

# APPENDIX A

## The detailed Search Strategy of Individual Databases (Chapter 4)

### Full electronic Search Strategy for each of the databases (Searched on 19/11/2022)

#### PubMed

ID	Search
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#1 - **(Government Keyword)** - "Government Schemes"[tw] OR "Government Spending"[tw] OR "Government Initiatives"[tw] OR "Government Policy"[tw] OR "Government Policies"[tw] OR "Union Government"[tw] OR "Central Government"[tw] OR "State Government"[tw] OR "Regional Government"[tw] OR "Public Schemes"[tw] OR "Public Scheme"[tw] OR "Public Financing"[tw] OR "Public Subsidy"[tw] OR "Public Subsidies"[tw] OR "Health Budget"[tw] OR "Government Subsidy"[tw] OR "Government Subsidies" OR Policy[tw] OR Policies[tw].

#2 - **(Government Mesh term)** - ("Policy"[Mesh] OR "Public Policy"[Mesh] OR "Policy Making"[Mesh] OR "Health Policy"[Mesh] OR "Fiscal Policy"[Mesh]) OR ("Government"[Mesh] OR "State Government"[Mesh] OR "Local Government"[Mesh] OR "Government Programs"[Mesh] OR "Government Agencies"[Mesh] OR "Financing, Government"[Mesh]).

#3 - **(Out-Of-Pocket Expenditures Keyword)** - "Out-Of-Pocket"[tw] OR "Out-Of-Pockets"[tw] OR OOP[tw] OR OOPs[tw] OR OOPE[tw] OR Catastrophic[tw] OR Catastrophic\*[tw] OR "Household Out-Of-Pocket"[tw] OR "Financial"[tw] OR "Utilisation"[tw] OR "Health expenditures"[tw] OR "Health care cost"[tw] OR "Drug cost"[tw] OR Expenditures[tw] OR Expenditure[tw] OR Spending[tw] OR Spend[tw] OR Spends[tw] OR Spent[tw] OR Spents[tw] OR Expense [tw] OR Expen\*[tw] OR Cost[tw] OR Cost\*[tw].

#4 - **(Out-Of-Pocket Expenditures Mesh term)** - (("Health Expenditures"[Mesh]) OR ("Public Expenditures"[Mesh] OR "Financing, Personal"[Mesh])) OR "Drug Costs"[Mesh].

#5 - **(Medicines Keyword)** - Medicine[tw] OR Medicines[tw] OR Drug[tw] OR Drugs[tw] OR Medication[tw] OR Medications[tw] OR "Prescription drug" [tw] OR "Pharmaceutical" [tw] OR Polypharmacy[tw].

#6 - **(Medicines Mesh term)** - ("Nonprescription Drugs"[Mesh] OR "Medicine"[Mesh] OR "Biological Products"[Mesh] OR "Herbal Medicine"[Mesh]) OR ("Pharmaceutical Preparations"[Mesh] OR "Prescription Drugs"[Mesh] OR "Veterinary Drugs"[Mesh] OR "Drugs, Essential"[Mesh] OR "Drugs, Generic"[Mesh]).

#7 - **(India Keyword)** - India[tw] OR Indian[tw] OR India's[tw] OR Indians[tw] OR "Indian Subcontinent" [tw] OR "Indian Sub-continent" [tw].

#8 - **(India Mesh term)** - "India"[Mesh].

#9 - #1 OR #2.

#10 - #3 OR #4.

#11 - #5 OR #6.

#12 - #7 OR #8.

#13 - #9 AND #10 AND #11 AND #12.

Limit to English AND Full Text AND from 2000/1/1 - 2022/11/19.

## **Cochrane**

### **ID**

### **Search**

#1 ("Government Schemes"):ti,ab,kw OR ("Government Spending"):ti,ab,kw OR ("Government Initiatives"):ti,ab,kw OR ("Union Government"):ti,ab,kw OR ("Central Government"):ti,ab,kw (Word variations have been searched).

#2 ("State Government"):ti,ab,kw OR ("Regional Government"):ti,ab,kw OR ("Public Schemes"):ti,ab,kw OR ("Public Financing"):ti,ab,kw OR ("Public Subsidy"):ti,ab,kw (Word variations have been searched).

#3 ("Health Budget"):ti,ab,kw OR ("Government Subsidy"):ti,ab,kw OR ("Policies"):ti,ab,kw OR ("Policy"):ti,ab,kw OR ("Policy Making"):ti,ab,kw (Word variations have been searched).

#4 ("Public Policy"):ti,ab,kw OR ("Local Government"):ti,ab,kw OR ("Government Agencies"):ti,ab,kw OR ("Financing, Government"):ti,ab,kw OR ("Government Programs"):ti,ab,kw (Word variations have been searched).

#5 #1 OR #2 OR #3 OR #4.

#6 ("Out-Of-Pocket"):ti,ab,kw OR ("OOP"):ti,ab,kw OR ("OOPs"):ti,ab,kw OR ("OOPE"):ti,ab,kw OR ("Catastrophic"):ti,ab,kw (Word variations have been searched).

#7 ("Household Out-Of-Pocket"):ti,ab,kw OR ("Financial"):ti,ab,kw OR ("Utilisation"):ti,ab,kw OR ("Health expenditures"):ti,ab,kw OR ("Health care cost"):ti,ab,kw (Word variations have been searched).

#8 ("Drug cost"):ti,ab,kw OR ("Expenditures"):ti,ab,kw OR ("Spending"):ti,ab,kw OR ("Spend"):ti,ab,kw OR ("Spent"):ti,ab,kw (Word variations have been searched).

#9 (“Expense”):ti,ab,kw OR (“Cost”):ti,ab,kw OR (“Price”):ti,ab,kw OR (“Health Expenditures”):ti,ab,kw OR (“Financing, Personal”):ti,ab,kw (Word variations have been searched).

#10 #6 OR #7 OR #8 OR #9.

