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Tuberculosis Skin Test and Interferon Gamma Release Assays Usage among Privately Insured Persons in the US

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Abstract

Objective: Describe tuberculin skin test (TST) and interferon gamma release assays (i.e., QFT and T-Spot) usage among privately insured persons in the US over a 15-year period.

Methods: We used current procedural terminology (CPT) codes for TST and IGRAs to extract outpatient claims (2000–2014) and determined the usage (claims/100,000). Chi-square test for trend in proportions was used to describe usage trends for select periods.

Results: TST was the dominant (>80%) test in each year. Guideline publication preceded the assignment of QFT and T-Spot CPT codes by one year (2006 for QFT; 2011 for T-Spot). QFT usage was higher ($p<0.01$) than T-Spot in each year. The average annual increase in the use of QFT was higher than that of T-Spot (35/100,000 vs. 3.8/100,000), and more so when the analytic period was 2011–2014 (65/100,000 vs. 38/100,000). However, during that four-year period (2011–2014), TST use trended downward—average annual decrease of 28/100,000. The annual proportion of enrollees tested ranged from 1.1%–1.5%.

Conclusions: These results suggest a gradual shift from the use of TST to the newer IGRAs. Future studies can assess the extent, if any, to which the shift from the use of TST to IGRAs evolve over time.

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Disclaimer

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the United States Centers for Disease Control and Prevention (CDC). Mention of company names or products does not imply endorsement by the CDC.

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Keywords

Trend analyses; tuberculin skin test; interferon gamma release assays; claims data

INTRODUCTION

Tuberculin skin tests (TSTs) and the newer interferon gamma release assays (IGRAs) are both used to aid in the detection of active tuberculosis (TB) and to diagnose latent tuberculosis infection (LTBI). For over a century Mantoux TSTs have been the standard test for TB infection in most parts of the world,[1, 2] although the less accurate multiple percutaneous Tine TST was also used in the past.[3] TSTs involve intradermal injections of tuberculin purified protein derivative (PPD) in order to identify an immune response. The more recent discovery of the critical role played by interferon gamma in regulating cell-mediated immune responses to *M. tuberculosis* (MTB) resulted in the commercial production of the IGRAs for the detection of TB infection[4, 5]—QuantiFERON®-TB [QFT] (QIAGEN Biotechnology, Hilden, Germany) and T-SPOT®.TB test [T-Spot] (Oxford Immunotec Limited, Abingdon, United Kingdom). IGRAs use synthetic peptides representing early secreted antigenic target 6 (ESAT-6) and culture filtrate protein 10 (CFP-10) which are present in the genomes of relatively few mycobacteria. Consequently, they avoid the problem of PPD's cross-reactivity with antigens from a larger number of mycobacterial species, including bacille Calmette-Guerin (BCG) which is used for vaccination in many parts of the world.[6–9] Additionally, IGRAs do not require a second visit to clinically assess test results.[8]

In the United States (US), IGRAs were introduced as alternatives to the TSTs for the diagnosis of TB infection.[8, 10–12] The QuantiFERON®-TB [QFT] test was approved by the Food and Drug Administration (FDA) in 2001 followed by the QuantiFERON®–TB Gold [QFT-G] (QIAGEN Biotechnology, Hilden, Germany) in 2005.[8] The Centers for Disease Control and Prevention (CDC) published guidelines for using the QFT in 2003 and for the QFT-G in 2005.[11, 12] In 2010, the CDC published updated guidelines after the FDA approved two new IGRAs tests— the QuantiFERON®–TB Gold In-Tube [QFT-GIT] and T-Spot, which have improved specificity over the earlier IGRAs.[8] These guidelines state that IGRAs and TSTs may be used without preference in most scenarios where MTB testing is appropriate, although IGRAs are preferable for groups unlikely to return to have TSTs read and persons having received BCG, while TSTs are preferred for children aged <5 years. Routine testing with both is not generally recommended.[8]

Even though IGRAs were introduced over a decade ago,[8] information on their use and how their use compares with that of the TSTs in the US is lacking. In this study, we analyzed temporal outpatient claims data to describe the use of TSTs and IGRAs among privately insured persons in the US over a 15-year period (2000–2014). Given the pivotal role these tests play in diagnosing latent TB infection (LTBI) and active TB in the US,[13] information on their use in relation to changes in testing guidelines/recommendations is important. Additionally, tracking the relative use of these tests over the years might help to explain or

advance our understanding of potential trend changes in the reported cases of LTBI and TB disease in the US.

