Public Procurement, Policy, Socioeconomic Challenges, and Healthcare Burden in India: An Integrated Study on Medicine Distribution, Costs, and Out-of-Pocket Expenditures

Thesis submitted in partial fulfilment

for the Award of Degree

Doctor of Philosophy

By

Manikandan Arumugam

Department of Pharmaceutical Engineering and Technology

Indian Institute of Technology

Banaras Hindu University

Varanasi-221005

21161014 **2024**

CERTIFICATE

It is certified that the work contained in the thesis titled **"Public Procurement, Policy, Socioeconomic Challenges, and Healthcare Burden in India: An Integrated Study on Medicine Distribution, Costs, and Out-of-Pocket Expenditures"** by **Manikandan Arumugam** has been carried out under my supervision and that this work has not been submitted elsewhere for a degree.

It is further certified that the student has fulfilled all the requirements of Comprehensive Examination, Candidacy, and SOTA for the award of Ph.D. Degree.

Prof (Dr) Hemalatha Siva

Head of the Department

(Supervisor)

DECLARATION BY THE CANDIDATE

I, **Manikandan Arumugam**, certify that the work embodied in this thesis is my own bonafide work and carried out by me under the supervision of **Prof (Dr) Hemalatha Siva** from July 2021 to December 2024, at the Department of Pharmaceutical Engineering and Technology, Indian Institute of Technology (BHU), Varanasi. The matter embodied in this thesis has not been submitted for the award of any other degree/diploma. I declare that I have faithfully acknowledged and given credits to the researchers wherever their works have been cited in my work in this thesis. I further declare that I have not willfully copied any other's work, paragraphs, text, data, results, etc., reported in journals, books, magazines, reports dissertations, theses, etc., or available at websites and have not included them in this thesis and have not cited as my own work.

Date:

Place: IIT (BHU), Varanasi

(Manikandan Arumugam)

DECLARATION BY THE SUPERVISOR

It is certified that the above statement made by the student is correct to the best of our knowledge.

Prof (Dr) Hemalatha Siva

Head of the Department

(Supervisor)

COPYRIGHT TRANSFER CERTIFICATE

Title of the Thesis : Public Procurement, Policy, Socioeconomic Challenges, and Healthcare Burden in India: An Integrated Study on Medicine Distribution, Costs, and Out-of-Pocket Expenditures.

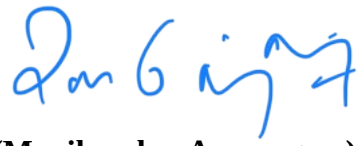
Name of the Student : Manikandan Arumugam

Copyright Transfer

The undersigned hereby assigns to the Indian Institute of Technology (Banaras Hindu University) Varanasi all rights under copyright that may exist in and for the above thesis submitted for the award of the **Doctor of Philosophy**.

Date:

Place: IIT (BHU), Varanasi



(Manikandan Arumugam)

Note: However, the author may reproduce or authorize others to reproduce material extracted verbatim from the thesis or derivative of the thesis for author's personal use provided that the source and the Institute's copyright notice are indicated.

ACKNOWLEDGEMENTS

I am very grateful to **Bharat Ratna Mahamana Pandit Madan Mohan Malaviya Ji** for providing such a divine platform. I extend my special thanks and gratitude to **Yogi Adityanath**, the Honorable Chief Minister of Uttar Pradesh, the Government of Uttar Pradesh, and the Government of India for granting me permission to pursue my Ph.D., enabling me to further my academic aspirations.

I thank my supervisor and HOD, **Prof. (Mrs.) Siva Hemalatha**, Department of Pharmaceutical Engineering & Technology, IIT (BHU), for her invaluable expertise, unwavering support, and inspiring mentorship throughout my research journey.

I would like to express my sincere gratitude to **Dr. Pramood Kumar Jain**, the then Director of IIT BHU, for his steadfast support and guidance in facilitating my Ph.D. registration. His encouragement was instrumental in embarking on this academic journey. I also thank **Dr. A.N. Sahu and Dr. Abha Mishra** (RPEC members) for their valuable insights and constructive evaluations. Their expertise and feedback have significantly shaped the direction and quality of my research.

I would like to express my gratitude to **Prof. Brahmeshwar Mishra, Prof. Sanjay Singh, Prof. S.K. Singh, Prof. Sushant Kumar Shrivastava, Prof. Sairam Krishnamurthy, Prof. Senthil Raja, Prof. M.S. Muthu, Dr. Ruchi Chawla, Dr. Gyan Prakash Modi, Dr. Vinod Tiwari, Dr. Sunil Kumar Mishra, Dr. Prasanta Kumar Nayak, Dr. Shreyansh Kumar Jain, Dr. Ashish Kumar Agrawal, Dr. Rajnish, Dr. Deepak Kumar, Dr. Dinesh Kumar, Dr. Jairam Meena, and Dr. Ashok Kumar**.

I extend my heartfelt gratitude to **Mr. S.P. Elangovan IAS (Retired), Mr. Umanath IAS,** Special Secretary to the Chief Minister of Tamil Nadu, **Mr. Devesh Chaturvedi IAS, Mr. Kanchan Verma IAS, Ms. Yamini Sarangi IAS, Ms. Poma Tuda IAS, Ms. Kartikeya Goel IAS, Mr. Muralidhar Reddy IAS, Mr. G.S. Naveen Kumar IAS, Ms. Anupuma Jorwal IAS, Mr. Balamurali IAS, and Mr. Akshath Verma IAS** for their encouragement and support during my Ph.D. journey.

I would like to express my heartfelt and special thanks to **Dr. K.M. Noorulla**, Associate Professor at Arsi University, Ethiopia, for his constant support, encouragement, and motivation throughout my Ph.D. journey.

I also acknowledge the **Technical and Non-technical staff** for their invaluable support throughout my Ph.D. journey.

I extend my special thanks to the **Medical Corporations and their Staffs** in Tamil Nadu, Kerala, Andhra Pradesh, Uttar Pradesh, Odisha, Rajasthan, and Chhattisgarh for their invaluable support in data collection during my Ph.D. journey. Your contributions have significantly enriched my research.

I would like to extend my special thanks to the **District Administration of Agra, CMO Agra, the Indian Medical Association (IMA Agra)**, and both public and private hospitals in Agra for their invaluable support throughout my Ph.D. journey.

I would also like to express my heartfelt gratitude to **Dr. J.P. Singh, Dr. Vinay Kumar, Dr. Selvaraj Sakthivel, Dr. Pawan Kumar, Dr. Gnana Prakash, Dr. Mohd Yasir, Mr. Manish Kalwaniya, Dr. Swetlana Gautam, Mr. Gagan Singh, and Kaushal Singh** for their expertise and guidance, which have significantly enriched my research experience.

My heartiest thanks to **Ms. Nikitha, Mr. Desh Deepak, Mr. Neeraj Kumar, Ms. Amrita, and Mr. Obulu -** research scholars who supported this project by sharing their knowledge, suggestions, and value addition.

Last but not least, my heartfelt thanks go to the **Almighty** for His blessings and guidance, and to my **family members**:

Special thanks to my wife, **Mrs. Tabitha Manikandan**, for her unwavering support and encouragement, and to my son, **Master Vishwanath**, whose joy and laughter have been a constant source of motivation throughout my Ph.D. journey.

I also thank **Mr. Arumugam, Mrs. Valli Arumugam, Mrs. Anandalakshme Elangovan, Mr. Samuel Suresh, Mrs. Prassunna, Mr. Sasi Kumar, Mrs. Sathya Sasikumar, Miss Vandita, Mr. Sasidharan, Miss Soundarya** for their unwavering love, support, and encouragement throughout my Ph.D.

Manikandan Arumugam

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF ABBREVIATIONS/ACRONYMS

ab - Abstract
ABS - Abstract
AIDS - Acquired Immunodeficiency Syndrome
AIIMS - All-India Institute of Medical Sciences
AML - Additional Medicines List
APMSIDC - Andhra Pradesh Medical Services & Infrastructure Development Corporation
ASHA - Accredited Social Health Activist
ATT - Anti-TB Therapy
AWW - Anganwadi Worker
BPG - Benzathine Penicillin G Injection
CBHI - Community-based Health Insurance
CDS - Centralized Drug Procurement
CES - Consumer Expenditure Surveys
cGMP - Current Good Manufacturing Practices
CGMSCL - Chhattisgarh Medical Services Corporation Limited
CHARLS - China Health And Retirement Longitudinal Study
CHC - Community Health Centers
CHE - Catastrophic Health Expenditure/Current Health Expenditure
CMO - Chief Medical Officer
CPR - Centre for Policy Research
DBT - Direct Benefit Transfers
DGGHE - Domestic General Government Health Expenditure
DLI - Digital Library of India
DM - Diabetes mellitus
DOT - Directly Observed Therapy
DOTS - Directly Observed Treatment, Short-Course
ECD - Elective Cesarean Delivery
EMD - Earnest Money Deposit
EML - Essential Medicines List
FCFS - First-Come, First-Serve
GDP - Gross Domestic Product
GGE - General Government Expenditure
GLP - Good Laboratory Practice
GMP - Good Manufacturing Practices
HIV - Human Immunodeficiency Virus

HMS - Health and Morbidity Survey
ICMR - Indian Council of Medical Research
ICSSR - Indian Council of Social Science Research
INR - Indian Rupees
IPHA - Indian Public Health Association
IQR - Inter-Quartile Range
IVF - *in-vitro* fertilization
JAS - Jan Aushadhi Scheme
JSY - Janani Suraksha Yojana
KAMRC - Kala-azar Medical Research Centre
KEY - Keywords
km - Kilometers
KMSCL - Kerala Medical Services Corporation Limited
KPIs - Key Performance Indicators
kw - Keywords
LMIC - Low- and Middle-Income Countries
MDR - Multidrug-resistant
MeSH - Medical Subject Headings
MoF - Ministry of Finance
MoHFW - Ministry of Health and Family Welfare
MRI - Magnetic Resonance Imaging
MSME - Micro, Small, and Medium Enterprises
NCD - Non-communicable Disease
NHA - National Health Authority
NHM - National Health Mission
NPPA - National Pharmaceutical Pricing Authority
NSSO - National Sample Survey Organization
NTEP - National Tuberculosis Elimination Program
NTEP - National Tuberculosis Elimination Programme
OCP - Oral Contraceptive Pills
OCV - Oral Cholera Vaccine
OECD - Organisation for Economic Co-operation and Development
OOP - Out-of-Pocket
OOPE - Out-of-Pocket Expenditure/Out-of-Pocket Expense
OPD - Out Patient Department
OSMCL - Odisha State Medical Corporation Limited
OTC - Over-the-counter