#11 (“Medicine”):ti,ab,kw OR (“Medicines”):ti,ab,kw OR (“Drug”):ti,ab,kw OR (“Drugs”):ti,ab,kw OR (“Medication”):ti,ab,kw (Word variations have been searched).

#12 (“Medications”):ti,ab,kw OR (“Prescription drug”):ti,ab,kw OR (“Pharmaceutical”):ti,ab,kw OR (“Polypharmacy”):ti,ab,kw OR (“Nonprescription Drugs”):ti,ab,kw (Word variations have been searched).

#13 (“Biological Products”):ti,ab,kw OR (“Herbal Medicine”):ti,ab,kw OR (“Pharmaceutical Preparations”):ti,ab,kw OR (“Drugs, Essential”):ti,ab,kw OR (“Drugs, Generic”):ti,ab,kw (Word variations have been searched).

#14 #11 OR #12 OR 13

#15 (“India”):ti,ab,kw OR (“Indian”):ti,ab,kw OR (“India’s”):ti,ab,kw OR (“Indians”):ti,ab,kw OR (“Indian Subcontinent”):ti,ab,kw (Word variations have been searched).

#16 (“Indian Sub-continent”):ti,ab,kw OR (“Hindustan”):ti,ab,kw OR (“Bharat”):ti,ab,kw (Word variations have been searched).

#17 #15 OR # 16.

#18 #5 AND #10 AND #14 AND #17.

## **Scopus (TITLE-ABS-KEY)**

<b>ID</b>	<b>Search</b>
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#1 - "Government Schemes" OR "Government Spending" OR "Government Initiatives" OR "Government Policy" OR "Government Policies" OR "Union Government" OR "Central Government" OR "State Government" OR "Regional Government" OR "Public Schemes" OR "Public Scheme" OR "Public Financing" OR "Public Subsidy" OR "Public Subsidies" OR "Health Budget" OR "Government Subsidy" OR "Government Subsidies" OR policy OR policies.

#2 - "Out-Of-Pocket" OR "Out-Of-Pockets" OR oop OR oops OR oope OR catastrophic OR catastrophic\* OR "Household Out-Of-Pocket" OR "Financial" OR "Utilisation" OR "Health expenditures" OR "Health care cost" OR "Drug cost" OR expenditures OR expenditure OR spending OR spend OR spends OR spent OR spends OR expense OR expen\*or AND cost OR cost\*.

#3 - Medicine OR medicines OR drug OR drugs OR medication OR medications OR "Prescription drug" OR "Pharmaceutical" OR polypharmacy.

#4 - India OR indian OR india's OR indians OR "Indian Subcontinent" OR "Indian Subcontinent".

#5 - #1 AND #2 AND #3 AND #4.

## **Google Scholar**

"Government efforts" OR "Government initiatives" OR "Government interventions" OR "Public policy measures" OR "Healthcare financing" AND

"Out-of-pocket expenditures" OR "Out-of-pocket costs" OR "Out-of-pocket healthcare expenses" OR "Out-of-pocket spending" AND

"Medicines" OR "Pharmaceuticals" OR "Prescription drugs" OR "Medication costs" AND

"India" OR "Indian" OR "Indian provinces" OR "States in India" OR "Regional governments"

### **Grey Literature (only on India Sites, Manually Searched)**

#1 - "Government efforts" OR "Government initiatives" OR "Government interventions" OR  
"Public policy measures" OR "Healthcare financing".

#2 - "Out-of-pocket expenditures" OR "Out-of-pocket costs" OR "Out-of-pocket healthcare  
expenses" OR "Out-of-pocket spending".

#3 - "Medicines" OR "Pharmaceuticals" OR "Prescription drugs" OR "Medication costs".

### **Full account of how the Grey Literature was Searched**

When conducting a grey literature search, a systematic approach was used. It typically involved identifying relevant sources such as specialized databases, Institutions and organizations focused on healthcare research, and official websites of government departments and agencies. By formulating appropriate search terms and utilizing keywords related to the research topic, comprehensive searches were conducted manually with each specific set of keywords by using the “OR” operator, and with/without the use of the “AND” operator. Moreover, all searches about grey literature were done on Indian databases and websites only. For each hit, the screening to check the eligibility concerning our research question were did manually. Unfortunately, there was no literature included in the review, as the search results didn’t pick any literature that answers the specific review questions other than some duplicates. The details of the databases and sites are as follows.

**Database - Shodhganga:** It is a repository of Indian theses and dissertations that includes a significant amount of grey literature related to various subjects. Website: <https://shodhganga.inflibnet.ac.in/>.

**Database - The Digital Library of India (DLI):** It is a digital repository of books, manuscripts, and other literary works that are in the public domain or have been made available for free access. Website: <https://ndl.iitkgp.ac.in/>.

### **Official websites of government departments and agencies in India -**

***The Ministry of Health and Family Welfare (MoHFW):*** It is a government ministry in India that is responsible for formulating and implementing health and family welfare policies. Its main objective is to provide accessible, affordable, and quality healthcare services to the citizens of India. Website: [www.mohfw.gov.in](http://www.mohfw.gov.in). The search was conducted in Google concerning the above site by typing the keywords followed by 'site:www.mohfw.gov.in' in the Google search bar.

***The Ministry of Finance (MoF):*** It is a government ministry in India responsible for the formulation and implementation of financial and economic policies. Its primary objective is to maintain and enhance economic stability, promote sustainable growth, and ensure fiscal discipline. Website: [www.finmin.nic.in](http://www.finmin.nic.in). The search was conducted in Google concerning the above site by typing the keywords followed by 'site:www.finmin.nic.in' in the Google search bar.

***The National Health Authority (NHA):*** It is an organization in India that is responsible for implementing and overseeing the Pradhan Mantri Jan Arogya Yojana (PMJAY), also known as Ayushman Bharat. PMJAY is a flagship health insurance scheme that aims to provide access to quality healthcare services to economically disadvantaged families in India. The website

serves as a comprehensive platform to provide information and resources related to PMJAY and other healthcare initiatives undertaken by the NHA. Website: [www.pmjay.gov.in](http://www.pmjay.gov.in). The search was conducted in Google concerning the above site by typing the keywords followed by 'site:www.pmjay.gov.in' in the Google search bar.

