# CHAPTER 4

# FINANCIAL BURDEN OF MEDICINES

This chapter focuses on the systematic review used to assess the government efforts in India and its provinces on the burden of out-of-pocket expenditures on medicines. This study aims to provide a comprehensive picture of how medication expenses impact households and individuals financially by systematically reviewing and synthesizing the data from India on the out-of-pocket expenditure (OOPE) burden of medicine. Given that healthcare expenses account for a significant portion of medication expenditures, particularly in low-income households, this study examines the extent of the OOPE on drugs. By employing a systematic approach to the data synthesis based on published evidence and a transparent methodological framework, this study can guarantee the validity and reliability of its findings and advance the knowledge of how public healthcare policies may impact the level of OOPE on medications in India.

## 4.1 Background of the Study

The issue of out-of-pocket expenditures (OOPE) for healthcare has emerged as a critical concern in the context of low and middle-income countries (LMICs). These expenditures accumulate when households finance their medical needs directly, without significant support from government health systems or insurance schemes. High OOPE in LMICs indicates structural flaws in healthcare finance, which causes substantial economic consequences for families (Wagstaff & Doorslaer, 2003). Achieving universal health coverage (UHC), which is a goal essential for enhancing health outcomes and hence fostering social equity, is greatly hampered by such costs (Xu et al., 2007).

The prevalence of OOPE is particularly pronounced in the Indian healthcare system, where approximately 70% of total healthcare expenses are borne out of pocket, predominantly for

purchasing medicines (Shahrawat & Rao, 2012). This financial burden is disproportionately felt by the most vulnerable populations, especially those in rural areas and those with lower socioeconomic status (Sisay et al., 2021). In a country where economic disparities exist alongside a growing burden of non-communicable diseases (NCDs), the financial strain on households becomes more pronounced (Nethan et al., 2017). As NCDs increasingly become a leading cause of mortality, the need for effective healthcare strategies to manage these conditions has never been more urgent (Prabhakaran et al., 2018).

India's pharmaceutical industry, known for its production of low-cost generic medications, operates within a complex landscape where access to essential medicines is often inadequate. Despite being a key player in the global pharmaceutical market, with significant volumes of production, a substantial percentage of the population suffers from limited access to necessary medications (WHO, 2004). Public health spending remains alarmingly low - below 1% of GDP - resulting in increased reliance on OOPE (Government of India, 2021). This circumstance places vulnerable populations at heightened financial risk, as many families are forced to divert their savings or incur debt to cover treatment costs (Okediji et al., 2017).

Furthermore, public policies aimed at mitigating OOPE, such as the Pradhan Mantri Bharatiya Janaushadhi Pariyojana (PMBJP), have faced operational challenges. Poor supply chain management, limited awareness, and a decrease in the availability of free medicines in public healthcare facilities hinder the efficacy of such initiatives (Mukherjee, 2017). Given the substantial economic burden imposed by OOPE on households, it becomes crucial to assess the effectiveness of various government interventions aimed at reducing such expenditures related to healthcare, particularly in the pharmaceutical sector. Studies indicate that approximately 63% of out-of-pocket payments are allocated towards medication purchases (National Health Systems Resource Centre, 2022), highlighting the vital role that pharmaceuticals play in overall healthcare spending. The economic survey conducted in 2020-

21 suggested that enhancing public health expenditure from 1% of GDP to 2.5-3% could significantly lower the proportion of OOPE from 65% to around 30% of total health expenditure, reflecting the potential impact of increased funding on reducing the financial burdens faced by households (Government of India, 2021).

In light of these challenges and the ongoing need to improve access to essential medications, this study aims to systematically evaluate the impact of government policies and initiatives aimed at reducing financial burdens associated with medicines. Additionally, the study explores potential pathways for reform within the healthcare system that can enhance the availability of affordable healthcare services and medications. By consolidating existing research and examining current practices, this study aims to contribute to a better understanding of how public policy can effectively address the pressing issue of OOPE in India, ultimately fostering a more equitable healthcare system that can sustain the health needs of all citizens.

***Systematic Review Questions***

- What is the burden on Medicine OOPE in India?
- What are the Government Initiatives/Schemes/Policies to reduce Medicines OOPE in India?
- Are the Government Initiatives/Schemes/Policies on Medicines reducing the burden of Out-Of-Pocket Expenditure (OOPE) in India?

## 4.2 Methodology

### 4.2.1 Registration and Reporting of the Protocol

To enhance the methodological rigor and transparency, the protocol of this systematic review is registered in PROSPERO “International Prospective Register of Systematic Reviews” database, ensuring alignment with established best practices in systematic review methodology.

The study followed the PRISMA "Preferred Reporting Items for Systematic Reviews and Meta-Analyses" guidelines, which provide a framework to ensure structured and consistent reporting across all stages of the review process (Moher et al., 2009). The protocol was registered under the ID: CRD42022342755 (Manikandan A et al., 2022) on PROSPERO, which enables public access to the detailed methodological plan, offering a reference for replication and verification of the study's objectives, methodology, and data synthesis approach. By adhering to the PRISMA checklist, this systematic review maintained a transparent and structured approach, enabling future researchers and reviewers to assess the quality, relevance, and replicability of the findings.

### 4.2.2. Data Sources and Search Strategy

To ensure a comprehensive assessment of OOPE on medicines, this study developed an extensive search strategy to gather studies published between the years 2000 to 2022, focusing on the past two decades of research, a period during which the Indian healthcare system underwent numerous policy changes. The timeframe chosen reflects a period of intensified focus on health economics, healthcare financing, and the evolution of out-of-pocket spending within India.

#### *4.2.2.1 Electronic Databases Used*

To capture a wide range of perspectives on the OOPE burden of medicines, the study searched five major electronic databases:

- **PubMed:** A free database that provides biomedical literature, on access to research articles and abstracts in life sciences and healthcare.
- **Cochrane Library:** A repository of databases, which include high-quality systematic reviews and clinical trials on healthcare to help make decisions.

- **Google Scholar:** A scholarly literature search engine, covering a wide range of subjects within the disciplines of science, technology, engineering, and medicine.
- **Scopus:** A journal and citation database of research literature in the sciences, social sciences, and arts and humanities with tools to search citations, related articles, categories, and authors.
- **Grey Literature:** Reports, theses, and policy documents, all of which can be an immensely useful source of research material, not published in traditional academic outlets, but placed in a repository for research materials.

This selection of databases was strategically chosen to encompass multidisciplinary insights into the burden of medicine OOPE, from public health impact to socioeconomic implications, ensuring thorough coverage of relevant literature across health, social, and economic domains.

#### *4.2.2.2 Keywords and Search Strategy*

The search strategy is based on four concept maps with the keywords and the Medical Subject Headings (MeSH) terms. The four key concept maps are developed with a focus on answering the review questions. The concept maps are “recognizing government efforts”, “identifying outcome measure of Out-of-Pocket expenditures”, “medicines”, and “country”, respectively.

The keywords with alternatives are combined with Boolean operators to formulate a structured search strategy to obtain the focused results. The concept maps with the keywords and alternatives are presented in **Table 4.1**. Within the concept, the "OR" conjunction is used, while between different concepts, the "AND" conjunction is used. Almost, the same search strategy is employed in all of the aforementioned databases. The detailed search strategy of individual databases is included as supplemental material (**Appendix A**).