PCB – Pollution Control Board
PFI - Population Foundation of India
PHC - Primary Health Care
PHFI - Public Health Foundation of India
PICO - Patient/Population, Intervention, Comparison and Outcomes
PLWHA - People living with HIV/AIDS
PMJAY - Pradhan Mantri Jan Arogya Yojana
PPM - Public-Private Mix
PRISMA - Preferred Reporting Items for Systematic Reviews and Meta-Analyses
Pub - Public Sector
Pvt - Private Sector
Raj - Rajasthan
RHD - Rheumatic Heart Disease
RMSCL - Rajasthan Medical Services Corporation Limited
Rs - Indian Rupees
RSBY - Rastriya Swasthya Bima Yojana
SAGE - Study on Global AGEing and Adult Health
SD - Standard Deviation
SDG - Sustainable Development Goals
SES - Socioeconomic Status
SNHAS - Subnational Health Accounts
SVD - Spontaneous Vaginal Delivery
TB - Tuberculosis
THE - Total Health Expenditure
ti - Title
TN - Tamil Nadu
TNMSC - Tamil Nadu Medical Services Corporation
TPT - TB Prevention Therapy
UHC - Universal Health Coverage
UPMSCL - Uttar Pradesh Medical Supplies Corporation Limited
USD - United States Dollar
VHAI - Voluntary Health Association of India
VL - Visceral Leishmaniasis
WB - West Bengal
WHO - World Health Organization
WHO/HAI - World Health Organization/Health Action International

PREFACE

The surge in medical out-of-pocket expenditures (OOPE) incurred by households and individuals, particularly in low and moderate-income countries (LMICs), is a pressing issue. OOPE for medicines is the most inequitable form of medical care financing, representing a significant obstacle to universal health coverage (UHC). High OOPE often forces individuals to forego essential medical care or face financial instability, with pharmaceutical expenses constituting a substantial portion of these costs. In LMICs, up to 56% of healthcare budgets are spent on medications.

India, with a population of approximately 1.40 billion, faces significant challenges in healthcare delivery, exacerbated by urbanization and demographic shifts toward non-communicable diseases (NCDs). The healthcare system is overburdened, with OOPE on medicines accounting for 70% of total healthcare expenditure. Public policy plays a crucial role in addressing OOPE, yet many households lack access to affordable healthcare, resulting in financial crises.

Tuberculosis (TB) remains a major infectious disease, with India experiencing high incidence rates. The limited affordability of TB treatment, coupled with high OOPE and inadequate health infrastructure, hampers efforts to achieve universal health coverage. Various national initiatives aim to reduce OOPE and improve medicine availability but are overshadowed by the growing needs of a large population.

The financial burden of pregnancy and childbirth in India is influenced by socioeconomic and demographic factors, with a significant portion of OOPE related to maternity services. The high costs associated with prenatal and postnatal care disproportionally impact lower-income groups, revealing the need for effective policy interventions. Geographic disparities in

healthcare access further exacerbate these challenges, emphasizing the necessity for expanded insurance coverage and support programs.

India's public drug procurement and distribution system faces numerous challenges, influenced by diverse regional strategies and complex state-specific policies. Inefficiencies and quality issues are prevalent due to inadequate regulation and fragmented frameworks. Evaluating these procurement processes is essential, focusing on efficiency, cost-effectiveness, and quality to enhance drug availability and public confidence.

Given the facts, this integrated study aims to holistically examine the multifaceted challenges surrounding healthcare access and medication distribution in India. The specific objectives of this integrated study include

- ***Study 1 - On Financial Burden of Medicines***: To evaluate the impact of government efforts to reduce out-of-pocket expenditures for medicines in India (Systematic way of data synthesis based on published evidence).

- ***Study 2 - On TB Drug Therapy Challenges***: To explore socioeconomic and health policy challenges concerning the availability, accessibility, and affordability of quality drug therapy among people living with tuberculosis.

- ***Study 3 - On Financial Considerations in Pregnancy Outcomes***: To assess the impact of financial considerations on pregnancy outcomes and enhance healthcare access for expectant mothers.

- ***Study 4 - On Public Drug Procurement Performance***: To conduct a performance assessment of public drug procurement across seven different states from diverse geographic regions in India, focusing on procurement efficiency, cost-effectiveness, and the quality of distribution systems.

CHAPTER 1

INTRODUCTION

1.1 Background

Access to comprehensive and affordable healthcare is widely recognized as a fundamental human right, preserved in international agreements and declarations (Algharibi et al., 2024). It is not merely a desirable social goal but a critical determinant of individual well-being, economic productivity, and overall societal development (Diener & Seligman, 2004). Effective healthcare systems, however, are complex and resource-intensive, requiring robust and equitable financing mechanisms to ensure that all individuals can access necessary services without suffering financial hardship. This is a significant challenge globally, particularly in low- and middle-income countries grappling with limited resources, competing development priorities, and often, fragile healthcare infrastructures (Meessen, 2018).

One of the most pressing issues in healthcare financing is the rising cost of healthcare services and medicines. Advances in medical technology, while undeniably beneficial in improving diagnosis, treatment, and overall health outcomes, often come at a high price. New drugs, complex surgical procedures, and sophisticated diagnostic tools contribute to escalating healthcare expenditures, making it increasingly difficult for individuals and families, particularly those with limited incomes, to afford essential treatments (Cunningham, 2010).

Several converging factors further exacerbate this financial burden. Globally, populations are aging, leading to a higher prevalence of chronic diseases that require ongoing and often expensive management. The rise of non-communicable diseases like diabetes, cardiovascular disease, and cancer adds another layer of complexity to healthcare systems already struggling to meet existing needs. Furthermore, inequalities in access to healthcare services, both within and between countries, persist, creating disparities in health outcomes and exacerbating the

financial burden of illness for the most vulnerable populations (World Health Organization, 2024).

These challenges underscore the critical need for effective and equitable healthcare financing mechanisms that protect individuals and families from the potentially catastrophic financial burden of illness. Ideally, healthcare systems should strive to provide financial risk protection, ensuring that individuals are not pushed into poverty or forced to forego essential care due to costs. However, in many parts of the world, particularly in low- and middle-income countries, individuals and households continue to bear a significant proportion of healthcare costs directly out of their own pockets. This is known as out-of-pocket expenditure (OOPE) (Thakur & Sangar, 2022).

High levels of OOPE can have detrimental consequences for individuals, households, and health systems as a whole. It can lead to financial hardship, and medical impoverishment (where healthcare costs push people into poverty), and create barriers to accessing timely and essential care. Individuals faced with high OOPE may delay seeking care, opt for cheaper but potentially less effective treatments, or forgo care altogether, leading to poorer health outcomes and potentially increasing healthcare costs in the long run (Buchan et al., 2013).

1.2 Sustainable Development Goals 3 (SDG 3) - Good Health and Well-being

Universal Health Coverage (UHC) is the strategy on which most of the focus toward the achievement of the United Nations Sustainable Development Goal 3: “Good Health and Well-being” depends. The SDGs are officially known as the sustainable development Goals and they are a set of 17 goals (**Figure 1.1**) that were adopted by the United Nations General Assembly in the year 2015 and the targets should be met by the year 2030. The 3rd Goal is focused directly on “health” stating, “Ensure healthy lives and promote well-being for all ages for all” (United Nations General Assembly, 2015).

Figure 1.1: Sustainable Development Goals (17 SDGs)

Source – United Nations

UHC is built on three key components: as highlighted by the WHO in 2019, "accessibility, quality, and affordability". This means that every citizen must afford the required health care they require from professionally competent providers of adequate quality, and efficiency, and without undue financial consequences arising from direct out-of-pocket payments for health services. UHC implementation focuses on such components as it seeks to address issues of equity in health facility usage to enable the achievement of a better population's health and wellbeing (Rodney & Hill, 2014).

It has been established that UHC brought forth a large improvement in response to health issues. The National Health Insurance Scheme plan of India, developed to achieve UHC resulted in decreases in out-of-pocket expenses, and hospitalization and therefore improved access and reduced financial burden (Virk & Atun, 2015).

However, there are some gaps found when trying to attain UHC and SDG 3: The challenges are limited resources, human capital availability, and required improvement in health systems

(Darrudi et al., 2022). Moreover, concerns like the increased burden of NCDs and recrudescence of infectious diseases including COVID 19 are some of the emerging challenges (WHO, 2022).

1.3 Out-of-Pocket Expenditure in Healthcare

Out-of-pocket expenditure in healthcare refers to the direct payments made by individuals and households at the point of service utilization. This includes payments for a wide range of healthcare goods and services, including:

- ***Consultations:*** Fees paid to doctors, nurses, and other healthcare professionals for consultations, examinations, and medical advice.
- ***Medications:*** Costs associated with purchasing prescription and over-the-counter drugs, vaccines, and other pharmaceutical products.
- ***Diagnostic tests:*** Expenses incurred for laboratory tests, imaging scans (such as X-rays, ultrasounds, and MRIs), and other diagnostic procedures.
- ***Hospital stays:*** Charges for inpatient care, including room and board, nursing care, surgical procedures, and other hospital-based services.
- ***Traditional medicine:*** Payments made to traditional healers, practitioners of alternative medicine, and providers of complementary therapies (Department of Health and Human Services, 2019).

OOPE represents a significant aspect of healthcare financing globally, but its impact is felt most acutely in low- and middle-income countries. In these settings, where social security systems and public health insurance schemes are often limited in scope and coverage, individuals and households bear a disproportionately high burden of healthcare costs directly out of their own pockets (Essue et al., 2018).

1.3.1 Overview of OOPE in Developing Countries

Out-of-pocket expenses (OOPEs) are often regarded as the most inequitable method of paying for healthcare (WHO, 2020). The World Health Organization identifies high levels of OOPE as a major impediment to achieving universal health coverage, a situation where all individuals and communities have access to needed health services without suffering financial hardship. In many developing countries, OOPE constitutes the primary source of healthcare financing, accounting for a substantial proportion of total health expenditure (McIntyre & Mills, 2012). This heavy reliance on OOPE has several negative consequences:

1.3.1.1 Financial Hardship and Medical Impoverishment

High levels of OOPE can lead to significant financial hardship for individuals and households, particularly those with low incomes and limited financial resources. Unexpected medical expenses can deplete savings, force families to sell assets and push them into a cycle of debt and poverty. This phenomenon, known as medical impoverishment, is a major concern in developing countries, where even relatively small healthcare expenses can have devastating financial consequences (Kruk et al., 2009).

1.3.1.2 Barriers to Access and Utilization of Healthcare Services

The fear of incurring high medical expenses can deter individuals from seeking timely and essential healthcare. People may delay seeking care, opt for self-medication or traditional remedies, or forgo care altogether, leading to poorer health outcomes and potentially increasing healthcare costs in the long run. This is particularly problematic for vulnerable populations, such as women, children, the elderly, and those living in poverty, who are often the most in need of healthcare services but least able to afford them (Remme et al., 2020).

