Assessment of declines in reported tuberculosis cases--Georgia and Pennsylvania, 2009.; United States results of mycobacterial laboratory testing and tuberculosis declines in Georgia and Pennsylvania with number of specimens, absolute change, and percent change for 2008 and 2009

Morbidity and Mortality Weekly Report
March 25, 2011

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Section: Pg. 338; Vol. 60; No. 11

Length: 3902 words

Body

In 2009, the largest single-year percentage decrease in tuberculosis ($\underline{\textit{TB}}$) $\underline{\textit{cases}}$ was reported since national $\underline{\textit{TB}}$ surveillance began in the United States in 1953. Overall, $\underline{\textit{TB}}$ rates decreased 11.4% to 3.8 $\underline{\textit{cases}}$ per 100,000 population, compared with an average annual decline of 3.8% each year since 2000 (1,2). Georgia and Pennsylvania were $\underline{\textit{among}}$ 36 states reporting decreases from 2008; $\underline{\textit{TB}}$ $\underline{\textit{case}}$ rates fell 14.3% (from 4.9 to 4.2) in Georgia and 38.7% (from 3.1 to 1.9) in Pennsylvania. Concerned about the possibility of unidentified $\underline{\textit{TB}}$ $\underline{\textit{cases}}$, the Georgia Division of Public Health and the Pennsylvania Department of Health, in collaboration with CDC, conducted investigations centering on four hypotheses for the declines: 1) surveillance artifact, 2) underreporting, 3) underdiagnosis, and 4) actual decline. This report summarizes the results of those investigations, which found no evidence of surveillance artifact, underreporting, or underdiagnosis substantial enough to account for the magnitude of the declines. Instead, a decrease in the number of laboratory-confirmed Mycobacterium tuberculosis complex diagnoses and a decrease in the percentage of suspected $\underline{\textit{TB}}$ $\underline{\textit{cases}}$ ultimately counted as meeting the $\underline{\textit{TB}}$ $\underline{\textit{case}}$ definition; both suggested a true decline in $\underline{\textit{TB}}$ in 2009. The population groups with the largest declines were foreign-born persons and children. Continued $\underline{\textit{TB}}$ surveillance, including vigilance in suspecting, diagnosing, and reporting $\underline{\textit{TB}}$ $\underline{\textit{cases}}$ to public health departments, will help clarify the cause of this decline and determine long-term $\underline{\textit{TB}}$ trends in the United States.

The investigations in the two states were conducted during March-May 2010 and included systematically assessing changes in <u>TB</u> surveillance practices, cross-matching health department data with records from reporting entities and secondary sources, reviewing laboratory records, and analyzing state <u>TB</u> registries for epidemiologic changes. Reports of suspected <u>TB cases</u> sent by health-care providers and laboratories to public health departments in Georgia and Pennsylvania are entered into Georgia's State Electronic Notifiable Disease Surveillance System (SENDSS) and Pennsylvania's version of the National Electronic Disease Surveillance System (PA-NEDSS). In Pennsylvania, electronic reports also are downloaded automatically from laboratory databases into PA-NEDSS. Once a report is investigated locally, designated health department officials determine whether it meets Council of State and Territorial Epidemiologists criteria to be counted as a <u>case</u>.*

To assess for surveillance artifact (i.e., whether <u>case</u> counts were artificially low as a result of changes or delays in reporting, investigating, or counting, including changes in criteria for counting reports as <u>cases</u>) in 2009, public health staff members in both states were interviewed, and trend analyses of SENDSS and PA-NEDSS data were conducted. The number of suspected <u>TB case</u> reports, the proportion of those reports ultimately counted as <u>cases</u>, and selected surveillance quality measures (e.g., mean time from initial report to count inclusion) were evaluated for 2008-2009 in Georgia and 2007-2009 in Pennsylvania (where 2007 was the comparison year because delayed

counting of <u>cases</u> first reported in 2005-2007 was known to have inflated the 2008 <u>case</u> count artificially). In Georgia, officials in the 13 counties with declines of three or more reported <u>cases</u> provided their independent <u>case</u> counts to determine concordance with SENDSS. In addition, paper reports not yet entered into SENDSS were reviewed to identify additional <u>cases</u>. Similarly, suspected <u>TB</u> reports included in PA-NEDSS that had not been counted as <u>cases</u> were reexamined if they had laboratory or clinical characteristics suggestive of <u>TB</u>.