**Table 4.1: Concept Maps, Keywords, and Alternatives for Search Strategy**

| | | | |
|---|---|---|---|
| Concept Map 1 | **Government** | Keyword & Alternatives | "Government Schemes", "Government Spending", "Government Initiatives", "Government Policy", "Government Policies", "Union Government", "Central Government", "State Government", "Regional Government", "Public Schemes", "Public Scheme", "Public Financing", "Public Subsidy", "Public Subsidies", "Health Budget", "Government Subsidy", "Government Subsidies", "Policy", "Policies" |
| | | MeSH Term | "Policy", "Public Policy", "Policy Making", "Health Policy", "Fiscal Policy", "Government", "State Government", "Local Government", "Government Programs", "Government Agencies", "Financing, Government" |
| Concept Map 2 | **Out-of-Pocket Expenditures** | Keyword & Alternatives | "Out-of-Pocket", "Out-Of-Pockets", “OOP”, “OOPE”, “Catastrophic”, "Household Out-of-Pocket", "Financial", "Utilization", "Health expenditures", "Health care cost", "Drug Cost", “Expenditures”, “Spending”, “Spent” |
| | | MeSH Term | "Health Expenditures", "Public Expenditures", "Financing, Personal", "Drug Costs" |

| | | | |
|---|---|---|---|
| Concept Map 3 | **Medicines** | Keyword & Alternatives | "Medicine", "Medicines", "Drug", "Drugs", "Medication", "Medications", "Prescription drug", "Pharmaceutical", "Polypharmacy" |
| | | MeSH Term | "Nonprescription Drugs", "Medicine", "Biological Products", "Herbal Medicine", "Pharmaceutical Preparations", "Prescription Drugs", "Veterinary Drugs", "Drugs, Essential", "Drugs, Generic" |
| Concept Map 4 | **India** | Keyword & Alternatives | "India", "Indian", "India's", "Indians", "Indian Subcontinent", "Indian Sub-continent" |
| | | MeSH Term | "India" |

### 4.2.3. Criteria for Study Selection

#### *4.2.3.1 Framework for Literature Search*

To structure the literature search, the PICO framework is utilized as per the PRISMA guidelines:

- **Population:** Individuals, households, or patients in India.
- **Intervention:** Evaluation of government efforts, policies, strategies, or subsidies aimed at reducing the burden of OOPE on medicines.
- **Comparison:** This systematic review does not involve a comparison group.
- **Outcome:**
  - ✓ *Primary Outcome:* Direct expenses, such as OOPEs on medications.
  - ✓ *Secondary Outcome:* Direct and indirect catastrophic health expenditures (CHEs) - defined as healthcare expenses surpassing specified thresholds according to WHO,

- ✓ 10% of total family spending.
- ✓ 20% of total household earnings.
- ✓ 40% of non-food spending.

#### *4.2.3.2 Cost Considerations*

From the patient's perspective, OOPE(s) are defined as payments made to healthcare institutions that were not compensated. Additionally, both direct and indirect costs incurred are assessed such as,

- ✓ Diagnosis, and Doctor consultation charges
- ✓ Treatment/Surgery
- ✓ Transportation costs
- ✓ Loss of productivity/wages

By considering these costs, this study also aimed to estimate the burden of medicine OOPE as a proportion of overall healthcare expenses.

#### *4.2.3.3 Inclusion Criteria*

- ➢ A comprehensive literature review without imposing limitations on the study design is conducted and all relevant studies published between 2000 and 2022 are included.
- ➢ Studies that offered a secondary analysis by comparing out-of-pocket expenditures (OOPEs) or financial catastrophes, even if their primary outcome is not OOPE on medicines, are also included.
- ➢ From the research that involved multiple South Asian or Asian countries or middle-income countries, only the data from Indian studies are included.
- ➢ If an article is not accessible for its full text, authors are approached, and the articles are considered if they are made readily accessible.

#### *4.2.3.4 Exclusion Criteria*

The specific exclusion criteria which are applied as follows,

- ✓ Studies with titles and abstracts deemed irrelevant to review focus.
- ✓ Research not conducted on Indian demographics.
- ✓ Articles not in the English language.
- ✓ Technical notes, case studies, commentary, editorials, issue briefings, conference papers, literature reviews, and studies lacking specific objectives, data analysis, or peer review are omitted.
- ✓ Articles that reported differences in financial catastrophes or OOPEs arising from medications, but lacked categorization in data tables and interpretation are also excluded.

### 4.2.4. Data Analysis

#### *4.2.4.1 Data Collection Process*

After identifying studies that met the inclusion criteria, a conventional data collection form (**Table 4.2**) is used to obtain the data systematically. Detailed information regarding the articles such as the study's citation, authors, publication type, and year are collected. Study objectives, design, sources of data, sampling strategy, and study setting are also among the collected features. In addition to a brief overview of the study demographics, data on participant characteristics and population size are also obtained. Direct and indirect cost types are assessed as outcomes and examined if the reports revealed a decrease in OOPEs or CHEs on medicines. Finally, the type of statistical investigation and findings are also examined.

#### *4.2.4.2 Quality Appraisal of the Included Studies*

In order to appraise the quality of the articles fulfilling the inclusion criteria, two independent reviewers were employed and they used a checklist that was adapted from a tool previously

utilized by Mirza and Jenkins (Mirza & Jenkins, 2004), with slight modifications to fit the current study needs. The quality checklist consisted of nine criteria such as the clarity of the study's objectives, sample size justification, and the representativeness of the sample. It also involved checking for explicit inclusion and exclusion criteria, the definitiveness of outcome measurements, and the consistency and accuracy of these measurements. Furthermore, it appraised the adequacy of data description, suitability of statistical analysis, and the discussion on the generalizability of the findings. Each "YES" response is allotted one point and a "NO" response receives zero points.

The methodological quality of the data sources and collection methods for drug-related OOPE, healthcare costs, and household financial details are not appraised. All available details are considered and taken as such, as there is very limited literature available on this topic. As a part of the comprehensive approach, the included studies are graded as high, moderate, or satisfactory quality. This grading was based not only on the reported outcomes but also on the combined ratings of both reviewers.

#### *4.2.4.3 Cohen's Kappa Coefficient*

In the quality appraisal process, the grading of two reviewers is further subjected to Cohen's kappa coefficient (κ) statistical measure to evaluate the inter-rater reliability/level of agreement between them. Unlike the simple percent agreement calculations, the Kappa Coefficient accounted for the possibility of agreement occurring by chance. This may provide a more robust measure of reliability between the graders/raters.