1.3.1.3 Inequitable Healthcare Utilization and Health Outcomes

High OOPE creates inequities in healthcare utilization and health outcomes, as individuals' ability to access and afford healthcare becomes largely determined by their financial capacity rather than their healthcare needs. This undermines the principle of equity in healthcare and perpetuates health disparities between different socioeconomic groups (Andrulis, 1998).

1.3.1.4 Inefficient Healthcare Systems

Heavy reliance on OOPE can also contribute to inefficiencies in healthcare systems. When individuals pay for healthcare services directly, it can create perverse incentives for over-provision of services, unnecessary testing, and inflated prices. Furthermore, the lack of prepayment mechanisms and risk-pooling arrangements associated with high OOPE makes it difficult for healthcare providers to plan and invest in essential services, leading to underinvestment in public health infrastructure and human resources for health (Asante et al., 2020).

1.3.2 OOPE in the Indian Healthcare System

India's healthcare system exemplifies the challenges and complexities associated with OOPE in developing countries. Despite significant economic growth in recent decades, India continues to face a high burden of disease, limited public healthcare infrastructure, and a predominantly private healthcare sector. This has resulted in a heavy reliance on OOPE, which accounts for a substantial proportion of total health expenditure in the country (Manchanda & Chaudhary, 2015).

1.3.2.1 Factors Contributing to High OOPE in India

- Limited Public Health Infrastructure: India's public healthcare system, while theoretically providing free or subsidized care, is often characterized by limited

resources, inadequate infrastructure, and shortages of qualified healthcare professionals, particularly in rural and underserved areas. This often forces people to seek care from the private sector, where costs are significantly higher.

- Dominance of Private Healthcare: The private healthcare sector in India is vast and largely unregulated, with a wide range of providers, from small clinics to large corporate hospitals (Sengupta & Nundy, 2005).

1.3.3 OOPE Burden of Medicine in India

Out-of-pocket expenditure on medicine is a huge burden to individuals and households. National Health Accounts Estimates for India (2018-19) revealed that 63 % of the total health expenditure in India is on medicines and other therapeutics products (National Health Systems Resource Centre, 2022). OOPE on medicine primarily comprises two components, which are direct medical cost categories consisting of (a) money spent on prescription drugs, and (b) money spent on over-the-counter (OTC) drugs (Prinja et al., 2012). According to the World Bank, 2017 about 85% of Indians buy their drugs from private retailing outlets. Due to heavy dependence on private healthcare services and absence of a health insurance system and an inadequate state-financed healthcare system, there are increased incidences of households being pulled back into poverty due to out-of-pocket health expenses.

1.3.3.1 Government Programs to Reduce OOPE Burden on Medicines

Considering the major issue of medicine OOPE, different measures have been taken by the Indian government and state governments to minimize the challenge posed by out-of-pocket expenses on medicines. Some of the initiatives are,

- *State-level initiatives:* All the states in India have come up with strategies that help to address the problem of out-of-pocket expenses on medications. They introduced the

Free Medicine policy in the state, whereby all government hospitals and primary health care centres provide essential drugs on a free basis.

- *National Health Policy 2017:* In 2017, the government came up with a new National Health Policy that aimed at focusing on UHC. Another goal of the policy is the out-of-pocket payment on health care services including drugs to be less than 30 percent of total health expenditure by the year 2025.
- *Pradhan Mantri Jan Arogya Yojana (PMJAY) or Ayushman Bharat:* This was officially launched in 2018, and aimed at offering secondary and tertiary care hospitalization for over 100 million identified vulnerable families, particularly the poor, marginalized, and disadvantaged. PMJAY includes over 1,200 health care packages which include medicine and it targets to decrease the OOP cost of health care services.
- *National Pharmaceutical Pricing Authority (NPPA):* The NPPA controls the field of prices of some critical and life-saving drugs in the territory of India. In particular, through the regulation of such prices, the NPPA contributes to minimizing the out-of-pocket expenses on essential medicines. In December 2016, the NPPA implemented a price cap for 348 essential medicines including cancer, heart disease, and diabetes.
- *Generic Medicines Promotion:* The Indian government has encouraged the use of low-cost generics to bring the cost of treatment and out-of-pocket expenses for medicines down. It is generally recognized that generic medicines are cheaper compared to branded medicines because they don't have marketing costs as the branded medicines have. By encouraging people to make use of generic medicines the government seeks to ensure that people get access to medicines at an affordable cost.
- *Jan Aushadhi Scheme*: This scheme was developed by the government in 2015 to bring GENERIC and affordable medicines to the public. The scheme's objective is to achieve a reduction on average of OOPE on medicines through increasing access to quality

generic medicines at reasonable costs. Presently, there are over 3,900 Jan Aushadhi centres available throughout India till December 2019.

- *Telemedicine:* Telemedicine has been gently evoked and encouraged by the Indian government to provide essential services such as medicines to rural and remote areas. Telemedicine is also able to reduce the overall cost of traveling and consultation charges.

1.3.4 Need for Evaluation of Government Initiatives on Medicine OOPE

Despite the government's considerable initiatives in reducing out-of-pocket expenditures for medicines, significant challenges persist. Therefore, there is an urgent need to assess the impact of these government efforts to identify ongoing challenges and inform future policy interventions. By evaluating the effectiveness of current programs, stakeholders can better understand their influence on healthcare access, determine areas requiring improvement, and develop strategies to effectively minimize OOPE, ultimately enhancing healthcare access for all individuals in India.

1.4 Socioeconomic Influences on Healthcare Expenditure

Socioeconomic status (SES) plays a major role in shaping individuals' healthcare expenditure decisions, with financial capability often serving as the primary determinant of the extent to which individuals invest in health services. As per the literature, the various socioeconomic factors, such as income level, educational attainment, and employment status, significantly influence both the accessibility and effectiveness of healthcare services. As critical social determinants of health, these factors are intricately linked to healthcare costs, particularly in the context of the financial burden associated with infectious diseases such as tuberculosis (TB), maternal health outcomes, and the prevalence of non-communicable diseases (NCDs). The disparities in spending patterns highlight the challenges faced by lower SES groups, who

may struggle to afford necessary medical care, thereby exacerbating health inequalities and affecting overall health outcomes.

The financial status of individuals significantly influences their healthcare spending, with lower-income households often facing medical costs that exceed their ability to pay, resulting in inadequate access to essential care and poorer health outcomes. In contrast, higher-income families can afford private healthcare services, which typically leads to better health. Education is another critical factor; it empowers individuals with the knowledge needed to make informed health decisions. For instance, educated women are more likely to seek early prenatal care and understand the importance of proper nutrition for themselves and their children. Furthermore, employment status plays a vital role in healthcare access: those without jobs often struggle to obtain health insurance, leading to higher rates of preventable hospital visits. Conversely, employed individuals tend to utilize healthcare services more effectively, managing chronic conditions and reducing serious complications related to non-communicable diseases.

1.4.1 Need for Evaluation of Socioeconomic Status in Healthcare Access and Expenditure

Assessing socioeconomic status (SES) is essential for understanding and addressing the disparities in healthcare expenditure and access. A comprehensive evaluation of SES can provide insights into the barriers faced by various groups, enabling targeted interventions aimed at improving health outcomes. For instance, conducting assessments that encompass not only income level but also educational attainment, employment status, and even social support networks can help identify those most at risk for inadequate healthcare access.

Moreover, integrating SES assessment into healthcare policies and programs can facilitate the development of tailored strategies that address specific needs within lower SES populations. Such strategies may include financial assistance programs, educational campaigns to increase health literacy, and initiatives to expand access to affordable healthcare services. By prioritizing

SES in health assessments, stakeholders can better allocate resources, improve healthcare accessibility, and ultimately work towards reducing health disparities across different socioeconomic groups. This holistic approach can lead to more equitable health systems that cater to the needs of all individuals, regardless of their financial circumstances.

1.5 Public Drug Procurement in India

Public drug procurement in India plays a critical role in ensuring the availability and quality of essential medications across the country. The effectiveness of this process is influenced by various factors, including regional demographic and economic conditions, which necessitate tailored strategies that cater to local health needs and administrative capabilities (Kanthe, 2010; Khan et al., 2013). Each state employs its procurement policies, leading to significant differences in the quality and efficiency of drug distribution. These disparities highlight the importance of aligning procurement approaches with state-specific legal frameworks and health requirements to enhance service delivery (Bansal et al., 2024).

1.5.1 Challenges in Public Drug Procurement

Despite its essential functions, public drug procurement in India faces numerous obstacles. Significant inefficiencies within the procurement system, driven by inadequate regulatory oversight and fragmented legal structures, lead to a notable percentage of drugs failing to meet quality control standards (Kaur et al., 2021). Reports indicate that up to 20 percent of procured drugs are deemed substandard (Weir et al., 2005), which not only undermines public trust but also exacerbates the financial burdens on low-income populations dependent on private healthcare and branded medicines (Khanday, 2019; Verma, 2019).

The complexities of drug procurement and distribution are further compounded by varying strategies across states and the necessity to navigate medical and legal intricacies (Jadhav et al., 2020; Nikam et al., 2019). A lack of reliable data regarding drug availability and

accessibility often impairs effective policy-making, stalling progress toward improving health equity (Singh et al., 2013). To advance health outcomes and service delivery, frameworks incorporating performance indicators and accountability measures are essential (Fiszbein et al., 2011).

1.5.2 Need for Performance Assessment in Public Drug Procurement and Distribution

Conducting a performance assessment study of public drug procurement and distribution is essential for identifying disparities in drug availability and quality. It will highlight existing inefficiencies in procurement processes, informing targeted interventions to enhance access to essential medicines.

A focused evaluation will help uncover specific regulatory and operational challenges impacting the quality of procured drugs. Understanding these factors is crucial for developing effective policies that ensure safe and reliable medication distribution.

By integrating study findings into healthcare strategies, stakeholders can create tailored solutions to address diverse state-specific needs, ultimately leading to improved health outcomes and greater equity in healthcare access across various populations. Prioritizing performance assessment in public drug procurement will help establish a more effective health system that meets the essential medical requirements for all individuals.

1.6 Focus of the Integrated Research Approach in this Thesis

Given all the above facts, this thesis focuses on the integrated study approach to evaluate the impact of government efforts on reducing the OOPE burden on medicines in India, through a systematic way of data synthesis based on published evidence (Systematic Review based Research).

The study approach also aims to explore socioeconomic and health policy challenges regarding the availability, accessibility, and affordability of drug therapy among the people living with tuberculosis in public and private hospitals in the Agra district of Uttar Pradesh, India.

Additionally, this research assesses the implications of socioeconomic and demographic factors on financial considerations, particularly how they influence pregnancy outcomes and access to healthcare support for expectant mothers.

To address these interconnected issues, the study also emphasizes the necessity for multifaceted assessments aimed at improving drug availability, quality, and public confidence. It seeks to evaluate the efficiency, effectiveness, and quality of public drug procurement systems across India by developing a specific set of performance indicators. Ultimately, this comprehensive approach aims to identify disparities and inform targeted interventions to enhance health outcomes for diverse populations.

