



# HIV testing, antiretroviral therapy, and treatment outcomes in new cases of tuberculosis in Brazil, 2011

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## Suggested citation

Torrens A, Bartholomay P, Silva S, Khogali M, Verdonck K, Bissell K. HIV testing, antiretroviral therapy, and treatment outcomes in new cases of tuberculosis in Brazil, 2011. *Rev Panam Salud Publica*. 2016;39(1):26–31.

## ABSTRACT

**Objective.** To assess the implementation of HIV-related interventions for patients with tuberculosis (TB), as well as TB treatment outcomes in patients coinfected with HIV in Brazil in 2011.

**Methods.** This was a cross-sectional, operational research study of HIV-related interventions among TB cases and the sociodemographic and clinical characteristics of TB-HIV coinfected patients. It also used a retrospective cohort design to determine the association between antiretroviral therapy (ART) and favorable TB treatment outcomes. The source of data was a linkage of 2011 administrative health databases used by the National TB and HIV/AIDS Programs.

**Results.** Of 73 741 new cases of TB reported, 63.6% (46 865 patients) were tested for HIV; 10.3% were positive. Of patients with HIV, 45.9% or 3 502 were on ART. TB favorable outcome was achieved in 63.1% or 2 205 coinfected patients on ART and in only 35.4% or 1 459 of those not on ART. On multivariate analysis, the relative risk for the association between ART and TB treatment success was 1.72 (95% Confidence Interval = 1.64–1.81).

**Conclusions.** The linkage between national TB and HIV datasets has created a convenient baseline for ongoing monitoring of HIV testing, ART use, and TB treatment outcomes among coinfected patients. The low rates of HIV screening and ART use in 2011 need to be improved. The association between ART and treatment success adds to the evidence supporting timely initiation of ART for all patients with TB-HIV coinfection.

## Key words

Tuberculosis; HIV; coinfection, HIV, TB; antiretroviral therapy; treatment outcome; operations research; Brazil.

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Both tuberculosis (TB) and human immunodeficiency virus (HIV) present huge challenges for the health, social, economic, and developmental wellbeing of populations around the world (1). Collaboration between TB and HIV programs is essential for tackling the dual TB-HIV epidemic (2). In its policy

framework for TB-HIV collaborative activities, the World Health Organization (WHO) promotes integrated TB-HIV activities to improve care and support for individuals affected by both diseases (3). Despite the considerable progress made by TB and HIV programs, collaboration is often not straightforward and

countries have found it hard to meet the targets for implementing collaborative activities (4, 5).

WHO recommends screening all TB patients for HIV and offering antiretroviral therapy (ART) to all patients with TB and HIV coinfection, irrespective of their CD4 count. To reduce mortality among people living with HIV/Acquired Immune Deficiency Syndrome (AIDS) who have TB, health services need to ensure that all patients with coinfection are on ART, either before or after the start of TB treatment (6).

Brazil has high burdens of both TB and HIV. With more than 71 000 new cases of TB and 4 700 TB-related deaths each year, it ranks 16<sup>th</sup> on a list of 22 high TB-burden countries (6). In Brazil, TB ranks third among all deaths attributed to infectious diseases and is first among infectious diseases for those living with HIV/AIDS (7, 8). The country's HIV/AIDS prevalence is estimated to be 0.4% among the general population and 10% among TB patients. There are an estimated 718 000 people living with HIV/AIDS in Brazil (9).

For several years, the National TB Program (NTP) in Brazil has been implementing WHO-recommended HIV interventions for patients with coinfection. In 2013, the NTP published national guidelines on implementation of TB-HIV activities (10). However, there has been no routine analysis to see how many patients at the state level have actually been receiving this care, and whether these interventions have favorably influenced TB treatment outcomes. This is partly because the national TB information system has, until recently, lacked the information required to monitor whether patients with coinfection are on ART. This data, especially when broken-out by state, could help determine whether activities are being implemented by TB programs and what gaps or other problems exist that need to be resolved. Such data could also identify which states experienced successful implementations that could be emulated by others.

Thus, the present study aimed to assess implementation of HIV-related interventions for patients with TB, as well as TB treatment outcomes for patients with coinfection, using routine data from Brazil's TB and HIV/AIDS programs. The specific objectives were to: (a) describe HIV screening for new TB cases;

(b) describe sociodemographic and clinical characteristics of cases of TB-HIV coinfection; and (c) determine the association between ART and favorable TB treatment outcomes.