**Indian research institutes, think tanks, and non-governmental organizations working in the field of healthcare or public health –**

***The Public Health Foundation of India (PHFI)***: It is an independent organization working towards strengthening public health in India. It is a public-private partnership that focuses on policy advocacy, capacity building, research, and implementation of programs to address public health challenges. Website - [www.phfi.org](http://www.phfi.org). The search was conducted in Google concerning the above site by typing the keywords followed by 'site:www.phfi.org' in the Google search bar.

***The Indian Council of Medical Research (ICMR)***: It is the apex body in India responsible for the formulation, coordination, and promotion of biomedical research. It is one of the oldest and largest medical research organizations in the world, contributing significantly to the field of scientific research and healthcare in India. Website - [www.icmr.gov.in](http://www.icmr.gov.in). The search was conducted in Google concerning the above site by typing the keywords followed by 'site:www.icmr.gov.in' in the Google search bar.

***The All-India Institute of Medical Sciences (AIIMS)***: It is a prestigious medical institution in India that offers undergraduate and postgraduate medical education, conducts medical research, and provides specialized healthcare services. It is considered one of the premier medical institutes in the country. The website showcases the research activities and achievements of AIIMS, and details about ongoing research projects, publications, collaborations, and conferences organized by the institute. Website - [www.aiims.edu](http://www.aiims.edu). The

search was conducted in Google concerning the above site by typing the keywords followed by 'site:www.aiims.edu' in the Google search bar.

***The Centre for Policy Research (CPR):*** It is one of India's leading public policy think tanks, committed to deepening the understanding of public policies and processes to promote informed dialogue and effective governance. It has a prolific body of research in areas such as economics, politics, education, environment, law, urbanization, international relations, and more. Website - [www.cprindia.org](http://www.cprindia.org). The search was conducted in Google concerning the above site by typing the keywords followed by 'site:www.cprindia.org' in the Google search bar.

***The Population Foundation of India (PFI):*** It is a non-governmental organization that aims to promote effective formulation and implementation of gender-sensitive population, health, and development strategies and policies. It includes resources such as research papers, reports, and publications that provide insights into population trends, health indicators, and social development issues in India. Website - [www.populationfoundation.in](http://www.populationfoundation.in). The search was conducted in Google concerning the above site by typing the keywords followed by 'site:www.populationfoundation.in' in the Google search bar.

***The Indian Council of Social Science Research (ICSSR):*** It is a governmental body in India that promotes research in the field of social sciences. It aims to review the progress of social science research and sponsor research studies that are of vital importance to society and the nation. It hosts a host of publications including research reports, seminar proceedings, journals, and other related material authored by ICSSR or other affiliated entities. Website - [www.icssr.org](http://www.icssr.org). The search was conducted in Google concerning the above site by typing the keywords followed by 'site:www.icssr.org' in the Google search bar.

***The Voluntary Health Association of India (VHAI):*** It is a non-profit organization dedicated to improving the health and well-being of individuals in India. It provides information about

their various programs, initiatives, and campaigns aimed at promoting public health and addressing key health issues in the country. Website - [www.vhai.org](http://www.vhai.org). The search was conducted in Google concerning the above site by typing the keywords followed by 'site:www.vhai.org' in the Google search bar.

***The Indian Public Health Association (IPHA):*** It is a professional association that focuses on promoting public health in India. It serves as a platform for sharing information on public health initiatives, research, policy advocacy, and training opportunities. Website - [www.iphaonline.org](http://www.iphaonline.org). The search was conducted in Google concerning the above site by typing the keywords followed by 'site:www.iphaonline.org' in the Google search bar.

### **List of the 56 articles Excluded with Reasoning for Exclusion**

<b>S. No</b>	<b>Research Article – First Author</b>	<b>Reason for Exclusion</b>
<b>No Defined Outcome (n=20)</b>		
1.	Williams 2011 [1]	The study focuses on auditing antibiotic prescribing patterns in an ICU and not addressed OOPE and Govt Intervention, and not directly align with the objective of this systematic review.
2.	Roy 2012 [2]	The study is about the cost variability of medicines among different private pharmacies and does not directly align with this objective.
3.	Dror 2012 [3]	The study on RSBY shares a common context of healthcare financing, and does not directly address the impact of out-of-pocket expenditures on medicines, making it distinct from the focus of this systematic review.
4.	Kotwani 2013 [4]	The study focused on data on procurement cost and availability of medicines by medical corporations and compared them with international reference prices.

5.	Little 2014 [5]	The study focused on the costs and consequences of using interferon-gamma release assays (IGRAs) for the diagnosis of active tuberculosis (TB) and was not directly aligned with the objective of the study.
6.	Megiddo 2014 [6]	The study assesses the cost-effectiveness of different treatment and preventive measures for acute myocardial infarction (AMI) in India, but not on OOPe.
7.	Abbas 2014 [7]	The study focuses on the costs of implementing different interventions for controlling rabies in Tamil Nadu, India. It assesses the financial implications of various interventions for both human and animal populations in combating rabies, and not directly align with the objective of this systematic review.
8.	Bose 2015 [8]	The study examines the utilization of inpatient care by different socio-economic groups, regions, and gender, and not directly align with the objective of this systematic review.
9.	Peasah 2015 [9]	The study examines the costs associated with acute respiratory infections (ARI) in north India, lacks categorization in data tables and interpretation on medicines in particular.
10.	Dror 2016 [10]	The study is about self-medication practice and the financial position between community-based health insurance (CBHI) insured and uninsured.
11.	Megiddo 2016 [11]	The study focuses on the health and economic benefits of publicly financed national epilepsy programs, it does not specifically address the burden of out-of-pocket expenditures on medicines, and moreover, it is a simulation study.
12.	Sharma 2016 [12]	The insulin access study focuses on insights into the availability, prices, and market dynamics of insulin in the private sector, and its scope differs from this systematic review.