1.7 Organization of the Thesis

The thesis is divided into eight chapters. The first chapter is a general introduction to the research work, and the second chapter is a literature review. Chapter three discusses the general and specific objectives of this integrated study. Chapters four to seven include research related to the various objectives. The final chapter presents a summary and conclusion of the integrated study.

Chapter 2: Literature Review

This chapter discusses various kinds of literature related to the research work and identifies the gaps related to financial implications in healthcare, including out-of-pocket expenditures (OOPE), socioeconomic status, health policy challenges, and public drug procurement, with a

particular emphasis on medicines. The literature review is organized into the following four sections:

- Government efforts in reducing the burden of medicine OOPE
- Burden of OOPE on Infectious Diseases such as Tuberculosis
- Burden of OOPE among Pregnant Women
- Public Drug Procurement and Distribution

Chapter 3: Objectives of the Integrated Study

This chapter discusses the general objectives (Goals), and the specific objectives of this integrated study.

Chapter 4: Financial Burden of Medicines

This chapter discusses on systematic review evaluating the effectiveness of government policies implemented over the past 20 years to reduce out-of-pocket expenditures (OOPE) for medications in India. It analyzes relevant literature and data, highlighting significant findings related to OOPE, socio-economic factors, and the financial burden on households, ultimately calling for improved financial protection in healthcare.

Chapter 5: TB Drug Therapy Challenges

This chapter examines the participation and healthcare service utilization of 2,244 individuals, focusing on differences between the public and private healthcare sectors. It discusses demographics, treatment access for tuberculosis, out-of-pocket expenditures, and the implications of government support. The chapter analyzes factors influencing service utilization, and challenges faced in accessing care, and offers policy recommendations to improve healthcare delivery and reduce financial burdens on patients.

Chapter 6: Financial Considerations in Pregnancy Outcomes

Chapter 6 examines the financial burdens faced by women during pregnancy and childbirth. It investigates how socioeconomic factors influence healthcare utilization, out-of-pocket expenditures, and access to maternal care through surveys and in-depth interviews with pregnant women. The chapter highlights the cost implications of different delivery settings and analyzes the effectiveness of government programs designed to support maternal health. It also discusses challenges within public healthcare facilities and offers policy recommendations to alleviate financial pressures on pregnant women.

Chapter 7: Public Drug Procurement Performance

Chapter 7 focuses on evaluating the performance of public drug procurement processes in seven Indian states. It analyzes key performance indicators related to efficiency, cost-effectiveness, and quality of procurement practices. The study assesses how different states manage drug procurement, the impact of health budget allocations, and the relationship between procurement systems and health outcomes. The chapter aims to identify best practices and areas for improvement, particularly for states facing challenges in drug accessibility and efficiency.

Chapter 8: Summary and Conclusions

Chapter 8 concludes the major findings of the study, along with its contribution, limitations, and scope for future research.

Overall, this integrated study evaluates the multifaceted challenges of healthcare access and financial burdens within the Indian healthcare system, offering various aspects of health financing, policy effectiveness, and service delivery.

Beginning with Chapter 4, the study systematically reviews government policies aimed at reducing out-of-pocket expenditures (OOPE) for medications over the past two decades. In Chapter 5, the focus shifts to tuberculosis (TB) drug therapy and the healthcare service utilization patterns of 2,244 individuals. This chapter reveals critical disparities between public and private healthcare sectors, showing how socioeconomic factors influence access to treatment. In Chapter 6, the study explores another critical area, which is the financial considerations faced by women during pregnancy and childbirth. It underscores the financial pressures affecting women's health choices, linking these challenges back to the broader themes of OOPE and the necessity for comprehensive support systems. Finally, Chapter 7 evaluates the public drug procurement processes across seven Indian states, assessing their efficiency, cost-effectiveness, and quality. By analyzing how these processes impact healthcare accessibility and affordability, the chapter provides insights into best practices and areas for improvement within drug procurement.

Collectively, this integrated study offers a holistic perspective on the interconnected nature of healthcare challenges in India. It identifies the pressing need for targeted reforms in policy and practice to alleviate financial pressures on patients and enhance healthcare delivery across various demographics.

CHAPTER 2

LITERATURE REVIEW

The literature survey aims to provide a comprehensive understanding of the gaps related to financial implications in healthcare, including out-of-pocket expenditures (OOPE), socioeconomic status, health policy challenges, and public drug procurement, with a particular emphasis on medicines. The literature review is organized into the following four sections:

- Government efforts in reducing the burden of medicine OOPE
- Burden of OOPE on Infectious Diseases such as Tuberculosis
- Burden of OOPE among Pregnant Women
- Public Drug Procurement and Distribution

2.1 Government Efforts in Reducing the Burden of Medicine OOPE

1. **Joe (2015)** evaluated the distressed healthcare financing system in India that involved OOPE for medical services, which were often supported by loans, selling of assets, or financial assistance from friends and family. According to the study, over 60% of hospitalization cases in rural areas and 40% in urban areas depend on this type of funding, with marginalized populations particularly women, the elderly, and lower socioeconomic classes being the most impacted. Non-communicable diseases, especially cancer, heighten the likelihood of financial strain, with notable gender disparities in borrowing practices. To lessen these financial pressures, the study recommends better healthcare coverage and social protection laws (Joe, 2015).

2. **Eun-Ja Park et al., (2015)** performed a study in Korea to compare the OOPE burden on elderly and nonelderly patients suffering from chronic health problems. They concluded that in comparison to nonelderly patients, the elderly had higher OOP drug

expenses and were more liable to the impact of such expenditures. They recommended that such payment policies should be implemented for medicinal products that consider the economic status of elderly patients (Park et al., 2015).

3. **Wagstaff et al., (2019)** examined the OOPE in 146 countries from all World Bank income groups, assessing their distribution, relationships with macroeconomic and health system variables, and effects on income and consumption. They concluded that OOPE was progressive for the rich when measured in relation to consumption and it was regressive for the poor when measured in relation to income (Wagstaff et al., 2020).

4. **Bijlmakers et al., (2019)** performed a cross-sectional study in Malawi to fulfill a surgical need by OOPE and catastrophic household expenditures. They concluded that OPP household expenses for necessary surgery were significant and frequently catastrophic, putting households particularly those that were already needy at risk of falling into even greater poverty. The essential expansion of surgical services in rural Malawi must be accompanied by financial risk prevention measures. Financial risk prevention must be taken to roll out this issue special for poor patients (Bijlmakers et al., 2019).

5. **Ozieh et al., (2019)** performed a study to examine the trends of increased OOPE burden on kidney disease patients in the USA. They surveyed between 2002-2011 and selected kidney patients above 17 years with OOP burden. The participants were insured and uninsured with low, medium, and high economic status. Their findings revealed that economically sound ensured patients were not bothered about OOPE burden but uninsured and economically poor individuals with kidney disease remained vulnerable. So, the vulnerability of kidney disease patients with high OOPE should be taken into consideration during policymaking and implementation (Ozieh et al., 2019).

6. **Iragorri et al., (2021)** conducted a systematic review to evaluate the OOPE burden on cancer patients and their caretakers. They reported that the monthly expenses for cancer treatment in the United States ranged from USD 180 to USD 2600, while those in Canada, Western Europe, and Australia were lower. Further, in high-income countries, cancer-related costs were 16% of annual income, but in low and middle-income countries, it was around 42%. The study emphasized the necessity of better healthcare coverage to reduce financial burden and guarantee equitable access to medical facilities for cancer treatment or management (Iragorri et al., 2021).

7. **Bedado et al., (2022)** conducted a cross-sectional study on patients who visited govt hospital, in East Shoa Zone, Ethiopia. The finding explored that a significant number of patients (332 respondents out of 378 - 87.8%) were paid OOPE for healthcare expenditures. Age of the respondents with education status, average monthly income, family size, and living status, were associated with the OOPE. The study emphasized the necessity of stakeholder and governmental measures, such as Social Health Insurance and Urban CBHI, to lessen financial constraints and guarantee fair access to healthcare (Bedado et al., 2022).

8. **Sangar et al., (2022)** utilized the data from a survey conducted by "The National Sample Survey Organization (NSSO)" in 2014, They analyzed the economic cost of OOP health expenditure in India. Their findings showed that OOP expenditure disproportionately affects lower-income populations for outpatient care, resulting in 8% of the population living below the poverty line. Vulnerable populations such as Muslims, scheduled castes, rural dwellers, and agricultural laborers are the most impacted, highlighting the necessity for India to alter its financing strategy for healthcare (Sangar et al., 2022).

9. **Mekuria et al., (2023)** evaluated the financial stress of OOPE on medicine in Ethiopia. The study stated that a large amount of healthcare costs in Ethiopia are incurred through OOPE for medications. A study of national household surveys revealed that while the proportion of households experiencing catastrophic medical payments declined marginally (1.0% - 0.73%) from 2010 to 2016, the total number of individuals impacted increased. OOP payments for medicine resulted in poverty for more than 11,000 households in 2015/16. Economic status, geographical location, and the nature of health services were significant determinants of these disparities. The study advocates for enhancements in the supply of medicine within public facilities and the establishment of risk protection mechanisms, particularly concerning inpatient care (Mekuria & Ali, 2023).

10. **Islam et al., (2024)** reported the impact of medical treatment loans on health care utilization and OOPE. This study was conducted through a randomized controlled trial in 24 microfinance branches in northern Bangladesh. Their findings revealed that excluding the loaned amount did not affect the overall increase in OOPE (Nazmul Islam et al., 2024) .

11. **Garcia-Diaz et al., (2024)** conducted a study in three African (Malawi, Tanzania, and Uganda) countries on the persistence of catastrophic OOPE. They demonstrated how the vulnerability of specific groups to persistent catastrophic OOPE, particularly those who lived in rural areas, had less education, were elderly, or had experienced hospitalizations (Garcia-Diaz et al., 2024) .

12. **Wuraola et al., (2024)** performed a prospective study on the OOPE of breast cancer. The study examined both direct and indirect OOPE associated with breast cancer treatment in a singular tertiary care facility in South West Nigeria. They concluded

around 70 % of sufferers at care facilities encounter catastrophic health expenditures due to OOPE related to obtaining care (Wuraola et al., 2024).

13. **Kaladharan et al., (2024)** studied how the OOPE of emerging nations was affected by variables like Gross Domestic Product (GDP), Domestic General Government Health Expenditure (DGGHE), government health schemes, and different health financing programs. The analysis indicated that government schemes and health insurance programs decrease OOPE, whereas DGGHE and GDP contribute to their rise. The research demonstrated the necessity of minimizing OOPE to attain universal health coverage, advocating for a comprehensive strategy that encompasses preventive care, extensive insurance, robust public health systems, and strict regulation of pharmaceutical pricing (Kaladharan & Manayath, 2024).

