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An information system for monitoring tuberculosis cases: implementation research protocol using RE-AIM for a health region in Brazil

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Abstract

Tuberculosis is an infectious bacterial disease and one of the biggest public health problems in the world despite being curable. Research is still needed that considers operational aspects of treatment and control of its spread. Considering this scenario, the need to develop software that provides real-time information about the patient's path along health information systems for clinical decision-making is fundamental. Because of this, a region made up of 26 municipalities will implement a computerized system to monitor tuberculosis cases, the SISTB. However, the implementation of new technology can result in the creation of new functions and cause changes in the existing ones. Implementation research can be used as an approach where evidence can be provided to guide the use of digital technology in tuberculosis care. The RE-AIM framework provides a model to inform this research. Thus, this work aims to report the protocol of a study to evaluate the implementation of a health information system to assist in the monitoring of tuberculosis treatment, using the RE-AIM. The implementation will be carried out in 5 phases: i) define the locations that will receive the intervention; ii) prepare people to receive the intervention iii) train key people; iv) adapt the SISTB and/or the training according to the discussions in the previous phase; v) follow up and monitor the support of the technology. The data collected for the evaluation will come from the database of the implemented system, questionnaires, and training meetings. The forecast for the study conclusion is the end of 2023. As a result, we hope that the SISTB implementation will increase the positive outcomes of tuberculosis patients' treatment.

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1. Introduction

Tuberculosis (TB) is a curable disease and, until the coronavirus (COVID-19) pandemic, it was the leading cause of death from a single infectious agent [1]. The treatment is considered long, lasting at least six months, and to ensure that the medications are taken correctly, the Directly Observed Treatment (DOT) is recommended, which consists of observing patients taking the medications at least during the intensive phase of treatment (the first two months) [2].

The global plan to fight TB, approved in 2015 at the World Health Assembly, may not meet the targets set for 2035 [3]. Years of progress in contributing services and reducing the burden of disease have been rolled back due to the COVID-19 pandemic. As a result of the pandemic, there has been a global drop in the number of people diagnosed with TB. While there were large increases in diagnoses between the years 2017 and 2019, there was an 18% drop between 2019 and 2020, from 7.1 million to 5.8 million diagnoses [1]. Global TB targets are mostly far from being met [1]. To achieve the goals, research and innovation were identified as one of the three essential pillars for ending the TB epidemic through discovery and equitable access to innovative tools and approaches at national and global levels [4].

In this scenario, digital technologies and computing methods for obtaining scientific results play a central role, such as helping patients and caregivers to improve the experience in health facilities, improve treatment processes and automate the management of health information [5,6]. Thus, research that considers operational aspects of the treatment and control of its dissemination are still needed. Considering this scenario, the need to develop software that provides real-time information about the patient's path along health information systems for fast and adequate clinical decision-making is fundamental. A system that includes information on TB cases in a unified database may provide a regional epidemiological scenario, assisting in the action plan to fight the disease.

In order to assist in the TB treatment, an information system called SISTB [7,8] was developed. The system was implemented in a municipality [8,9], but it is intended to expand its reach to a region composed of 26 municipalities. However, the implementation of a new technology can change the way of working and result in the creation of new roles and responsibilities, as well as requiring changes in existing ones [10]. It is necessary to understand the environments where digital technologies will be implemented to identify their potential role in the various aspects of TB care. In this way, it is possible to use implementation research as an approach where it is possible to investigate the challenges and provide evidence to guide the correct use and expansion of digital technology in TB care [11].

Implementation research is an interface between tools, strategies, and interventions and their use in health systems [12]. It considers real-world conditions, providing the basis for context-specific decision-making, which is crucial to turning theory into practical reality [12, 13]. In implementation research, different sources and perspectives are explored, to describe the processes used in the implementation of initiatives, as well as the contextual causes that affect these processes, seeking to understand what is going right or wrong in the implementation [13]. Implementation research links intervention effectiveness with research on effective processes for incorporating interventions into existing settings, and the RE-AIM framework provides a model to inform this research [14]. The RE-AIM framework was developed to facilitate the translation of research into practice, considering both internal and external validity [14, 15]. It has five dimensions: Reach, Effectiveness, Adoption, Implementation, and Maintenance. They operate at the individual, staff, and setting levels and interact to determine the impact of an intervention on the population [15].

