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Isoniazid Therapy for *Mycobacterium tuberculosis* Infection in HIV Clinics, Los Angeles, California

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Abstract

Setting—Publicly-funded HIV clinics in Los Angeles County, California, USA.

Objective—HIV-infected persons are a high priority group for targeted testing and treatment for *Mycobacterium tuberculosis* infection in the United States. We describe rates of isoniazid initiation and completion among HIV-1 and *M. tuberculosis* co-infected persons in Los Angeles County.

Design—We conducted a cross-sectional study using routinely collected surveillance data from publicly-funded HIV clinics. We examined differences in isoniazid treatment initiation and

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completion between four clinic categories: the three largest clinics (Clinics A, B, and C) and "Other" clinics (pooled data for remaining 10 clinics).

Results—During 2010–2013, 802 (5.3%) of 15,029 HIV-1-infected persons tested positive for *M. tuberculosis* infection. Isoniazid was initiated in 581 (72.4%) persons, of whom 457 (78.7%) completed therapy. We found significant differences between clinics for treatment initiation (range: 59.1% – 93.4%) and completion (range: 58.8% – 82.3%). Overall, 57% (457/802) of HIV and *M. tuberculosis* co-infected persons completed the recommended treatment (range across clinics: 34.8% – 76.3%).

Conclusion—We identified significant gaps in treatment for *M. tuberculosis* infection among HIV-infected persons in Los Angeles County. Interventions are needed to improve initiation and completion of treatment for *M. tuberculosis* infection in this population.

Keywords

HIV/TB co-infection; isoniazid preventive therapy; tuberculosis prevention; latent tuberculosis infection; tuberculosis elimination

INTRODUCTION

Tuberculosis (TB) incidence continues to decline in the United States at a rate of 2.2% reduction in number of new cases per year.[1] A substantially faster rate of decline is needed to achieve the TB elimination goal of <1 case per million persons by 2050.[1] Mathematical modeling has shown that TB elimination will not be possible in the United States without considerable expansion of testing and treatment for *Mycobacterium tuberculosis* infection.[2] Given the enormous "reservoir" of an estimated 10 million *M. tuberculosis* infected persons living in the United States, targeted testing and treatment of populations who are at high risk for TB reactivation has been recommended.[3–5]

Human immunodeficiency virus (HIV)-infected persons are a high priority group for testing and treatment for *M. tuberculosis* infection in the United States.[5] Co-infection with HIV is the strongest known risk factor for progression to active TB disease among *M. tuberculosis*-infected persons.[5] A recent population-representative study of *M. tuberculosis*-infected persons in the United States found that the TB reactivation rate was 1.82 cases per 100 person-years among HIV-infected persons compared to 0.07 cases per 100 persons-years among HIV-uninfected persons.[6] In addition, targeted testing and treatment for *M. tuberculosis* infection among HIV-infected persons was found to be a cost-effective intervention compared to targeted interventions in most other risk groups.[7]

The U.S. Centers for Disease Control and Prevention (CDC) recommends routine screening of HIV-infected persons for *M. tuberculosis* infection with a tuberculin skin test (TST) or an interferon-gamma release assay (IGRA), and daily administration of isoniazid for 9 months for those who test positive and have no evidence of active TB disease.[3,5] However, little is known regarding rates of *M. tuberculosis* infection treatment in routine HIV care settings. Previous studies of TB screening among HIV-infected person in the United States were limited by their small sample sizes and narrow focus on a specific HIV risk group, such as

people who inject drugs.[8,9] Improved understanding of current practice could inform the development of interventions to improve TB prevention efforts among HIV-infected persons.

