

Evaluation of implementation of the protocol for managing tuberculosis/HIV coinfection in specialized care services in the state of Ceará, Brazil*

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ABSTRACT

Objectives. Identify barriers and strategies for implementation of the protocol for managing tuberculosis/human immunodeficiency virus (TB/HIV) coinfection in specialized care services in Ceará state, through implementation research.

Methods. The study followed the iPIER methodology, a new initiative to help improve the implementation of health programs through the use of research that is conducted as a part of the implementation process. Data were collected on the structure and processes of 22 services, and barriers were explored in four focus groups with 28 participants, from the standpoint of the health team, administrators, and users. The discussions were transcribed and interpreted with regard to the objectives of the study.

Results. The information on structure and process revealed that six services manage TB/HIV coinfection and 16 do not. The barriers were: team members were unaware of the protocol; lack of clinical practice guidelines in the services; specialized care services working at all three levels of the health system; inadequate spaces for treatment of airborne diseases; and lack of communication with primary health care sectors for patient transfers. The results were discussed with teams and administrators in seminars held in the services and with program managers for sexually transmitted infections, human immunodeficiency virus, AIDS, hepatitis, and tuberculosis.

Conclusions. Direct dialogue between administrators, implementers, users, and researchers generated knowledge about the services and led to joint preparation of modifications in workflow aimed at acceptance and use of the protocol; however, users continue to resist adherence to treatment.

Keywords

Tuberculosis; HIV; protocols; health services; Brazil.

Tuberculosis (TB) is related to poor living conditions and is an aggravating

factor for people with human immunodeficiency virus (HIV) infection—one that has repercussions on mortality from AIDS in Brazil (1) and is a reality throughout Latin America (2). People with this coinfection are up to 34 times more prone to developing tuberculosis than the general population and HIV infection is often diagnosed as tuberculosis develops (3).

The public network for TB treatment in Brazil was structured and decentralized

in the 1990s with TB control policies based on primary health care. The care network for AIDS is relatively recent, however, and control efforts concentrate on the secondary and tertiary levels of care (4). In the state of Ceará, poverty and low levels of schooling also contribute to an increased relevance of TB/HIV coinfection, increased reactivation of latent infections, and problems with adherence to treatment. The cure rate dropped from 73.2% in 2004 to 59.2% in

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2014, and the dropout rate in 2014 (12.7%) is above the 5% rate the World Health Organization (WHO) considers acceptable (5–8).

In Brazil, a Ministry of Health policy on TB/HIV coinfection calls for HIV testing for all persons affected by TB, and for the tuberculin test (PPD) and treatment of active pulmonary TB and latent infection by *M. tuberculosis* (LTBI) in people infected with HIV (9).

In 2013, a clinical protocol was adopted for managing TB/HIV coinfection, as part of the clinical protocol of therapeutic directives for managing HIV infection in adults (10), for implementation in specialized care services for people with HIV infection. Despite the Ministry of Health adopting the new protocol, there is still a significant lag between the national average and implementation levels in the state of Ceará. In Brazil, 69% of subjects diagnosed with TB were tested for HIV, with 10% coinfection in 2014. The 58.2% testing rate in Ceará is below the national average; coinfection stands at 14.6% and has been trending upward in the last two years (5, 11).

In Brazil's health system, specialized care services are the preferred location for managing persons with TB/HIV coinfection (9). The challenge for health administrators in Ceará is promoting increased access to the care recommended in the TB/HIV coinfection protocol, by investing in the full functioning of the state and municipal care network (6).

In the case of TB/HIV coinfection, there are thought to be barriers related to professional teams resisting responsibility for the health of persons with TB/HIV coinfection, as well as fragmented monitoring by local and regional government AIDS and tuberculosis control programs.

Based on the aforementioned, this study aims to identify strategies for improving adoption of the TB/HIV management protocol through evaluation research, with the participation of the network of health services, administrators, and professionals as key research agents with a commitment to improving user access.