Therefore, this work reports a protocol to evaluate the implementation of a technological intervention, that is, a health information system to assist in the monitoring of TB treatment.

2. Objectives

The first objective is to characterize the way TB treatment is handled in a region composed of 26 municipalities, with the following sub-objectives: to characterize the TB treatment support services in each municipality in the region; determine the referral flow of assistance from the municipalities; to identify the behavior of the flow of information on treatment between services and municipalities.

The second objective is to evaluate the implementation of the information system in TB services in the region using the RE-AIM framework as support, with the following sub-objectives: building a pre-implantation protocol considering the diversity of municipalities; evaluate the implementation of the system using RE-AIM; assess the intention to continue using the system.

The third objective is to identify the barriers and facilitators in the implementation and use of the system.

3. Methods

3.1. Intervention

The intervention of this study is to implement an information system to assist in monitoring TB treatment in health services in a region comprising 26 municipalities. The purpose of the SISTB is to replace the paper forms used in the treatment, especially the daily follow-up form of the DOT so that all information is accessed immediately after registration by different professionals and services [7-9].

Additionally, it is expected to centralize treatment data to provide better support for case investigation. In the region where the study will be carried out, different data on TB cases can be found in distinct systems, such as the Tuberculosis Case Monitoring and Notification System (TBWEB), the Notifiable Diseases Information System (SINAN), the Tuberculosis Special Treatments Information System (SITE-TB), the Laboratory Environment Manager (GAL), the National Primary Health Care Information System (eSUS-AB), and, finally, the electronic medical records of each municipality/service. Thus, SISTB will include an interoperability layer, making it possible to exchange data with other information systems used by the services to reduce duplicate registrations, rework for health professionals, and obtain information from as many sources as possible in a single system [7, 16-18]. Access to the aforementioned systems will be requested to carry out the interoperation between them and the SISTB. In cases where interoperability is not possible, the data from that system will be requested to be used as a secondary source to obtain as much data as possible of treatment cases in all possible instances.

SISTB will also include an evidence-based decision support system and national protocols to monitor and analyze data collected or produced in the various TB patient care settings. Thus, it will be possible to incorporate data processing, analysis, and machine learning techniques to assess the clinical situation and probable patient risks in real time [7, 19, 20].

3.2. Study context

The study context will be a health region composed of 26 municipalities, based in Ribeirão Preto, State of São Paulo, Brazil, with an estimated population of 1,400,000 inhabitants [21]. In this region, care in specialized services (secondary level of care) for TB is carried out in the four largest municipalities. Primary Health Care (PHC) units and emergency services in all cities are the gateways to TB cases. There is a reference hospital for TB cases that require hospitalization related to severe drug reactions, extrapulmonary forms, patients co-infected with the human immunodeficiency virus (TB/HIV), and cases of resistance to the bacillus. In 2018, the total number of confirmed TB cases in the region, according to SINAN, was 537. The main outcomes were: 366 cures, 73 treatment dropouts, and 19 deaths from TB [22]. Directly Observed Treatment is performed in most municipalities, especially in cases of non-adherence to treatment or in cases of resistant TB.

3.3. Pre-implementation planning

To fulfill the first objective, interviews will be carried out with managers and professionals of health services to characterize the way TB treatment is handled in the region. Due to the heterogeneity between the municipalities and the services offered by them, it is essential to know the particularities of each location. In this way, two types of interviews will be carried out, one to characterize how TB treatment is offered, how is the flow of intra-municipal and inter-municipal patients, and information flow. The other interview will characterize the services through which the patients' transit to evaluate the possible places that will receive the intervention. The interview will help to define the service in terms of the technological structure (e.g., technological infrastructure) to define the feasibility of implementing the intervention. Still in the pre-implementation phase, with these first data collected, it is intended to identify some possible barriers, so adjustments can be made, either in the SISTB or in the implementation protocol.