To assess for underreporting, SENDSS and PA-NEDSS records were cross-matched with line lists from different sources of patients with potential <u>TB</u> diagnoses in 2008 and 2009. Both state public health laboratories participated, as did the City of Philadelphia public health laboratory and 43 (46%) of 92 licensed private laboratories in Georgia and 131 (81%) of 161 in Pennsylvania that provided these data as part of a survey. Additional cross-matching in Georgia included infection-control records from the 13 Atlanta hospitals that reported the most <u>cases</u> of <u>TB</u>. Records of patients with a <u>TB</u>-related code from the International Classification of Diseases, Ninth Revision (ICD-9)[dagger] in the state's hospital discharge database, but not in SENDSS (i.e., unmatched patients), also were assessed further.

To assess for underdiagnosis, the public health laboratories serving the two states ran systematic queries on the total number of patients who had specimens tested for M. tuberculosis complex (e.g., M. tuberculosis, M. bovis, or M. africanum) by culture or by nucleic acid amplification testing and the proportion with M. tuberculosis complex confirmed by either test. Investigators also assessed whether any changes in laboratory policies or practices might account for the unexpected drop in reported <u>TB</u>. Similar data were gathered via a survey sent to licensed private laboratories in the two states. In Georgia, 57 (62%) of 92 private laboratories responded with these data, as did 131 (81%) of 161 in Pennsylvania. Nonresponding laboratories in Pennsylvania did not have fewer PA-NEDSS reports in 2009 compared with 2008; in Georgia, such changes could not be assessed. In addition, <u>TB</u> diagnosis trends in the hospital discharge records provided by the Pennsylvania Health Care Cost Containment Council for Southeastern Pennsylvania, which covers approximately 40% of the state's population (3), were examined; ICD-9 codes were used to identify possible **TB**-related hospitalizations.

To assess the evidence supporting an actual decline in <u>TB</u>, Georgia and Pennsylvania <u>TB cases</u> counted in 2009 were compared with 2008 <u>cases</u> for changes in patient characteristics that could affect the likelihood of having laboratory-confirmed <u>TB</u> (e.g., age and site of disease). Linear regression of log-transformed <u>case</u> counts during 1999-2009 was used to determine the expected numbers of <u>cases</u> <u>among</u> U.S.-born and foreign-born persons; observed numbers outside the 95% prediction interval were considered significant.

Investigation of Surveillance Artifact

No changes or delays in surveillance practices were found in Georgia. Excluding results of overseas <u>TB</u> screening in newly arriving <u>immigrants</u>, the number of suspected <u>TB</u> reports in 2008 was comparable to that in 2009. The mean numbers of days between initial report, entry into SENDSS, and inclusion in the state <u>case</u> count also were comparable. However, despite no changes in the criteria for counting suspected <u>TB</u> as <u>cases</u>, the percentage of initial reports ultimately counted as <u>cases</u> declined, from 77% (478 of623) in 2008 to 66% (415 of 619) in 2009. The independent counts in the 13 counties with the largest declines were concordant with SENDSS data; one uncounted <u>TB case</u> was found <u>among</u> paper reports not yet entered into SENDSS.