14. **Archana Sawshilya (2020)** identified several challenges in the implementation of the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) arising from the pharmaceutical industry. Key issues include pharmaceutical companies' reluctance to support generics due to fears of market share loss, corruption among officials, and dependency on Central Public Sector Undertakings (CPSUs) which struggle to meet demand. Additionally, bureaucratic hurdles impede the opening of new stores and lead to frequent unavailability of essential medicines, driving patients towards branded alternatives. Marketing practices targeting medical practitioners also hinder the acceptance of generics, while delays in payment processing from the Bureau of Pharma PSUs of India (BPPI) affect the operational viability of manufacturers. These factors collectively create significant barriers to achieving PMBJP’s objectives (Archana Sawshilya, 2020).

15. **Tekulapally et al., (2024)** conducted a cross-sectional study on the awareness, attitude, and usage of generic medicines among prescribers and patients at a tertiary care

teaching hospital. It was found that while all prescribers knew of "generic medicines," only 56% could define them accurately. Awareness among patients was even lower, with just 36% having heard of generics and only 27% understanding their definition. Despite 87% of prescribers and 54% of patients agreeing that generics reduce therapy costs, trust issues persist, with 46% of prescribers and 33% of patients preferring branded medicines. Additionally, 41% of patients doubted the quality of generics due to their lower prices. These findings highlight the need for educational efforts to build trust and dispel misconceptions about the efficacy and safety of generics, particularly those offered by initiatives like the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) (Tekulapally et al., 2024).

2.2 Burden of OOPE on Infectious Diseases such as Tuberculosis

16. **Tanimura et al., (2014)** conducted a systematic review to evaluate the reasons for the financial burden. They suggested some strategies against the economic burden of tuberculosis in low and middle-income countries. Poorly and MDR patients were the major sufferers with expenses accounting for 58% of an individual's and 39% of a household's yearly income. To face the economic burden, patients took loans and sold their household assets. In addition to ensuring equitable financing and delivery of healthcare services that minimize both direct and indirect costs, it is essential to provide TB patients and their families with adequate income substitution and other social safeguards (Tanimura et al., 2014).

17. **Muniyandi et al., (2019)** conducted a study to evaluate India’s new strategy for ensuring that no family would be affected by TB up to 2020 due to the catastrophic costs. The study assessed the variables of catastrophic health expenditures, proposed solutions for alleviating these costs for families impacted by tuberculosis, and examined

the strategies and interventions implemented by health programs to alleviate/mitigate these expenses (Muniyandi & Ramachandran, 2019).

18. **Reuter et al., (2020)** reported that around 20 billion children are exposed to TB every year underscoring a significant global paediatric health crisis. They evaluated challenges associated with the TB burden and strategies to solve these challenges. This study, with particular attention on identifying children who were already exposed, detecting the severity of infections, evaluating disease risk, treating patients, and encouraging stakeholder collaboration to eradicate TB (Reuter et al., 2020) .

19. **Chadha et al., (2022**) researched to examine the lag time for new TB patients who were registered at Bengaluru's public health facilities to start anti-TB therapy (ATT) due to lack of OOPE and delayed appearance of symptoms. About 228 sufferers about delay and cost appeared in the interview before ATT. Results suggested that patients initially sought care at private clinics but received diagnoses and treatment in public facilities after an average delay of 68 days. On average, patients incurred costs of $402, with increased expenses associated with extra-pulmonary tuberculosis and extended delays. Approximately 20% experienced significant financial distress, with numerous individuals resorting to borrowing funds or liquidating assets. It is essential to implement measures that minimize delays, costs, and financial burdens on poor patients (Chadha et al., 2022) .

20. **Bashir et al., (2022)** conducted a study to evaluate the capability of newly established tuberculosis labs to prevent or manage the TB. They reported that India's National Tuberculosis Elimination Program (NTEP) collaborated with FIND India to enhance tuberculosis testing through the establishment of 61 laboratories, significantly augmenting testing capacity. This study showed that these laboratories exhibit 69%

efficiency and are projected to manage significantly increased testing capacity by 2025, thereby supporting India's objective to eradicate tuberculosis (Bashir et al., 2022).

21. **Ryckman et al., (2023)** conducted a study to evaluate the cost-effectiveness of TB prevention therapy (TPT) for household contacts and individuals living with HIV/AIDS (PLWHA) in 29 incidence countries. TPT was highly suggested for people living with HIV/AIDS and young children in households; however, it was a little bit expensive. The study utilized a model to demonstrate that TPT was cost-effective in reducing TB cases and mortality, particularly among young children, and continues to provide benefits across all age groups. The implementation of TPT has the potential to substantially decrease morbidity and mortality, rendering it a valuable investment despite associated costs (Ryckman et al., 2023).

22. **Kumar et al., (2023)** examined the pricing service in "northern India public health facilities under the National Tuberculosis Elimination Program (NTEP)". Results indicate that the average cost of delivering NTEP services was greater at CHCs (US$ 5243.1) compared to PHCs (US$ 1031.9). At CHCs, the majority of the cost (80%) was due to outpatient, diagnostic, and treatment while in the case of PHCs, the major cost was due to outpatient, monitoring, and meeting and training services. Human resource expenses were the main factor influencing the cost per treated TB patient, which was US$182.5 at CHCs and US$101.4 at PHCs (Kumar & Prinja, 2023) .

23. **Chadhar et al., (2023)** studied the impact of the Nikshay Poshan Yojana on TB sufferers. A cross-sectional study was conducted in India at the Ballabgarh (WB) tuberculosis unit for 6 months with 146 patients. The mean expenditure for TB-related services was Rs 30,046, with numerous households encountering significant financial burdens. Despite the Nikshay Poshan Yojana, A majority of patients managed their financial burdens by obtaining loans (30.8%) or selling their assets (9.6%). Despite the

existence of universal health coverage, tuberculosis patients continue to encounter significant financial burdens, indicating a need for enhanced financial support and improved healthcare services (Chadhar et al., 2023).

24. **Assefa et al., (2024)** reported a systematic review of patients' financial burden for the diagnosis and treatment of TB. This systematic review was conducted for Ethiopia, which offered a free TB diagnosis and treatment but still 50 % of patients have to pay catastrophic costs, particularly during the pre-diagnostic and intense treatment phases. The major reason for the cost enhancement might be MDR-TB, co-infection like TB-HIV, and residency in rural areas. The authors recommended some strategies to reduce the financial burden *viz* "by community-based therapy, active case-finding, digital adherence tools, and improved insurance coverage" (Assefa et al., 2024)**.**

25. **Santos et al., (2024)** examined the health and socioeconomic features linked to poor treatment results for TB-affected children and adolescents in Brazil. The study was conducted on 88,270 patients (children, 0-9 years and adolescents, 10-17 years) retrospectively in "Brazil notified to the national *Sistema de Informação de Agravos de Notificação (Sinan)* from Jan 1, 2001, to Dec 31, 2022". Out of the 88,270 patients, 30.6 % were under direct observation therapy (DOT) and got favourable treatment outcomes. Unfavourable treatment outcomes were observed in patients with co-infections like TB-HIV who did not receive the DOT. To reduce the mortality of such patients, Govt helped the sufferers with cash transfers. Even though Brazil's TB treatment success rates are within WHO standards, this study suggested some strategies like improved DOT, integrated HIV-TB treatments, and holistic care to address inequities in vulnerable populations (Santos et al., 2024) .

26. **Yadav et al., (2024)** conducted a study to evaluate the OOPE faced by Indian TB patients. Despite a well-developed DOTS program for TB patients in India, a significant

number of households experience economic difficulties and face challenges by borrowing funds or selling their existing assets. This burden was greatly influenced by variables such as hospitalization length, lack/availability of proper facilities at the proper time, less income, and education. In addition to proposing hardship financing as an alternate metric to evaluate the efficacy of TB control initiatives, the report recommends re-examining the coverage of subsidies for TB treatment (Yadav et al., 2019).

27. **Dutta et al., (2024)** examined the significant financial burden accompanying TB treatment and its impact on patients and their families. The study revealed that numerous patients incur significant expenses for treatment, leading to financial difficulties for some families. Many patients resorted to taking loans or selling livestock to manage their circumstances. The study indicates that despite Universal Health Coverage, tuberculosis patients continue to encounter significant expenses and require supplementary financial assistance and improved healthcare services (Dutta et al., 2024).

28. **Kaurav et al., (2023)** prepared a review manuscript that stated catastrophic costs are a major hurdle in the management of TB. TB, which is frequently associated with poverty, puts a significant financial strain on families, particularly when medical expenses exceed 20% of their yearly income. Just in India, 18% of these catastrophic medical costs are incurred. To solve this, a nationwide cost survey should be carried out to comprehend the financial burden that tuberculosis places on households, pinpoint the main causes of these expenses, and create plans to lower them. Additionally, to increase the efficacy of present therapies, more research and creative approaches are required (Kaurav & Bharti, 2023).

29. **Chopra et al., (2023)** looked at the incidence of pulmonary tuberculosis (PTB) risk factors among homeless people in several parts of Delhi, India. They concluded that because of their high-risk factors and poor living situations, homeless people were more likely to be infected with PTB. The study was performed on 200 homeless individuals for PTB screening. There were 17 of these who were diagnosed with active PTB, meaning that there were 85 instances for every 1000 people. Smoking (41.2%), chewing tobacco (47.1%), drinking alcohol (47.1%), HIV (5.9%), and diabetes (5.9%) were the most common risk factors. PTB was more common among females, yet a greater proportion of males were diagnosed. The high PTB rate among the homeless requires prompt attention, and further study is crucial to substantiate these findings (Chopra et al., 2023).

30. **Prasanna et al (2018)** performed an explanatory mixed-method study to evaluate the Catastrophic costs of tuberculosis care in Puducherry, India. The research sought to evaluate patient expenses associated with diagnosis and treatment, determine the percentage of households experiencing catastrophic costs, and investigate coping mechanisms among newly diagnosed and previously treated tuberculosis patients. TB care costs were $195 on average, with 32.4% of households having catastrophic costs (above 20% of annual income). Patients with HIV or hospitalization had more catastrophic expenditures than normal TB patients. Pledging jewellery and borrowing money were common coping techniques, with cash aid being the most effective (Prasanna et al., 2018).

31. **Lambert et al., (2013**) conducted a study in an urban area of South America, to evaluate the delayed treatment and OOPE for TB. Compared to males, the total delay in treatment was greater for females. Similarly, more delay was observed in private hospitals than in public hospitals. Out-of-pocket expenses for private treatment were

more, amounting to $21.9 compared to $5.4. Interventions targeting healthcare practitioners, particularly physicians, may decrease delays and extraneous costs (Lambert et al., 2005).