MATERIALS AND METHODS

We used claims data from the Truven Health MarketScan® Commercial Claims Database. This database consists of employer and health plan-sourced individual-level healthcare claim data, linking detailed patient information (including inpatient and outpatient care and laboratory testing) across sites and over time. As of 2014, the data contained claims information on over 43 million individuals representing 25% of the employer-based privately insured population in the US and two-thirds of the US population had private health insurance.[14] The database contains retrospective data on de-identified enrollees (Truven Health MarketScan® Commercial Claims Database). As a result, institutional review board approval was not required for this study.

Outpatient medical claims contain current procedural terminology (CPT) codes which are used to uniformly document medical procedures and services provided to patients.[15] We identified all CPT codes representing TSTs and IGRAs in use in 2000–2014. Although there are three QuantiFERON-TB tests (QFT, QFT-G and QFT-GIT), CPT coding does not differentiate them. Consequently, we examined QuantiFERON-TB tests collectively. We used the respective brand names for the CPT codes representing the two brands of IGRAs that have been approved by the FDA[16] —0010T and 86480 for QuantiFERON®-TB (QFT) and 86481 for T-SPOT®.TB test (T-Spot). CPT code 86580 represents TST and 86585 represents the tuberculosis skin test–tine (TST [Tine]). A complete list of the CPT codes and information regarding the changes are presented in Table 1.

Using these codes, we extracted the associated claims from the MarketScan Commercial outpatient data for 2000–2014 and used the annual enrollments to compute claims rate (number of claims per 100,000 enrollees per year) as the measure of usage for each CPT code. To evaluate numerical differences in the computed claims rates between the different tests, we used 2-sided z tests. We demonstrated the differences in test usage graphically by plotting the trends for all the individual tests on the same set of x-y axes and performed chi-square test for trends in proportion to describe the trends in usage for each of the tests and for all the tests altogether. For easier interpretation, the resulting estimated slope coefficients from the chi-square trend test were transformed and interpreted as the average annual change in claims rate over the select/specified period. A positive slope coefficient implied an upward trend, while a negative slope coefficient implied a downward trend.

We conducted the trend analyses on select periods. Specifically, we determined the average annual change in the claims rate for the following periods: 2000–2014, 2000–2006, 2006–2014 and 2011–2014 (TST and All tests); 2000–2006 (TST [Tine]); 2006–2014, 2006–2011 and 2011–2014 (QFT), and 2011–2014 (T-Spot). We also estimated the annual proportion of enrollees tested (i.e., the proportion of enrollees who had a claim for at least one of the tests) for each year over the entire period (2000–2014).

The data extraction was done using DataProbe online version 5.2.11 (Truven Health Analytics Inc., Ann Arbor, MI). Microsoft Excel, version 2013 (Microsoft Corporation, Redmond, WA) was used for calculating the claims rates and generating the charts. The chi-square trends in proportions tests were conducted in STATA version 14.0 (StataCorp LP).