The kappa value ranges from -1 to 1, where

- Less than 0: Poor agreement
- 0.01–0.20: Slight agreement
- 0.21–0.40: Fair agreement

- 0.41–0.60: Moderate agreement
- 0.61–0.80: Substantial agreement
- 0.81–1.00: Almost perfect agreement

**Table 4.2: Data Collection Form**

| **Detailed Information** | |
|---|---|
| Reviewer's initials<br>Bibliography<br>Publication/publishing press<br>Year of Publication | |
| **Study Features** | |
| Objective<br>Methodology<br>Source of data<br>Sampling process<br>Rationale for sample size determination<br>Study area | |
| **Participant Features** | |
| Overview of the study population<br>Population size | |
| **Outcomes Measured** | |
| Different types of medical expenses<br>Reported differences in medicine OOPE<br>Reported differences in medicine CHE<br>Statistical analysis undertaken<br>Key outcomes<br>Generalizability in research | |

#### *4.2.4.4 Publication Bias and Meta-Analysis Assessment*

The risk of publication bias is not evaluated adequately because most of the included studies are cross-sectional, in which some of the studies do not report the study design but seem to be "cross-sectional" with minor confounder-related transformations, and only a limited number of research addressed disparities in well-being, utilization of services, utilization pattern, health accounts, and medical comorbidities, which could contribute to the desired outcome.

Moreover, a meta-analysis for this review cannot be carried out since there is high heterogeneity in methodology, participant characteristics, and data analysis between the studies. The findings of the articles concerning the study objective, which is to examine the burden of OOPEs and CHEs on medicines and to evaluate the effectiveness of government efforts in India are reported in this study. A descriptive summary based on the main findings of every article is made, including any conclusions the authors (the included study authors) draw about the significance of their findings.

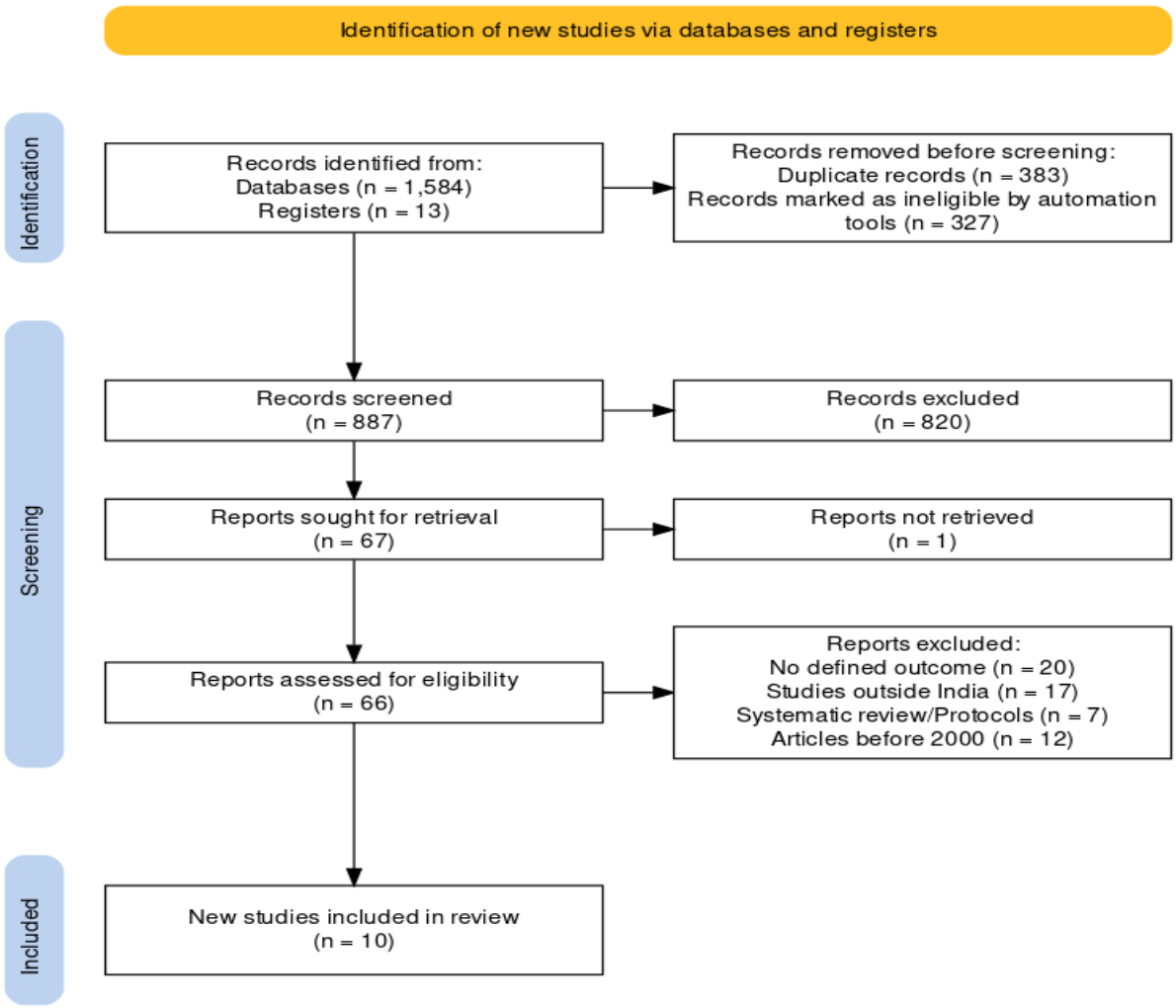
## 4.3 Results

The initial screening from all the databases ended up with 1597 articles. Among that, 383 duplicates, and 327 items that are flagged as ineligible by automated methods are removed. After removing, there were 887 articles for screening, and based on their titles and abstracts 820 articles were excluded. Of these, 67 articles are sought for retrieval, among these 1 article was not retrieved due to the unavailability of the full text. Therefore, 66 articles were assessed for eligibility by screening the full text of the articles. As a result, 10 of them met the inclusion criteria, while 20 articles didn't have a defined outcome, 17 articles were studied outside India, 7 articles were systematic reviews/protocols, and 12 articles were found to be studied before 2000. The Prisma flow chart is shown in **Figure 4.1**.

### 4.3.1 Features of the Included Studies

The quality assessment findings, which is the methodical integrity assessment of the included studies performed by the two independent reviewers are presented in **Table 4.3**. The quality assessment findings of both the reviewers reached an agreement of about 76.66% of the studies that were included and the Cohen's kappa score (κ score) is 0.54, which indicates a moderate agreement between the reviewers. The studies included are generally summarized with the description of the participant demographics and the methodology of the survey conducted in the included studies are presented in **Table 4.4,** and the description of the statistical analysis and outcomes reported in the included studies are presented in **Table 4.5**.