Similarly, surveillance practices in Pennsylvania did not appear to change substantially in 2009. Delayed counting of <u>cases</u> first reported during 2005-2007 is known to have artificially inflated the 2008 <u>case</u> count in Pennsylvania. One suspected <u>TB</u> report from 2005, three from 2006, and 48 from 2007 were not counted as <u>cases</u> until 2008 (Figure 1). However, even after adjusting Pennsylvania's 2008 <u>case</u> count for this known surveillance artifact (i.e., subtracting 52 <u>cases</u>), a 30% annual decline was still observed in 2009, and the number of suspected <u>TB</u> reports to public health authorities remained stable. The mean number of days between initial report and investigation was comparable during 2007-2009. However, as in Georgia, the percentage of initial reports ultimately counted as <u>TB</u> <u>cases</u> declined from 14% (276 of 1,995) in 2007 to 12% (236 of2,030) in 2009. (Pennsylvania has a larger number of suspected <u>TB</u> reports, compared with Georgia, because of automatic downloads from laboratory databases into

PA-NEDSS.) <u>Among</u> the suspected <u>TB</u> reports not counted as <u>cases</u> in Pennsylvania in 2009, a total of 409 met the criteria for further investigation, but only six were determined to be verified and countable.

Investigation of Underreporting

In Georgia, the SENDSS cross-match with line lists of patients with positive <u>TB</u> results from the state public health laboratory, 43 private laboratories, and 13 hospitals detected no unreported <u>cases</u>. <u>Among</u> patients with <u>TB</u> ICD-9 codes in the hospital discharge database, 45% (244 of 539) in 2008 and 43% (178 of 416) in 2009 (fourth quarter data unavailable) were not found in SENDSS. Seventy-three of these 422 unmatched patients were selected for further review based on having ICD-9 codes that corresponded to countable <u>TB</u> for >50% of hospital records. [section] Further medical review was possible for 28 (85%) of 33 unmatched records in 2008 and for 37 (93%) of 40 in 2009. One unreported 2009 <u>case</u> (culture negative <u>TB</u> pleurisy) was found.

[FIGURE 1 OMITTED]

In Pennsylvania, the PA-NEDSS cross-match with line lists of patients with positive M. tuberculosis complex results from public health laboratories and from 58 private laboratories found 13 potentially unreported <u>cases</u>, of which none proved to be countable (seven were in non-Pennsylvania residents, and six were nontuberculous mycobacteria).

Investigation of Underdiagnosis

Review of 2008 and 2009 laboratory data in both states showed that the total number of patients who had specimens tested for mycobacteria <u>increased</u> in the public health laboratories (i.e., 4.7% in Georgia and 11.6% in Pennsylvania), but the proportion of patients with specimens that tested positive for M. tuberculosis complex decreased 19.8% in the Georgia State Public Health Laboratory and 28.8% in Pennsylvania public health laboratories (Table). In the 10 private laboratories that provided these data in response to the Georgia survey, a parallel decline was noted. <u>Among</u> 131 private laboratories responding to the Pennsylvania survey, similar numbers of specimens were received for M. tuberculosis complex testing annually during 2007-2009, but the proportion that tested positive for M. tuberculosis complex decreased 36% from 2008 to 2009 (Figure 2). In neither state were changes noted in the types of specimens processed or in the methods or procedures (at public health labs) for laboratory diagnosis of <u>TB</u>.

Analysis of the southeastern Pennsylvania hospital discharge dataset showed that the total number of inpatient hospitalizations was stable, with 707,601; 699,893; and 696,846 discharges in 2007, 2008, and 2009, respectively. Time-trend analysis revealed that the percentage of all hospitalizations with either pulmonary or extrapulmonary <u>TB</u> as a primary or secondary diagnosis was approximately 0.04% each year; further subset analyses by <u>TB</u>-related ICD-9 codes revealed no other **TB** diagnosis-related changes during this period.