13.	Mukherjee 2017 [13]	The study focuses on comparing the cost of generic medicines under the Jan Aushadhi (Medicine for the Masses) Scheme (JAS) with cheaply available branded medicines and not directly aligned with this review objective.
14.	Gwatidzo 2017 [14]	The study found that diabetes medication use was not a statistically significant predictor of catastrophic healthcare expenditure on medications in India. A study that does not establish a significant relationship between medication use and expenditure may not provide relevant insights for this review.
15.	Prinja 2017 [15]	The HPV vaccination study specifically evaluates the cost-effectiveness of the vaccination program and does not align directly with the research question and criteria set for this systematic review.
16.	Sarangi 2018 [16]	The study specifically examines cost variations among neuropsychiatric drugs in the Indian market and no evaluation on OOPE burden, and does not directly align with the research question and criteria set for this systematic review.
17.	Chaillon 2019 [17]	The study focuses on the cost-effectiveness and budgetary impact of HCV treatment in India, specifically addressing concerns surrounding reinfection and the availability of low-cost direct-acting antivirals, and it does not directly align with the research question and criteria set for this systematic review.
18.	Rout 2019 [18]	The study examines out-of-pocket expenditures for maternal and child health services and not on medicines, it does not directly align with the research question and objectives of this systematic review.
19.	Sawers 2020 [19]	The study focused on the economic costs and benefits of alleviating chronic lymphedema in the context of lymphatic filariasis and the benefits of implementing limb care

		programs and not directly align with the objective of this systematic review.
20.	Behera 2021 [20]	The study focused on the overall economic burden of NCDs on households and did not evaluate the Medicine OOPe and lacks categorization in data tables and interpretation on medicines in particular.
<b>Articles Before 2000 (n=12) *</b>		
21.	Ramaiah 2000 [21]	Data was obtained from the years 1998 and 1999 sources.
22.	Shobhana 2000 [22]	Data collected was for the past one-year period from 1998 (The study article communicated year).
23.	Singh 2000 [23]	Study year 1996-97.
24.	Shobhana 2000 [24]	Study period between January to June 1998.
25.	Murthy 2001 [25]	Study conducted in 1998.
26.	Thomas 2001 [26]	Study data obtained in 1998.
27.	Garg 2001 [27]	Study based on data between 1993-94.
28.	Bhatia 2001 [28]	Study conducted in 1993.
29.	Babu 2002 [29]	Study on 1999-2000.
30.	Ray 2002 [30]	Study period between September 1998 to August 1999.
31.	Rajagopal 2003 [31]	Studied for last 17 years back from 2003.
32.	Pandav 2012 [32]	Study during 1990.
<b>Outside India (n=17) **</b>		
33.	Marshall 2002 [33]	British Columbia - Study Setting
34.	Hutchinson 2006 [34]	United States of America - Study Setting
35.	Zarkin 2008 [35]	United States of America - Study Setting
36.	Wirtz 2012 [36]	Mexico - Study Setting
37.	Mujinja 2014 [37]	Tanzania - Study Setting
38.	Jia 2016 [38]	China - Study Setting
39.	Khan 2017 [39]	Swaziland, Africa - Study Setting
40.	Morgan 2018 [40]	Australia - Study Setting
41.	He 2018 [41]	China - Study Setting
42.	Aljunid 2018 [42]	Malaysia - Study Setting
43.	Kuhl 2019 [43]	Kenya and Uganda - Study Setting
44.	Pisu 2019 [44]	United States of America - Study Setting

45.	Bodajko-Grochowska 2020 [45]	Poland - Study Setting
46.	Debellut 2022 [46]	Niger, West Africa - Study Setting
47.	Serván-Mori 2022 [47]	Bangladesh - Study Setting
48.	Wirtz 2022 [48]	Kenya - Study Setting
49.	Ismaïl 2022 [49]	Tunisia - Study Setting
<b>Review/Systematic Review (n=7)</b>		
50.	Kumarasamy 2007 [50]	Review
51.	Azad 2007 [51]	Review
52.	Green 2010 [52]	Systematic review
53.	Acosta 2014 [53]	Systematic review
54.	Nandi 2015 [54]	Review
55.	Gheorghe 2018 [55]	Systematic review
56.	Sum 2018 [56]	Systematic review

\* Actually study /study data before 2000, and got published on or after 2000.

\*\* Initially considered as multinational study for eligibility assessment because automated tools picked them up, but found no Indian context available.

### **References (List of the 56 articles excluded with reasoning for exclusion)**

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## **APPENDIX B**

### **TB Drug Therapy Challenges (Chapter 5)**

#### **Format for the Assessment of the Burden of OOPE on Medicines of TB Drug Therapy**

#### **QUANTITATIVE ANALYSIS - Informed Consent and Information Sheet**

##### **Consent Form**

The study has been described to me in a language that I understand, and I freely and voluntarily agree to participate. My questions about the study have been answered. I understand that my identity will not be disclosed and that I may withdraw from the study without giving a reason at any time and this will not negatively affect me in any way. I understand there will be no reimbursement for participation.

At all times the researcher will keep the source of the information confidential and refer to me and my words by a number or invented name. The written transcripts or notes of the actual survey & interview will only be released to supervisors who will assist in the data analysis, the number of the invented name will be used in these transcripts.

I understand the procedure. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form in English/Hindi.

I consent to partake in this study, as well as I give my concern to publishing the results.

---

**Participant Signature/Thumb Impression & Name**

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**Date**

---

**Investigator/Data Collector/Data Entry Staff's Signature & Name**

---

**Date**

## Background Information for Health Facility

### Facility Identification

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Name of the Health Facility

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Facility Code (To be filled by  
Investigators)

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Type of Health Facility

- Government Health Care Facility
- Private Health Care Facility

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Level of Health Facility\*

- Primary Care
- Community Health Care
- Medical College Hospital/Tertiary Care
- District Hospital/Quaternary Care

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\*Applies to both Types of Health Care facilities.