## MATERIALS AND METHODS

### Study design and population

This was an operational research study. It used a cross-sectional design to assess HIV-related interventions among TB cases and to describe sociodemographic and clinical characteristics of TB-HIV coinfecting patients. A retrospective cohort design determined the association between antiretroviral treatment (ART) and favorable TB treatment outcomes. The study included all 73 741 new cases of TB diagnosed and reported by all states in Brazil from 1 January 2011–31 December 2011, that had been entered into the TB national information system with ICD-10 codes A15-A19 (11).

### Setting

**Health system.** Brazil is a federal republic comprised of 27 states. The country's NTP and national HIV/AIDS program are both headquartered in Brasilia and have branches at the state and municipality levels where diagnostic and treatment services are integrated with general health care. Federal guidelines drive TB and HIV/AIDS control (12, 13) in the country and states, and municipalities have the autonomy to implement the recommendations according to local needs. A national network of TB laboratories work with the NTP and are overseen by the National Coordination of Public Health Laboratories, also headquartered in Brasilia, and the National Reference for TB Laboratory in Rio de Janeiro city (14).

Since 2011, standard protocol for TB testing in Brazil has been two smears for all persons presenting with respiratory symptoms or patients with radiological or clinical suspicion of TB; culture for persons with TB diagnosis smear negative or extrapulmonary TB; and culture plus drug susceptibility test (DST) for new cases with a known drug-resistant TB contact, for high-risk groups (e.g., health care workers, indigenous people, the homeless, those HIV-positive, and prisoners), for suspected failure, and for

retreatment after loss to follow-up and relapse (11).

**HIV-related interventions for patients with TB.** According to national guidelines, all patients with TB are to be offered voluntary HIV counseling and testing with a rapid diagnostic test and enzyme-linked immunosorbent assay (ELISA); plus, ART should be provided free-of-charge to all patients with TB-HIV coinfection (10). Although it is recommended that all patients with TB-HIV coinfection be treated and followed by a specialized HIV/AIDS center to ensure one point-of-care, anecdotal evidence suggests that in practice this is not happening in most of Brazil. Many patients have to visit one health unit for TB treatment and another for HIV/AIDS care and treatment, usually at different locations.

**Information systems for TB and HIV.** In 2011, the TB information system had fields in which to record HIV test results or prior concomitant AIDS, but no field for recording whether a patient was on ART or not. Also in 2011, the HIV/AIDS recording system was composed of several information systems whose aim was to record CD4 counts and viral load results, ARV dispensing, and AIDS notification. HIV/AIDS patients follow up was a challenge and fields to record active TB were only present in the AIDS notification database. Although efforts have been made to collaborate, there is no standardized national mechanism for sharing information between the TB and HIV/AIDS programs and patient codes differ in each information system. In November 2013, the first linkage of TB and HIV/AIDS national databases was performed using the most recent cohort of TB outcomes, those from 2011, available at the national level.

### Data variables and sources

Study variables were extracted from administrative health databases used by the NTP and by the National HIV/AIDS Program. TB data were obtained from the *Sistema de Informação de Agravos de Notificação* (National Communicable Diseases Information System; SINAN). Data about HIV/AIDS were obtained from the databases of the *Sistema de Controle de Exames Laboratoriais da Rede Nacional de Contagem de Linfócitos*

CD4+/CD8+ e Carga Viral (System for Laboratory Exams Control; SISCEL) and the *Sistema de Controle Logístico de Medicamentos* (Medicines Logistics Management System SICLOM). Individuals who had at least one CD4 cell count or viral load test or had picked up a supply of ARV medications were included. A record linkage was performed with Reclink® software, version 3 (Instituto de Saúde Coletiva, Universidade Federal do Rio de Janeiro, Rio de Janeiro, Brazil). The following variables were used to match records: name, date of birth, and mother's name. Exclusion errors were assumed to be random and due to misspelling of names in the administrative records, thus not introducing any relevant bias in the analysis.

Data on HIV testing and status were extracted from the TB information system. Negative and pending results were then cross-checked with the national HIV/AIDS program information system and corrected to positive if they had been recorded as positive in the latter.

All demographic and clinical characteristics for patients with TB-HIV coinfection were extracted from the NTP information system, except for data on ART. The latter came from the National HIV/AIDS Program information system.

## Analysis

Numbers and proportions were calculated to report on HIV testing, HIV status, and the demographic and clinical characteristics of patients with TB-HIV coinfection.

