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Drug utilization studies from secondary databases in latent tuberculosis: a scoping review protocol

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Abstract

This article introduces a protocol for a scoping review that aims to map and synthesize Drug utilization studies from secondary databases in latent tuberculosis The protocol is intended to document the processes involved in the methodological planning and execution of a scoping review guided by Joanna Briggs Institute guidelines and developed using the 2015 PRISMA-Protocols (PRISMA-P) checklist. The PCC strategy (population, concept and context) systematized the search for studies published in Pubmed, Scopus, BVS, Embase and Web of Science from January 2015 to December 2022. The selection of articles will be carried out in two steps (titles and abstracts, followed by the assessment of the full text of the articles), by two independent reviewers, with the resolution of disagreements by a third reviewer. The results will be analyzed qualitatively/quantitatively and will be organized by themes. The checklist present in the Preferred Reporting Items for Systematic Reviews and Meta-Analysis extension for Scoping Reviews (PRISMA-ScR) will be used to guide the final review report. We hope that this scoping review will shed light on Drug Utilization Research in the field of latent tuberculosis, which is still understudied, especially in Brazil

Keywords: Drug utilization Studies, Latent Tuberculosis, Preventive treatment

Estudos de utilização de medicamentos de bases de dados secundárias em tuberculose latente: um protocolo de revisão de escopo

Resumo

Este artigo apresenta um protocolo para uma revisão de escopo que tem como objetivo mapear e sintetizar estudos de utilização de medicamentos realizados a partir de bases de dados secundárias sobre o tema da tuberculose latente. O protocolo pretende documentar os processos envolvidos no planeamento metodológico e na execução de uma revisão orientada pelas diretrizes do Joanna Briggs Institute e desenvolvida com recurso à checklist PRISMA-Protocols (PRISMA-P) de 2015. A estratégia PCC (população, conceito e contexto) sistematizou a busca por estudos publicados nas bases Pubmed, Scopus, BVS, Embase e Web of Science no período de janeiro de 2015 a dezembro de 2022. A seleção dos artigos será realizada em duas etapas (títulos e resumos, seguida da avaliação do texto completo dos artigos), por dois revisores independentes, com a resolução de discordâncias por um terceiro revisor. Os resultados serão analisados qualitativamente/quantitativamente e serão organizados por temas. A lista de verificação presente no Preferred Reporting Items for Systematic Reviews and Meta-Analysis extension for Scoping Reviews (PRISMA-ScR) será utilizada para orientar o relatório final da revisão. Esperamos que esta revisão de escopo lance luz sobre a pesquisas de utilização de medicamentos no campo da tuberculose latente, que ainda é pouco estudada, especialmente no Brasil

Palavras-chave: Estudos de utilização de medicamentos, Tuberculose latente, Tratamento preventivo

Introduction

In 2017, the Brazilian Ministry of Health (MoH) launched the National Plan for the End of Tuberculosis as a Public Health Problem by 2035, which, aligned with World Health Organization (WHO) strategies [1], proposing elimination of Tuberculosis (TB) in Brazil. This plan includes not only strategies for diagnosis and treatment, but also national surveillance of Latent Tuberculosis Infection (LTBI) [1–4].

LTBI affects approximately two billion people worldwide and is a driver of the global tuberculosis pandemic. This asymptomatic state caused by *Mycobacterium tuberculosis* confers an increased risk of progression to active TB disease, especially in immunocompromised individuals such as people living with HIV (PLHIV). Treatment of LTBI- also known as TB preventive treatment- was recently recommended by WHO, which also established the importance of a specific screening strategy in countries with high TB prevalence. However,

in most countries with high TB incidence, only a small proportion of people with LTBI are actually identified, evaluated and treated [5,6].

Despite the large number of clinical trials conducted in recent decades worldwide, that evaluate the efficacy of different anti-tuberculosis drugs and their combinations, studies on safety and effectiveness are less common at aggregate level or population-based, especially on LTBI. Since 1979, the Brazilian MoH Standardized the regimens and took full control of the distribution of anti-tuberculosis drugs in the country, which opened a great opportunity to study all the drugs used against tuberculosis by the Brazilian population. As a consequence, Brazil has acquired vast experience in conducting these types of studies: between the 1970s and 1980s the country carried out 8 national "chemotherapy" surveys evaluating the safety and effectiveness of the medicines used against tuberculosis [7,8].