MATERIALS AND METHODS

Study design

This project followed the iPIER methodology, a new initiative aimed

at facilitating improvements in program implementation through research that is embedded within those programs, conducted by the Alliance for Health Policy and Systems Research (AHP SR), in collaboration with the Pan American Health Organization (PAHO). The iPIER model considers program implementers to be key research agents in order to understand health systems deficiencies that create barriers to implementation, and to identify solutions. Research on program execution is embedded within existing processes in order to support the effectiveness of health policies through research conducted as a part of the implementation process. A detailed description of how the research methodology is applied can be found in the iPIER concept paper (12) and the study on evaluation of TB-HIV/AIDS treatment protocol implementation in specialized care services in the state of Ceará (6). To conduct the evaluation, the team prepared a flow chart summarizing the stages of the study (Figure 1).

The study involved two public health institutions and one nongovernmental organization—the *Rede Nacional de Pessoas Vivendo com HIV* [National Network of People Living with HIV]. The study team was comprised of five researchers: three from the tuberculosis program, one from the HIV/AIDS program, and one scientific investigator.

The research protocol was submitted to committees on Brazil's platform in February 2015 (registration number CAAE 42719815.3.000.5469, Resolution 466/2012 of the National Health Council). After it was approved in Brazil, it was sent to PAHO's Ethics Review Committee (PAHOERCS 2015.04-0021), receiving final approval from both committees in April 2015.

Location of the study

The state of Ceará is located in the Northeastern region of Brazil and has a territory of 148,825 km² and a population of 8,452,381. In all, 75% of the population is concentrated in urban areas, due to climatic factors, lack of water, and poverty in the countryside. Individual and social vulnerabilities contribute to the spread of tuberculosis and the AIDS epidemic (11, 13).