3.4. Implementation

The implementation will be carried out in 5 phases: i) definition of the places that will receive the intervention; ii) preparing people to receive the intervention, holding a meeting to explain the purpose of the system and the implementation plan; iii) training of key people at each location; iv) adaptation of the SISTB and/or training according to the discussions in the previous phase; v) follow-up and monitoring.

Professionals who will have direct contact with SISTB will be identified and will respond to the Organizational Commitment Questionnaire (OCQ) [23] and the Questionnaire to evaluate the performance of health services in primary care in TB control applied to health professionals (ADODSAB) [24], as proposed by the protocol developed by Rui et al [25] to evaluate a software for monitoring the Directly Observed Treatment. The OCQ and ADODSAB questionnaires will be answered again, together with the Computer System Usability Questionnaire (CSUQ) [26], after 3 months of using the system. Finally, results from each questionnaire will be compared with those of the moment before implementation. Fig. 1 illustrates the timeline of the implementation phases, when the questionnaires will be applied, and the meetings.

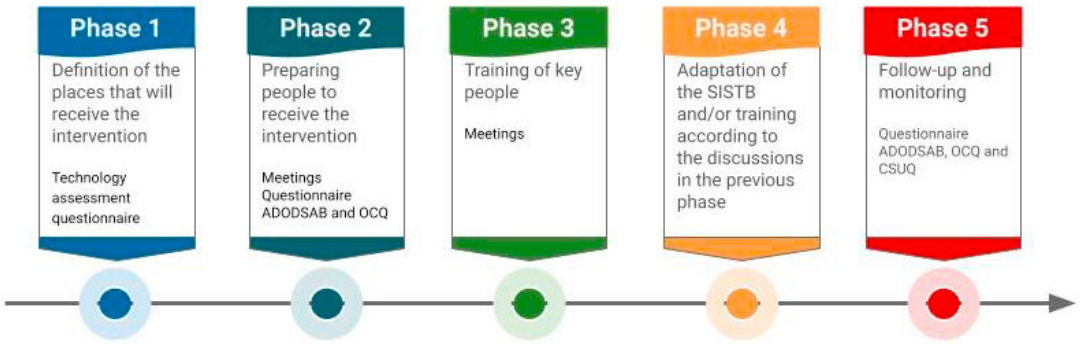

Fig. 1. Timeline of implementation phases

3.5. Implementation analysis using RE-AIM

This study will be guided by the RE-AIM model to assess five dimensions (Reach, Effectiveness, Adoption, Implementation and Maintenance) [15]. RE-AIM was selected for this intervention because it addresses crucial points of implementation in real-world environments and identifies facilitating and hindering factors to achieve success, items relevant to external validity [27]. The analyzed items in each dimension were based on the RE-AIM [14, 15, 28] and on a literature review carried out by the authors to verify the use of the model to assess the implementation of SIS. Table 1 shows the study questions and their respective data sources.

Table 1. RE-AIM dimensions, study questions and data source

Dimension	Question	Data source
Reach	Absolute number, proportion and characteristics of patients registered in SISTB	SISTB database
	Registration rate (were all patients undergoing treatment registered in SISTB?)	SISTB database / official record
Effectiveness	Has there been a change in organizational motivation?	Questionnaire OCQ
	Did the intervention affect service performance?	Questionnaire ADODSAB
	Abandonment rate (percentage of professionals who used the system in the first month and did not use it later)	SISTB database
	Overall satisfaction with SISTB	Questionnaire CSUQ
	SISTB usability	Questionnaire CSUQ
	Was the SISTB effective? Are modifications needed for greater effectiveness?	Meetings with staff and researchers
Adoption	Setting inclusion/exclusion criteria	Technology assessment questionnaire
	Number of eligible and invited settings	Technology assessment questionnaire
	Number of participating settings	SISTB database
	Characteristics of settings participating	Technology assessment questionnaire
	Staff inclusion/exclusion criteria	Research team follow-up / Meetings with staff and researchers
	Absolute number, proportion and characterization of staff who used the SISTB	Questionnaire ADODSAB / SISTB database
	Average of staff participating per setting	SISTB database
	System use	SISTB database
Implementation	Absolute number, frequency and duration of meetings for SISTB usage training	Research team follow-up
	Description of meetings to understand the implementation process	Research team follow-up
	Extent to which the protocol performed as expected	Research team follow-up
	What enabling factors were identified?	Research team follow-up / Meetings with staff and researchers
	What barriers to implementation were identified?	Research team follow-up / Meetings with staff and researchers
Maintenance	Continuity of the intervention after the research	SISTB database
	Reasons for discontinuity	Research team follow-up
	Program institutionalization	Research team follow-up
	Organizational abandonment rate	SISTB database
	What reinforcing factors were identified?	Research team follow-up / Meetings with staff and researchers

