in 2010 and 89.0% (95%CI 82.5–95.5) in 2012.

The laboratory register was available and complete at 27 (84.4%) facilities for 2010 and 31 (96.8%) facilities for 2012 (Table 1). The results of diagnostic AFB samples were evaluated at 24/32 (75.0%) facilities, at which diagnostic samples were evaluated for 13 194 patients; 1865 (14.1%) had at least two AFB-positive sputum samples and 9567 (72.5%) had negative results for all three sputum samples. Of the 1322 (10.0%) presumed TB cases who initiated but did not complete all three diagnostic sputum samples, 89 (0.7%) had initial AFB-positive results. Patient-identifying information was collected at only 11 facilities for patients who did not provide all three initial diagnostic sputum samples. For these facilities, samples from 8826 patients were evaluated, of which 1377 (15.6%) had at least one positive sample. Of the 77 (5.6%) presumed TB cases who did not complete all three diagnostic AFB tests, 10 (13.0%) were receiving treatment at another facility, according to information in the 2012 ICC database.

The 2012 respiratory symptomatic registry was in use and complete or partially complete at 24 of the 32 (75.0%) facilities evaluated (Table 1). Aggregate data were collected at the 11 (45.8%) facilities using this register consistently; at these facilities, 621 (median 11.0%, range 4.4–35.1) of 3839 patients with symptoms had 2 positive smears. Selected cases from 20/24 (83.3%) facilities with available registries were abstracted and matched to the TB case registry. Of 140 AFB-positive cases evaluated, 22 (15.7%) were not found in the TB case registry at the facility.

## DISCUSSION AND CONCLUSIONS

Our TB surveillance evaluation demonstrated a strongly performing system. Underreporting from the PNLT facilities to the national level does not appear to be an important reason for incomplete case notification in Haiti. Aggregated case totals seen at the facilities closely match database totals in 2012, and nearly all abstracted cases were found in the central databases.

Although there was generally good agreement between data from facility registers and data in the central databases, there were some important discrepancies related to sputum and HIV test results, and delays in entry of final treatment determinations limit the utility of the central databases for timely case-level analysis of treatment outcomes. Completeness and

accuracy of data entry should be reinforced, particularly in the recording of HIV test results and treatment determination. Standard operating procedures could be developed to assist with this activity. Transition to electronic registries<sup>8</sup> at selected facilities with existing capacity could improve linkage between different functions at the facilities and reduce data entry requirements at the national level.

There are potential missed diagnostic and followup opportunities with current sputum requirements. In accordance with current guidelines, improvements to TB surveillance could include verification that complete diagnostic evaluations are conducted for presumptive TB cases and allow for a smear-positive diagnosis based on a single sputum specimen to better capture smear-positive patients.<sup>9,10</sup> Expanded use of the respiratory symptomatic and contact tracing registries could aid in TB case detection; however, further evaluation is needed to determine the effectiveness of these activities.

Although treatment outcomes were not a focus of this evaluation, our evaluation demonstrated more favorable outcomes than had been previously reported nationally in 2010.<sup>1</sup> The higher treatment success rates that we observed may reflect our weighting toward larger facilities, if outcomes are better at larger facilities.

This evaluation had several important limitations. Smaller facilities may be under-represented because of our stratification. Abstracted cases from each facility may not be representative of all cases from the facilities or overall, and aggregate data from the selected facilities need to be interpreted with caution. This evaluation was focused on anti-tuberculosis treatment facilities registered with the PNLT; while the evaluation would have missed patients receiving treatment at facilities not registered with the PNLT, this is thought to be rare, as anti-tuberculosis drugs in Haiti are only available through the PNLT.

Overall, the TB surveillance evaluation demonstrated improvement in reporting of registered TB to the PNLT in Haiti between 2010 and 2012. Further improvement in case notification will require improved case detection and diagnosis. Efforts should focus on finding persons with TB through complete diagnosis and expanded case-finding efforts. Active screening at health facilities and contact tracing are likely to be important approaches to improve case finding. While the yield of these efforts at the visited facilities varied, a more detailed evaluation might inform the prioritization and implementation of these activities.

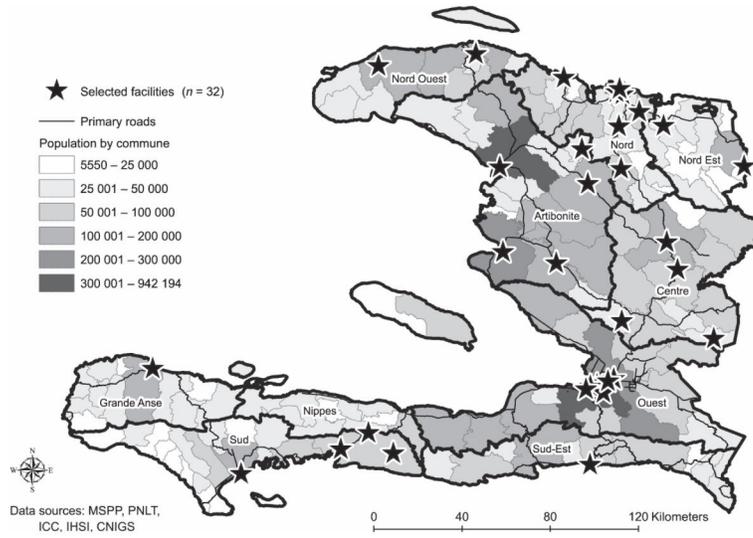
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**Figure.**  
Tuberculosis evaluation sites selected in Haiti.

