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Research Protocol

Public Health Section

Proportion of Tuberculosis Patients Incurring Catastrophic Health Expenditure in India: A Systematic Review and Meta-analysis Research Protocol

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ABSTRACT

Introduction: Globally and at the national level in India, Tuberculosis (TB) programs aim to achieve zero Catastrophic Health Expenditure (CHE) on TB. However, there is evidence through the observational studies reporting CHE incurred by Indian families on TB. Furthermore, the contribution of India to the global TB burden is high both in morbidity and mortality.

Need of the study: A systematic review and meta-analysis will be conducted to estimate the proportion of Indian patients who incur the CHE among Indian TB patients.

Aim: This study aimed to determine the proportion of Indian TB patients incurring CHE, identify factors contributing to CHE among these patients and estimate the mean/median CHE amounts nationally and regionally due to TB in India.

Materials and Methods: Three databases, PubMed, Embase and Scopus, will be used to search for English-language studies reporting the proportion, determinants and mean/median CHE among Indian TB patients. Grey literature will be identified through Google searches and reference screening. Two independent reviewers will screen studies, with disagreements resolved by a senior researcher. Risk of bias will be assessed using the Newcastle-Ottawa Scale (NOS) and the Mixed Methods Appraisal Tool. The review will estimate CHE proportions with 95% confidence intervals and examine predictors, with subgroup, sensitivity and publication bias analyses (I^2, Egger's, Begg's, trim-and-fill). Results will be presented using forest, funnel, Galbraith and leave-one-out plots. Evidence quality will be assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) tool.

Keywords: High morbidity, Impoverishment, Insurance, Social protection, Social security

INTRODUCTION

The Tuberculosis continues to be a major global public health challenge. Excluding the acute Coronavirus Disease-2019 (COVID-19) peak, TB is the leading cause of death due to a single infectious disease and is listed by World Health Organisation (WHO) as one of the top 10 causes of death around the globe [1]. The burden is disproportionately high in Low and Middle-Income Countries (LMICs). Countries such as India (25%), Indonesia (10%), China (6.5%), the Philippines (6.8%), Pakistan (6.3%), Nigeria (4.8%), Bangladesh (3.6%), South Africa (3.6%) and the Democratic Republic of the Congo (3.9%) made up 71%. Of these, the top five contributed to 55% of the global burden. The report also underlines that India is home to one-third of Multiple Drug Resistant (MDR)/Rifampicin Resistant TB (MDR/RR-TB) cases (32%) and accounts for 28% deaths globally. Approximately, 60% of the difference between the estimated number of individuals worldwide who developed MDR/RR-TB in 2024 (incident cases of MDR/RR-TB) and the number of individuals enrolled in treatment in 2024 was accounted for in five nations.

These nations were India (33%), the Philippines (9.3%), Indonesia (7.3%), China (6.1%) and Pakistan (4.1%) [1].

The WHO's End TB strategy aims to eliminate catastrophic expenditures for households affected by TB, reduce TB incidence by 80% and reduce TB deaths by 90% by 2030 [2]. Health expenditure is considered catastrophic when it jeopardises a household's capacity to cover its basic subsistence needs [3]. Health systems should be designed to minimise out-of-pocket expenses for patients when accessing care. This requires not only expanding universal health coverage to reduce direct medical expenses (such as consultation fees, diagnostic tests and medications), but also strengthening the health system and improving patient care pathways. A low level of catastrophic expenditure serves as an indicator of a well-functioning health system within an economy [4].

The CHE transpires when a household incurs substantial out-of-pocket healthcare costs, resulting in financial distress or impoverishment [5]. Some defined thresholds of CHE are: 10%, 20% and 40% [6,7]. CHE 10 implies that a household spends more than 10% of its total income on healthcare and so is considered catastrophic at this level [8]. To realise the goal of zero catastrophic expenditure, it is vital to understand the proportion of people still incurring expenditure above a certain threshold and the factors driving it. This will enable us to reshape and manoeuvre the programmatic initiatives.