Here, we describe the prevalence of *M. tuberculosis* infection and rates of isoniazid initiation and completion using a large database of HIV-1-infected persons in Los Angeles (LA) County, California. Given the evidence of a dynamic spectrum of *M. tuberculosis* infection with no true latent phase, we chose not to use the term "latent TB infection" in this article.[10]

STUDY POPULATION AND METHODS

Study design

We conducted a retrospective cross-sectional analysis of routinely collected TB screening data in LA County, California. We included data from HIV-infected persons aged ≥18 years screened for *M. tuberculosis* infection with a TST or an IGRA between January 1, 2010 – December 31, 2013 at 13 Ryan White HIV/AIDS Program clinics, which are publicly-funded community-based facilities providing care for approximately 40% of the HIV-infected persons in LA County. TST positivity was defined as skin induration of ≥ 5 mm. A cutoff of ≥ 0.35 IU/ml was used to define positivity for QuantiFERON-TB Gold In-Tube (Qiagen; Hilden, Germany), the IGRA used in the included clinics. We excluded patients who had prior history of isoniazid treatment, history of treatment for active TB, or evidence of active TB disease at evaluation. This study was reviewed by the LA County Department of Public Health Institutional Review Board and granted exempt status.

Statistical analysis

We examined three outcomes: 1) prevalence of *M. tuberculosis* infection, and 2) initiation and 3) completion of isoniazid therapy. We examined differences in treatment initiation and completion between four clinic categories: each of the three largest clinics (Clinics A, B, and C) and "Other" clinics (pooled data for remaining 10 clinics). Clinics A and B are free-standing non-profit health centers, while Clinic C is a hospital-based public clinic.

We performed multivariable Poisson regression modeling with robust variance to estimate prevalence ratios while controlling for independent variables.[11] Separate models were constructed with each outcome as the dependent variable. All independent variables were specified *a priori* and included in the final model regardless of their statistical significance. We included the following variables in all models: sex, age group (<30, 30–39, 40–49, ≥50 years), race/ethnicity, foreign-born vs. US-born, clinic, and IGRA vs. TST use. Models for treatment initiation and completion additionally included variables for multiple positive tests and conversion from negative to positive result.

RESULTS

During 2010 – 2013, 15,346 HIV-infected persons were screened for *M. tuberculosis* infection with a TST alone (n = 7411 [48.3%]), IGRA alone (n = 3851 [25.1%]), or both tests (n = 4084 [26.6%]). Of the IGRAs, 2.8% were indeterminate. IGRA use increased substantially during the study period from 1.4% of the tests in 2010 to 73.4% in 2013. Among persons with multiple test results, TST conversions and reversions occurred in 76

(1.8%) of 4214 persons and 5 (38.5%) of 13 persons, respectively. IGRA conversions and reversions occurred in 107 (5.3%) of 2007 persons and 18 (37.5%) of 48 persons, respectively.

We excluded persons with previous history of isoniazid treatment or active TB treatment (n = 191), evidence of active TB disease (n = 30), and no evaluable TST or IGRA results (n = 96) from subsequent analysis (Figure 1). Of the remaining 15,029 (97.9%) persons, 13,180 (87.7%) were male, 7203 (47.9%) were Latino, and 6002 (39.9%) were foreign-born (Table 1). Among foreign-born persons, the most frequently reported countries of birth were: Mexico (52.6%), El Salvador (10.7%), and Guatemala (7.5%). The median age was 43 years (interquartile range = 34 – 50 years).

Patient characteristics differed across clinics (Table 1). Higher proportions of patients were male (97.2%) and non-Latino white (40.0%) at Clinic B than at other clinics. Clinic C had highest proportions of Latino (67.6%) and foreign-born (59.4%) patients. Use of IGRAs (vs. TSTs only) also differed across clinics, ranging from 83.1% at Clinic B to 24.9% at other clinics (Table 1).

Overall, 802 persons (5.3%) tested positive for *M. tuberculosis* infection (Table 2). The prevalence of *M. tuberculosis* infection ranged from 4.0% in Clinic A to 8.1% in Clinic B. In multivariable analysis, diagnosis of *M. tuberculosis* infection was associated with male sex (adjusted prevalence ratio [aPR]= 1.8; 95% CI, 1.4 – 2.4), foreign-born status (vs. U.S.-born; aPR=1.8; 95% CI, 1.5 – 2.2), receiving care at Clinic B (vs. Clinic A; aPR = 1.8; 95% CI, 1.5 – 2.2) and Clinic C (vs. Clinic A; aPR = 1.5; 95% CI, 1.2 – 1.9), and having been tested with an IGRA (vs. TST only; aPR = 1.4; 95% CI, 1.2 – 1.6) (Table 3).