**Table 1**Availability of requested 2010 and 2012 TB tools at facilities ( $n = 32$ )

	Yes, available and complete $n$ (%)	Yes, available but partially complete $n$ (%)	No, not available <sup>*</sup> $n$ (%)
TB case registry			
2010	30 (93.8)	—	2 (6.0)
2012	32 (100.0)	—	—
TB laboratory registry			
2010	27 (84.4)	2 (6.3)	3 (9.4)
2012	31 (96.9)	—	1 (3.1)
Contact tracing registry			
2012	7 (21.9)	16 (50.0)	9 (28.1)
Respiratory symptomatic registry			
2010	6 (18.8)	—	26 (81.3)
2012	21 (65.6)	3 (9.4)	8 (25.0)
Patient cards			
2010	12 (37.5)	19 (59.4)	1 (3.1)
2012	24 (75.0)	8 (25.0)	—

\* TB case registries were missing at two facilities for 2010. One facility did not perform sputum-based diagnosis on site. TB = tuberculosis.

**Table 2**

## Aggregated TB case totals

	Site data	ICC database	PNLT database <sup>*</sup>
2010 case totals ( <i>n</i> = 30 facilities)	3711	3350	—
AFB-positive cases	2065	1865	—
HIV-tested cases	2842	2355	—
HIV-positive cases	615	520	—
Cases cured	1582	1440	—
Cases completing treatment	1115	1209	—
Cases transferred	445	175	—
Cases lacking treatment determination	37	37	—
Patients misdiagnosed with TB	12	—	—
2012 case totals ( <i>n</i> = 30 facilities) <sup>†</sup>	3705	3677	3719
AFB-positive cases	2111	2051	1985
HIV-tested cases	3346	3118	3123
HIV-positive cases	769	724	697
Cases cured	1179	772	—
Cases completing treatment	974	660	—
Cases transferred	190	116	—
Cases lacking treatment determination	865	1143	3719
Patients misdiagnosed with TB	3	—	—

TB = tuberculosis; ICC = International Child Care; PNLT = Programme national de Lutte contre la Tuberculose; AFB = acid-fast bacilli; HIV = human immunodeficiency virus.

<sup>\*</sup> For the 2012 PNLT database, treatment completion information had not been entered at the time of the comparison.

<sup>†</sup> Only 30 facility registries could be evaluated because ICC data from two facilities (Centre médico social de Gebeau and Hôpital Dumarsais Estime) had not been completely entered into the databases at the time of evaluation.

**Table 3**

2010 and 2012 TB database evaluation using abstracted case data from 32 facilities in Haiti

	<u>ICC database (2010)</u>	<u>ICC database (2012)</u>	<u>PNLT database (2012)</u>
<b>Total cases abstracted</b>	<b>(n = 323) n (%)</b>	<b>(n = 351) n (%)</b>	<b>(n = 351) n (%)</b>
Records found for comparison	285 (88.2)	327 (93.2)	324 (92.3)
Duplicates found	2 (0.6)	5 (1.4)	1 (0.3)
Database/TB case registry mismatches*			
Age	68 (23.9)	23 (7.0)	22 (6.8)
Address	118 (41.4)	24 (7.3)	19 (5.9)
Name	2 (0.7)	4 (1.2)	5 (1.5)
Mother's name	—	—	98 (30.2)
Sex	5 (1.8)	5 (1.5)	6 (1.6)
Type of TB (pulmonary vs. extra-pulmonary)	16 (5.6)	14 (4.3)	11 (3.4)
Type of TB case (new vs. retreatment, etc.)	16 (5.6)	29 (8.9)	22 (6.8)
Weight at initial examination	83 (29.1)	36 (11.0)	31 (9.6)
Registration date	—	—	35 (10.8)
Date of initial treatment	44 (15.4)	23 (7.0)	—
Difference <5 days	12 (27.3)	4 (17.4)	—
AFB date	—	—	270 (83.3)
Difference <5 days	—	—	67 (24.8)
AFB results	9 (3.2)	8 (2.4)	27 (8.3)
Different result recorded	9 (100)	8 (100)	6 (22.2)
Blank in database	—	0	21 (77.8)
HIV tested	41 (14.4)	21 (6.4)	18 (5.6)
HIV test date	84 (29.5)	62 (19.0)	61 (18.8)
Difference <5 days	5 (6.0)	8 (12.9)	55 (90.2)
HIV test results	35 (12.3)	24 (7.3)	26 (8.0)
Different result recorded	20 (57.1)	4 (16.7)	3 (11.5)
Blank in database	15 (42.9)	20 (83.3)	23 (88.5)
Final treatment determination <sup>†</sup>	158 (55.4)	111 (33.9)	—
Different treatment determination value recorded	26 (16.5)	14 (12.6)	—
Blank in database	132 (83.5)	97 (87.4)	—
Final treatment determination date <sup>†</sup>	170 (59.6)	134 (41.0)	—
Different date recorded	20 (11.8)	34 (25.4)	—
Difference <5 days	9 (5.3)	5 (3.7)	—
Blank in database	150 (88.2)	100 (74.6)	—

TB = tuberculosis; ICC = International Child Care; PNL T = Programme national de Lutte contre la Tuberculose; AFB = acid-fast bacilli; HIV = human immunodeficiency virus.

\* Where type of mismatch could be broken down further, the proportion of the total error was determined.

<sup>†</sup> Final treatment determination was not evaluated in the PNL T database due to unavailability of these data for analysis.