Most systematic reviews on TB care are either global in scope or focus on selected groups of countries, addressing specific aspects such as TB types or stages, incidence, prevalence, detection strategies and risk of infection [9-15]. Prior to the implementation of the "End TB Strategy," a systematic review of 49 studies conducted across low- and middle-income countries- including India, the Dominican Republic, Bangladesh, Ghana, Vietnam, Thailand, Myanmar, China, Tajikistan and Kenya- reported that the average total cost amounted to 58% of individual annual income and 39% of household income [16]. Another systematic review encompassing 76 studies from low-, middle- and high-income settings found that, despite subsidised TB care, patients continued to incur substantial costs, particularly for hospitalisation and non TB medications. Additionally, patients with drug-resistant TB experienced significantly higher financial burden [17]. A review of 29 studies predominantly based in India, China, Indonesia, Uganda and South Africa found that approximately half of households (43%) affected by TB experienced CHE when applying a 10% threshold of income [18]. With a higher threshold of 20%,

40% of the 196 pulmonary TB patients surveyed in Uganda faced catastrophic costs [19]. Thus, the financial burden associated with seeking TB diagnosis and treatment remains a substantial barrier to care at the global level.

Given the significant share of India in TB cases and related deaths, it is imperative to delve into the catastrophic cost scenario. Despite the provision of free TB care through the National TB Elimination Program (NTEP), over one-third of patients in Puducherry experienced catastrophic expenses [20]. Among the rural patients, approximately half consult private clinics and 20% purchase anti-TB drugs from private pharmacies, which increase the out-of-pocket expenditure [21]. A 30-60% of the patients with drug-susceptible TB across Assam, Maharashtra, Tamil Nadu and West Bengal incurred catastrophic expenditure [22]. The TB disproportionately affects people in the working age group in India, which further increases the income and productivity loss [23,24]. Addressing TB in India is essential for global TB elimination efforts, as progress here will significantly influence global outcomes.

Despite the availability of free diagnosis and treatment under the National TB Elimination Program, TB continues to impose a significant financial burden on Indian families. Many Indian TB patients lose livelihood support, direct and indirect costs related to diagnosis and treatment, which pushes them into poverty. Given this understanding, estimating the CHE incurred by Indian TB patients has become critical for monitoring both the NTEP target and WHO's End-TB targets. Nonetheless, the evidence on CHE remains fragmented and varies across different settings in India. Although several observational studies are available [21,24-27], there is no comprehensive systematic review or meta-analysis that estimates the proportion of Indian patients experiencing CHE, identifies its key drivers, or quantifies the mean/median CHE attributable to TB in India. The present systematic review will fill the gap by synthesising existing data and a robust national estimate to inform policies and social protection schemes.

Primary objectives: To determine the pooled proportion of Indian patients incurring CHE due to TB.

Secondary objectives: To identify the factors contributing to the CHE among Indian TB patients and to estimate the mean/median total CHE (regional/national) due to TB in India.

MATERIALS AND METHODS

According to Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA-P), this protocol was registered with PROSPERO on 1st December 2025 (ID: CRD420251242934). The PRISMA-P checklist was used to write this protocol [28]. The Population, Intervention/Exposure, Comparison, Outcome and Study Designs (PICOS) framework will be used to finalise which studies to include and which to exclude. The search process preceded writing this protocol.

The literature search will be conducted across three databases: PubMed, Embase and Scopus [Table/Fig-1].

Inclusion and Exclusion criteria:

Population: The analysis will include studies conducted among all types of TB (pulmonary TB, extra-pulmonary TB, drug-sensitive TB and drug-resistant TB) in Indian settings, encompassing populations of all ages, sexes and socio-economic groups.

Exclusion criteria will involve excluding studies that were conducted outside India and populations other than TB patients.

Intervention/Exposure: Studies will be included that report the experience of CHE (both direct and indirect costs and/or a combination of both) among Indian TB patients and will consider the CHE at any threshold level, such as 10%, 20%, or 40%.

Name of the database	Search details	Total articles
PubMed	{"Tuberculosis (TB)"(MeSH Terms) OR "Tuberculosis (TB)" (All Fields) OR "TB"(All Fields)} AND {"Catastrophic Health Expenditure (CHE)"(All Fields) OR "catastrophic health spending"(All Fields) OR "catastrophic cost"(All Fields) OR "out-of-pocket expenditure"(All Fields) OR "financial burden"(All Fields) OR "health expenditure"(All Fields) OR "healthcare expenditure"(All Fields) OR "economic burden"(All Fields) OR "cost of illness"(All Fields)} AND {"India"(MeSH Terms) OR "India"(All Fields) OR "Indian"(All Fields)}	190
Scopus	TITLE-ABS-KEY (("TB" OR "TB") AND ("Catastrophic Health Expenditure (CHE)" OR "catastrophic health spending" OR "catastrophic cost" OR "out-of-pocket expenditure" OR "financial burden" OR "health expenditure" OR "healthcare expenditure" OR "economic burden" OR "cost of illness") AND ("India" OR "Indian"))	187
Embase	('tuberculosis'/exp OR tuberculosis:ti,ab OR TB:ti,ab) AND ('Catastrophic Health Expenditure (CHE)':ti,ab OR 'catastrophic health spending':ti,ab OR 'catastrophic cost':ti,ab OR 'out of pocket expenditure':ti,ab OR 'financial burden':ti,ab OR 'health expenditure':ti,ab OR 'healthcare expenditure':ti,ab OR 'economic burden':ti,ab OR 'cost of illness':ti,ab) AND ('india'/exp OR india:ti,ab OR indian:ti,ab)	117
Total		494