Evidence Suggesting Actual Declines in TB

Because the investigations in Georgia and Pennsylvania found little evidence to support the first three hypotheses for the decline in reported <u>TB cases</u>, more consideration was given to whether the surveillance findings represented an actual decline in 2009. The relative proportions of counted <u>TB cases</u> that met the national <u>case</u> definition based on laboratory criteria essentially were unchanged: from 362 (76%) of Georgia's 478 <u>TB cases</u> in 2008 to 303 (73%) of 415 in 2009, and from 214 (78%) of Pennsylvania's 276 <u>TB cases</u> in 2007 to 190 (81%) of 236 in 2009. In both states, the declines noted from 2008 to 2009 by site of disease appeared approximately consistent (i.e., a 15% decline in pulmonary and 13% decline in extrapulmonary in Georgia, with declines of 36% and 45%, respectively, in Pennsylvania). Also in both states, children aged <15 years were the age group that experienced the largest decrease in reported <u>TB cases</u> (by 38% in Georgia and 79% in Pennsylvania) in 2009. Linear regression analysis of <u>cases</u> during 1999-2009 showed that observed <u>case</u> counts <u>among</u> foreign born-persons declined significantly in both states in 2009. Based on the prediction interval for the number of <u>TB cases</u> reported <u>among</u> foreign-born persons, Georgia would have expected 182-247, but observed 176; Pennsylvania would have expected 131-239, but observed 127. <u>Among</u> U.S.-born persons, smaller declines were not statistically

significant. For U.S.-born persons, the 235 observed <u>cases</u> were within the 201-295 prediction interval in Georgia, and 108 observed <u>cases</u> were within the 94-197 prediction interval in Pennsylvania.

[FIGURE 2 OMITTED]

Editorial Note

After unexpected declines in 2009 in the number of <u>TB cases</u> reported in Georgia and Pennsylvania, investigations in the two states applied an extensive systematic approach to assess whether the declines were actual. Although the investigations did not reexamine every initial report of suspected <u>TB</u> to determine whether it was or was not counted properly, hundreds of such reports and thousands of statewide hospital and laboratory records were reexamined, ultimately finding only two uncounted <u>cases</u> in Georgia and six in Pennsylvania that should have been counted in 2009; of these eight <u>cases</u>, all except one Georgia <u>case</u> had been reported to public health authorities but not recorded in the surveillance system. The results of these investigations provide strong evidence against underreporting as the cause for the decline. The results are similar to those of a previous study of <u>TB case</u>reporting completeness in seven U.S. states during 1994-1995, which found few unreported <u>cases</u> (4).

The investigations determined that, whereas the number of positive <u>TB</u> results declined, the total number of individual patients and specimens tested for <u>TB</u> remained stable or <u>increased</u> in the public health laboratories serving the two states. A similar trend in the states' private laboratories also suggested that the decline in <u>TB</u> diagnoses in Georgia and Pennsylvania was not the consequence of health-care providers' failing to consider a diagnosis of <u>TB</u> in 2009. Pennsylvania's stable percentage of hospitalizations with <u>TB</u>-related diagnoses during 2007-2009 provides further evidence against underdiagnosis and might suggest a decline in less severe manifestations of <u>TB</u> disease that do not require hospitalization.

The findings in this report are subject to at least three limitations. First, this investigation could not examine whether underdiagnosis occurred because of failure of patients to seek medical attention for <u>TB</u> symptoms. For example, factors affecting patient access to medical care, such as immigration status or financial constraints, were not assessed (5). Second, neither state assessed underdiagnosis or underreporting at outpatient provider sites where patients with less severe disease might have been managed. Finally, one of the methods used to assess whether hospitals might have underreported <u>TB cases</u> relied on how well ICD-9 codes corresponded to known <u>TB cases</u> without medical record reviews to test the validity of the ICD-9 code itself.