### **Part I. Self-administered questionnaire for the data collection on the Burden of Medicine OOPE in People living with TB**

**Purpose:** This study is designed to determine the Burden of Medicine OOPE in People living with TB in selected public & private health facilities of Agra district, UP, India by assessing the Healthcare Service Utilization, Availability, Accessibility, Affordability, OOPE on Medicines, and Health Policy Benefits. Your participation is very important to the successful completion of this study. Please be frank in filling out this questionnaire/responding to the questionnaire, as it will be solely used for research purposes. This survey will be confidential,

and anonymous, and data will be analyzed in aggregates. The Data entry staff can assist in filling out the questionnaire for the respondents, whose education level is none/lower.

## SECTION 1

### **Socio-demographic and Medical Characteristics, and OOPE of the study participants, including policy measures**

Q1. Name of respondents

Ans:

Q2. Residence

- Rural
- Urban

Q3. Sex

- Male
- Female

Q4. Age of Respondent

- <15
- 15-30
- 31-45
- >45

Q5. Education Level of Respondent

- None
- High School or Below
- Higher Secondary or Diploma
- Degree/Graduates or Above

Q6. Occupation

- Casual Labour
- Cultivator
- Home Maker
- Employed (Salaried)
- Employed (Self)
- Student

Q7. Monthly Family Income

- <5000 INR
- 5001-10000 INR
- 10001-15000 INR
- >15000 INR

Q8. Active TB Stage?

- Primary Infection

- Pulmonary
- Extra Pulmonary
- Multidrug-resistant TB (MDR)
- Active TB with Comorbidities

Q9. Has everyone in the family been screened?

- Yes
- No

Q10. If yes to Q9, then the number of TB cases?

- 0
- 1
- 2
- 3
- 4

Q11. Are all the family members taking Tuberculosis Preventive Treatment (TPT)?

- Yes
- No

## SUB-SECTION 1

### If respondents availing services in a public healthcare facility

Q12. OPD visit/consultation charges per visit

- Free of Charge
- <500 INR
- 501-1000 INR
- >1000 INR

Q13. Expenses in the diagnosis of TB

- Free of Charge
- <500 INR
- 501-1000 INR
- 1001-2000 INR
- >2000 INR

Q14. Are all medicines available in the hospital?

- Yes
- No

If NO, where did the patients get the medicine?

- Other Government Hospital
- Private Medical Store
- Other

Q15. Is all medicine affordable?

- Yes
- No

Q16. Expenditure on medicine every month?

- Free of Charge
- <500 INR
- 501-1000 INR
- 1001-2000 INR
- >2000 INR

Q17. Expenditure of respondent in case of hospitalization Multidrug-resistant (MDR)?

- Free of Charge
- <3000 INR
- 3001-5000 INR
- >5000 INR

Q18. Expenses of the respondent on vitamins and supplements?

- Free of Charge
- <2000 INR
- 2001-4000 INR
- 4001-10000 INR

- >10000 INR

Q19. Other Expenses

- <500 INR
- 500-1000 INR
- 1001-2000 INR
- >2000 INR

Q20. How Many times do respondents visit hospitals every month?

- One
- Two
- Three
- Four & Above

Q21. Has the respondent received 500 INR/month for nutrition from the Government as aid?

- Yes
- No

Q22. Respondent's source of expenditure on TB

- Daily Wages
- Family Dependent
- Farming
- Government Aid
- Insurance
- Loan
- Salary
- Savings
- Business

Q23. Was a Frontline Health Worker (ASHA/AWW) contacted during the Treatment Period?

- Yes
- No

Q24. Frontline Health Worker visits to Patient Home?

- None Visited
- TB Health Visitor
- Asha Worker
- Senior Treatment Supervisor
- Any Other from the Health Department

## SUB-SECTION 2

### If respondents availing services in a private healthcare facility

Q25. OPD visit/consultation charges per visit

- Free of Charge
- <500 INR
- 501-1000 INR
- >1000 INR

Q26. Expenses in the diagnosis of TB

- Free of Charge
- <500 INR
- 501-1000 INR
- 1001-2000 INR
- >2000 INR

Q27. Are all medicines available in the hospital?

- Yes
- No

If NO, where did the patients get the medicine?

- Other Government Hospital
- Private Medical Store
- Other

Q28. Is all medicine affordable?

- Yes
- No

Q29. Expenditure on medicine every month?

- Free of Charge
- <500 INR
- 501-1000 INR
- 1001-2000 INR
- >2000 INR

Q30. Expenditure of respondent in case of hospitalization Multidrug-resistant (MDR)?

- Free of Charge
- <3000 INR
- 3001-5000 INR
- >5000 INR

Q31. Expenses of the respondent on vitamins and supplements?

- Free of Charge
- <2000 INR
- 2001-4000 INR
- 4001-10000 INR

- >10000 INR

Q32. Other Expenses

- <500 INR
- 500-1000 INR
- 1001-2000 INR
- >2000 INR

Q33. How Many times do respondents visit hospitals every month?

- One
- Two
- Three
- Four & Above

Q34. Has the respondent received 500 INR/month for nutrition from the Government as aid?

- Yes
- No

Q35. Respondent's source of expenditure on TB

- Daily Wages
- Family Dependent
- Farming
- Government Aid
- Insurance
- Loan
- Salary
- Savings
- Business

Q36. Was a Frontline Health Worker (ASHA/AWW) contacted during the Treatment Period?

- Yes
- No

Q37. Frontline Health Worker visits to Patient Home?

- None Visited
- TB Health Visitor
- Asha Worker
- Senior Treatment Supervisor
- Any Other from the Health Department

## **QUALITATIVE ANALYSIS - Informed Consent and Information Sheet**

### **Consent Form**

The study has been described to me in a language that I understand, and I freely and voluntarily agree to participate. My questions about the study have been answered. I understand that my identity will not be disclosed and that I may withdraw from the study without giving a reason at any time and this will not negatively affect me in any way. I understand there will be no reimbursement for participation.