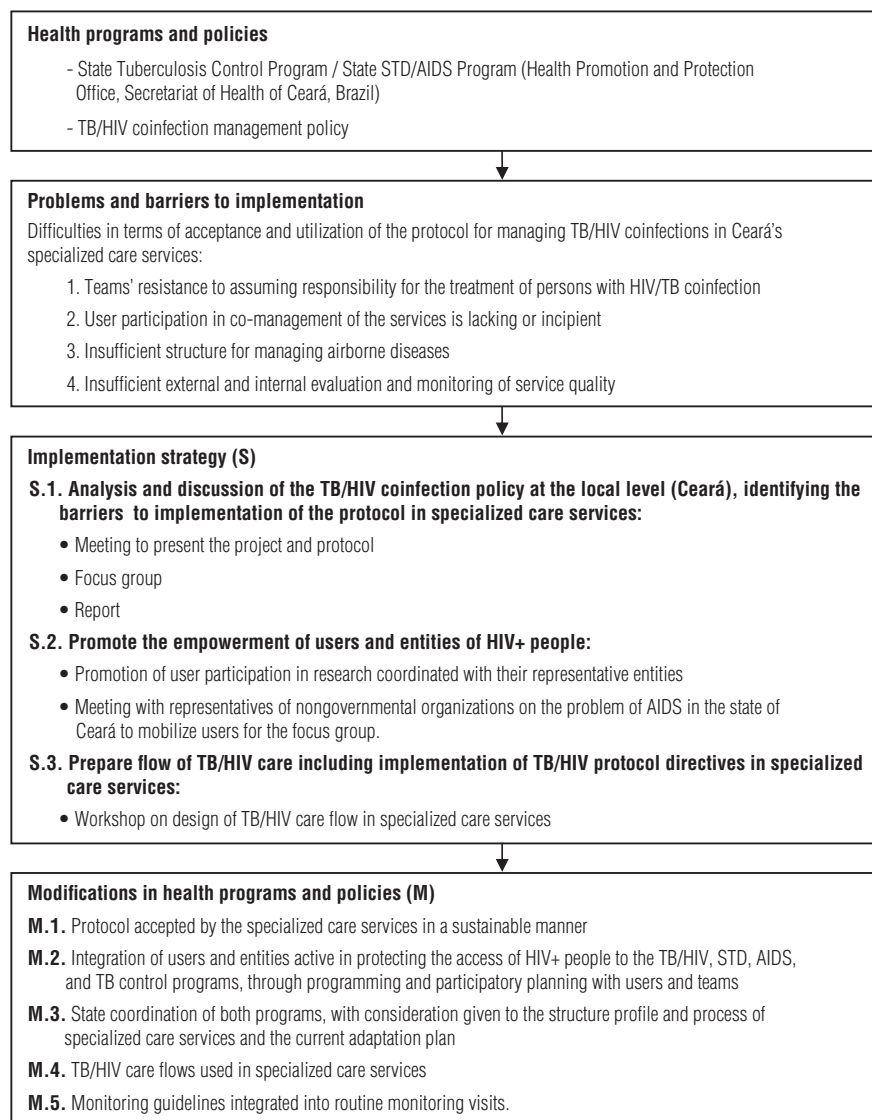
Data collection

Data were collected between April and June 2015, based on secondary data sources: reports from the National Census of Health Facilities (CNES), the Information System for Notifiable Diseases (SINAN), and the Mortality Information System (SIM). The baseline for structures and processes in the 22 services was established on the basis of the answers to seven sets of questions on: installed capacity and physical structure, human and material resources, investigation of diagnosed tuberculosis cases, surveillance and indicators, diagnostic methods, and intervention and therapies. The qualitative stage used focus groups (service administrators, professionals, and users) to learn about experiences in access, utilization, and possible barriers that could impact implementation of the protocol.

Focus groups were the principal sources of primary data. The data collection tools were: a set of key topics to draw out opinions about the services from each focus group. Questions were tailored to the characteristics of the participants and the priority agenda (for users: tuberculosis, access, and opinion about the service; and for professionals and administrators: knowledge about the existence of the protocol, availability in their service, utilization, acceptance, and implementation).

Data analysis

The quantitative data were organized in a database, according to the level of complexity of the health system, testing infrastructure, pharmaceutical inputs, investigation of contacts, and treatment of LTBI data were then entered into STATA® 11.0 software. The processed data were presented to administrators and health professionals at a seminar. The qualitative data were obtained in the focus groups, transcribed and submitted for content analysis, and a set of techniques was established for analyzing dialogues using systematic, objective procedures for describing the content of the messages, aimed at the inference of knowledge related to the conditions in which they were produced or received (14).

FIGURE 1. Implementation flow of TB/HIV coinfection management in specialized care services in Ceará, Brazil, 2015

STDs = sexually transmitted diseases; AIDS = acquired immunodeficiency syndrome; HIV = human immunodeficiency virus.

RESULTS

Structure of the care network for people living with HIV/AIDS in the state of Ceará

The care network for people infected with HIV in the state of Ceará is comprised of 22 specialized care services—12 in the capital and 10 in the interior, where the epidemic has greater epidemiological importance (Figure 2).

The distribution of specialized care services in the state health network varied depending on their level of integration (primary, secondary, and tertiary care) in

the Unified Health System (SUS), which helped determine the structure, availability of physical space, and teams (Figure 3).

The study found that 10% of the services conducted imaging and 20% used the sputum test to detect acid-fast bacilli (AFB) for patients with HIV. The services in the interior of the state, compared with those in the capital, have deficiencies in equipment infrastructure and team training, although half of them had a physical structure that surpassed that of services in the capital (Figure 4).

With respect to the teams in the 22 specialized care services, only six (27.2%) were found to have complex

infrastructure with multidisciplinary teams, laboratory, radiology, pharmacy, equipment, and physical area (Figure 4). The rest had only physicians and nurses. The majority of the professionals were physicians (72), followed by nurses (40), pharmacists (23), social workers (22), psychologists (22), and biochemists (16). With regard to the training of professionals to manage TB/HIV coinfection, in the period 2012-2014, the physician teams in 14 services (63.6%) and the nursing teams in 11 (50%) were found to have received training; while social workers, biochemists, and psychologists, in the majority of the services, had not received specific training until 2015.

The services in the capital were better organized for managing TB/HIV coinfection: most (75%) conducted the PPD test, LTBI was treated, and treatment regimens for TB and LTBI were in place. Half of the services in the interior offered the PPD test, 10% had specific drugs for tuberculosis, and 30% had available treatment for LTBI (Figure 5).

Qualitative aspects of protocol implementation

The focus group qualitative method encouraged discussion and the exchange of ideas among the participants in each group (administrators and service managers, professionals and users).