A multivariate model was used to estimate the association between being on ART and treatment success. Treatment success was defined as having the following favorable TB treatment outcomes: bacteriologically confirmed cure and treatment completed. Variables with completeness above 80% and statistical significance in a bivariate analysis ( $P < 0.05$ ) were included in the multivariate model to assess and adjust for potential confounders. Relative risks and confidence intervals were calculated using Poisson regression with a robust variance model (15). Poisson was preferred to logistic regression because the study's outcome of interest (treatment success) was frequent in the study population. In such situations, i.e., cohort studies with common outcomes, logistic regression would yield odds

ratios that overstate the relative risks they are supposed to approximate, and Poisson regression is considered more suitable than logistic regression for estimating adjusted relative risks (16). Data were analyzed with the Stata®/MP12 (StataCorp LP, College Station, Texas, United States).

## Ethics

Ethics approval was obtained from the Ethics Advisory Group of the International Union Against Tuberculosis and Lung Disease (Paris, France) and authorization to conduct this study was received from the Ethics Committee on Research at the Hospital das Forças Armadas (Brasília; protocol number 992.381). Since the study involved routine program data and did not contain patient identifiers, the issue of informed patient consent did not apply. The final dataset used for analysis was only accessible to the study investigators and was held in strict confidentiality.

## RESULTS

Of the 73 741 new cases of tuberculosis diagnosed and registered in 2011 in Brazil, 63.6% (46 865 cases) were screened for HIV. This proportion was not homogeneous among the country's states. It ranged from 84.9% in Santa Catarina to 39.9% in Alagoas. In 15 states, the proportion of cases screened was below the national average (Table 1).

Among all new cases of tuberculosis in the country, 7 628 had a positive HIV result, which represented a proportion of TB-HIV coinfection of 10.3%. The states with the highest proportion of coinfection were Santa Catarina (22.8%) and Rio Grande do Sul (21.1%) (Table 1). Of the 7 628 patients with coinfection, 45.9% or 3 502 were actively on ART. At the state level, this ranged from 0.0% in Roraima to 70.0% in Amapá. The highest proportions of coinfection patients on ART were, in descending order, in Amapá, Distrito Federal, Acre, and Paraná. Of the total TB-HIV coinfections, 70.5% (5 380 patients)

**TABLE 1. Human immunodeficiency virus (HIV) testing, results, and antiretroviral therapy (ART) treatment among new cases of tuberculosis (TB) in Brazil, 2011**

Federal states <sup>a</sup>	Total new TB cases		HIV test done		HIV positive		ART	
	No.	No.	%	No.	%	No.	%	
Total	73 741	46 865	63.6	7 628	10.3	3 502	45.9	
Rondônia	20	359	63.9	50	8.9	20	40.0	
Acre	562	234	67.0	11	3.2	7	3.6	
Amazonas <sup>b</sup>	349	1 130	51.4	254	11.6	2	0.8	
Roraima <sup>b</sup>	2 198	107	70.9	15	9.9	0	0.0	
Pará	151	1 899	49.9	273	7.2	138	50.5	
Amapá	3 802	152	66.7	10	4.4	7	70.0	
Tocantins	228	100	53.2	8	4.3	2	25.5	
Maranhão	188	1 234	56.0	142	6.4	64	45.1	
Piauí	2 205	382	44.6	47	5.5	24	51.1	
Ceará	857	2 025	54.8	267	7.2	76	28.5	
Rio Grande do Norte	3 698	472	47.3	84	8.4	32	38.1	
Paraíba	998	592	53.6	79	7.1	42	53.2	
Pernambuco	1 105	2 150	49.3	522	12.0	174	33.3	
Alagoas	4 365	439	39.9	71	6.4	29	40.8	
Sergipe	1 101	364	63.6	34	5.9	11	32.4	
Bahia	572	2 201	41.8	304	5.8	103	33.9	
Minas Gerais	5 269	2 011	49.5	398	9.8	211	53.0	
Espírito Santo	4 059	880	69.7	101	8.0	57	56.4	
Rio de Janeiro	1 262	6 986	60.0	1 161	10.0	436	37.6	
São Paulo	11 646	13 849	83.2	1 765	10.6	1 006	57.0	
Paraná	16 644	1 921	81.0	254	10.7	156	61.4	
Santa Catarina	2 371	1 510	84.9	405	22.8	221	54.6	
Rio Grande do Sul	1 779	3 777	75.2	1 061	21.1	516	48.6	
Mato Grosso do Sul	5 020	597	65.0	77	8.4	34	44.2	
Mato Grosso	919	690	59.5	103	8.9	53	51.5	
Goiás	1 160	557	62.4	87	9.8	52	59.8	
Distrito Federal	892	236	73.5	42	13.1	29	69.0	

**Sources:** data compiled from the Ministry of Health of Brazil's SICLOM, SINAN, and SISCEL databases.

<sup>a</sup> Individual with missing information, by state ( $n = 20$ ).