At all times the researcher will keep the source of the information confidential and refer to me and my words by a number or invented name. The written transcripts or notes of the actual survey & interview will only be released to supervisors who will assist in the data analysis, the number of the invented name will be used in these transcripts.

I understand the procedure. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form in English/Hindi.

I consent to partake in this study, as well as I give my concern to publishing the results.

---

**Participant Signature/Thumb Impression & Name**

---

**Date**

---

**Investigator/Data Collector/Data Entry Staff's Signature & Name**

---

**Date**

## Background Information for Health Facility

### Facility Identification

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Name of the Health Facility

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Facility Code (To be filled by  
Investigators)

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Type of Health Facility  Government Health Care Facility  
 Private Health Care Facility

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Level of Health Facility\*  Primary Care  
 Community Health Care  
 Medical College Hospital/Tertiary Care  
 District Hospital/Quaternary Care

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\*Applies to both Types of Health Care facilities.

### Part I. Self-administered questionnaire for the data collection on the Burden of Medicine

#### OOPE in People living with TB

Purpose: This study is designed to determine the Burden of Medicine OOPE in People living with TB and to identify its contributing factors in selected public & private health facilities of Agra district, UP, India. Your participation is very important to the successful completion of this study. Please be frank in filling out this questionnaire, as it will be solely used for research purposes. This survey will be confidential, and anonymous, and data will be analyzed in aggregates. The Data entry staff can assist in filling out the questionnaire for the respondents, whose education level is none/lower.

## Section 1: Socio-demographic Characteristics of Respondents

This section contains questions that enable us to understand your answers to the other sets of questions in the next section.

Sex     M      F

Age in Years - \_\_\_\_\_

### Respondent's Role

- i.     Specialist
- ii.    General Practitioner
- iii.    Pharmacist
- iv.    Store Manager  
       (Pharmacy)
- v.     Health Officer
- vi.    Asha Worker
- vii.    Patient
- viii.   Patient Relatives
- ix.    Others (Specify)              \_\_\_\_\_

Total service (in Yrs) \_\_\_\_\_ (Other-than Patient & Patient Relatives)

**Section 2: Questions on Perceived factors contributing to the Burden of Medicine OOPE on People living with TB**

In this section, you are going to be asked about your feelings about factors contributing to the burden of OOPE on Medicines. For each statement below, please encircle one number which best describes the level of your agreement (0=Not Applicable [NA]; 1=Strongly Disagree [SD]; 2=Disagree [D]; 3= Neutral-N [Neither agree nor disagree]; 4= Agree [A] and 5= strongly Agree [SA]).

S.No	Perceived Factors	NA	SD	D	N	A	SA
1	TB disease prevalence or incidence itself is a major cause	0	1	2	3	4	5
2	Rising drug prices on medicines	0	1	2	3	4	5
3	Rising inflation	0	1	2	3	4	5
4	Govt spending on medicines is low	0	1	2	3	4	5
5	Govt not providing medicines free of cost in govt facilities	0	1	2	3	4	5
6	Medicines availability in govt hospitals is low	0	1	2	3	4	5
7	High-cost branded drugs are prescribed	0	1	2	3	4	5
8	Govt medical service utilization by the public is poor	0	1	2	3	4	5
9	Govt facility/infrastructure is poor & patients depend on private	0	1	2	3	4	5
10	Govt schemes in addressing OOPE are not adequate	0	1	2	3	4	5
11	Govt schemes in addressing OOPE are not reaching the public	0	1	2	3	4	5
12	Govt incentives on people living with TB are not sufficient	0	1	2	3	4	5
13	The majority of patients have not taken health insurance	0	1	2	3	4	5
14	Private medical service is good	0	1	2	3	4	5
15	Private medical service/Private medical store is the only cause	0	1	2	3	4	5
16	Real monthly disposable income per patient is very low	0	1	2	3	4	5
17	Delayed diagnosis and patient not following treatment plan lead to the increased burden on disease and OOPE	0	1	2	3	4	5

## **Part II. In-depth Interview (Respondents)**

In this section, the in-depth interview will be conducted, your oral answers will be recorded and analyzed to complete this study successfully.

### **Interview Guide (According to Respondent's Role)**

1. Tell me about the burden of OOPE on Medicines. (General View)?

Ans:

2. May you please explain what challenges you face in experiencing OOPE on medicines?

Ans:

3. What strategies you can undertake in improving the burden of OOPE on medicines?

Ans:

4. What do you think can be done differently at your treating health facility, if anything, to limit the burden of OOPE on medicines?

Ans:

5. What are your suggestions to the Government/Policy makers in reducing the burden of OOPE on medicines by the patients/households?

Ans:

## **APPENDIX C**

### **Financial Considerations in Pregnancy Outcomes (Chapter 6)**

#### **Format for the Assessment of the Financial Burden of OOPE on Pregnancy-Related Expenses**

#### **QUANTITATIVE ANALYSIS - Informed Consent and Information Sheet**

##### **Consent Form**

The study has been described to me in a language that I understand, and I freely and voluntarily agree to participate. My questions about the study have been answered to my satisfaction. I understand that my identity will not be disclosed and that I can withdraw from the study at any time without giving a reason, and this will not negatively affect me in any way. I understand that there will be no reimbursement for participation.

At all times, the researchers will keep the source of the information confidential and refer to me and my words by a number or invented name. The written transcripts or notes of the actual survey and interview will only be released to supervisors who will assist in the data analysis, and the number of the invented name will be used in these transcripts.

I understand the procedure, and I consent to partake in this study. I also give my consent for the results to be published. I have been given a copy of this form in both English and Hindi for my records.

**Participant Signature/Thumb Impression & Name**

**Date**

**Investigator/Data Collector/Data Entry Staff's Signature & Name**

**Date**

## **Background Information for Health Facility for other than Home Deliveries**

### **Facility Identification**

Name of the Health Facility

Facility Code (To be filled by Investigators)

Type of Health Facility

- Government Health Care Facility
- Private Health Care Facility

Level of Health Facility\*

- Primary Care
- Community Health Care
- Medical College Hospital/Tertiary Care
- District Hospital/Quaternary Care

\*Applies to both Types of Health Care facilities.