Among persons who tested positive for *M. tuberculosis* infection, 581 (72.4%) started isoniazid (Table 2). Treatment initiation rates ranged from 59.1% in Clinic C to 93.4% in Clinic B. Initiation of isoniazid treatment was independently associated with foreign-born status (vs. US-born; aPR = 1.1; 95% CI, 1.0 – 1.2), receiving care at Clinic B (vs. Clinic A; aPR = 1.4; 95% CI, 1.3 – 1.5), having been tested with an IGRA (vs. TST only; aPR = 1.1; 95% CI, 1.0 – 1.2), and having multiple positive test results (aPR = 1.4; 95% CI, 1.1 – 1.7) (Table 3).

Among persons who started isoniazid treatment, 457 (78.7%) completed 9 months of therapy (Table 2). Treatment completion rates ranged from 58.8% in Clinic C to 82.3% in other clinics. Reasons for stopping therapy included adverse drug reaction (n = 12; 9.7%), relocation (n = 9; 7.3%), refusal (n = 26; 21.0%), death (n = 1; 0.8%), and unknown/lost-to-follow-up (n = 76; 61.3%). In multivariable analysis, treatment completion was negatively associated with receiving care at Clinic C (vs. Clinic A; aPR = 0.7; 95% CI, 0.6 – 0.9) (Table 3).

The overall isoniazid therapy completion rate for HIV-1 and *M. tuberculosis* co-infected persons eligible for therapy was 57.0% (457/802; Table 2). The overall completion rate ranged from 34.8% in Clinic C to 76.3% in Clinic B (Table 2). In post hoc sensitivity analysis, we excluded data from Clinic B to determine the extent to which our overall results are driven by one high-performing clinic. Excluding Clinic B reduced the treatment

initiation rate to 64.1%, of whom 76.9% completed therapy, suggesting that data from Clinic B substantially increased the overall treatment initiation rate. The treatment completion rate among HIV-1 and *M. tuberculosis* co-infected patients eligible for isoniazid therapy in clinics other than Clinic B was 49%.

DISCUSSION

To our knowledge, our study of over 15,000 HIV-infected persons evaluated for *M. tuberculosis* infection is the largest of its kind in a low TB burden country. Among HIV-infected persons with no previous or current active TB disease, we found a 5.3% prevalence of *M. tuberculosis* infection based on TST or IGRA. A previous study of 600 HIV-infected persons in four Ryan White funded clinics found a similar prevalence of TST positivity, and treatment initiation and completion rates.[8] Findings from that study were limited by small sample size as only 20 TST positive persons were included.[8] Another study among 102 TST positive HIV-infected people who use drugs in Maryland found that 41% failed to start therapy.[9] Of those who started therapy, 60% completed treatment, representing only 35% of the 102 TST positive persons completed preventive therapy in that study.[9] In our analysis of 802 HIV-infected persons with TST or IGRA positivity, we found higher rates of treatment initiation and completion than the previous study. However, losses in the *M. tuberculosis* infection treatment cascade resulted in only 57% of eligible persons completing therapy.

We found significant variation in treatment initiation and completion rates between clinics. Differences between clinics persisted in multivariable models controlling for patient-related variables, which suggests that clinic differences are not solely due to the differences in patient characteristics. Notably, removing one high-performing clinic (Clinic B) from the analysis showed that fewer than half of the eligible person in the other clinics completed therapy.