**Figure 4.1: Prisma Flow Chart**



## Table 4.3: Methodical Integrity of the Included Studies

| Research Article – First Author | Definite Objectives | Sufficient Sample Size or Justification | Representative of Population or Justification | Explicit Inclusion and Exclusion criteria | Definite Outcome measured | Consistency and accuracy of measures justified | Sufficient data description | Suitable Statistical Analysis | Discussion on the Generalizability of the Study | [a] Total Score (Both Rev) | [a] Quality based on Total Score (Rev 1) | [a] Quality based on Total Score (Rev 2) | [b] Quality based on Outcomes |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Meheus 2006** (Meheus et al., 2006) | 1 | 0 | 1 | 0 | 1 | 1 | 1 | 1 | 1 | 6.5 | Satisfactory | Moderate | Moderate |
| **Prinja 2012** (Prinja et al., 2012) | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 8.5 | High | High | High |
| **Mogasale 2015** (Mogasale et al., 2015) | 1 | 1 | 1 | 0 | 0.5 | 1 | 0.5 | 0.5 | 1 | 6.5 | Moderate | Moderate | Moderate |
| **Rout 2016** (Rout et al., 2016) | 1 | 1 | 1 | 0.5 | 1 | 1 | 1 | 1 | 1 | 8.5 | High | High | High |
| **Bose 2018** (Bose & Dutta, 2018) | 1 | 1 | 1 | 0.5 | 1 | 1 | 1 | 0.5 | 1 | 8.5 | High | High | High |
| **Selvaraj 2018** (Selvaraj et al., 2018) | 1 | 1 | 1 | 1 | 0.5 | 1 | 1 | 0.5 | 1 | 8.5 | High | High | High |
| **Bahuguna 2018** (Bahuguna et al., 2018) | 0.5 | 1 | 0.5 | 0 | 0.5 | 1 | 1 | 0.5 | 1 | 6 | Satisfactory | Moderate | Satisfactory |
| **Basu 2020** (Basu et al., 2020) | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0.5 | 8 | High | High | High |
| **Arvind 2021** (Arvind et al., 2021) | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0.5 | 8.5 | High | High | High |
| **La 2022** (La et al., 2022) | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 9 | High | High | High |

*1- Yes, 0 – No, 0.5 – Partial (Satisfactory)*

*[a] The overall score represents the mean of the quality elements in each author's evaluation. Scores 8–9 were deemed high, 6-7 were deemed moderate, and under 6 were deemed satisfactory in quality.*

*[b] On the basis of the outcomes reported on medicine OOPE, the quality was a consensus among both authors.*

*Rev-Reviewer.*

## Table 4.4: Description of the Participant Demographics and the Methodology of the Survey Conducted in the Included Studies

| First Author | General Information | | Study Characteristics | | | | | Participant Characteristics |
|---|---|---|---|---|---|---|---|---|
| | Year of Publication | Objectives | Study Design | Data Source | Sampling Technique | Study Setting | Study Population | Population Size |
| **Meheus** (Meheus et al., 2006) | 2006 | To estimate the direct and indirect costs of VL treatment with standard Amphotericin B deoxycholate. | NR[a] | P[*] | NR[a] | Hospital | Patients of KAMRC in Muzaffarpur, Bihar, India. | 77 patients (50 inpatients and 27 follow-up patients). |
| **Prinja** (Prinja et al., 2012) | 2012 | To identify disparities in utilization of services, OOP health spending, and health status. | NR[a] | S[*] by NSSO in its 60th Round Data (2004) on Morbidity and Health Care. | NR[a] | Household | Two States in north India namely, Haryana and Punjab, and the Union Territory of Chandigarh. | 3305 Households, in which Haryana (1400), and Punjab (1492), and the Union Territory of Chandigarh (412). |
| **Mogasale** (Mogasale et al., 2015) | 2015 | Determination of opportunity costs and household OOPE during the free oral cholera mass vaccination program. | Cross-Sectional | P[*] | Stratified, Simple Random Sampling | Private Households | Nine villages of rural Odisha, India, targeting government-driven free oral cholera mass vaccination campaign. | 600 households, 200 from each of three categories (two doses, one dose, and no dose). |
| **Rout** (Rout et al., 2016) | 2016 | To determine the out-of-pocket expenditures (OOPE) for various hospitalized conditions and to identify patient financial coping strategies. | NR[a] | P[*] | Random Sampling | Hospital | Two district hospitals (Secondary care hospitals), one from tribal and another from the coastal region of Odisha, India | 284 Patients (212 males, 72 females). |
| **Bose** (Bose & Dutta, 2018) | 2018 | To assess the states' public inpatient care utilization patterns, the effectiveness of their measures to reduce excessive OOPE, and the equality of these services. | NR[a] | S[*] by NSSO in its 71st Round Data (2014) on Social Consumption: Health, and 60th Round Data (2004) on Morbidity and Health Care. | Stratified Multi-Stage Sampling | Households | Three States in the 71st round & 60th round, namely TN, Raj, & WB. | From 71st round TN (3917), Raj (2912), WB (5019), and its corresponding household samples from 60th round TN (5139), Raj (3383), WB (5049). |
| **Selvaraj** (Selvaraj et al., 2018) | 2018 | To provide new empirical data on the economic effects of out-of-pocket (OOP) medicine expenses on households and identify those medical conditions that cause a substantial financial burden. | Repeated Cross-Sectional | S[*] by NSSO as CES for 1993–1994, 2004–2005, and 2011–2012, and HMS for 2014 from NSSO. | NR[a] | Households | Indian National Representative | CES between 100000 and 125000 households across different rounds, and HMS approximately 72000 households. |
| **Bahuguna** (Bahuguna et al., 2018) | 2018 | To analyze the Punjab state's subnational health accounts. | NR[a] | S[*] for data on health spending by the government from concerned public sector departments both at the state and | NR[a] | Government and Households | Punjab State, India | Not clearly defined, but obtained data from various sources. |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | central level, and estimates on OOPE from NSSO 71st round data, CES data, and Pharmatrac. | | | | |
| **Basu** (Basu et al., 2020) | 2020 | To determine diabetes-related OOP expenditures in tertiary care hospital outpatient clinics. | Cross-Sectional | P* from a quasi-experimental trial. | Consecutive Sampling | Hospital | Patients from the outpatient clinic of a major tertiary care government hospital in Delhi, India. | 375 adult Diabetes Mellitus patients comprising 201 males and 174 females. |
| **Arvind** (Arvind et al., 2021) | 2021 | To determine the total OOP expenses for RHD patients in India receiving BPG prophylaxis. | Prospective Study | P* | NR[a] | Hospital | RHD patients presenting for the follow-up to a tertiary care center in New Delhi, India. | 420 Patients |
| **La** (La et al., 2022) | 2022 | To investigate how multimorbidity is distributed and patterned in connection to socioeconomic level, as well as the relationship between multimorbidity and medicines OOPE by socioeconomic categories. | NR[a] | S* by WHO SAGE India (2015), and CHARLS China (2015). | SAGE (multistage stratified cluster sampling design), and CHARLS (multistage stratified probability-proportionate-to size sampling). | Households | For SAGE India, in six selected states (Assam, Karnataka, Maharashtra, Rajasthan, Uttar Pradesh, and West Bengal), household respondents were surveyed on a larger sample of individuals aged 50 and older and on a smaller comparative sample of populations aged 18–49. For CHARLS China, household respondents were surveyed on a larger sample of populations aged 45 and older. | SAGE India 2015 (n=7397), CHARLS China 2015 (n=11570) |

*P* – Acquisition of primary data directly from the authors, S* – Study involves conducting a secondary analysis of pre-existing data, NR[a] – Not Reported in the studies. VL-Visceral Leishmaniasis, KAMRC-Kala-azar Medical Research Centre, OOP-Out of Pocket, NSSO-National Sample Survey Organization, OOPE-Out of Pocket Expenditure, TN-Tamil Nadu, Raj-Rajasthan, WB-West Bengal, CES-Consumer Expenditure Surveys, HMS-Health and Morbidity Survey, BPG-Benzathine Penicillin G Injection, RHD-Rheumatic Heart Disease, SAGE-Study on Global AGEing and Adult Health, CHARLS-China Health And Retirement Longitudinal Study.*