### **Self-administered questionnaire for the data collection on the Burden of OOPE related to Pregnancy**

**Purpose:** This study is designed to determine the burden of Out-of-Pocket Expenditure (OOPE) during pregnancy and related healthcare in Agra district, UP, India. The study focuses on assessing healthcare service utilization, OOPE on pregnancy-related expenses, and health policy benefits in the context of socioeconomic and demographic correlates. Your participation is critical to the successful completion of this study. Please be honest in filling out this questionnaire/responding to the questions, as it will be used solely for research purposes. This survey will be confidential and anonymous, and data will be analyzed in aggregates. The data entry staff can assist in filling out the questionnaire for respondents whose education level is none or lower.

**Questionnaire for Socioeconomic, Demographic, Medical Characteristics, and OOPE of  
Study Participants**

**Part I: Demographic Information**

1. **ID:** (Automatically filled)
2. **Name of Block:**
3. **Name of Investigator (CHO):**
4. **Name of the Respondent:**
5. **Age Group of Respondent:**
  - 18-25
  - 26-35
  - 36-45
  - >45
6. **Level of Education of Respondent:**
  - None
  - High School or Below
  - Higher Secondary or Diploma
  - Degree/Graduates or Above
7. **Marital Status of Respondent:**
  - Single
  - Married
  - Divorced
  - Widowed

## **Part II: Medical and Health Information**

8. **Gravida of Respondent:** (Number of pregnancies):

9. **Occupation of Respondent:**

10. **Occupation of Respondent's Husband/Guardian:**

11. **Monthly Family Income:**

<5,000 INR

5,001-10,000 INR

10,001-15,000 INR

>15,000 INR

## **Part III: Health Service Utilization**

12. **Place of Getting Services:**

Government Facility

Private Facility

None

13. **Type of Delivery:**

Normal

Caesarean

14. **Number of Visits to Health Facility During Pregnancy:**

15. **Distance to Health Facility from Respondent Village:** (in KM)

**Part IV: Financial Information Regarding Health Services**

**16. Expenditure for OPD Visits/Consultation Charges Per Visit:**

**17. Expenditure in Transportation per ANC Visit:**

**18. Total Expenditure in Medicines and Supplies:**

**19. Expenditure in Laboratory Investigations:**

**20. Expenditure in Radiology Investigations:**

**21. Expenses in Newborn Care in the Hospital:**

**22. Expenditure on Nutrition:**

**23. Any Other Expenses:**

**24. Total Expenses in Pregnancy and Delivery:**

**25. Source of Money on Expenditure:**

- Daily Wages
- Farming
- Government Aid
- Insurance
- Loan
- Salary
- Savings
- Business

**Part V: Government Aid and Policy Interaction**

**27. Does Respondent Received JSY Benefit of 1400 Rupees:**

Yes

No

**28. Does ASHA Visit During Pregnancy:**

Yes

No

**Part VI: Consent and Confidentiality**

**Consent Form:**

I have been informed about the study, and I voluntarily agree to participate. I understand that my information will remain confidential and that I can withdraw at any time without any negative consequences.

**Participant Signature/Thumb Impression & Name:**

**Date:**

**Signature of Investigator/Data Collector:**

**Date:**

## **QUALITATIVE ANALYSIS - Informed Consent and Information Sheet**

### **Consent Form**

The study has been described to me in a language that I understand, and I freely and voluntarily agree to participate. My questions about the study have been answered. I understand that my identity will not be disclosed and that I may withdraw from the study without giving a reason at any time and this will not negatively affect me in any way. I understand there will be no reimbursement for participation.

At all times, the researcher will keep the source of the information confidential and refer to me and my words by a number or invented name. The written transcripts or notes of the actual survey & interview will only be released to supervisors who will assist in the data analysis, and the number of the invented name will be used in these transcripts.

I understand the procedure. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form in both English and Hindi.

I consent to partake in this study, as well as I give my consent to publishing the results.

**Participant ID (Used on Quantitative Study):**

**Participant Signature/Thumb Impression & Name**

**Date**

**Investigator/Data Collector/Data Entry Staff's Signature & Name**

**Date**

## **Self-administered questionnaire for the data collection on the Burden of OOPE related to Pregnancy-Related Expenses**

**Purpose:** This study is designed to determine the burden of Out-of-Pocket Expenditure (OOPE) during pregnancy and related healthcare in Agra district, UP, India. The study focuses on assessing healthcare service utilization, OOPE on pregnancy-related expenses, and health policy benefits in the context of socioeconomic and demographic correlates. Your participation is critical to the successful completion of this study. Please be honest in filling out this questionnaire/responding to the questions, as it will be used solely for research purposes. This survey will be confidential and anonymous, and data will be analyzed in aggregates. The data entry staff can assist in filling out the questionnaire for respondents whose education level is none or lower.

### Section 1: Perceived Factors Contributing to the Burden of OOPE on Pregnancy-Related Expenses

In this section, you are going to be asked about your feelings regarding factors that contribute to the burden of Out-of-Pocket Expenditure (OOPE) on Pregnancy-Related Expenses. For each statement below, please encircle one number which best describes the level of your agreement. **Rating Scale:** (1=Strongly Disagree [SD]; 2= Disagree [D]; 3= Neutral-N [Neither agree nor disagree]; 4= Agree [A] and 5= Strongly Agree [SA]).