With regard to care, the user population of specialized care services noted:

"I have witnessed, heard stories, right? (...) I am afraid to go to the post [primary care unit for treating tuberculosis] and for someone to find out that I am HIV positive and tell my family."

"Yes, the units need to get the skills to treat TB patients ... if people know that someone has tuberculosis, they already keep a certain distance, opening doors ...".

"[Tuberculosis] is a disease that still has much more stigma than HIV itself."

How the teams responded to the TB/HIV protocol:

"Only nurses received the protocol." (Administrator)

"I am not familiar with the protocol (...) the physician is always requesting the sputum

FIGURE 2. Location of specialized care services and their distance from the capital: Fortaleza, Ceará, Brazil, 2015.

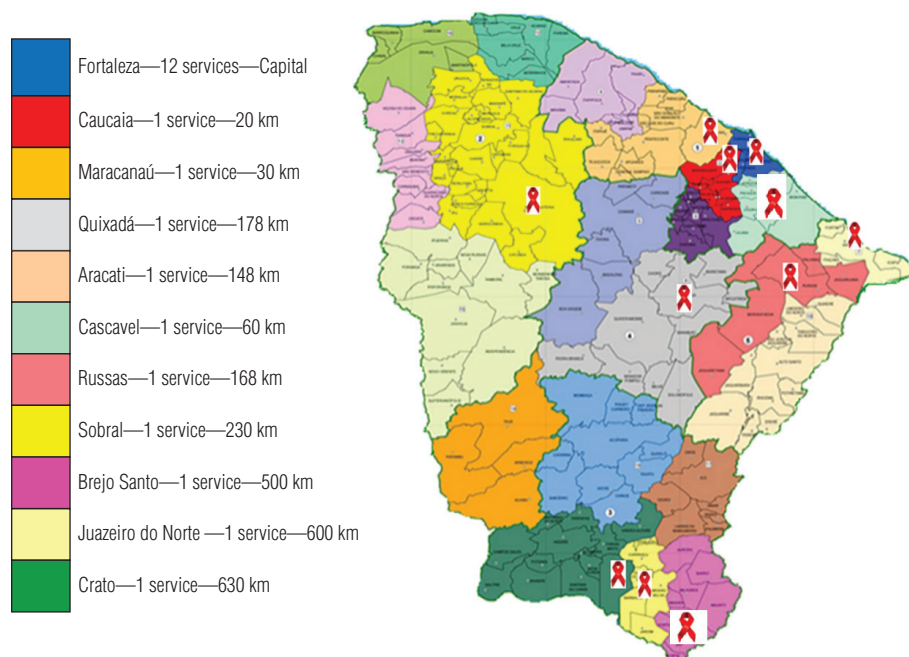
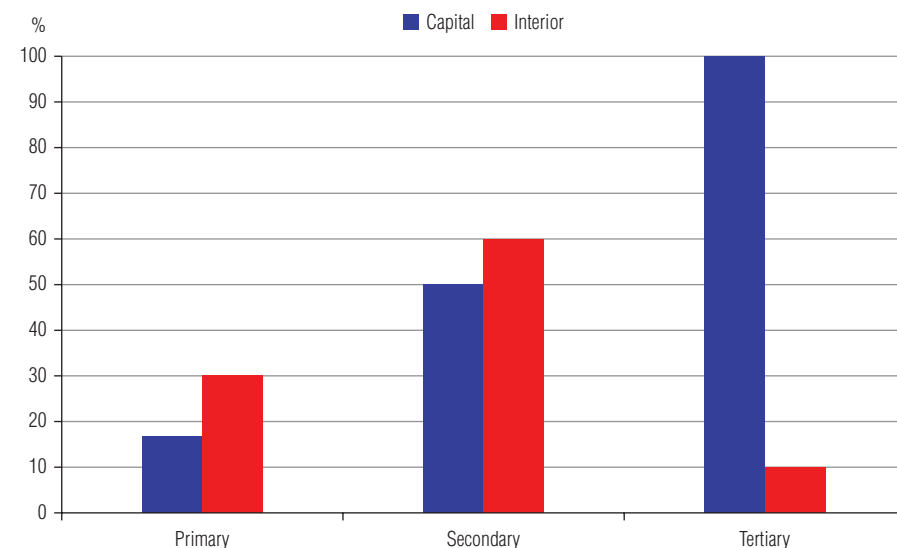