## Table 4.5: Description of the Statistical Analysis and Outcomes Reported in the Included Studies

| First Author | Outcomes | | | Statistical Analysis | |
|---|---|---|---|---|---|
| | **Outcome Measured** | **Total Expenditure/OOPE on Health Care/Medical Services per episode/visit** | **OOPE on Medicines as a proportion of Total Health Care/Medical Services** | **Type of Statistical Analysis** | **Key Findings** |
| **Meheus** (Meheus et al., 2006) | Direct and indirect costs associated with VL patient management from the societal, and household perspectives. | The median cost of Rs 15400 & Rs 9420 from the societal, and household perspectives, respectively (equivalent to 58% of annual household income).<br>The total amount of OOPE payments by the patient (relatives) over the entire length of hospitalization was Rs 3920. | The median cost of Rs 2334 (15%) & Rs 2160 (23%) from the societal, and household perspectives, respectively. | Descriptive statistics (IQR) | Loss of income because of illness and hospitalization and expenses for drugs were the largest cost components. |
| **Prinja** (Prinja et al., 2012) | Healthcare inequities and Direct catastrophic OOP hospitalization expenditure. | Median hospitalization expenditure accounted for Rs 5300, 7716 & 5000 in Haryana, Punjab & Chandigarh, respectively. | In Haryana, Punjab, and Chandigarh, 32.6, 19, and 46.8 percent of public sector OOP hospitalization expenditures were for medicines. | Descriptive statistics (IQR) | The morbidity and hospitalization rates reported in all three states showed a distribution that favored wealthy households, suggesting that low-income households are not utilizing health services sufficiently. Additionally, a significant portion of out-of-pocket spending in the public sector was allocated towards purchasing medicines. |
| **Mogasale** (Mogasale et al., 2015) | Indirect cost, travel, and productivity loss – Vaccine delivery cost | 24.6% - 38% of overall vaccine delivery costs. | Government-driven free oral cholera mass vaccination campaign | Descriptive statistics | Productivity loss due to potential foregone income loss. |
| **Rout** (Rout et al., 2016) | Direct and indirect costs associated with surgical, and nonsurgical conditions. | Mean total OOPE of Rs 1814 for nonsurgical hospitalization, and Rs 3081 for surgery-related hospitalization. | Mean OOPE of Rs 374 for nonsurgical hospitalization, and Rs 382 for surgery-related hospitalization. | Descriptive statistics | Poor financial protection on hospitalization, and the utilization rate of RSBY, a publicly financed scheme was low.<br>Hospital expenses were mostly made up of medicine and diagnostics. |

| | | | | | |
|---|---|---|---|---|---|
| **Bose** (Bose & Dutta, 2018) | Direct OOPE, Utilization pattern, and extent of equity in public in-patient services | Per episode OOPE during hospitalization.<br>TN (2004): Rs 1391.69 (Pub) & Rs 11766.71 (Pvt).<br>TN (2014): Rs 450.85 (Pub) & Rs 19264.71 (Pvt).<br>Raj (2004): Rs 6212.58 (Pub) & Rs 10691.45 (Pvt).<br>Raj (2014): Rs 3628.62 (Pub) & Rs 22946.43 (Pvt).<br>WB (2004): Rs 3222.24 (Pub) & Rs 13715.03 (Pvt).<br>WB (2014): Rs 5602.78 (Pub) & Rs 17951.06 (Pvt). | Per episode OOPE during hospitalization.<br>TN (2004): Rs 102.41 (Pub) & Rs 1125.90 (Pvt).<br>TN (2014): Rs 150.10 (Pub) & Rs 3920.06 (Pvt).<br>Raj (2004): Rs 1725.07 (Pub) & Rs 2228.25 (Pvt).<br>Raj (2014): Rs 1516.13 (Pub) & Rs 3451.26 (Pvt).<br>WB (2004): Rs 1326.12 (Pub) & Rs 1934.32 (Pvt).<br>WB (2014): Rs 1916.52 (Pub) & Rs 2816.03 (Pvt). | Descriptive statistics | Maximum public sector subsidies are given by TN, and WB provides a minimum for the public sector. |
| **Selvaraj** (Selvaraj et al., 2018) | Direct financial implications of medicines OOPE | 1993-94: 25.59%<br>2004-05: 36.3%<br>2011-12: 54.3% | 1993-94: 20.86%<br>2004-05: 26.0%<br>2011-12: 36.1% | Descriptive statistics | The majority of households' overall OOPE contributions go towards the purchase of medications. |
| **Bahuguna** (Bahuguna et al., 2018) | Direct and indirect CHE and OOPE | THE in terms of per capita is Rs 4963 (19.98% General Government Expenditure and 76.64% private household expenditure). | Households allocate 52% of their expenses towards drugs and pharmaceutical products. | Descriptive statistics | The healthcare system in Punjab is predominantly funded through private out-of-pocket expenditures. The allocation of funds for public health in Punjab is insufficient and it is less than 1% of GSDP. |
| **Basu** (Basu et al., 2020) | Direct and indirect costs associated with diabetes-related treatment. | Mean total costs of Rs 127 on medication and transportation. | Mean OOPE of Rs 63.5 in the previous 1 month, and ranged Rs 0-800. | Descriptive statistics | Diabetes patients miss clinic appointments due to the high expense of time and money for a 15-day prescription refill. |
| **Arvind** (Arvind et al., 2021) | Direct and indirect costs associated with rheumatic heart disease-related treatment. | Median monthly total OOPE of Rs 62.5 on medication, medication administration, and transportation. | Median OOPE of Rs 34, and ranged Rs 30-39. | Descriptive statistics (IQR) | When given benzathine penicillin G (BPG) prophylaxis, patients with rheumatic heart disease (RHD) incur substantial expenses. Almost 50% of total expenses are spent on transportation-related charges. |
| **La** (La et al., 2022) | Direct OOPE on medicines. | NR[a] | Multimorbidity with additional long-term physical conditions makes an overall 20.9% increase in medicine OOPE.<br>For stroke 131.6% increase in medicine OOPE.<br>For diabetes 91.5% increase in medicine OOPE. | Descriptive statistics (QR) | In India, multimorbidity was linked to significantly greater OOPE for medications than individuals who did not have multimorbidity. |

*NR[a] – Not Reported in the studies, VL-Visceral Leishmaniasis, Rs-Indian Rupees, OOPE-Out of Pocket Expenditure, IQR- Inter-Quartile Range, OOP-Out of Pocket, OPD-Out Patient Department, RSBY-Rastriya Swasthya Bima Yojana, TN-Tamil Nadu, Raj-Rajasthan, WB-West Bengal, Pub-Public Sector, Pvt-Private Sector, CHE-Current Health Expenditure, THE-Total Health Expenditure, GSDP-Gross State Domestic Product, RHD-Rheumatic Heart Disease, BPG-Benzathine Penicillin G Injection, QR-Quintile Regression.*

#### 4.3.1.1 Data Source of the Included Studies

The ten studies that met the inclusion criteria were published between 2006 and 2022 (Arvind et al., 2021; Bahuguna et al., 2018; Basu et al., 2020; Bose & Dutta, 2018; La et al., 2022; Meheus et al., 2006; Mogasale et al., 2015; Prinja et al., 2012; Rout et al., 2016; Selvaraj et al., 2018). Five studies out of ten studies gathered primary data through questionnaires and interviews rendered to the patients, households, or individuals (Arvind et al., 2021; Basu et al., 2020; Meheus et al., 2006; Mogasale et al., 2015; Rout et al., 2016).