[Table/Fig-1]: Search strategy for systematic literature review and meta-analysis.

Comparator: Since the objective of the study is related to the proportion of Indian patients incurring the CHE due to TB, the comparator is not applicable for the present study.

Outcomes: Studies will be included that report the proportion of Indian TB patients incurring CHE, drivers of CHE in Indian TB patients and mean/median expenditure due to TB.

Study design: Study designs include hospital- and community-based observational studies (prospective, retrospective, cross-sectional, case-control and cohort), as well as qualitative and interventional studies.

Study Procedure

Data selection, extraction and management: Article selection will take place in two stages. The initial screening at the title and abstract stage will be completed by two reviewers and then the disagreements will be mutually discussed. Full texts will be obtained for all articles reviewed. The second stage will consist of full-text screening.

The reviewers will independently divide and screen the studies. During the full-text screening stage, reasons for exclusion will be documented. Any disagreements will be resolved through discussion and if consensus is not reached, a third reviewer will adjudicate. In cases where the same study is reported in multiple publications, these will be linked and recorded as a single study.

Data will be extracted using a structured form developed in line with the study objectives and research questions. The form will undergo a pilot testing and calibration exercise before use. Subsequently, each reviewer will independently extract data using the standardised form. If additional information is required, attempts will be made to contact the original study authors, with a maximum of two follow-up attempts.

Extracted data will include, at a minimum, the following: study and reviewer identifiers; study characteristics (author, year of publication, study design); setting characteristics (national or sub-national—state, district and so on); population characteristics (adult or juvenile, age, sex, type of TB, type of facility sought, socio-economic status and other relevant information); outcomes (proportion of sample facing CHE); mean/median expenditure and drivers of catastrophic expenditure if reported; other study specifications (co-morbidities); and general comments.

Risk of bias: The risk of bias in the included studies will be evaluated using the NOS and the Modified-NOS for cohort and case-control studies, respectively, as well as for cross-sectional studies [29]. The Mixed Methods Appraisal Tool will be utilised for mixed-method investigations [30]. Two reviewers will check for bias and disagreements will be settled mutually. The scoring scheme for NOS is: 7-9 stars: low, 5-6 stars: moderate and less than 5 stars: high-risk of bias. The modified NOS will be classified into 6-7 stars, 4-5 stars and less than 4 stars, showing low, moderate and high-risk of bias, respectively. Since NOS does not cover all types of bias, such as reporting bias and selective outcome reporting the limitation section will acknowledge this [29]. The certainty of evidence will be assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE)-aligned approach for the cross-sectional studies [31]. Analysis will be conducted using Stata-18 (Stata Corp LLC, College Station, TX, USA).

Outcome Measures

The main outcomes for which data will be sought are as follows.

- **Proportion of Indian TB patients who have incurred the CHE due to TB:** Proportion of TB patients incurring catastrophic cost, where cost includes direct medical cost, such as medicines, consultation, indirect cost, such as transportation, food, accommodation and loss of wages.
- **Drivers of CHE among TB patients in India:** Factors leading to CHE, such as hospitalisation and private consultation.
- **Mean/Median CHE due to TB in India:** Mean or Median total cost (includes direct and indirect).

STATISTICAL ANALYSIS

The pooled proportion of Indian TB patients facing CHE will be calculated using a random-effects model with a 95% confidence interval, considering heterogeneity. A fixed-effects model will be applied if I^2 <25%; if I^2 >75%, the random-effects model will be used. For I^2 values between 25%-75%, sample size and study design will also be assessed. Graphical representations will include a forest plot, funnel diagram, Galbraith plot, leave-one-out meta-analysis and a bubble plot for various analyses. Publication bias will be evaluated using Egger's and Begg's tests, with the meta-trim-and-fill method applied if more than 10 studies are included. Model fit and residual heterogeneity will be evaluated using the Q statistic and τ^2 values, with statistical significance set at $p<0.05$.

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