The greatest loss in the treatment cascade occurred at the treatment initiation stage, as nearly 30% of TST/IGRA positive persons did not start therapy. Factors that might reduce treatment initiation rates include lack of trust in current tests for *M. tuberculosis* infection by patients and providers, since TSTs and IGRAs have been found to poorly predict TB progression among HIV-infected persons in low TB-incident settings.[12] Furthermore, studies of serial IGRAs have found high levels of within-individual variability, which complicates interpretation of positive results.[13] In our study, while the number of patients with a repeated test after an initial positive test was small, reversion rates were high for both TSTs and IGRAs, which could have reduced the level of confidence in positive test results. Development of improved diagnostic tests for *M. tuberculosis* infection with higher positive predictive value and lower within-individual variability should be a high priority. Another important barrier to treatment initiation could be the lengthy duration of currently recommended therapy for HIV-infected persons (9 months of daily isoniazid administration).[8] Development and approval of shorter and simpler treatment regimens for HIV-infected persons with *M. tuberculosis* infection might improve initiation and completion of therapy.

Despite these obstacles, the relatively high treatment initiation and completion rates at Clinic B suggest that improved treatment for *M. tuberculosis* infection is possible using currently available diagnostic and treatment tools. Clinic B employs a designated Medical Assistant who provides treatment support for every patient who tests positive for TST or IGRA. First, the Medical Assistant contacts the patient and imaging services to ensure that chest radiographs are taken. She then schedules the initial appointment for treatment. Once treatment is started, the Medical Assistant calls the patient monthly or more frequently as needed to monitor treatment progress. She also contacts the pharmacy to ensure that isoniazid is retrieved. No other clinic provides similar levels of treatment support for isoniazid therapy. Future studies should evaluate differences in treatment procedures across clinics, and whether Clinic B's treatment support model can be successfully implemented in other clinics.

Other potential interventions include patient and provider education to improve knowledge and perception of *M. tuberculosis* diagnosis and treatment. Furthermore, interventions tailored to specific patient populations at each clinic should be considered. For example, improvements in culturally and linguistically appropriate services might be needed to increase treatment rates among foreign-born patients. In addition, regularly scheduled joint monitoring of treatment rates at each clinic by clinic managers and the health department could encourage improvement of treatment practices.[8]

Our findings should be interpreted with consideration of the following limitations. First, our registry data did not include information on degree of HIV immunosuppression or comorbidities, such as chronic viral hepatitis, diabetes, immunosuppressive therapy, alcoholism, injection drug use, and social risk factors such as homelessness. Treatment practice might vary based on providers' perceptions of TB reactivation risk, toxicity, and treatment adherence among persons with comorbidities. We also did not have information on social, cultural, and linguistic barriers to treatment, including immigration status. Our reliance on routinely collected TB screening data for surveillance purposes could have led to under-ascertainment of prior treatment history, leading to inflated numbers of persons eligible for therapy and, thus, lower treatment completion estimates. Bacillus Calmette-Guérin (BCG) vaccination history is not routinely collected during TB screening. Treatment initiation might be lower among BCG-vaccinated patients, as BCG increases false positive TST results.[14] We also do not know whether providers inquired about possible exposure to TB. Providers could have made stronger treatment recommendations to patients suspected to be contacts of persons with active TB. Additional research is needed to understand reasons for low isoniazid initiation in this population. Lastly, while only 2.8% of our IGRA test results were indeterminate, false-negative results due to HIV-associated anergy could have led to an underestimate of the true prevalence of *M. tuberculosis* infection in our population.[3]

CONCLUSION

Among HIV-infected persons with indication for isoniazid preventive therapy, only 57% completed the full course of therapy. Increased efforts are needed to improve initiation and completion of TB preventive therapy for HIV-infected persons in LA County.