Five studies examined secondary data from a range of comprehensive surveys and organizations across various regions and periods in India such as the National Sample Survey Organization (NSSO). The NSSO conducts socio-economic sample surveys on matters such as education, employment, and health alongside various other factors. The NSSO works under the Indian Ministry of Statistics. The datasets used in those five studies generally provide broad and diverse insights into health and economic conditions. Specific data sources of the five studies, which used secondary data are as follows,

- ***Prinja 2012 Study*** - Utilized data from the National Sample Survey Organization (NSSO) 60th Round (2004), which is focused on "Morbidity and Health Care". This study analyzed a subset of 3,305 households specifically from Haryana, Punjab, and the Union Territory of Chandigarh (Prinja et al., 2012).
- ***Bose & Dutta 2018 Study*** – Utilized data from two rounds of the NSSO:
  - ✓ The 71st Round (2014) on "Social Consumption: Health", involving 11,848 households.
  - ✓ The 60th Round (2004) on "Morbidity and Health Care", covering 13,571 households.

These subsets included households from Tamil Nadu, Rajasthan, and West Bengal (Bose & Dutta, 2018).

- ***Selvaraj 2018 Study*** – Utilized data from several NSSO surveys:
  - ✓ "Consumer Expenditure Surveys (CES)" from the rounds of 1993-94, 2004-05, and 2011-12, covering between 100,000 and 125,000 households.
  - ✓ The "Health and Morbidity Survey (HMS)" of the NSSO from 2014, consisting of approximately 72,000 households (Selvaraj et al., 2018).
- ***Bahuguna 2018 Study*** - Examined data from several sources:
  - ✓ The NSSO 71st Round (2014) on "Morbidity and Health Care Survey".
  - ✓ "Consumer Expenditure Surveys (CES)" for 2011-12.
  - ✓ Additionally used Pharmatrac data from 2014.

The focus was on a specific subset of households in Punjab (Bahuguna et al., 2018).

- ***La 2022 Study*** - Utilized data from the WHO Study on Global Ageing and Adult Health (SAGE) India. This study analyzed data from a set of 7,397 households (La et al., 2022).

#### 4.3.1.2 Study Design of the Included Studies

Out of ten articles, six studies are cross-sectional, in which three didn't report the study design, but upon evaluation, found that the cross-sectional study was undertaken. The other three out of ten studies also didn't report the study design and analyzed secondary data, in which two studies used a stratified multi-stage sampling method (Bose & Dutta, 2018; La et al., 2022). One study was a prospective observational study design that specifically measures the desired outcome of our study objective (Arvind et al., 2021).

#### 4.3.1.3 Sample Population, Characteristics, and Socioeconomic Indicators of the Included Studies

All ten studies collected the required data from the patients or households in the form of surveys or from surveyed data. Overall, the study population ranged from 77 to 420 patients (involving inpatients, outpatients, and follow-up patients of males/females) and 600 to approximately 125000 households. All the studies reported healthcare costs/OOPE including medicines cost/OOPE, while six of ten studies provided respondents' socio-economic status (SES), including "education, income, occupation, age, marital status, employment status, etc" (Arvind et al., 2021; Basu et al., 2020; La et al., 2022; Meheus et al., 2006; Mogasale et al., 2015; Rout et al., 2016). However, three out of ten studies reported monthly per capita consumption expenditure (MPCE) class (Bose & Dutta, 2018; Prinja et al., 2012; Selvaraj et al., 2018) and one out of ten reported public expenditure (current public expenditure, public capital expenditure, total public expenditure) (Bahuguna et al., 2018) to differentiate the study population into quintiles of socioeconomic wealth. Seven studies reported significant OOPE with or without financial catastrophe associated with respondents (Arvind et al., 2021; Basu et al., 2020; Bose & Dutta, 2018; La et al., 2022; Prinja et al., 2012; Rout et al., 2016; Selvaraj et al., 2018). The other three studies did not exactly report OOPE but reported on costs indicating financial catastrophe (Bahuguna et al., 2018; Meheus et al., 2006; Mogasale et al., 2015).

#### 4.3.1.4 Outcomes Measured in the Included Studies

Meheus 2006, Basu 2020, and Arvind 2021 studies addressed visceral leishmaniasis (VL) patients at Muzaffarpur City in Bihar State India (Meheus et al., 2006), diabetes, and rheumatic heart disease patients in India's capital New Delhi, respectively (Arvind et al., 2021; Basu et al., 2020) and provided the costs/OOPEs associated with direct (including medicines) and indirect costs. Rout's 2016 study addressed the direct and indirect costs/OOPEs associated with surgical and nonsurgical conditions in Odhisa India (Rout et al., 2016). Prinja 2012 and Bose

2018 studies addressed the healthcare inequities, direct catastrophic OOPE, and utilization pattern of public healthcare services, the former studied in Haryana, Punjab, and Chandigarh states/provinces of India, while later studied in Tamil Nadu, Rajasthan, and West Bengal states/provinces of India (Bose & Dutta, 2018; Prinja et al., 2012). Mogasale's 2015 study addressed the indirect cost associated with the government-driven free oral cholera vaccine campaign in Odhisa India (Mogasale et al., 2015). Selvaraj's 2018 study is about the financial implications of medicines OOPE on an Indian national representative sample and compared the same for two decades (Selvaraj et al., 2018), while La 2022 study is about the OOPE in association with multimorbidity in six selected states/provinces of India (Assam, Karnataka, Maharastra, Rajasthan, Uttar Pradesh, and West Bengal) (La et al., 2022). Bahuguna's 2018 study analyzed the subnational health accounts of Punjab state in identifying the direct and indirect CHE and OOPE (Bahuguna et al., 2018).

### 4.3.2 OOPE on Medicines

#### *4.3.2.1 Diseases on Medicine OOPE*

Three out of 10 studies provided the burden of OOPE, which is directly studied on cost/OOPE due to some specific diseases. In general, patients with the disease have a burden on OOPE, but these studies are looking into the government's efforts and how they can reduce it. To determine the economic cost of treating VL using conventional Amphotericin B deoxycholate, which is presently the first-line treatment in Muzaffarpur, Meheus 2006 reported a costing analysis of VL patient management. An estimated Rs 15400 was spent on care for each episode of VL, which is equal to 58% of annual household income, of which Rs 2334 (15%) is spent on medicines. The economic costs related to VL are substantial and the government should ensure access to care for poor patients and public hospitals should subsidize the treatment of VL for the patient (Meheus et al., 2006).