<sup>b</sup> Not included in SICLOM.

were male; 82.9% (6 322 patients) were in the group from 15–49 years of age. With regard to ethnic background, 51.7% (3 947 patients) were afro-descendants compared to 39.0% (2 977 patients) white. Information on level of education was available for 56.0% (4 271 patients). Of these, 32.0% (1 365 patients) were illiterate or had only a primary education.

Regarding the type of TB, there was a lower proportion of smear-positive pulmonary cases (38.3%; 2 920 patients) and a higher proportion of smear-negative pulmonary cases (25.6%; 1 951 patients) among cases of TB-HIV coinfection when compared to the profile of all TB cases in the country (6). Pulmonary and extrapulmonary cases with a clinical diagnosis of TB represented 12.0% (917 patients) and 24.1% (1 840 patients), respectively. With regard to co-morbidities, 2.6% (200 patients) had self-reported diabetes mellitus and 15.7% (1 198 patients) had self-reported alcohol use disorder (Table 2).

TB treatment outcomes for TB-HIV coinfection cases are reported in Table 3. Favorable outcomes were more frequent in those on ART (63.1%; 2 205 patients) than those not on ART (35.4%; 1 459 patients). In a multivariate regression model adjusted for age, race, TB type, diabetes, alcoholism, and Directly Observed Therapy Short-course (DOTS), the relative risk for the association between being on ART and having a favorable TB treatment outcome was 1.72 (95% CI = 1.64–1.81).

## DISCUSSION

This is the first nation wide assessment and analysis, stratified by state, of HIV-related interventions for patients with TB-HIV coinfection in Brazil. The customized linkage between national TB and HIV databases has created a convenient baseline for ongoing monitoring of HIV testing, ART usage, and TB treatment outcomes among patients with TB-HIV coinfection.

Monitoring these indicators through time in Brazil is well-suited to its TB epidemic, which is very different from that of other South American and BRICS (Brazil, Russia, India, China, and South Africa) countries, thus making it difficult to compare results. Brazil is the only high-burden country in the Region of the Americas and although it is part of the 22 high-burden countries, it has

the lowest incidence rate among them and the BRICS countries.

Low rates of HIV screening in Brazil have been reported in recent years and are a cause of great concern (8). Although all TB cases are supposed to be screened for HIV, preferably with a rapid test in accordance with Ministry of Health recommendations (14, 15), in 2011, 36.4% or 26 876 new TB cases were recorded as “HIV status unknown.” Only two states, Rio Grande do Sul and Santa Catarina, had TB-HIV coinfection over 20%. HIV prevalence is known to be higher in these places than in the rest of the country (9), but HIV screening in TB patients has higher coverage (over 75%) in these two states. Since early diagnosis of TB-HIV coinfection is crucial for the timely ART initiation, which has a direct impact on patient survival, it is important to ensure that TB services can dramatically improve implementation of HIV testing, as well as data tracking (17).

With regard to ART use among patients with coinfection, it was concerning to find that only about one-half of patients were on ART, despite the recommendation (10) to initiate this therapy regardless of CD4 count. The guidelines (10) that support this recommendation came out recently, in 2013, and implementation across the country takes time. Some of the impediments are a shortage of training for medical teams at the local level, a lack of communication between TB and HIV/AIDS programs at municipal level, and non-integrated TB HIV/AIDS care (8). Stratification by state allowed identification of some important gaps in recording and reporting; for example, there was no information in the SICLOM database about ART in the states of Roraima and Amazonas. This is both a limitation of the analysis, as well as an important issue to be addressed.

This study's finding that favorable TB treatment outcomes were more frequent among TB-HIV coinfection patients on ART concurs with the findings of other studies (17–19). Outcomes are known to be worse for patients with TB-HIV coinfection compared to those who are HIV-negative (6). Moreover, the timely initiation of ART—within the 2nd–8th week of TB diagnosis and treatment initiation—has been shown to positively influence treatment outcomes (17).