Acknowledgments

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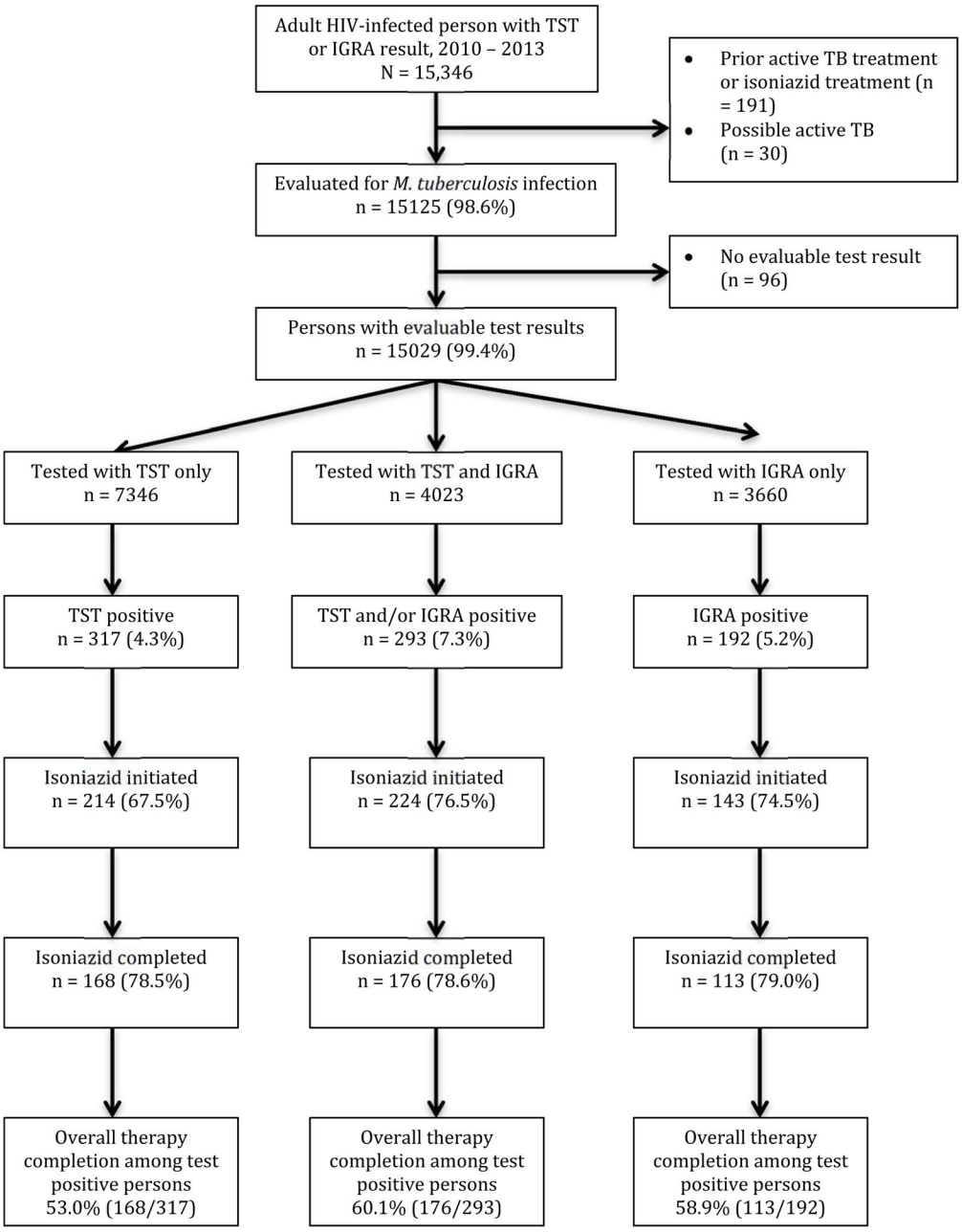

Figure 1.

Patients evaluated for *M. tuberculosis* infection in Ryan White supported HIV clinics, Los Angeles, CA, 2010 – 2013. TST = tuberculin skin test; IGRA = interferon-γ release assay

Table 1

Characteristics of patients undergoing tuberculosis screening by HIV clinic in Los Angeles County, California, 2010–2013