2.3 Burden of OOPE among Pregnant Women

32. **Chatterjee et al., (2008)** examined the prevalence of chronic illness among pregnant women and its effects on health spending and treatment availability. A cross-sectional study involving 6,294 women aged 19 - 45 revealed that 27% of pregnant women and 39% of nonpregnant women suffered from chronic disease. Access to care and overall healthcare expenses were comparable for pregnant women with and without chronic illnesses; however, OOPEs were increased for those with chronic ailments without extending the overall cost. Additional research is required to ascertain whether these commonalities endure post-delivery, considering the significant frequency of women with chronic illnesses within the childbearing age demographic (Chatterjee et al., 2008).

33. **Roberts et al., (2014)** studied OOPE and "insurance coverage for abortion in the United States". According to the report, many women in the United States face large out-of-pocket expenses for abortion services, especially for later gestational abortions. Although some individuals have financial support *via* Medicaid, private insurance, or other entities, more than half cited expenses as a reason for postponements in accessing care. Disparities in coverage within public and private insurance persist as a significant concern, disproportionately affecting low-income women (Roberts et al., 2014).

34. **Aikins et al., (2014)** assessed socioeconomic status on the costs incurred by pregnant women for health services in peri-urban Accra, Ghana. It was determined that women in higher income groups incurred greater medical and non-medical expenses, along with increased time and income losses, despite a higher likelihood of possessing health

insurance. The study suggested using community-based activities to raise awareness of health insurance plans and improve education on pregnancy-related healthcare (Aikins et al., 2015).

35. **Wu et al., (2014)** examined the OOPE in fertility. The research analyzed OOPE for reproductive procedures involving 332 couples sourced from many clinics. The median costs for each treatment option varied greatly, ranging from $912 for ovulation induction to $19,234 for IVF. The most expensive procedure was IVF, which cost an average of $15,435 more than IUI. Expenditures were not substantially correlated with pregnancy success, offering essential information for couples to budget for treatment costs (Wu et al., 2014).

36. **Foster et al., (2015)** examined and concluded that permitting OTC access to oral contraceptive pills (OCPs) without a prescription could markedly enhance their utilization among low-income women, especially if the OOPE was minimal or non-existent. This may result in a decrease in unwanted pregnancies (by 7 - 25%) and related public healthcare expenditures, underscoring the prospective public health and economic advantages of OTC access to effective contraception (Foster et al., 2015).

37. **Elliott et al., (2016)** investigated the financial burden and stress of males pursuing reproductive treatment. 64% of the 111 participants had OOPE of more than $15,000, with procedures accounting for the majority of these costs. Those who depended on savings or took on loans were most impacted, with over half reporting financial difficulty. The results underscore the financial difficulties associated with male infertility therapy and their influence on healthcare choices (Elliott et al., 2016).

38. **Kim et al., (2018)** examined the impact of socioeconomic status (SES) on pregnancy results in South Korea, where all expectant mothers get financial assistance for prenatal

care. According to the study, compared to women from higher SE backgrounds (NHI beneficiaries), women from lower SE backgrounds (Medical Aid recipients) were more likely to suffer from “preterm delivery, abortion, Caesarean delivery, preeclampsia, obstetric hemorrhage, and poor prenatal care”. Even with universal access to prenatal care, these unfavourable results raise the possibility of additional obstacles, which call for more research by health authorities (Kim et al., 2018).

39. **Wollum et al., (2020)** studied the effects of OOPE for an OTC progestin-only pill on use in case of unwanted pregnancy in American women. It concludes that eliminating or reducing costs substantially enhances usage, particularly among low-income women, potentially resulting in a decrease in unplanned pregnancies by as much as 8% per year. Cost-effective pricing and insurance coverage were essential for equitable access and mitigating contraceptive disparities (Wollum et al., 2020).

40. **Callander et al., (2021)** by using a big dataset examined how government financing, OOPE, and maternal healthcare services were distributed among socioeconomic categories in Australia. The OOPE for women with better socioeconomic positions were greater ($2,432 vs. $1,026 for “disadvantaged women”), as they sought more private and specialized treatments. Medicare funding predominantly benefited affluent women, whereas public hospital funding was allocated to support disadvantaged women. According to the report, policy changes are necessary to increase underprivileged women's access to and affordability of maternal care (Callander et al., 2021).

41. **Gunarathne et al., (2022)** reported a systematic review on OOPE during pregnancy. The purpose of the study was to thoroughly examine the scope, causes, contributing variables, and consequences of pregnancy-related health-related OOPE (Gunarathne et al., 2022).

42. **Jones et al., (2022)** studied the connection between social factors of health and maternal mortality in the UK. It examined how these variables raise the risk of death during pregnancy, particularly for underprivileged women, and emphasized the difficulties in delivering quality care even in the face of free maternity services. In order to support pregnant women who were at risk and improve maternal outcomes, the study advocates for better data collection, prevention, and intervention (Jones et al., 2022).

43. **Sarmiento et al., (2023)** conducted a study to evaluate the "cost-effectiveness of elective cesarean delivery (ECD) versus spontaneous vaginal delivery (SVD) concerning short-term maternal outcomes in a low-risk obstetrical population in Colombia". For low-risk pregnancies, SVD was more economical and had better short-term mother outcomes than ECD. During a 42-day postpartum interval, SVD was more cost-effective, being $324 less expensive, and provided superior Quality Adjusted Life Years (QALYs). The research underscores the necessity for health policies that advocate for SVD (Sarmiento et al., 2023).

44. **Janaki et al., (2024)** evaluated "socioeconomic determinants affecting maternal health during pregnancy". Socioeconomic variables profoundly influence maternal health, resulting in inequities in healthcare access and outcomes for pregnant women. This investigation underscores disparities influenced by "income, education, employment, and housing", advocating for specific solutions like enhanced healthcare access, educational improvements, job assistance, and governmental reforms to guarantee fair mother care (Janaki & Prabakar, 2024).

2.4 Public Drug Procurement and Distribution

45. **NHSRC New Delhi (2012)**, provided the "Assessment criteria for state drug procurement and distribution system". It provided a total 5 measurable elements

(standards) for the state drug procurement and distribution system in states (National Health Systems Resource Centre, 2012).

46. **Singh et al., (2013)** analyzed drug procurement models across five Indian states *viz* "Tamil Nadu, Kerala, Odisha, Punjab, and Maharashtra" to evaluate their functional efficiencies based on "53 process and price parameters". Data were gathered *via* interviews with key informants and field personnel. The analysis indicated that autonomous procurement organizations demonstrated greater efficiency in payments, drug pricing, and inventory management. The research delineates essential success factors and advocates for additional investigation to enhance policy formulation in this domain (Vikram Singh et al., 2013).

47. **Reghu et al., (2013)** evaluated the drug "procurement and distribution system in Tamil Nadu state of India". In 1994, Tamil Nadu created the Tamil Nadu Medical Service Corporation (TNMSC) was established, which revolutionized public drug procurement. TNMSC has transformed the public medication procurement system with its well-designed and scientifically structured program (Reghu et al., 2013).

48. **Kjos et al., (2016)** analyzed the pharmaceutical system at government hospitals in Vietnam, emphasizing medicine procurement, storage, and delivery. This study employs qualitative methodologies to create a conceptual model that underscores the impact of governmental policies on structure while permitting functional flexibility. Comparing Vietnam's approach to international standards, the findings offer a framework for benchmarking and quality enhancement (Kjos et al., 2016).

49. **Rovers et al., (2017)** researched to examine the role of pharmacists in facilitating access to medication in rural Australia, using a 24-step drug distribution model created through qualitative approaches. Essential elements encompassed supplier selection,

budgeting, and dispensing, with an emphasis on enhancing cold chain integrity. The results endorsed policy, system architecture, and education in remote healthcare (Rovers & Mages, 2017).

50. **Beall et al., (2017)** evaluated "a method for comprehending the generic acquisition of HIV medications by developing nations under patent protection". This research linked "procurement records from the WHO's Global Price Reporting Mechanism to antiretroviral (ARV) patent data derived from a World Intellectual Property Organization patent study". Over fifty percent of generic procurements were aligned with patent protection in either the exporting or importing country, despite the rarity of patents in these areas. The study suggested that developing countries might persist in acquiring generic formulations of essential antiretroviral drugs. The interplay of legal flexibilities, including voluntary license agreements, had likely played a crucial role in improving access to generics. The study suggested further investigation to understand the implications of these findings (Beall & Attaran, 2017).

51. **Dixit et al (2020)** explored the strategy for generic drug distribution in Rajasthan, India, focusing on "supply chain, sourcing, ordering, logistics, inventory management, and information systems". Techniques such as value stream mapping, analytical tools, 5S methodology, and performance measurement systems were examined to formulate plans for enhanced resource utilization (Dixit et al., 2019).

52. **Vledder et al. (2019)** conducted a study in Zambia utilizing a randomized trial involving 439 health facilities across 24 districts. This study was to explain the optimal supply chain configuration for distributing essential medicines within the public sector of low-income nations. The study indicated that a direct distribution system, in which clinics procure medicines directly from a central agency, markedly decreased stockouts relative to conventional multi-tiered systems. This strategy enhances responsibility and

aligns decision-making with staff competencies; however, it may encounter challenges from political and systemic factors, despite its demonstrated effectiveness (Vledder et al., 2019).

53. **Soares et al., (2019)** reported a scoping review related to drug procurement in South American countries. The review identifies deficiencies "concerning the medication procurement processes, specifically in relation to market dynamics, execution duration, supplier information, and types of purchases". Although all nations were analyzed using the WHO/HAI methodology, which enabled data collection on availability and pricing, these elements were little examined. The scoping study offers a comprehensive examination of public medicine procurement, to expand discourse, promote collaborations, and pinpoint knowledge deficiencies in this domain (Soares et al., 2019).

54. **Anggriani et al., (2020)** examined the "impact of pharmaceutical policy reforms on the prices of medicine procurement" in Indonesia. A pre-post observational study was conducted to compare the data from 2013 -2017. The results demonstrated that 79.6% of medications underwent substantial price reductions, with 39% exhibiting decreases greater than 50%. Prices increased for specific patented medications and those with limited brand alternatives. Public and private hospitals demonstrated similar trends in price reductions, including for non-e-catalogue medications; however, the prices of branded generics in private hospitals remained unchanged. The reforms resulted in a significant reduction in medicine procurement costs (Anggriani et al., 2020).

55. **Dubois et al., (2021)** examined the centralized drug procurement (CDS) system in 7 low and middle-income countries. They studied "how CDS influences costs". They examined 3 years data of 40 essential medicines and concluded that the CDS system lowers prices, but less in concentrated supplier marketplaces (Dubois et al., 2021).