**TABLE 2. Sociodemographic and clinical characteristics of new tuberculosis (TB) cases coinfecting with human immunodeficiency virus (HIV), Brazil, 2011**

Sociodemographic and clinical characteristics	No.	%
Total	7 628	100.0
Gender		
Male	5 380	70.5
Female	2 248	29.5
Age (years)		
< 15	153	2.0
15–49	6 322	82.9
≥ 50	1 153	15.1
Race (color <sup>a</sup> )		
European-descendant (white)	2 977	39.0
Afro-descendant (black)	1 052	13.8
Asian-descendant	35	0.5
Pardo <sup>b</sup>	2 895	38.0
Indigenous	32	0.4
Not recorded	637	8.4
Education		
Illiterate	179	2.4
Primary	1 186	15.6
Secondary	1 635	21.4
Higher	897	11.8
University	374	4.9
Not recorded	3 357	44.0
Type of TB		
Pulmonary smear positive	2 920	38.3
Pulmonary smear negative	1 951	25.6
Pulmonary, clinically diagnosed	917	12.0
Extrapulmonary	1 840	24.1
Not recorded	2 920	38.3
Diabetes mellitus		
Yes	200	2.6
No	6 583	86.3
Not recorded	845	11.1
Alcohol use disorder		
Yes	1 198	15.7
No	5 563	72.9
Not recorded	867	11.4
Antiretroviral treatment		
Yes	3 502	45.9
No	4 126	54.1

**Sources:** data compiled from the Ministry of Health of Brazil's SICLOM, SINAN, and SISCEL databases.

<sup>a</sup> Brazil's official categories according to color as determined by the *Instituto Brasileiro de Geografia e Estatística* (Brazilian Institute of Geography and Statistics).

<sup>b</sup> Miscegenation afro-descendants and/or european-descendants and/or indigenous peoples.

## Limitations

Despite the importance of the unfinished agenda regarding infectious diseases in Brazil, it was not possible to include the study population's level of education in the analysis because this data was missing from more than 20% of the records. Another limitation was the timing of ART initiation was not evaluated. Nevertheless, there was a statistically significant association between ART use and favorable outcomes in the

**TABLE 3. Tuberculosis (TB) treatment outcome for TB patients coinfecting with human immunodeficiency virus (HIV), according to antiretroviral drug therapy (ART) status, Brazil, 2011**

Treatment outcomes	On ART		Not on ART		Adjusted relative risk (95% confidence interval) <sup>c,d,e</sup>	P-value
	No.	%	No.	%		
Total <sup>a</sup>	3 495	100.0	4 121	100.0		
Favorable outcomes <sup>b</sup>	2 205	63.1	1 459	35.4	1.72 (1.64–1.81)	< 0.001
Lost follow-up	449	12.8	507	12.3		
Died	559	16.0	931	22.6		
Not evaluated	282	8.1	1 224	29.7		

**Sources:** data compiled from the Ministry of Health of Brazil's SICLOM, SINAN, and SISCEL databases *de Notificação* (National Communicable Diseases Information System), *Sistema de Controle de Exames Laboratoriais* (System for Laboratory Exams Control), and the *Sistema de Controle Logístico de Medicamentos* (System for Logistic Control of Drugs).

<sup>a</sup> Cases of multidrug resistant tuberculosis were excluded from the cohort of treatment outcomes ( $n = 12$ ).

<sup>b</sup> Bacteriologically-confirmed cure and treatment completed.

<sup>c</sup> Favorable compared with unfavorable outcomes (lost follow-up, died, not evaluated).

<sup>d</sup> Poisson regression model (robust variance) adjusted for: age group, race, type of TB, diabetes, alcohol use disorder, and Directly Observed Therapy, Shortcourse.

<sup>e</sup> Number of observations was 6 173, since 1 455 records had missing values in one or more of the variables included in the model.

multivariate analysis. The strengths of this study include its national scope, stratification by state, and the creation of a dataset based on the best available data from national databases.

## Conclusions

After 2011, the study period for this analysis, a field for recording ART use was added to the TB information system. This made the monitoring of both important indicators—HIV testing and ART use—much more feasible on a routine basis. Nonetheless, the 2011 dataset results will serve as an important baseline for future monitoring. They will enable the NTP to monitor the demographic and clinical profile of TB-HIV coinfecting patients, to assess whether HIV-related interventions have improved in Brazil since the 2013 guidelines were published,

and to determine whether various TB-HIV collaboration initiatives at national, state, and local levels are actually improving outcomes for coinfecting patients.