RESULTS

The line charts representing the estimated annual test usage (number of claims per 100,000 enrollees) are depicted in Figure 1. The category III CPT code (0010T) was excluded from our analyses because there were fewer than 32 claims during each of the four years that the code was valid (2002–2005)[17, 18]

Tuberculin skin test (Mantoux TST)

The TST was by far the most commonly used test over the entire analytical period (Figure 1). For each year, the TST claims rate were significantly ($p<0.01$) higher than each of the other tests, comprising >80% of the total number of claims in each year. The TST claims rate increased slightly from 1,255 per 100,000 enrollees in 2000 to 1,281 per 100,000 enrollees in 2014, although the lowest rate was in 2004 (1,073 per 100,000 enrollees) and the highest claims rate was in 2009 (1,416 per 100,000 enrollees). Thus, the overall trend for TST usage over the entire analytic period was slightly upward—average annual increase of 14 per 100,000 enrollees ($p<0.01$). The trend test for 2006–2014 was slightly lower but positive at 11 per 100,000 enrollees ($p<0.01$). However, for 2011–2014, we found a downward trend (negative slope) at an annual decrease of 28 per 100,000 enrollees ($p<0.01$), corresponding to a claims rate decrease from 1,372 per 100,000 enrollees in 2011 to 1,284 per 100,000 enrollees in 2014 (Figure 1).

Tuberculin skin test–tine (TST [Tine])

We found a steep decline in the use of TST-Tine over the analytic period. The claims rate for the TST-Tine decreased from 179 per 100,000 enrollees in 2000 to 4 per 100,000 enrollees in 2006 (Figure 1). In fact, we did not find any claims for TST-Tine after 2008. We estimated a downward trend (negative slope) at an annual decrease of 36 per 100,000 enrollees ($p<0.01$) for the 2000–2006 period.

QuantiFERON®-TB (QFT)

The claims data showed a steep upward trend (positive slope) in the usage of QFT starting from 2006. The estimated claims rate increased from 2 per 100,000 enrollees in 2006 to 263 per 100,000 enrollees in 2014. The estimated slope coefficient was 35 per 100,000 enrollees ($p<0.01$) from 2006 to 2014. However, the estimated slope coefficient was higher for the more recent period (2011–2014) than for earlier period (2006–2011)—65 vs. 12 per 100,000 enrollees (Figure 1).

T-SPOT®.TB test (T-Spot)

The T-Spot claims rate increased from 4 per 100,000 enrollees in 2011 to 15 per 100,000 enrollees in 2014. The trend test indicated an upward trend (positive slope) of an average

annual increase of 3.8 per 100,000 enrollees (p<0.01) from 2011–2014. The estimated claims rates for each year from 2011–2014 were significantly lower (p<0.01) than those for the TST and QFT.

All tests

When we added up the claims for all the tests in each year over the entire analytic period, the trend mirrored that of the TST through 2010, after which time the TST claims declined while overall claims increased. The estimated claims rate was 1564 per 100,000 enrollees in 2000, 1119 per 100,000 enrollees in 2004 (lowest rate) and then trended upward to 1562 per 100,000 enrollees in 2014. As a result, although the overall trend slope was estimated at 15 per 100,000 enrollees (p<0.01), we found the direction of the trends between two periods (2000–2006 and 2006–2014) to be substantially different—switching from an average annual decrease of 30 per 100,000 enrollees [p<0.01]) to an average annual increase of 48 per 100,000 enrollees [p<0.01]), although the rate was slightly lower (40 per 100,000 enrollees [p<0.01]) in the latter period (2011–2014). The estimated proportion of enrollees who had a claim for at least one of the tests in each year over the entire period (2000–2014) ranged between 1.1% and 1.5%.

DISCUSSION

To examine and describe the trends in the use of TSTs and IGRAs for the detection of TB infection among privately insured persons in the US, we analyzed temporal outpatient claims data over a 15-year period (2000–2014). The TST remained the dominant tests among the four tests that we analyzed, making up a substantially high majority (>80%) of the total number of claims that we found for each year. There are likely multiple reasons for the TSTs continued dominance, including provider and patient familiarity—TSTs have been the standard test for TB infection in most parts of the world for over a century.[1, 2] Additionally, IGRAs are more expensive than TST.[19, 20]