56. **Callejas et al., (2021)** analyzed the welfare effects of a public procurement initiative in Ecuador, wherein the government provides cancer treatment medications at no cost, to assist low-income populations. This analysis contrasted a targeting strategy (TS) with a first-come-first-serve (FCFS) system. The results indicated that economically poor patients were more likely to self-select the FCFS due to more benefits. Even though the TS sometimes was more effective in addressing the needs of the poorest patients. However, the policy may distort supply-side incentives, leading to an increase in market prices for low-cost drugs while leaving high-cost drugs unaffected (Callejas & Mohapatra, 2021).

57. **Boche et al., (2022)** performed a mixed to evaluate pharmaceutical procurement practices and challenges at the Ethiopian Pharmaceuticals Supply Agency. It highlighted deficiencies, such as extended lead times, poor forecast accuracy, and difficulties including poor data quality, staff limitations, and communication problems, but also found benefits, such as using a procurement list and obtaining favourable pricing for the majority of items (Boche et al., 2022).

58. **Ke et al., (2024)** evaluated the impact of centralized drug procurement policy (CDP) on the drug price and availability of drugs. Since 2018, China's coordinated CDP helped to lower drug prices and hence patient costs while guaranteeing steady drug supply and market shares for successful businesses (Ke et al., 2024).

CHAPTER 3

OBJECTIVES

3.1 General Objective of this Integrated Study

- In light of the findings from the literature survey, this integrated study aims to holistically examine the multifaceted challenges surrounding healthcare access and medication distribution in India.
- **Goals:** To emphasize the need for effective policy interventions and improved procurement processes that enhance the quality of medicines, alleviate healthcare costs, and ensure equitable accessibility, availability, and affordability of essential medications for all population.

3.2 Specific Objectives of this Integrated Study

- **Study 1 - On Financial Burden of Medicines:** To evaluate the impact of government efforts to reduce out-of-pocket expenditures for medicines in India (***Systematic way of data synthesis based on published evidence***).
- **Study 2 - On TB Drug Therapy Challenges:** To explore socioeconomic and health policy challenges concerning the availability, accessibility, and affordability of quality drug therapy among people living with tuberculosis in Agra district, Uttar Pradesh, India.
- **Study 3 - On Financial Considerations in Pregnancy Outcomes:** To assess the impact of financial considerations on pregnancy outcomes and enhance healthcare access for expectant mothers in Agra district, Uttar Pradesh, India.

- **Study 4 - On Public Drug Procurement Performance:** To conduct a performance assessment of public drug procurement across seven different states from diverse geographic regions in India, focusing on procurement efficiency, cost-effectiveness, and the quality of distribution systems.

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 Bibliography Publication/publishing press Year of Publication	
Study Features	
Objective Methodology Source of data Sampling process Rationale for sample size determination Study area	
Participant Features	
Overview of the study population Population size	
Outcomes Measured	
Different types of medical expenses Reported differences in medicine OOPE Reported differences in medicine CHE Statistical analysis undertaken Key outcomes 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

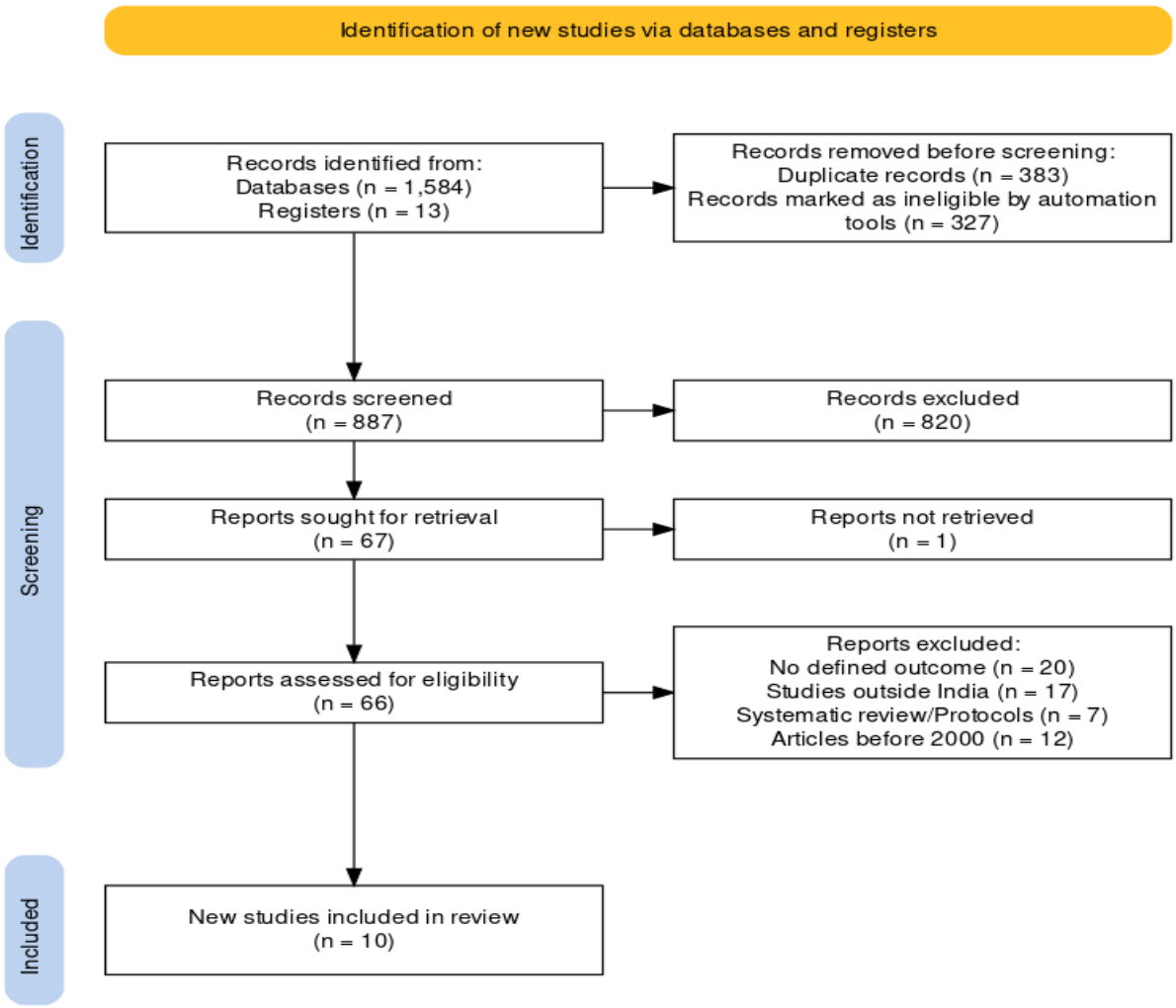


Table 4.3: Methodical Integrity of the Included Studies

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). 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. 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. TN (2004): Rs 1391.69 (Pub) & Rs 11766.71 (Pvt). TN (2014): Rs 450.85 (Pub) & Rs 19264.71 (Pvt). Raj (2004): Rs 6212.58 (Pub) & Rs 10691.45 (Pvt). Raj (2014): Rs 3628.62 (Pub) & Rs 22946.43 (Pvt). WB (2004): Rs 3222.24 (Pub) & Rs 13715.03 (Pvt). WB (2014): Rs 5602.78 (Pub) & Rs 17951.06 (Pvt).	Per episode OOPE during hospitalization. TN (2004): Rs 102.41 (Pub) & Rs 1125.90 (Pvt). TN (2014): Rs 150.10 (Pub) & Rs 3920.06 (Pvt). Raj (2004): Rs 1725.07 (Pub) & Rs 2228.25 (Pvt). Raj (2014): Rs 1516.13 (Pub) & Rs 3451.26 (Pvt). WB (2004): Rs 1326.12 (Pub) & Rs 1934.32 (Pvt). 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% 2004-05: 36.3% 2011-12: 54.3%	1993-94: 20.86% 2004-05: 26.0% 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. For stroke 131.6% increase in medicine OOPE. 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.

CHAPTER 5

TB DRUG THERAPY CHALLENGES

This chapter discusses the socioeconomic and health policy challenges regarding availability, accessibility, and affordability of drug therapy among people living with TB. The study is conducted by utilizing a mixed-methods approach. The data is collected from a large set of sample participants across both public and private healthcare facilities and examined. This research highlights the implications of out-of-pocket expenditure (OOPE) burden on patients, and explores the significance of health policies in optimizing drug supply to the diverse socioeconomic patients. This research aims in understanding the barriers in effective TB treatment and offers targeted recommendations to policymakers in improving service delivery in India.

5.1 Background of the Study

Tuberculosis (TB) is one of the major infectious diseases affecting approximately one-third of the world's population (Sotgiu et al., 2014). With an incidence rate of 210 cases per 100,000 individuals and a mortality rate of 38%, tuberculosis is the leading infectious disease in India (Bagcchi, 2023; Sulis et al., 2014). As the most populous country, faces a healthcare system overburdened by its growing population. Private healthcare costs are out of reach for 3 million households, and drug prices continue to rise (Tripathi et al., 2019). In developing countries like India, impoverished households account for 85% of healthcare costs (Dash & Mohanty, 2019). As a result, many patients face financial barriers that hinder their access to effective treatment and care.

Rural and low-income populations in India face high out-of-pocket expenditures (OOPE), with the mean OOPE estimated at 14,660 INR and higher (Srinadh & Yadav, 2022), limiting access to quality healthcare services and affordable medicine (McIntyre et al., 2006). Consequently,

inadequate healthcare resources and the unaffordability of medicine for the people living with TB impede the achievement of universal health coverage (UHC) (Ranabhat et al., 2020). Moreover, less than 35% of the population has access to basic medical care, predominantly relying on private providers for treatment (Mathewos Oridanigo et al., 2021).

The Indian government spends 2.1% of GDP on health (Aggarwal, 2023), limiting the capacity and quality of healthcare services due to low spending. The public healthcare structure in the country is immensely burdened by the increasing population, perpetually diverting patients to private hospitals. Subsequently, there is a significant risk of pushing low-income patients into poverty. The private sector accounts major share of national health expenditure in India, with medicines being the largest component of OOPE. The government has initiated several health initiatives aimed at eradicating TB and reducing OOPE, including the Pradhan Mantri Bhartiya Janaushadi Pariyojna, the TB-DOT program, and the Ayushman Bharat health insurance scheme (Ranabhat et al., 2020). Nevertheless, household out-of-pocket healthcare expenditure has conventionally been a significant component of India's overall health expenditure. According to the National Health Accounts (NHA), the figure has improved over the years, to 47.1% in 2019-2020 from 62.6% in 2014-2015 (NHSRC, 2015, 2020).

In the view of all the above facts, this study aims to explore the socioeconomic and health policy challenges regarding the availability, accessibility, and affordability of drug therapy among the people living with TB in Agra district, Uttar Pradesh, India. By addressing these critical challenges, this research aims in understanding the barriers in effective TB treatment and to inform policy recommendations to enhance healthcare delivery and outcomes in the study region and beyond.