FIGURE 3. Profile of specialized care services by level of complexity in the health system, availability of physical space, and sustainability of services, Ceará, 2015



test that is done now, a fast test, indeed! But the issue is that I do not have a good basis for testing.” (Administrator)

“If it does not work, it is because they are ‘difficult’. You can have the entire team ... everyone with the protocol and everything needed to function, but if the person does not want to, it doesn’t happen.” (Administrator)

Points in favor of implementing the TB/HIV protocol:

“I really do not have many complaints. It is very practical to read.” (Professional)

“I think that if the team is good and you read, you are able to implement it.” (Professional)

“Everyone has a protocol in the service.” (Professional)

“Honestly, I did the TB training, I returned to the service and received the TB-HIV protocol.” (Professional)

“... in terms of HIV-TB, I never did any training; they sent me there, right? And everything that I learned was through reading on the Internet and seeing what was happening there.” (Professional)

Implementation of the protocol in practice:

“Tuberculosis within the specialized care service is a new development; before, our HIV patients, when they were diagnosed, were going to the basic health unit [primary care] to be treated. And now with this new system [Protocol] (...) when it opened, then treatment started in our unit.” (Administrator)

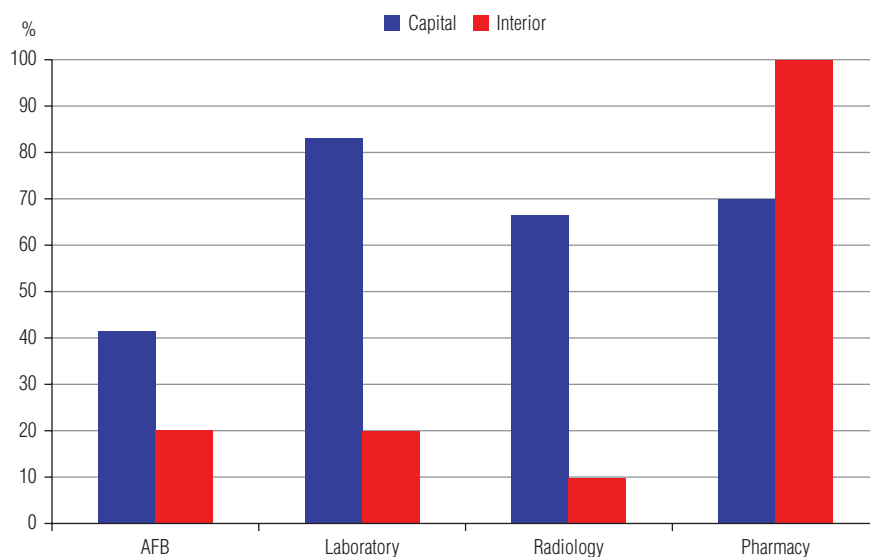
In the focus groups, the implementation barriers identified include (but are not limited to): discrimination against and stigmatization of tuberculosis, insufficient human resources, low level of commitment to addressing the two diseases, differences in recommendations, and frequency of consultations for TB/HIV, excessive demand in specialized services and inadequate structures in the services for treating communicable diseases.