The findings in both Georgia and Pennsylvania of a decrease in the percentage of suspected <u>TB</u> reports that ultimately were counted as <u>cases</u> and a decrease in the proportion of tested specimens yielding M. tuberculosis complex support an actual decline in incident <u>TB</u> disease in 2009. The decreased proportion of laboratory-confirmed <u>TB</u> cannot be explained by a commensurate <u>increase</u> in the types of <u>cases</u> typically associated with culture-negative <u>TB</u> (e.g., pediatric or extrapulmonary <u>TB</u> [6,7]). Children experienced the largest decline in reported <u>TB</u>, a finding suggesting either less <u>TB</u> transmission or changes in immigration patterns. Similarly, the decline in <u>TB cases among</u> foreign-born persons might reflect an actual decline because of changes in migration following the economic downturn (i.e., decreased immigration or <u>increased</u> emigration of job-seekers) or improved preimmigration <u>TB</u> detection and treatment <u>among</u> U.S.-bound <u>immigrants</u> per CDC's technical instructions for prevention and treatment of <u>TB among immigrants</u> (8). Varying implementation dates and the small number of <u>cases</u> in Georgia and Pennsylvania from countries that have implemented the revised instructions prevented an assessment of the impact of these overseas screening changes.

Although recent changes in migration patterns or in overseas <u>TB</u> screening of new <u>immigrants</u> are possible explanations for an actual U.S. decline in <u>TB</u> in 2009, clinicians and health systems should maintain vigilance for <u>TB</u> and promptly report new <u>TB cases</u> to public health authorities. A decline because of delayed diagnosis resulting from obstacles to care also remains a possibility, although preliminary 2010 <u>TB</u> surveillance data did not demonstrate a compensatory <u>increase</u> in the number of <u>cases</u> (9). Monitoring for patients with more advanced disease is important to prevent worse morbidity and <u>increased</u> mortality from <u>TB</u>. Continued analyses of new public health surveillance and other data sources will help to better discern long-term trends in <u>TB</u> in the United States.

What is already known on this topic?

In 2009, tuberculosis (<u>TB</u>) incidence in the United States decreased to 3.8 <u>cases</u> per 100,000 population, the lowest recorded rate since national <u>TB</u> surveillance began in 1953. The 11.4% decrease from 2008 was the greatest single-year decrease ever recorded.

What is added by this report?

Findings from systematic investigations in Georgia and Pennsylvania, two states that experienced unexpectedly large decreases in <u>TB</u> incidence in 2009, indicate that the decline in new <u>TB</u> disease in those states appeared actual and not attributable to surveillance artifact, health-care provider underdiagnosis, or underreporting.

What are the implications for public health practice?

The <u>TB</u> surveillance systems in Georgia and Pennsylvania appear to be functioning appropriately. Current efforts to diagnose, treat, and report <u>TB</u> <u>cases</u> should be vigorously maintained as the United States moves closer to the goal of <u>TB</u> elimination.

Acknowledgments

This report is based, in part, on contributions by A Chakragiri, S Daniel, K Buford, Georgia Div of Public Health; J Bush, Georgia Dept of Community Health; and T Navin, L Armstrong, B Pratt, C Jeffries, J Becerra, G Grant, and LA Ramsey, Div of *TB* Elimination, National Center for HIV/AIDS, Viral Hepatitis, STD, and *TB* Prevention, CDC.

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^{*} Available at http://www.cdc.gov/osels/ph surveillance/nndss/casedef/tuberculosis current.htm.

([dagger]) ICD-9 codes (http://www.cdc.gov/nchs/icd/icd9.htm) for TB are 010-019; code 011 is specific for pulmonary TB disease.

([section]) Georgia investigators estimated which ICD-9 codes corresponded to countable <u>TB</u> on the basis of the counted 2008-2009 <u>TB cases</u> (i.e., known to have <u>TB</u>) in SENDSS. First, they recorded the frequency of all the <u>TB</u>-related ICD-9 codes that appeared in hospital discharge records. For each ICD-9 code with a frequency greater than three, the numerator for the estimate was the number of hospital records with that ICD-9 code that also matched a counted <u>TB case</u> in SENDSS, and the denominator was the total number of records with that ICD-9 code. The discharge diagnosis codes estimated to correspond to countable <u>TB</u> for >50% of records were 011.2, 011.23, 011.24, 011.26, 011.6, 011.63, 011.64, 011.66, 011.91, 011.92, 011.93, 011.94, 011.96, 012.0, 012.04, 013.0, 013.04, 015.53, 017.2, and 018.9.