We found a steep decline in the use of TST-Tine from 2000–2006, which is consistent with concerns of inaccurate results and growing unpopularity. In 1982 the Mantoux TST was considered clinically preferable to the TST-Tine, although the TST-Tine was still used in practice.[21] Recently (2005), the American Thoracic Society (ATS), the CDC, and the Infectious Disease Society of America (IDSA) in a joint statement directed that the TST-Tine was not recommended for the diagnosis of tuberculosis infection,[22] and was its CPT code was deleted by the American Medical Association (AMA) in 2006.[17, 23]

Our study also revealed an intriguing chronological relationship between CDC recommendation/guideline publications and the evolution of CPT codes. As noted above, within a year after the release of the joint statement recommending against the TST-Tine (by ATS, CDC and IDSA[17, 23]), the AMA deleted the CPT code for the TST-Tine. CDC's publication of the QFT guidelines in 2005[11] was followed by the assignment/introduction of the QFT CPT code effective January 2006,[17, 23] and then CDC's publication of the updated IGRAs guidelines in 2010 was followed by the assignment/introduction of the T-Spot CPT code in 2011 (Figure 1).[24]

Because of the rapid innovative changes in medical service delivery, fueled by the rapid advancements in medical knowledge and technology, the CDC regularly publishes guidelines/recommendations of FDA-approved TB tests for public health officials, health-care providers, and laboratory workers in the US.[8, 11, 12] These CDC guidelines are largely aimed at increasing test acceptance and completion rate among those targeted for testing.[12] It is conceivable that the assignment of the CPT codes for QFT and T-Spot by the AMA were likely prompted by the publication of their respective guidelines by CDC in the preceding years, and consequently influenced their increasing use in the US. While the shortage of TST supplies during the early part of 2013[25] may have contributed to the increasing use of IGRAs, our study showed that the increasing trend towards the use of IGRAs began before this shortage occurred and prevailed after.

Limitations

Many limitations of our study pertain to the periods when there were no assigned test-specific CPT codes. Although we found a category III CPT code that might have been used for the IGRAs,[17] we found very few claims for that CPT code. It may be that this code was not commonly reimbursed by payers. Secondly, after the FDA approval of T-Spot in 2008, providers submitting claims for reimbursement for the T-Spot would have been required to use the QFT (86480) code for T-Spot prior to the assignment of the unique T-Spot code in 2011.[26, 27] Therefore, to the extent that the QFT codes were used for T-Spot from 2008–2010, we might have underestimated the use of T-Spot and overestimated the use of QFT, although the extent of the bias is challenging to measure. However, after the 2012 increase in Medicare reimbursement for 86481 (T-Spot)[20] it is more likely that providers were coding with the correctly assigned codes for the two IGRAs in 2012–2014. Additionally, as mentioned previously, although there are three types of QFT tests (QFT, QFT-G and QFT-GIT), we were not able to differentiate between them. Thus, our study does not provide any information on the relative use of these three tests.

Similarly, although the TST-Tine test was no longer recommended for the diagnosis of tuberculosis infection in the US after 2005 and the CPT code was discontinued in 2006, providers who chose to continue to use the test were advised to use the TST code (86580) in place of the 86585 for TST-Tine thereafter.[23] This means that we might have overestimated the use of TST and underestimated the use of TST-Tine after 2005. Again, based on the data we have, we cannot measure the extent of these biases; however, the biases are likely small given the trend observed prior to 2006 and the recommendations against the use of the TST-Tine test.[22]

Another limitation of the study relates to our inability to get an unbiased measure of “usage” from the billing activity reflected in claims data. Because claims data are primarily generated in the process (and for the purpose) of billing, the claims do not fully represent the use of the test.[28]

The sample we used is a convenience sample because the MarketScan database contains information on large employers and health plans that choose to participate on an annual basis and does not include medium and small firms.[29] As a result, it might not be generalizable to the entire employer-based privately insured population in the US. There

may also be some inaccurate or missing information in the database.[30, 31] Finally, we do not have insight into patients' characteristics associated with the use of IGRAs versus TSTs because we did not analyze the associated clinical and demographic data.