DISCUSSION

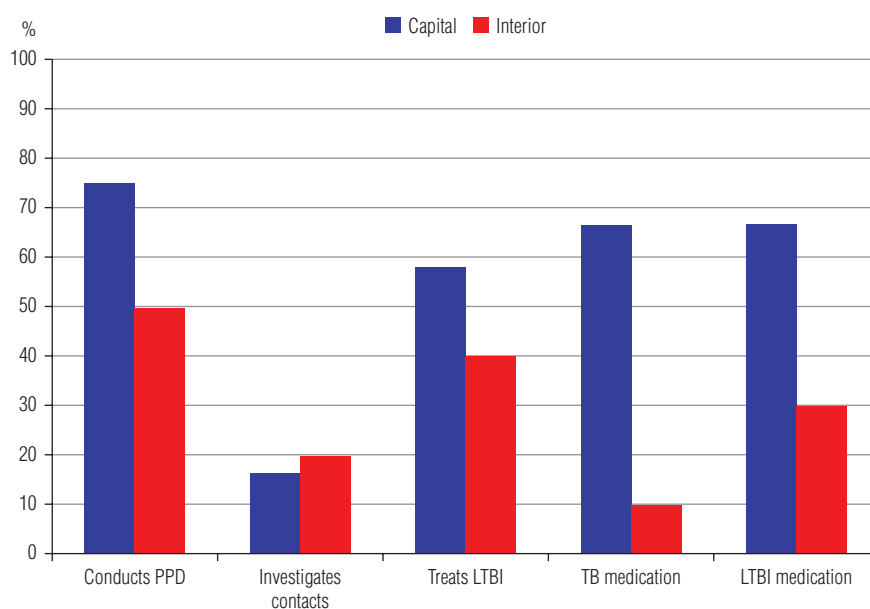
With regard to services, the organization model was found to be mainly directed at caring for people with HIV/AIDS.; Only six (27%) of the services have specific TB control measures and, where they do exist, they are carried out haphazardly, modifying the protocol’s recommendations on managing coinfection, including latent tuberculosis infection. Shortcomings were identified in professional training to meet the needs of people with TB/HIV coinfection. This suggests a low level of investment by the Ministry and the State in the ongoing refresher training needed for the entire health care team.

The services do not have a complex physical structure suited to caring for people with TB/HIV coinfection in terms of biosafety, access to drugs and complementary TB diagnostic testing (Figure 4), and consultations with specialists. This complicates timely diagnosis of tuberculosis.

One implementation strategy was to provide feedback on the infrastructure profile. On that occasion, there was discussion of the administrative measures

FIGURE 4. Specialized care service infrastructure to manage TB/HIV coinfection in the state of Ceará, Brazil, 2015

TB = tuberculosis; HIV = human immunodeficiency virus; AFB = acid-fast bacilli

FIGURE 5. Management of TB/HIV coinfection in specialized care services in the state of Ceará, Brazil, 2015

TB = tuberculosis; HIV = human immunodeficiency virus; PPD = purified protein derivative skin test; LTBI = latent tuberculosis infection.

for adapting the physical space and re-defining internal flows to care for people with TB/HIV coinfection in the specialized services. According to the study's findings, the administrators will be in a position to produce material appropriate for the widest possible dissemination of the standards to teams and users, since immediate changes in the physical structure of the services are not possible. Integrated

monitoring with representatives of the TB and HIV/AIDS programs was established to promote acceptance, adoption, and utilization of the protocol as a strategy for expanding the supply and coverage of care for people with TB/HIV coinfection.

To monitor adoption of the protocol, indicators were used such as the number of new cases of TB/HIV coinfection reported by the specialized care service

teams in the SINAN, demand for TB treatment programs for users of specialized care service, the interest of administrators and professionals in the demand for and supply of training, requests for TB diagnostic testing supplies, and inclusion of TB/HIV on the agendas of the collegiate bodies in the Single Healthcare System (SUS).

The TB management protocol requires adherence to treatment, with medication

taken daily under supervision—an activity suited to primary care and one that specialized care services cannot do for lack of infrastructure and insufficient understanding, on the part of the team, that this is a primary care function (1, 3, 8, 15). Looking at the problem from the patient's standpoint, some users indicated they would prefer to be treated close to home in primary care, since otherwise daily travel to supervised treatment is difficult (9, 10). Another group of patients fears their serological status will be revealed in their community (social stigma) and would prefer to take the treatment on their own, without professional supervision. The two situations suggest that coordination is required to respect patients' decision-making rights (13). In the health system, standards and directives need to be tailored to users' needs and autonomy, respecting the principles of decentralization and local capacities.

This fact is likely the result of the existing primary care model and it is therefore logical that professionals working on the front line of primary care are allocated the resources to increase capacity. Another critical factor hindering implementation of the TB/HIV protocol is the limited availability of supplies and drugs to treat tuberculosis in the specialized services: only eight TB services had the appropriate antibiotic regimens for tuberculosis.