* Delayed counting of <u>cases</u> artificially inflated the 2008 <u>case</u> count in Pennsylvania. One suspected <u>TB case</u> from 2005, three from 2006, and 48 from 2007 were not counted as <u>cases</u> until 2008. Subtracting these 52 <u>cases</u> from the 2008 Pennsylvania total reduced the decrease in 2009 from 38.7% to 29.6%.

Reported by

Data type

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TABLE. Results of mycobacterial laboratory testing--Georgia and

Pennsylvania, 2008 versus 2009 Georgia State laboratory Absolute % 2008 2009 change change Data type No. of primary clinical -123 9,098 8,975 -1.4 specimens ([dagger]) No. of patients who had 2,788 2,919 +131 +4.7 specimens tested by mycobacterial culture 253 212 -41 -16.2 No. of patients who had specimens that tested positive by mycobacterial culture Percentage of patients who had -19.8 9.1% 7.3% -1.8 specimens with positive % pts Mycobacterium tuberculosis complex cultures Georgia Private laboratories (n = 10)% Absolute

2008

2009

change

change

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No. of primary clinical	14,62 2	14,24 0	-382	-2.6
specimens ([dagger])				
No. of patients who had	8,257	7,523	-734	-8.9
specimens tested by				
mycobacterial culture				
No. of patients who had specimens that tested	68	46	-22	-32.4
positive by mycobacterial				
culture				
Percentage of patients who had	0.8%	0.6%	-0.2	-25.0
specimens with positive				% pts
Mycobacterium tuberculosis				
complex cultures				
				Pennsylvania
				State and Philadelphia public
				health laboratories (n = 2) *
			Absolute	%
Data type	2008	2009	change	change
No. of primary clinical	2,266	2,370	104	+4.6
specimens ([dagger])				
No. of patients who had specimens tested by	536	598	62	+11.6
mycobacterial culture				
No. of patients who had specimens that tested	116	85	31	-26.7
positive by mycobacterial				
culture				
Percentage of patients who had	22.6 %	16.1 %	-6.5	-28.8
specimens with positive				% pts
Mycobacterium tuberculosis				

Classification

complex cultures

Language: ENGLISH

Document-Type: Fulltext

Publication-Type: Report

Journal Code: MORMOWER

Acc-No: 7005324

Subject: TUBERCULOSIS (92%); PUBLIC HEALTH ADMINISTRATION (91%); PUBLIC HEALTH (90%); SURVEILLANCE (90%); INVESTIGATIONS (90%); EPIDEMIOLOGY (89%); DISEASES & DISORDERS (89%); DISEASE REPORTING (89%); TRENDS (89%); HEALTH DEPARTMENTS (89%); SURVEILLANCE TECHNOLOGY (78%); POPULATION & DEMOGRAPHICS (78%); DEMOGRAPHIC GROUPS (77%); CRIMINAL INVESTIGATIONS (74%); HEALTH CARE PROFESSIONALS (69%); BACTERIA (66%)

Industry: EPIDEMIOLOGY (89%); HEALTH DEPARTMENTS (89%); HEALTH CARE PROFESSIONALS (69%); HEALTH CARE (50%)

Product: 806996 (Specialty hospitals NEC); 807000 (Medical and dental laboratories); 807100 (Medical laboratories)

Geographic: PENNSYLVANIA, USA (95%); UNITED STATES (92%); United States; North America (NOAX); United States (USA); United States (USAX); Georgia (state) (USGA); Northeastern US (USNRX); Pennsylvania (USPA); Southeastern US (USSEX)

SPECIAL FEATURE: Table

Load-Date: April 29, 2011

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