			Clinic			
Characteristic		**All patients**	**A**	**B**	**C**	**Other**
Total		15029	5988	2819	1716	4506
Sex						
	Female	1776 (11.8)	474 (7.9)	67 (2.4)	248 (14.5)	987 (21.9)
	Male	13180 (87.7)	5493 (91.7)	2738 (97.1)	1462 (85.2)	3487 (77.4)
	Unknown	73 (0.5)	21 (0.4)	14 (0.5)	6 (0.3)	32 (0.7)
Age (years)						
	<30	2140 (14.2)	807 (13.5)	486 (17.2)	121 (7.1)	726 (16.1)
	30 – 39	3583 (23.8)	1433 (23.9)	774 (27.5)	368 (21.4)	1008 (22.4)
	40 – 49	5314 (35.4)	2143 (35.8)	972 (34.5)	618 (36.0)	1581 (35.1)
	50+	3992 (26.6)	1605 (26.8)	587 (20.8)	609 (35.5)	1191 (26.4)
Race/ethnicity						
	Non-Latino White	3779 (25.1)	1960 (32.7)	1127 (40.0)	167 (9.7)	525 (11.7)
	Non-Latino Black	3310 (22.0)	1215 (20.3)	390 (13.8)	328 (19.1)	1377 (30.6)
	Asian/Pacific Islander	512 (3.4)	201 (3.4)	140 (5.0)	53 (3.1)	118 (2.6)
	Latino	7203 (47.9)	2504 (41.8)	1123 (39.8)	1160 (67.6)	2416 (53.6)
	Other	75 (0.5)	35 (0.6)	21 (0.7)	6 (0.3)	13 (0.3)
	Unknown	150 (1.0)	73 (1.2)	18 (0.6)	2 (0.1)	57 (1.3)
Country of birth						
	Foreign-born	6002 (39.9)	2013 (33.6)	909 (32.2)	1020 (59.4)	2060 (45.7)
	U.S.-born	8791 (58.5)	3870 (64.6)	1879 (66.7)	691 (40.3)	2351 (52.2)
	Unknown	236 (1.6)	105 (1.8)	31 (1.1)	5 (0.3)	95 (2.1)
Test used						
	IGRA only	3660 (24.4)	1715 (28.6)	1162 (41.2)	257 (15.0)	526 (11.7)
	TST and IGRA	4023 (26.8)	1696 (28.3)	1181 (41.9)	548 (31.9)	598 (13.3)
	TST only	7346 (48.9)	2577 (43.0)	476 (16.9)	911 (53.1)	3382 (75.1)

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Table 2

Prevalence of *M. tuberculosis* infection, isoniazid treatment initiation and completion among HIV-infected persons in Los Angeles County, California, 2010 – 2013.

Characteristic		Number of persons screened	TST/IGRA positive n (%)	Treatment started n (% of those with positive test)	Treatment completed n (% of those who started treatment)	Treatment completion among TST/IGRA positive %
Total		15029	802 (5.3)	581 (72.4)	457 (78.7)	57.0%
Sex						
	Female	1776	54 (3.0)	36 (66.7)	30 (83.3)	55.6%
	Male	13180	744 (5.6)	544 (73.1)	426 (78.3)	57.3%
	Unknown	73	4 (5.5)	1 (25.0)	1 (100)	25.0%
Age (years)						
	<30	2140	109 (5.1)	81 (74.3)	61 (75.3)	56.0%
	30 – 39	3583	197 (5.5)	152 (77.2)	122 (80.3)	61.9%
	40 – 49	5314	302 (5.7)	213 (70.5)	165 (77.5)	54.6%
	50+	3992	194 (4.9)	135 (69.6)	109 (80.7)	56.2%
Race/ethnicity						
	Non-Latino White	3779	173 (4.6)	133 (76.9)	101 (75.9)	58.4%
	Non-Latino Black	3310	111 (3.4)	78 (70.3)	64 (82.1)	57.7%
	Asian/Pacific Islander	512	45 (8.8)	39 (86.7)	31 (79.5)	68.9%
	Latino	7203	459 (6.4)	322 (70.2)	253 (78.6)	55.1%
	Other	75	3 (4.0)	2 (66.7)	1 (50.0)	33.3%
	Unknown	150	11 (7.3)	7 (63.6)	7 (100)	63.6%
Birthplace						
	Foreign-born	6002	448 (7.5)	330 (73.7)	263 (79.7)	58.7%
	U.S.-born	8791	343 (3.9)	244 (71.1)	188 (77.0)	54.8%
	Unknown	236	11 (4.7)	7 (63.6)	6 (85.7)	54.5%
Clinic						
	A	5988	240 (4.0)	159 (66.3)	127 (79.9)	52.9%
	B	2819	228 (8.1)	213 (93.4)	174 (81.7)	76.3%
	C	1716	115 (6.7)	68 (59.1)	40 (58.8)	34.8%