In this context, more comprehensive drug utilization studies that include management and effectiveness of interventions and referred to as Drug Utilization Research (DUR), are of special importance. DUR aims to examine patterns of treatment use and adherence as well as assess the determinants of drug utilization. Over the years, the scope of DUR has broadened; methods of analysis have become more sophisticated, and the use of secondary data has increased. [9]

Secondary data used in DUR are usually derived from information routinely collected for administrative purposes and as part of patient care, such as drug sales, medical billing, and prescriptions. Also, electronic healthcare databases (EHD) are commonly used in many countries to study drug safety. This Large dataset may bring forth population-based information on supply and demand, which may be associated with relevant outcomes.[9]

Although linking data on drug use with diagnoses, mortality and other health outcomes has become routine in Europe, North America and Asian countries, in low- and middle-income countries, precisely those that concentrate the greatest burden of tuberculosis, this type of research is much less common, notably in Latin America, where integration of health data is difficult and data linkage practically nonexistent. [9,10]

The importance of studying the available literature on the use of medications in LTBI is especially urgent now that the country has recently (2021) incorporated a new treatment regimen. Until then two regimens were recommended for the treatment of LTBI in Brazil: one with rifampicin and the other with isoniazid. The latter was more commonly used and produced locally by the Brazilian Ministry of Health's Farmanguinhos laboratory. Currently, the recommendation is to use Rifapentin, also recommended by WHO in 2018, as an alternative to the 9-month monotherapy with isoniazid traditionally used in countries with high incidence of tuberculosis. The recommendation is that Rifapentine be given in combination with isoniazid for three months (3HP) in weekly directly observed doses (DOTS) in the treatment of LTBI. [11] The protocol aims to describe the scope of DUR on medicines use (utilization profile of drugs) in LTBI conducted in secondary databases around the world and published in scientific literature.

Methods

Study design

Scoping reviews are a form of knowledge synthesis, used to map the existing literature in a particular field in terms of its nature, characteristics, key concepts and volume. Scoping reviews incorporate a range of study designs to comprehensively summarize and synthesize evidence with the aim of informing practice, programs, and policy and providing direction to future research priorities. This type of review can also be used for clarification of the working definitions and conceptual boundaries of a topic or field making it possible to identify thematic, bibliometric, conceptual and organizational aspects of the issue at hand.

Our choice for this type of review is due to our aim to learn about the wide range of DUR conducted with diverse methodological designs related to the theme. In this case, we aim to explore, describe and review latent TB approached through DUR in secondary data**.** The results can be shown in an accessible format, and the process to achieve this must be rigorous and systematic.

In our analysis, we will follow the five steps proposed in a methodological frameworks for conducting a ''scoping study'' published by Arksey and O'Malley [12]: 1)identifying the research question, 2) searching for relevant studies, 3)selecting studies, 4) charting the data, 5)collating, summarizing and finally reporting the results. This scoping review will also follow the Preferred Reporting Items for Systematic Reviews and Meta-Analysis extension for Scoping Reviews checklist (PRISMA-ScR) [13].

In a survey carried out in September 2022 on the Open Science Framework (OSF) platform which allow the registration of scoping review protocols, no scoping or systematic review was identified in progress or published related to the proposed theme. This protocol has been registered in this database (DOI: 10.17605/OSF.IO/WQH8J).

Research guiding questions

This scoping review will comprise studies on drug utilization research involving LTBI. Three research questions structure the literature search and data extraction, as well as the analyses on the key concepts and evidence identified in the proposed scoping review:

What is the drug use profile in preventive TB treatment (drugs, therapeutic regimens, single or combined schemes)?

Regarding Drug Utilization Research (DUR) that present drug profiles in tuberculosis preventive treatment, what are the main study designs/sources of data and countries where they are published, authors institutions (mapping);

What epidemiological data related to disease and service outcomes can be related to the drug use profile?

These research questions will guide the definition of the study's specific inclusion criteria, providing a clear framework for the development of the scoping review in its 5 stages discussed above. In addition, these questions guided the definition of the guiding cores of the review (Population, concept and context), used to define the key words and for the construction of the search syntax in the databases[14] (Table 1).

Table 1. Population, Concept and Context of the proposed scoping review.