Strengths

Our study has several strengths. Despite both the crucial role that tuberculosis screening plays in the control and prevention of tuberculosis infection and the high percentage of Americans with private insurance coverage,[14, 32] our search of the literature did not reveal any prior study that looked at the trends in the use of TST and IGRAs among privately insured persons in the US. Given that the passage of the Affordable Care Act is expected to increase the provision of TB health care services in the private sector,[33] this study provides information about the use of these TB tests in settings that will be of increasing importance for TB prevention and control in the US.

Second, this study is based on a large national sample of data that describe health care services provided to millions of people in the US, enabling us to identify subtle changes in clinical practice. Furthermore, because our data represents claims for billed services rendered over the course of 1.5 decades (2000–2014), we were able to examine changes occurring over that long time period. Third, this study revealed the potential influence of CDC guideline publications on the assignment (and discontinuation) of CPT codes by the AMA, and their use. Finally, our findings provide important benchmarks upon which to base and compare future studies on the use of these tests.

Conclusions

TST was the most commonly used test (>80% each year) over the analytic period. However, our results showed that in the last four years of our analyses (2011–2014), there appeared to be a gradual shift to increasing use of IGRAs. Our study also revealed that the publication of CDC IGRAs guidelines potentially impacted the use of the IGRAs in the US private health sector. Based on our findings, it is important to continue to monitor the use of these tests in relation to testing guidelines/recommendations, and assess the extent, if any, to which the shift from the use of TST to IGRAs evolves over time. Additionally, future studies can examine how the IGRAs are being used in relation to TSTs (confirmatory/primary), including their potential impact on LTBI and active TB diagnoses overtime.

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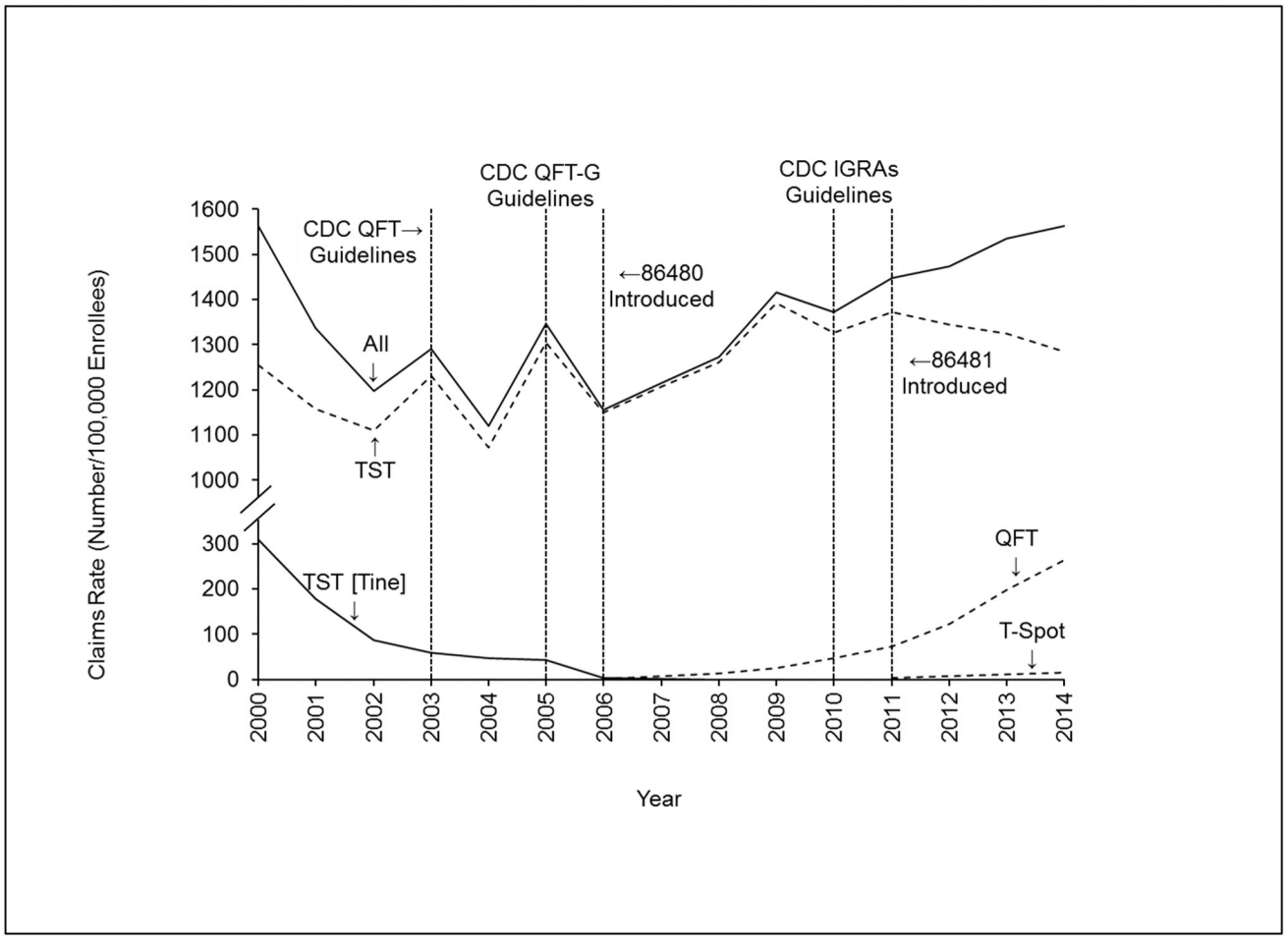