Characteristic		Number of persons screened	TST/IGRA positive n (%)	Treatment started n (% of those with positive test)	Treatment completed n (% of those who started treatment)	Treatment completion among TST/IGRA positive %
	Other	4506	219 (4.9)	141 (64.4)	116 (82.3)	53.0%
Test used						
	TST only	7346	317 (4.3)	214 (67.5)	168 (78.5)	53.0%
	TST and IGRA	4023	293 (7.3)	224 (76.5)	176 (78.6)	60.1%
	IGRA only	3660	192 (5.2)	143 (74.5)	113 (79.0)	58.9%

TST = tuberculin skin test; IGRA = interferon-γ release assay

Table 3

Factors associated with *M. tuberculosis* infection and isoniazid treatment initiation in multivariable Poisson regression models with robust variance, Los Angeles County, California, 2010 – 2013.

Characteristic		TST/IGRA positivity PR (95% CI) n = 14,834*	Treatment initiation PR (95% CI) n = 791*	Treatment completion PR (95% CI) n = 574*
Sex				
	Female	1.0	1.0	1.0
	Male	1.8 (1.4 – 2.4)	1.0 (0.8 – 1.2)	0.9 (0.8 – 1.1)
Age (years)				
	<30	1.0	1.0	1.0
	30 – 39	0.9 (0.7 – 1.2)	1.0 (0.9 – 1.2)	1.1 (0.9 – 1.2)
	40 – 49	1.0 (0.8 – 1.2)	1.0 (0.9 – 1.1)	1.0 (0.9 – 1.2)
	50+	0.9 (0.7 – 1.1)	1.0 (0.8 – 1.1)	1.1 (0.9 – 1.3)
Race/ethnicity				
	White	1.0	1.0	1.0
	Black	0.9 (0.7 – 1.1)	0.9 (0.8 – 1.0)	0.9 (0.8 – 1.1)
	Latino	1.1 (0.9 – 1.3)	1.0 (0.8 – 1.1)	1.0 (0.9 – 1.3)
	Asian/Pacific Islander/Other	1.3 (0.9 – 1.7)	0.9 (0.8 – 1.0)	1.0 (0.8 – 1.2)
Country of birth				
	U.S.-born	1.0	1.0	1.0
	Foreign- born/Unknown	1.8 (1.5 – 2.2)	1.1 (1.0 – 1.2)	1.1 (1.0 – 1.2)
Clinic				
	A	1.0	1.0	1.0
	B	1.8 (1.5 – 2.2)	1.4 (1.3 – 1.5)	1.0 (0.9 – 1.2)
	C	1.5 (1.2 – 1.9)	0.9 (0.7 – 1.0)	0.7 (0.6 – 0.9)
	Other	1.3 (1.1 – 1.6)	1.0 (0.8 – 1.1)	1.0 (0.9 – 1.1)
Test used				
	TST	1.0	1.0	1.0
	IGRA	1.4 (1.2 – 1.6)	1.1 (1.0 – 1.2)	1.1 (1.0 – 1.2)
Multiple positive tests				
	No	N/A	1.0	1.0
	Yes	N/A	1.4 (1.1 – 1.7)	0.8 (0.5 – 1.3)
TST/IGRA conversion				
	No	N/A	1.0	1.0
	Yes	N/A	1.0 (1.0 – 1.1)	1.0 (0.9 – 1.1)

TST = tuberculin skin test; IGRA = interferon-γ release assay

*Data for patients with unknown sex or race/ethnicity were excluded from the models (n = 195 for the TST/IGRA positivity model; n = 11 for the treatment initiation model; and n = 7 for the treatment completion model).