Basu 2020 examined the factors influencing Diabetes mellitus (DM) patients' out-of-pocket expenses at a tertiary care hospital's outpatient clinic. Nearly half of DM outpatients in a major government tertiary hospital pay OOP for antidiabetic drugs. Lower SES patients were more regular among them, and they missed fewer appointments. The practicality and cost-effectiveness of providing glucometer strips and diabetes medications at no cost to patients in Indian public health institutions warrant investigation. Additionally, policy measures to initiate long-term dispensing of diabetes-related medications should also be examined (Basu et al., 2020).

One study, Arvind 2021, estimated the overall OOP expenses associated with secondary prophylaxis of rheumatic heart disease (RHD) in children. Individuals who receive benzathine penicillin G as a secondary prophylaxis for rheumatic heart disease face significant expenses that are not covered by any financial protection. The cost of acquiring the medication accounts for 30% of the overall cost, while the average expenses for getting the drug administered and traveling to the healthcare facility make up 22% and 48% of the total mean costs, respectively. Strategic enhancement of healthcare access and drug supply chains can potentially lead to a reduction in the overall cost of secondary prophylaxis in the context of national strategies towards RHD control (Arvind et al., 2021).

#### *4.3.2.2 Surgical and Non-surgical Hospitalization on Medicine OOPE*

One out of 10 studies reported the OOPE differences in surgical and non-surgical hospitalization studied on 284 patients. Rout's 2016 study on surgical and non-surgical OOPE is insightful. These findings are crucial to developing health financing strategies to protect low-income people, who mostly use public hospitals in the country. The majority of public hospital patients are low-SES. Despite using public hospital services, most patients pay out of pocket. The study found that a significant proportion of households, specifically 45%, lacked any form

of financial protection. Additionally, a majority of households, approximately 61%, resorted to borrowing, either partially or fully, to cover their hospitalization expenses. Furthermore, the "Rashtriya Swasthya Bima Yojana (RSBY)" public-funded national health insurance scheme's utilization rate was also poor. Medicines account for 20.6% of the overall mean OOPE (Rs 374 out of Rs 1,814) for nonsurgical hospitalization, while it is 12.4% (Rs 382 out of Rs 3,081) for surgery-related hospitalization (Rout et al., 2016).

#### *4.3.2.3 Healthcare Inequities on Medicine OOPE*

Two studies deal with healthcare inequities and utilization patterns of public healthcare schemes in addressing OOPE. The study conducted by Prinja in 2012 examined disparities in self-reported morbidity, utilization of health services, out-of-pocket healthcare expenditures, and utilization of public subsidies. There exists a disparity in healthcare utilization between individuals of varying socioeconomic status, with the affluent exhibiting a higher frequency of hospitalizations and the economically disadvantaged experiencing a greater prevalence of unaddressed medical requirements. Medicines alone accounted for 32.6, 19 and 46.8% of public sector OOP hospitalization spending in Haryana, Punjab, and Chandigarh, respectively, deterring impoverished households. Enhancing the capacity of the public sector has the potential to result in an increased distribution of benefits to impoverished individuals and may contribute to the mitigation of disparities in access. To safeguard households from the financial burden of private-sector hospitalization, it is recommended that prepayment mechanisms be established for the lower quintiles. Enhancing the accessibility of cost-free pharmaceuticals at public sector establishments is recommended as a means of mitigating out-of-pocket expenses and, consequently, enhancing utilization (Prinja et al., 2012).

Bose 2018 looked at how well policies worked to achieve Sustainable Development Goals (SDGs). To attain Universal Health Coverage by 2030, SDG-3 focuses on "financial risk

protection, access to quality essential health-care services, and access to safe, effective, quality, and affordable essential medicines and vaccines for all." According to the report, general public facility use has significantly increased in Tamil Nadu (TN) and Rajasthan (Raj), whereas it has dropped in West Bengal (WB). After implementing numerous health finance options, it is clear from the outcomes that the TN model has been successful in reaching its health objectives. RAJ is also benefiting by implementing similar strategies. However, WB has fallen short of its objectives, and targeted policies are needed to strengthen the state's use of the public sector (Bose & Dutta, 2018).

#### *4.3.2.4 Financial Implications and Multimorbidity on Medicine OOPE*

Two out of 10 studies addressed specifically the financial consequences of out-of-pocket payments for medications on households and the impact on medicine OOPE due to multimorbidity, respectively. Selvaraj's 2018 study examined Indian households' financial pressure from out-of-pocket (OOP) drug payments. From 1993-1994 to 2011-2012, overall medical OOP expenditure climbed from 20.86% to 36.1%. The data show that out-of-pocket healthcare and drug costs affect poverty estimations. Over the past two decades, households' out-of-pocket (OOP) medical spending has impoverished them. Using a 10% out-of-pocket (OOP) threshold on total consumption spending, 18% of Indian households face financial disaster. OOP medical spending accounts for 11% of financial disasters. Households with cancer patients had the greatest monthly out-of-pocket (OOP) spending for inpatient and outpatient care. Enhancing governmental intervention in the provision of free medicines at public healthcare facilities holds promise in significantly mitigating medicine-related expenditures and overall out-of-pocket (OOP) payments of households, thereby reducing OOP-induced impoverishment (Selvaraj et al., 2018).

La 2022 investigated the multimorbidity pattern and its effect on medicine OOPE in India. The results show that the prevalence of multimorbidity was 42.2%, in people with 45 years of age or older. An increased medicine OOPE was significantly associated with the increasing number of chronic diseases. Stroke was associated with the highest medicine OOPE, while diabetes, remains the second highest. Expanding health insurance coverage to all individuals and ensuring the affordability of essential medicines is key to reducing OOPE (La et al., 2022).

#### *4.3.2.5 Subnational Health Accounts on Medicine OOPE*

The sub-national health accounts of Punjab state were mapped by Bahuguna 2018, and they found that the measures currently being used to increase the number of publicly subsidized health insurance plans in India are only partially effective at lowering catastrophic costs. The households pay for more than 76.64% of all health care expenses, whereas the "General Government Expenditure (GGE)" contribution is 19.98% only. More than 52% of OOPE expenditures by households are for medicines and pharmaceuticals. India has some of the world's lowest spending rates on public health (Bahuguna et al., 2018).

#### *4.3.2.6. Indirect costs and Productivity loss on Vaccine delivery*

Mogasale 2015 conducted an estimation of the costs incurred by 600 private households in Odisha during a mass vaccination campaign for the oral cholera vaccine (OCV). The study quantified the loss of income resulting from the time invested in vaccination by both the recipients and their carers. The study found that the cost incurred by individuals for receiving oral cholera vaccines ranged from 24.6% to 38.0% of the total vaccine delivery costs, depending on the extent of productivity loss experienced by the vaccine recipients. The expenses incurred by private households due to productivity loss resulting from receiving a free oral cholera vaccine constitute a significant portion of the total vaccine delivery cost. This factor may impact vaccine uptake, regardless of the free government-led vaccine campaign.

Policymakers and program managers must acknowledge the significance of private costs and deliberate on how to strike a balance between programmatic delivery costs and the private household costs associated with receiving vaccines (Mogasale et al., 2015).