Despite the considerable progress that has been made, collaborative interventions remain far from expected targets. Analysis of TB-HIV collaborative activities are not commonly included in the monitoring and evaluation routine of tuberculosis control programs; however, assessing these activities is paramount to better planning and should be routinely monitored by TB and HIV/AIDS programs at all levels.

**Acknowledgements.** This research was conducted through the Structured Operational Research and Training Initiative (SORT IT), a global partnership led by the Special Programme for Research

and Training in Tropical Diseases at the World Health Organization (WHO/TDR). The model is based on a course developed jointly by the International Union Against Tuberculosis and Lung Disease (The Union) and *Medécins sans Frontières*. The specific SORT IT program which resulted in this publication was jointly developed and implemented by the Communicable Diseases Research Program and the Regional Tuberculosis Control Program, Pan American Health Organization (PAHO); the Operational Research Unit (LUXOR) at *Médecins Sans Frontières*, Brussels Operational Center, Luxembourg; the Centre for Operational Research, The Union, Paris, France; the Institute of Tropical Medicine, Antwerp, Belgium and the University of Antioquia, Medellín, Colombia.

**Funding.** The SORT IT programme was funded by TDR/UNICEF/UNDP/WORLD BANK/WHO, PAHO/WHO, The Union, MSF, U.S. Agency for International Development (USAID), Award No. AID-LAC-IO-11-0000,1 and the Department for International Development (DFID). The funders had no role in the study design, data collection and analysis, decision to publish, or preparation of the manuscript.

**Conflict of interests.** None declared.

**Disclaimer.** Authors hold sole responsibility for the views expressed in the manuscript, which may not necessarily reflect the opinion or policy of the RPSP/PAJPH and/or PAHO.

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Manuscript received on 19 August 2015. Revised version accepted for publication on 9 November 2015.

## RESUMEN

### Pruebas de detección del VIH, tratamiento antirretrovírico y resultados del tratamiento en casos nuevos de tuberculosis en Brasil en 2011

**Objetivo.** Evaluar la ejecución de las intervenciones relacionadas con el virus de la inmunodeficiencia humana (VIH) en los pacientes con diagnóstico de tuberculosis y examinar los desenlaces del tratamiento antituberculoso en los pacientes coinfectados por el VIH en Brasil en 2011.

**Métodos.** Estudio de investigación operativa. Mediante un diseño transversal se evaluaron las intervenciones relacionadas con el VIH en los casos de tuberculosis y se describieron las características sociodemográficas y clínicas de los pacientes coinfectados por el VIH y la tuberculosis; con un diseño retrospectivo de cohortes se determinó la asociación entre el tratamiento antirretrovírico y los desenlaces favorables del tratamiento antituberculoso. Los datos se obtuvieron mediante un enlace administrativo de las bases de datos de salud del 2011 que utilizaron el Programa Nacional contra la Tuberculosis y el Programa contra el VIH/sida.

**Resultados.** De los 73 741 casos nuevos de tuberculosis notificados, se practicó detección del VIH en 63,6% (46 865 pacientes) y los resultados fueron positivos en 10,3%. De los pacientes coinfectados por el VIH, 45,9% o 3 502 pacientes, recibían tratamiento antirretrovírico. Se alcanzó un desenlace favorable de la tuberculosis en 63,1% (2 205) de los pacientes coinfectados que recibían tratamiento antirretrovírico, y en solo 35,4% (1 459) de los pacientes coinfectados que no recibían este tratamiento. Según el análisis multivariante, el riesgo relativo de asociación entre el tratamiento antirretrovírico y el éxito del tratamiento antituberculoso fue 1,72 (intervalo de confianza de 95%: de 1,64 a 1,81).

**Conclusiones.** El enlace de los registros nacionales sobre la tuberculosis y la infección por el VIH creó una referencia de base útil para el seguimiento continuo de la utilización de las pruebas de detección del VIH, la administración del tratamiento antirretrovírico y los desenlaces del tratamiento antituberculoso en los pacientes coinfectados. Es necesario mejorar las bajas tasas de detección sistemática del VIH y de administración del tratamiento antirretrovírico que se observaron en el 2011. Esta correlación entre el tratamiento antirretrovírico y el éxito del tratamiento antituberculoso avala la evidencia que respalda la iniciación oportuna del tratamiento antirretrovírico en todos los pacientes que presentan coinfección por el VIH y la tuberculosis.

#### Palabras clave

Tuberculosis; VIH; coinfección, VIH, TB; terapia antirretroviral; resultado del tratamiento; investigación operativa; Brasil.