Figure 1.

Chart showing trends in the claims rate (number of tests/100,000 enrollees) of tuberculin skin test (TST) and interferon gamma release assays (IGRAs) among privately insured persons in the United States, 2000–2014.

CDC, Centers for Disease Control and Prevention; QFT, QuantiFERON-TB; QFT-G, QuantiFERON-TB Gold; IGRAs, interferon gamma release assays

Table 1.

Current procedural terminology (CPT) codes representing and/or associated with tuberculin skin test (TST) and interferon gamma release assays (IGRAs), their description, the years they were in use, the CPT code category (I or III), and notes regarding the use of these codes. Category I CPT codes are used to uniformly document FDA-approved medical procedures and services commonly provided to patients, while category III CPT codes are temporary codes assigned to new procedures and technologies which may not meet the stringent category I criteria.[15]

CPT code	Description (Source: American Medical Association online CPT search[34])	Years	CPT Code Category	Notes
86480	Tuberculosis test, cell mediated immunity antigen response measurement; gamma interferon (QuantiFERON®–TB [QFT])[a]	2006 to present	I	Represented both the QuantiFERON®–TB [QFT] and the T-SPOT®.TB [T-Spot] tests between 2008 and 2010.[24, 27]
86481	Tuberculosis test, cell mediated immunity antigen response measurement; enumeration of gamma interferon-producing T-cells in cell suspension (T-SPOT®.TB [T-Spot])[a]	2011 to present	I	
86580	Skin test; tuberculosis, intradermal	Pre-2000 to present	I	Generally represented the Mantoux tuberculin skin test (TST); also represents the tine test beginning in 2006.[17, 23]
86585	Skin test; tuberculosis, tine test.	Pre-2000 to 2005	I	Code discontinued when the tine test was no longer recommended. If the tine test was used in 2006 or after, code 86580 was to be used.[17, 23]
001T0	Tuberculosis test, cell mediated antigen response measurement. (QuantiFERON®–TB [QFT])[a]	2002 to 2005	III	Replaced by the Category 1 CPT code 86480.[17]

[a]We used the respective brand names for CPT codes 86480 (QuantiFERON®–TB [QFT]) and 86481 (T-SPOT®.TB test [T-Spot]) because they were the only two IGRAs approved by the FDA,[16]