S. No	Perceived Factors	SD	D	N	A	SA
1	Rising costs of prenatal and postnatal care services create a significant financial strain	1	2	3	4	5
2	Rising inflation increases the overall cost of pregnancy-related healthcare	1	2	3	4	5
3	Government spending on prenatal and postnatal care is insufficient	1	2	3	4	5
4	Prescriptions often include high-cost branded maternity drugs and supplies that are expensive	1	2	3	4	5
5	Limited availability of essential medicines and supplies in government hospitals leads to additional costs	1	2	3	4	5
6	Utilization of government maternity medical services is poor due to perceived inadequacies	1	2	3	4	5
7	Inadequate government maternity care facilities lead to a reliance on more expensive private services	1	2	3	4	5
8	Government schemes targeting the reduction of OOPE for maternity care are not sufficient	1	2	3	4	5
9	Government schemes for reducing OOPE in maternity care are not effectively reaching the target population	1	2	3	4	5
10	Most pregnant women do not have sufficient health insurance coverage to cover pregnancy-related expenses	1	2	3	4	5
11	Private maternity medical services are perceived to offer better quality of care compared to public services	1	2	3	4	5
12	Dependence on private maternity services, which are more costly, significantly contributes to OOPE	1	2	3	4	5
13	Low real monthly disposable income worsens the financial impact of pregnancy-related expenses	1	2	3	4	5

## **Section 2: In-depth Interview (Respondents)**

In this section, the in-depth interview will be conducted. Your oral answers will be recorded and analyzed to complete this study successfully.

### **Interview Guide (Adapted to the Study on Pregnancy-Related Expenses):**

1. Tell me about the burden of OOPE on pregnancy-related healthcare. (General View)?

Ans:

2. Can you please explain what challenges you face in experiencing OOPE on pregnancy-related healthcare?

Ans:

3. What strategies do you think can help in improving the burden of OOPE on pregnancy-related healthcare?

Ans:

4. What do you think can be done differently at your treating health facility, if anything, to limit the burden of OOPE on pregnancy-related healthcare?

Ans:

5. What are your suggestions to the Government/Policy makers in reducing the burden of OOPE on pregnancy-related expenses for patients/households?

Ans:

# APPENDIX D

## Public Drug Procurement Performance (Chapter 7)

### Data Collection Tool

#### Study on Procurement Performance on State Level Drug Procurement, Quality, Supply Chain Management, and Financial Management

#### Section I – General Information

Study State -		
S. No	Data Point	Value/Details
1	Population	
2	Total Health Budget 2021-22	
3	Budget Allocation for Medicines Supplies (2021-22) General Covid	
4	Year of Study/Data	<b>2020 - 2021</b>
5	Process/Procedure of Purchase of Medicines	
6	Responsibility of Medicine Procurement	
7	Autonomy of Procurement Agency	
8	Distribution Process	

**Section II – Medicine Availability**

<b>S. No</b>	<b>Data Point</b>	<b>Value/Details</b>
1	No. of medicines at PHC level	
2	No. of medicines at CHC level	
3	No. of medicines at District Hospital level	
4	No. of medicines at medical college level	
5	No. of Generic medicines used	
6	No. of formulations (If Generics used)	
7	No. of medicines in EML (Essential Medicine List)	
8	No. of Specialty drugs	
9	No. of drugs with multiple drugs, combination	
10	Total number of drugs	

### Section III – Purchase Process

<b>S. No</b>	<b>Data Point</b>	<b>Value/Details</b>
1	Type of Tendering Process	
2	Centralized/Decentralized	
3	Tender Fees	
4	Types of Suppliers Eligible	
5	GMP	
6	Time for submission of Tender	
7	Need of Pharmacist	
8	Sample Test for Evaluation of Technical Bid	
9	Volume of drugs in Annual Procurement Tender	
10	Market Standing	
11	Two bid system followed	
12	Annual Turnover	
13	Price Breakdown	
14	Earnest Money Deposit	
15	Management Cost	
16	Penalty clause for supply default	

#### Section IV – Quality Control Process

S. No	Data Point	Value/Details
1	Quality Control Parameters defined	
2	Quality Assurance in Procurement	
3	Penalty clause for Quality default	
4	Company blacklisted for all tenders	
5	Company blacklisted for a particular product	
6	Type of tender	
7	Tender fees	
8	EMD	
9	Tender eligibility	
10	Annual turnover required	
11	Eligibility of Manufacturer	
12	GLP requirement	
13	Qualified personals	
14	Details of instruments	
15	Quality test parameters	
16	Inspection of laboratories	
17	Time duration of testing for tablets capsules	
18	Time duration of testing for IV fluids and Injections	
19	Laboratory blacklisted during the year	

## Section V – Expiry Drug Management

<b>S. No</b>	<b>Data Point</b>	<b>Value/Details</b>
1	Limit of expiry percentage every year	
2	Process of disposal of medicine	
3	Able to Achieve the Target every year	

## APPENDIX E

### List of Publications

#### Published/Accepted

1. **Manikandan Arumugam**, K M Noorulla, Mohd Yasir, Manish Kalwaniya, Swetlana Gautam, Hemalatha Siva. (2024) Socioeconomic and health policy challenges to the availability, accessibility, and affordability of drug therapy among people living with tuberculosis towards public and private hospitals in Agra district, Uttar Pradesh, India: a cross-sectional study. *Frontiers in Health Informatics*, 13 (3), 4624-4636. (Scopus Indexed, Published).
2. **Manikandan Arumugam**, KM Noorulla, Mohd Yasir, Manish Kalwaniya, Hemalatha Siva (2024) Financial burdens of pregnancy: Understanding socioeconomic, demographic correlates and out-of-pocket costs. *Research J. Pharm. and Tech.*, 17 (12), xxx, (Scopus Indexed, Accepted).

#### Under Communication

1. **Manikandan Arumugam**, KM Noorulla, Mohd Yasir, Hemalatha Siva. Evaluating the impact of the Government efforts of India and its Provinces on the burden of out-of-pocket expenditures on medicines: a systematic review – (*Current Issues in Pharmacy and Medical Sciences*) - (Scopus Indexed, Communicated).
2. **Manikandan Arumugam**, Vinay Kumar Gupta, Hemalatha Siva. Public Drug Procurement and Distribution in India: A Performance Assessment Study Across Seven Different States from Diverse Geographic Regions – (*Research Journal of Pharmacy and Technology*) - (Scopus Indexed, Communicated).

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