## 4.4 Discussion

As far as current literature is concerned, this chapter on a systematic way of data synthesis based on published evidence represents the very first systematic review of the impact of government efforts on reducing out-of-pocket expenditures on medicines. This study is conducted with an extensive search by using precise search terms and applying stringent inclusion criteria. The study has revealed that despite a limited number of high-quality articles, there is evidence to suggest that the government is implementing multiple measures to alleviate the financial burden of out-of-pocket expenditures (OOPE) on healthcare, including medicines, but the efforts are not sufficient enough to achieve the goal. All the included studies somehow or other explained the burden of OOPE on medicines with an emphasis on the improvement of government interventions. From the overall healthcare expenditure, including the OOPE on healthcare, medicines constitute a large proportion (Ambade et al., 2022). The current study findings are also in line with explaining that medicines hold the major share of the OOPE burden. This finding could be generally explained by affordability issues, but more precisely it can be explained by polypharmacy, non-generic prescription, doctors prescribing branded medicines for incentives, monopoly market, non-subsidy or no free medicines, especially in public health facilities, which all can be collectively addressed by the government policies.

Visceral leishmaniasis (VL) is a vector-borne disease that poses a substantial public health threat in India. Bihar, Jharkhand, West Bengal, and Uttar Pradesh provinces exhibit the highest prevalence of this ailment (Deb et al., 2018). Drug therapy is the most common VL treatment, knowing the endemic area of the disease, the government should ensure access to care for poor

patients. The treatment of chronic diseases such as diabetes involves high economic costs, especially long-term drug therapy. Generally, government health facilities provide free medication and treatments, but the study examined, that a significant number of diabetic patients from government health facilities incur OOPE for antidiabetic medications. Specifically, an article in the diabetes care journal of the American diabetes association demonstrates that the financial burden has a devasting impact on people who are least able to afford the high cost of antidiabetic medicines. This has important implications for both public policy and social justice (Taylor, 2020).

The Tamil Nadu regional government of India has developed a scheme since 1995 that provides free medicine to all individuals who seek care at public health institutions (Manimegalai, 2021). Specifically, one of the included studies examined that Tamil Nadu is doing well in the provision of no-cost medicine in government hospitals and reducing the burden of OOPE, but still, large improvement and implementation are required in other examined provinces and the rest of Indian provinces, respectively. Providing free medicine from the hospital pharmacy is an efficient approach to affording financial security and accessibility concurrently (Bose & Dutta, 2018).

Another major concern is healthcare inequities and poor public service utilization, which the current study findings showed high OOPE, especially on medicines to the poorer quintiles. Additionally, the morbidity and hospitalization rates are disproportionately higher among the wealthier segments of society, indicating suboptimal utilization of healthcare services by households with lower incomes. These findings can be a result of India having a healthcare budget significantly lower than that of other developing nations. The Ethiopian government presumes that the issue of health inequality stands as a primary obstacle to the accomplishment of the Sustainable Development Goal (SDG) for Universal Health Coverage (UHC). The implementation of a community-based health insurance (CBHI) program has been undertaken

to enhance the utilization of health services among impoverished demographics. In order to furnish financial security against risk to individuals with low incomes, the government has predominantly subsidized healthcare expenses at the point of service through the implementation of cost-sharing and user-fee exemption programs (Hailu et al., 2021). Similarly, when medical treatment is not covered by health insurance or other social protection schemes, individuals are forced to bear the costs themselves, which can be unaffordable for many. This situation is commonly experienced in low-income countries or anywhere where there is limited access to affordable healthcare.

Subnational Health Accounts (SNHAs) have a significant impact on medicine Out-of-pocket expenditure (OOPE), especially in developing countries. SNHAs are a tool for tracking and analyzing health expenditures at the subnational level, such as districts or states/provinces. They provide information on healthcare spending by different income groups, geographical areas, and health conditions, which can help policymakers identify areas where resources are limited and the most significant healthcare needs (Borghi et al., 2018). One of the included study findings made use of a subnational health account and captured the OOPE expenditure in per capita terms, and there was a significant OOPE witnessed. Once again this can be explained by poor public spending, which emphasizes the importance of effective allocation and management of healthcare resources at the subnational level.

## 4.5 Limitations and Strengths of this Study

Although this study has notable strengths, it is important to acknowledge that there are certain limitations that could be addressed in future scope on this topic. The search conducted yielded a limited pool of ten studies that effectively addressed the review questions at hand. The search was expanded over the last 22 years, for reasons that there are a very limited number of studies published on OOPE medicines burden with emphasis on government interventions. However,

there are many recent articles on economic burdens on medicines, but those don't involve government interventions which is crucial for the study objective, as a result, those studies couldn't be considered. In this study, the observations from the included studies are only picked up and comparisons with the OOPE burden on private healthcare were not performed, even though some of the included studies have comparisons. This study is not focused on private healthcare facilities majorly, irrespective of the government's control over them. One study, which was from the private hospital Kala Azar Medical Research Centre (KAMRC) for VL treatment cost OOPE burden is included (Meheus et al., 2006), and this hospital being private, is the only hospital providing care for VL patients in the endemic area and also a charity hospital. Additionally, the integrity of the authors' data collection and sources from a methodical point of view is not assessed. Furthermore, the cost/OOPE in the majority of the studies was self-reported, and there is a huge heterogeneity among the included studies, for which a meta-analysis is not feasible.

Notwithstanding its limitations, this study represents the first-ever attempt to address a crucial gap in the existing literature. The findings of this study make a valuable contribution to the current understanding of the effects of government interventions aimed at mitigating financial risks associated with medicines in India.

## 4.6 Conclusions

This study presents a systematic review of the initiatives undertaken by the Government of India and its provinces over the past 17 years to minimize financial risks associated with medicine expenses. Despite the existence of various policies aimed at addressing out-of-pocket expenses (OOPE) related to medicines, healthcare expenditure remains a catastrophic financial burden for many Indians, particularly those in lower-income households. The findings suggest a need for further research to explore the underlying causes of high OOPE, especially

medicines-related expenses. It is imperative for the government to consider increasing public health expenditure and examine innovative strategies to improve healthcare financing, with a focus on aiding vulnerable and impoverished populations. Current policies should be revisited and potentially revised to better meet these objectives. The study underscores the significant financial strain OOPE for medicines places on individuals and families, highlighting the urgent need for the development of healthcare policies that ensure affordable and accessible services for all citizens, thereby preventing catastrophic financial consequences.

## 4.7 Strategic Recommendations Based on the Study's Findings

- ✓ The OOPE burden on medicines is increasing: increasing public health spending can address this issue.
- ✓ Increasing healthcare financing towards more affordable healthcare for vulnerable populations.
- ✓ Updating and reviewing the currently available healthcare policies to ensure accessible and affordable medicines.
- ✓ Implementing preventative care that leads to less long-term medical spending and out-of-pocket payments.
- ✓ Strengthening drug price regulations, and ensuring that the essential medicines are available at affordable prices, especially in the private healthcare sector.
- ✓ Creating and implementing affordable healthcare options through public-private partnerships that can leverage resources, expertise, and technology.
- ✓ Continuous monitoring to evaluate the impacts of healthcare spending and policies on a regular basis.