Criteria	Description
Population	Studies that included people living with latent tuberculosis, regardless of sex, age, comorbidities, among other aspects.
Concept	Drug Utilization Research (DUR) in secondary databases
Context	Latent TB Worldwide (without restrictions for country, city, and health level)

Search for relevant studies

The search strategy to identify published drug utilization research in the fight against latent tuberculosis took place collaboratively and was supported by an experienced librarian from the Oswaldo Cruz Foundation.

The following databases were searched: PubMed, Biblioteca Virtual em Saúde (BVS), Embase, Scopus and Web of Science. All searches were performed from the 29th to the 31st of December, 2022.

The search strategy was broad and adapted according to the syntax to be performed in each base, covering the theme by using descriptors in health sciences (DeCS, MeSH or Emtree), when available, and free words in the title, abstract and text of the manuscripts, involving three major cores: (a) Tuberculostatics and their combinations; (b) Drug Utilization Research (DUR) in secondary databases; and (c) Treatment of latent tuberculosis. The search was restricted to human studies and adapted according to the syntax for each base (Table 2).

Table 2. General structure of the terms and search strategy used according to the cores involved in the scoping review.

Core Terms	General structure (adapted according to database)
Tuberculostatics and their combinations	("Antitubercular Agents" OR "Anti-Tuberculosis Agent" OR "Anti Tuberculosis Agent" OR "Anti-Tuberculosis Drug" OR "Anti Tuberculosis Drug" OR "Drug, Anti-Tuberculosis" OR "Tuberculostatic Agents" OR "Tuberculostatic Agent" OR "Anti-Tuberculosis Drugs" OR "Anti Tuberculosis Drugs" OR "Anti-Tuberculosis Agents" OR "Anti Tuberculosis Agents" OR "Antitubercular Drugs" OR "Antitubercular Agent" OR "Antitubercular Drug" OR "Drug, Antitubercular")
Drug Utilization Research (DUR) in secondary databases	("Drug Utilization" OR "Drug Utilization Review" OR "Antimicrobial Stewardship" OR "Drug therapy" OR "Prescription Drug Misuse" OR "Pharmacoepidemiology" OR "Treatment Outcome" OR "Treatment Adherence and Compliance" OR "Therapeutic Adherence" OR "Inappropriate Prescribing" OR "Adverse effects") AND ("Pharmacy records" OR "Administrative data" OR "Administrative databases" OR "Hospital record" OR "Patient record" OR "Claims data")
Treatment of latent tuberculosis	("TB Preventive Treatment" OR "Tuberculosis preventive treatment" OR "Latent tuberculosis" OR "Latent Tuberculosis Infection" OR ILTB OR "tuberculosis chemoprophylaxis")

By means of cross-search in the initially selected articles, additional references were searched, seeking to identify other potential papers related to the theme and to increase research coverage.

We were interested in the application of DUR in the context of academic research. Furthermore, we were specifically interested in understanding how DUR might shed light on the numerous clinical controversies in the field of ILTB. As such we chose not to include grey literature.

The search strategies applied to each of the bases listed in the scientific literature, with the respective amount of retrieved references, are displayed in Table 3.

The chosen time frame was January/2015 to December/2022. This period covers approximately 7 years since the launching of the WHO End TB Strategy and the first meeting of the WHO Task Force for preventive treatment. However, for convenience proposes all articles were retrieved without date criteria and those published before 2015 were excluded.

Table 3. Search strategies and quantity of retrieved papers.