There is a systemic factor related to the distribution flow of TB supplies and drugs, whereby the basic network has priority. The pharmaceutical services in regional health bureaus, which are responsible for supplying the health network, are not always responsive to the need to modify distribution. This suggests that a change in the dialogue with pharmaceutical services is needed. This

is one of the implementation strategies to be adopted by the TB and AIDS technical areas for implementing the protocol; i.e. coordinating with the regional pharmaceutical representatives to redefine delivery flows of treatments in specialized care services.

To promote the changes agreed to with the teams, monitors were embedded in the two programs (TB and HIV), to support implementation of the new flow charts for care and to provide guidance, when necessary. Changes were made to processes in the monitoring tool, with the intention of planning continuing education for the services and reaching agreements with municipal and regional health administrators for indicator monitoring.

The problems identified in this research are useful in ongoing learning and education processes for teams and administrators (12, 15). The field interventions in the services and with users produced some signs of changes that were confirmed in the interviews, the field visits, the self-evaluation instrument completed in September 2015, and the final seminar. These included, most notably, an increase in dissemination of the protocol among administrators, professionals, and user representatives; inclusion of the protocol in the guidelines of the routine meetings in the services; more internal discussions on the problems and pathways for incorporating the protocol into the services; and changes in attitude among administrators regarding implementation (discerned through actions such as requests for record books for coinfection care, copies of the protocol, and additional training on tuberculosis), as well as increased demand from the TB services for supplies for TB management.

Conclusion

The iPIER evaluation model allowed for direct contact among administrators, implementers, and investigators, and for a significant number of people to immediately commit to implementing the protocol. It also improved knowledge of the barriers to implementing the protocol in terms of tuberculosis safety, diagnostic measures, and users' information needs. The changes occurred during the evaluation process, benefitting decision-making. The scientific evidence base of the protocol was put into practice in the services and adopted by at least 55% of them.

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Conflicts of interest. None declared by the authors.

Declaration. The author is responsible for the opinions expressed in this text, which do not necessarily reflect the opinion or policy of the Revista Panamericana de Salud Pública/Pan American Journal of Public Health (RPSP/PAJPH) and/or of PAHO.

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RESUMEN

Evaluación de la implementación del protocolo de manejo de coinfección de tuberculosis y VIH en los servicios de asistencia especializada del estado de Ceará, Brasil

Objetivos. Identificar barreras y estrategias para la implementación del protocolo “Manejo de coinfección por tuberculosis y virus de inmunodeficiencia humana (TBC/VIH)” en los servicios de asistencia especializada (SAE) de Ceará, mediante investigación evaluativa.

Métodos. Estudio desarrollado siguiendo la metodología iPIER, una nueva iniciativa con el propósito de apoyar mejoras en la ejecución de programas de salud a través de investigaciones integradas en ellos acerca de su ejecución. Se recogieron datos de estructura y procesos de 22 servicios y se exploraron las barreras mediante cuatro grupos focales, con 28 participantes, desde el punto de vista del equipo de salud, los administradores y los usuarios. Las discusiones fueron transcritas e interpretadas según los objetivos del estudio.

Resultados. Los datos de estructura y procesos revelaron que seis servicios realizan acciones de manejo de coinfección TB/VIH y 16, no lo hacen. Las barreras fueron: desconocimiento del protocolo en los equipos, ausencia de guías de práctica clínica en los servicios, inserción de los SAE en los tres niveles del sistema de salud, espacios inadecuados para tratar enfermedades de transmisión aérea y falta de comunicación con los sectores de atención primaria de salud para los traslados. Se discutieron los resultados con equipos y administradores en seminarios en los servicios y con los responsables de los programas de enfermedades de transmisión sexual, virus de inmunodeficiencia humana, sida, hepatitis y tuberculosis.

Conclusiones. El diálogo directo entre administradores, ejecutores, usuarios e investigadores generó conocimiento sobre los servicios y elaboración conjunta de modificaciones de flujos para la aceptación y utilización del protocolo; sin embargo, entre los usuarios persiste la resistencia para adherirse al tratamiento.

Palabras clave

Tuberculosis; VIH; servicios de salud; protocolos; Brasil.