In the first dimension - scope -, it will be determined how many patients were registered in the system from the total number of patients undergoing treatment. The characterization of the patients treated who were registered will

also be carried out. A measure of the delay in registration from diagnosis at the service will show how quickly the patient is entered into the system. By evaluating effectiveness, it is expected to know whether the intervention affected organizational motivation and service performance. Satisfaction with SISTB and the abandonment rate in the use of the system will also be evaluated. When evaluating the adoption, the exclusion criteria, the places included and the characterization of the participating professionals will be reported. The use of the system by the participants will be described with data collected from the SISTB database. Regarding the implementation, training sessions will be carried out with a group of professionals from each location. The professionals who participate in the meetings will be responsible for passing on the learning to co-workers. In the meetings, possible barriers or facilitators will also be investigated, whether in the implementation progress or related to the system. The last dimension, maintenance, will verify if there was abandonment or continuity in the use of SISTB after training and the reasons for such decision. The reinforcing factors related to the use of the system will also be investigated.

Data will be collected from several sources, including the SISTB database, the questionnaires and training meetings. Trained researchers will be responsible for collecting the data using electronic data capture (EDC) systems.

4. Final considerations

Information and communication technologies can contribute to the end of TB through improvements in the quality of patient care, surveillance, and service management [5]. This is a study to assess the implementation of a computerized system to track TB cases in a given region. The findings can help future systems implementation processes in environments with different levels of complexity.

Published evidence and best practices on digital health are essential aids to decision-makers and it is essential to disseminate the experience gained over time [5]. Implementation research comprises a research perspective that fosters collaboration between the actors involved, who must work together during research development to build trusting collaborations and encourage knowledge co-production [29].

Given the difficulty of integrating a new process or system within a health service, it must be considered that it is complex to characterize all the direct and indirect changes that the process will generate, especially when interventions interfere with people's routine. Interventions are not simple, and regardless of the restructuring that takes place, waiting for things to improve just by inserting the intervention is not enough. It is the responsibility of the implementation researcher to recognize and understand the repercussions that the execution of the new project can bring [13].

Finally, in this protocol, implementation research was used as a guide, as it seeks to work within the context of the real world, without trying to limit itself to the conditions of the population to avoid causal effects. Therefore, the population really represents the one that will be affected by the intervention [30]. The RE-AIM model was applied to assess the implementation process, as it is one of the most frequently applied [15], in addition to enabling a practical approach in the analysis of the resulting implications [13].

The forecast for the study conclusion is the end of 2023. As a result, we hope that the SISTB implementation will increase the positive outcomes of tuberculosis patients' treatment in the region of action. As a possible benefit for health professionals, it may help to organize the data produced in the service routine and, for the patient, there may be an improvement in the assistance received and in treatment adherence. The results of this research may serve as a basis for other studies related to software implementation in health services.

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Ethical aspects

All procedures performed in this study are in accordance with the ethical standards of the institutional and/or national research committee. All ethical requirements prescribed by Resolution 466/12 of the National Health Council of Brazil and its complementary ones will be met. The research was approved by the Research Ethics Committee of the Ribeirão Preto Medical School of the University of São Paulo - Certificate of Presentation for Ethical Evaluation 47317321.9.0000.5440 and 51283121.8.0000.5440. The planned questionnaires will be applied to the participants after the individual sign of an Informed Consent Term.

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