Database	Search Key	Number of references retrieved
Pubmed	("Antitubercular Agents"[All Fields] OR "anti tuberculosis agent"[All Fields] OR "anti tuberculosis agent"[All Fields] OR "anti tuberculosis drug"[All Fields] OR "anti tuberculosis drug"[All Fields] OR "drug anti tuberculosis"[All Fields] OR "Tuberculostatic Agents"[All Fields] OR "Tuberculostatic Agent"[All Fields] OR "anti tuberculosis drugs"[All Fields] OR "anti tuberculosis drugs"[All Fields] OR "anti tuberculosis agents"[All Fields] OR "anti tuberculosis agents"[All Fields] OR "Antitubercular Drugs"[All Fields] OR "Antitubercular Agent"[All Fields] OR "Antitubercular Drug"[All Fields] OR "drug antitubercular"[All Fields] OR "TB Preventive Treatment"[All Fields] OR "Tuberculosis preventive treatment"[All Fields] OR "Latent tuberculosis"[All Fields] OR "Latent Tuberculosis Infection"[All Fields] OR "ILTB"[All Fields] OR "tuberculosis chemoprophylaxis"[All Fields]) AND ("Drug Utilization"[All Fields] OR "Drug Utilization Review"[All Fields] OR "Antimicrobial Stewardship"[All Fields] OR "Drug therapy"[All Fields] OR "Prescription Drug Misuse"[All Fields] OR "Pharmacoepidemiology"[All Fields] OR "Treatment Outcome"[All Fields] OR "Treatment Adherence and Compliance"[All Fields] OR "Therapeutic Adherence"[All Fields] OR "Inappropriate Prescribing"[All Fields] OR "Adverse effects"[All Fields]) AND ("Pharmacy records"[All Fields] OR "Administrative data"[All Fields] OR "Administrative databases"[All Fields] OR "Hospital record"[All Fields] OR "Patient record"[All Fields] OR "Claims data"[All Fields])	30
Scopus	TITLE-ABS-KEY (("Antitubercular Agents" OR "Anti-Tuberculosis Agent" OR "Anti Tuberculosis Agent" OR "Anti-Tuberculosis Drug" OR "Anti Tuberculosis Drug" OR "Drug, Anti-Tuberculosis" OR "Tuberculostatic Agents" OR "Tuberculostatic Agent" OR "Anti-Tuberculosis Drugs" OR "Anti Tuberculosis Drugs" OR "Anti-Tuberculosis Agents" OR "Anti Tuberculosis Agents" OR "Antitubercular Drugs" OR "Antitubercular Agent" OR "Antitubercular Drug" OR "Drug, Antitubercular" OR "TB Preventive Treatment" OR "Tuberculosis preventive treatment" OR "Latent tuberculosis" OR "Latent Tuberculosis Infection" OR iltb OR "tuberculosis chemoprophylaxis") AND ("Drug Utilization" OR "Drug Utilization Review" OR "Antimicrobial Stewardship" OR "Drug therapy" OR "Prescription Drug Misuse" OR "Pharmacoepidemiology" OR "Treatment Outcome" OR "Treatment Adherence and Compliance" OR "Therapeutic Adherence" OR "Inappropriate Prescribing" OR "Adverse effects") AND ("Pharmacy records" OR "Administrative data" OR "Administrative databases" OR "Hospital record" OR "Patient record" OR "Claims data"))	78

Table 3. Search strategies and quantity of retrieved papers.

Database	Search Key	Number of references retrieved
Web of Science	("Antitubercular Agents" OR "Anti-Tuberculosis Agent" OR "Anti Tuberculosis Agent" OR "Anti-Tuberculosis Drug" OR "Anti Tuberculosis Drug" OR "Drug, Anti-Tuberculosis" OR "Tuberculostatic Agents" OR "Tuberculostatic Agent" OR "Anti-Tuberculosis Drugs" OR "Anti Tuberculosis Drugs" OR "Anti-Tuberculosis Agents" OR "Anti Tuberculosis Agents" OR "Antitubercular Drugs" OR "Antitubercular Agent" OR "Antitubercular Drug" OR "Drug, Antitubercular" OR "TB Preventive Treatment" OR "Tuberculosis preventive treatment" OR "Latent tuberculosis" OR "Latent Tuberculosis Infection" OR il1b OR "tuberculosis chemoprophylaxis") AND ("Drug Utilization" OR "Drug Utilization Review" OR "Antimicrobial Stewardship" OR "Drug therapy" OR "Prescription Drug Misuse" OR "Pharmacoepidemiology" OR "Treatment Outcome" OR "Treatment Adherence and Compliance" OR "Therapeutic Adherence" OR "Inappropriate Prescribing" OR "Adverse effects") AND ("Pharmacy records" OR "Administrative data" OR "Administrative databases" OR "Hospital record" OR "Patient record" OR "Claims data")	1
Embase	('antitubercular agents'/exp OR 'antitubercular agents' OR 'anti-tuberculosis agent' OR 'anti tuberculosis agent' OR 'anti-tuberculosis drug' OR 'anti tuberculosis drug' OR 'drug, anti-tuberculosis' OR 'tuberculostatic agents' OR 'tuberculostatic agent'/exp OR 'tuberculostatic agent' OR 'anti-tuberculosis drugs' OR 'anti tuberculosis drugs' OR 'anti-tuberculosis agents' OR 'anti tuberculosis agents' OR 'antitubercular drugs' OR 'antitubercular agent'/exp OR 'antitubercular agent' OR 'antitubercular drug' OR 'drug, antitubercular' OR 'tb preventive treatment' OR 'tuberculosis preventive treatment' OR 'latent tuberculosis'/exp OR 'latent tuberculosis' OR 'latent tuberculosis infection'/exp OR 'latent tuberculosis infection' OR iltb OR 'tuberculosis chemoprophylaxis'/exp OR 'tuberculosis chemoprophylaxis') AND ('drug utilization'/exp OR 'drug utilization' OR 'drug utilization review'/exp OR 'drug utilization review' OR 'antimicrobial stewardship'/exp OR 'antimicrobial stewardship' OR 'drug therapy'/exp OR 'drug therapy' OR 'prescription drug misuse'/exp OR 'prescription drug misuse' OR 'pharmacoepidemiology'/exp OR 'pharmacoepidemiology' OR 'treatment outcome'/exp OR 'treatment outcome' OR 'treatment adherence and compliance'/exp OR 'treatment adherence and compliance' OR 'therapeutic adherence' OR 'inappropriate prescribing'/exp OR 'inappropriate prescribing' OR 'adverse effects'/exp OR 'adverse effects') AND ('pharmacy records' OR 'administrative data'/exp OR 'administrative data' OR 'administrative databases' OR 'hospital record'/exp OR 'hospital record' OR 'patient record'/exp OR 'patient record' OR 'claims data')	1391
BVS	("Antitubercular Agents" OR "Anti-Tuberculosis Agent" OR "Anti Tuberculosis Agent" OR "Anti-Tuberculosis Drug" OR "Anti Tuberculosis Drug" OR "Drug, Anti-Tuberculosis" OR "Tuberculostatic Agents" OR "Tuberculostatic Agent" OR "Anti-Tuberculosis Drugs" OR "Anti Tuberculosis Drugs" OR "Anti-Tuberculosis Agents" OR "Anti Tuberculosis Agents" OR "Antitubercular Drugs" OR "Antitubercular Agent" OR "Antitubercular Drug" OR "Drug, Antitubercular" OR "TB Preventive Treatment" OR "Tuberculosis preventive treatment" OR "Latent tuberculosis" OR "Latent Tuberculosis Infection" OR iltb OR "tuberculosis chemoprophylaxis") AND ("Drug Utilization" OR "Drug Utilization Review" OR "Antimicrobial Stewardship" OR "Drug therapy" OR "Prescription Drug Misuse" OR "Pharmacoepidemiology" OR "Treatment Outcome" OR "Treatment Adherence and Compliance" OR "Therapeutic Adherence" OR "Inappropriate Prescribing" OR "Adverse effects") AND ("Pharmacy records" OR "Administrative data" OR "Administrative databases" OR "Hospital record" OR "Patient record" OR "Claims data")	27

Other exclusion criteria were articles without abstract, pre-clinical or non-clinical studies, clinical trials, reviews and opinion articles (Table 4).

Charting the data, summarizing and reporting the results will be carried out by two researchers independently, with disagreements and controversies discussed collectively with the study team. The matrix of indicators used for extraction is described in Table 5. These include information on the authors and institutions involved in the publication of the study, the study population, the methods, the sources of data and the outcomes.

We hope that this scoping review will shed light on Drug Utilization Research in the field of latent tuberculosis, which is still understudied, especially in Brazil

Table 4. Research Criteria.

Inclusion criteria	Exclusion criteria
Studies published in English, French, Spanish or Portuguese published until 31 December 2022	-Studies prior to the year 2015 (Note: 2015 was the first meeting of the WHO Task Force for -preventive treatment) -Studies with no abstracts -Preclinical or non-clinical studies -Clinical trials -Review studies of any type, with or without meta-analysis (although they may be used to help broaden the scope of the search for other studies. But they will not be included in the final list of studies) -Opinion articles, letters to the editor, editorials, essays, conference abstracts

Table 5. Data Extraction Matrix Indicators

Country of publication
Countries studied in the article
Institutional Affiliation 1st author
Language of publication
Source of funding
Research objective (assessment of effectiveness, safety, adherence, diagnostic achievement)
Type of data source (medical records, information system)
Study design/methodological approach (Main method/theoretical approach)
Population studied (e.g. elderly, children, population living with HIV, use of immunosuppressants, immigrants, street population, recent transplant patients and etc)

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Collaborators

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Conflict of interests statement

The authors declare that there are no conflicts of interest regarding this article.

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