5.2 Methodology

5.2.1 Study Design

This study uses a mixed-method approach (quantitative and qualitative) that investigates the socioeconomic and health policy challenges regarding the availability, accessibility, and affordability of TB drug therapy. Major public and private sector healthcare facilities located in the Agra district of Uttar Pradesh, India, are the focus of the study. The study area comprises around 359 public and more than 500 private health facilities with a catchment population of around 3.1 million.

5.2.2 Data Collection Methods

The quantitative aspect of the research is undertaken by a facility-based cross-sectional survey using self-administered questionnaires. Complementing the quantitative study, the qualitative part again uses a facility-based cross-sectional survey study with self-administered questionnaires and semi-structured in-depth interviews to explore the reasons for the OOPE in medicines and service utilization issues. All the studies are conducted between October 2022 and March 2023.

5.2.3 Study Population

Both the quantitative and qualitative studies are undertaken in selected major public and private health facilities of the Agra district especially treating tuberculosis. All the health facilities treating tuberculosis found in the Agra district are considered to be the potential source facilities, while the patients, patient's relatives, and health professionals were considered sources of information. The people living with TB and their relatives, health professionals such as treating doctors, health officers, pharmacy professionals, pharmacy store managers, and frontline health workers in the sampled health facilities during the period from October 2022 and March 2023 are contemplated as the study population. Among the health facilities of the

Agra district, the major facilities which served more than three years in treating tuberculosis are included in the study. The facility administration that showed unwillingness for the conduct of the study is excluded from the study.

5.2.4 Sampling Methodology

The sample size of health facilities is determined by a multi-stage sampling technique comprising both public and private health facilities at a ratio of 1:1 between rural and urban populations. Accordingly, 20 major health facilities are selected with which public and private health facilities are 10 each. The study participants for the quantitative study are people living with TB from the sampled facilities. A total sampling of all 2244 people living with TB of these sampled health facilities between October 2022 and March 2023 is carried out.

For the qualitative part of the study, health professionals, patients, and patient relatives around the sampled facilities during the study period and those having a willingness to participate are chosen using the purposive sampling technique. A total of 49 participants are selected for the qualitative study. Additionally, they are also purposively designated as key informants for the qualitative semi-structured in-depth interviews

The purposive selection is critical in identifying key informants, who are invited to participate in qualitative semi-structured in-depth interviews. These interviews aim to delve deeper into the participants' experiences, revealing the perceived factors contributing to OOPE and service utilization challenges. The insights gained from the interview not only supplement the statistical findings but also provide a narrative that captures the complexities of accessing TB treatment in the Agra district.

5.2.5 Questionnaire Development

To effectively address the research objectives of this study, an in-house questionnaire is developed for both quantitative and qualitative components based on the extensive research

needs assessment and with valuable inputs from various experts, including government health officials, administrative officials, hospital administration, and public health officers.

The quantitative study questionnaires are designed with clear research objectives in mind and aim to gather specific observations and insights that are crucial for informing decision-making processes.

The Likert scale questions and interview questions in the questionnaire for qualitative study are thoughtfully designed and developed, ensuring their relevance in capturing the targeted qualitative aspects that this study aims to explore. Careful consideration is given to the response options to offer participants a sufficient level of granularity in expressing their opinions, experiences, or attitudes. It is firmly believed that the in-house questionnaires are the most appropriate and effective approach for this study's objective. The English version of questionnaires used for both quantitative and qualitative studies are included as supplemental material (**Appendix B**).

5.2.6 Pre-testing and Validation

Each questionnaire (both quantitative and qualitative) is subjected to pre-testing and quality checks in a sample of 5 healthcare facilities to ensure reliability and effectiveness. A separate set of 5 healthcare facilities (3 Public and 2 Private) was intentionally selected, which were not included in the main study. This approach allowed to validation and refinement of the questionnaire, ensuring its optimal performance before implementing it in the main study.

The expertise and diverse perspectives of various professionals have greatly contributed to the questionnaire's content and design, ensuring that it elicits the necessary information accurately and comprehensively. In testing the questionnaire, the responses from the sample facilities are analyzed and critically examined for their performance in terms of clarity, relevance, and data reliability. Through this improvement and quality check process, potential ambiguities or issues

are identified and necessary adjustments are made to enhance the questionnaire's validity and consistency. By following this rigorous scientific approach, a robust foundation is established for the data collection. Moreover, using an in-house questionnaire provides several benefits, as it allows to maintain the control over the research process, customizes the questionnaire to specific research needs, and ensures a higher level of consistency and reliability compared to using third-party questionnaires.

5.2.7 Data Collection Process

The authors/data collectors collected the data using data abstraction formats and self-administered questionnaires, and the principal investigator conducted the qualitative semi-structured in-depth interviews. The data collection sheets included self-administered questionnaires, which contained questions about socio-demographic characteristics (area of residence, age, sex, level of education, occupation, and monthly income), medical characteristics, OOPE, and perceived contributing factors on OOPE and service utilization. Key informants are interviewed using a semi-structured approach designed to elicit their perspectives on the problem's causes and present initiatives to address them. Data collectors are trained for four days on the data collection instruments and processes before data collection. Two experts from the TB department of the district administration are invited to review the interview guide for an in-depth interview to ensure its face and content validity.

5.2.8 Analysis and Statistics

Medical characteristics and OOPE of the study participants, service utilization, and policy measures among public and private hospital patients are the critical components of the analysis. The analysis is performed in aggregate and descriptive parameters such as Frequency, Mean, and Standard Deviation (SD) are calculated for different variables. To investigate the potential association between sociodemographic variables and the choice of availing healthcare services

from either public or private providers, a bivariate chi-square test is conducted in GraphPad Prism® Version 5.01 statistical software. The sociodemographic variables considered in this analysis included (area of residence, age, sex, level of education, occupation, and monthly income). The associated *p-value* is reported and the *p-value* ≤ 0.05 is considered statistically significant.

In the Likert scale method employed in the qualitative study, respondents are asked to rate their level of agreement or disagreement with each statement (total of 17 factors) using a 5-point scale from 1 to 5. The scale ranged from "1 - Strongly Disagree" to "5 - Strongly Agree", and "0 – Not Applicable" is additionally included because of different respondent's role existence. Participants are instructed to select the response option that best represents their viewpoint. Based on the specific values of each response, the mean scores and standard deviation for each factor are computed based on the provided ratings. The analysis and interpretation of participant responses are used to evaluate the factors contributing to impaired public service utilization and out-of-pocket expenditure.

Data from an in-depth interview is subjected to a thematic analysis approach. Key themes such as contributing factors, and suggestions for improving the service utilization and reducing the OOPE on medicines are manually reviewed and handled.

5.3 Results

5.3.1 Quantitative Findings

5.3.1.1 Characteristics of the Study Sample

Among the 2244 participant patients in this study, approximately 61% opted for healthcare services from the private sector. This inclination towards private healthcare highlights significant trends regarding patient preferences and accessibility dynamics within the Agra district. The demographic characteristics of patients, differentiated by their choice of public

versus private healthcare sectors, are shown in **Table 5.1**, along with the p values for differences between the public and private sectors.

Table 5.1: Descriptive statistics on the socio-demographic characteristics of People Living with TB in the study facilities (Oct 2022-Mar 2023), Agra District, Uttar Pradesh, India (n=2244)

Variables	Type of Hospital for Availing Health Service		Bivariate Statistics – Chi-Squared test
	Public N (%), n=886	Private N (%), n=1358	*P* value*
Residence			
Urban	515 (58.1)	777 (57.2)	0.6699^{ns}
Rural	371 (41.9)	581 (42.8)	
Sex			
Male	482 (54.4)	740 (54.5)	0.9666^{ns}
Female	404 (45.6)	618 (45.5)	
Age			
<15 Years	58 (6.6)	65 (4.8)	0.0052^{ns}
15-30 Years	423 (47.7)	574 (42.3)	
31-45 Years	240 (27.1)	410 (30.2)	
>45 Years	165 (18.6)	309 (22.7)	
Level of Education			
None	282 (31.8)	434 (31.9)	**<0.0001**
High School or Below	473 (53.4)	658 (48.5)	
Higher Secondary or Diploma	101 (11.4)	249 (18.3)	

Degree/Graduates or Above	30 (3.4)	17 (1.3)	
Occupation			
Casual Labour	219 (24.7)	307 (22.6)	**<0.0001**
Cultivator	111 (12.5)	146 (10.8)	
Home Maker	192 (21.7)	401 (29.5)	
Employed (Salaried)	70 (7.9)	155 (11.4)	
Employed (Self)	93 (10.5)	97 (7.1)	
Student	201 (22.7)	252 (18.6)	
Monthly Income			
<5000 INR	344 (38.8)	409 (30.1)	**<0.0001**
5001-10000 INR	382 (43.1)	551 (40.6)	
10001-15000 INR	107 (12.1)	297 (21.9)	
>15000 INR	53 (6.0)	101 (7.4)	

**P value ≤ 0.05 was considered statistically significant, ns – non-significant*
N-Frequency, %-Percentage, n-total respondents in the respective category, INR-Indian Rupee currency.

The analysis revealed no statistically significant differences in healthcare sector choice based on residence area, age, or sex. This suggests that these factors do not heavily influence whether patients choose public or private healthcare facilities. On the other hand, significant associations are observed concerning the level of education, occupation, and monthly income. These variables are significantly linked to the choice of healthcare sector, indicating that socio-economic factors play a pivotal role in determining healthcare preferences. Patients with higher educational attainment or income levels, and those in specific occupational categories, exhibited a tendency to utilize private healthcare services more frequently.

5.3.1.2 Healthcare service utilization and Health policy benefits

Healthcare service utilization and health policy benefits among people living with TB are studied under the categories of hospital, active TB stage, family screening, preventive treatment for families, and frontline health worker intervention, and the related data are shown in **Table 5.2**.

In terms of hospital category utilization, the findings indicate a distinct pattern in patient preferences within both the public and private healthcare sectors. A significant proportion of patients, 50.4% (n = 886), utilized community health centres within the public sector. In contrast, 45.6% (n = 1358) of patients sought treatment from tertiary care hospitals within the private sector. This distribution highlights the differing roles and capacities of public versus private facilities in delivering TB treatment.

In both healthcare sectors, a majority of the people living with TB are found to be in the pulmonary infection stage during the study period (74.2% in the public sector and 81.7% in the private sector). This underscores the critical need for ongoing, aggressive TB detection and management strategies, especially considering the contagious nature and public health implications of pulmonary TB.

Upon further evaluation regarding family screening practices and preventive treatments, this study reveals significant disparities between the healthcare sectors. In the public sector, nearly 79% of patients (n = 886) underwent family screening for TB, but a contrast to only 25% (n = 1358) is seen in the private sector. Moreover, preventive treatment to the families in the public healthcare sector is successful for 71% of the patients, but a very low number (10%) concerned the private hospital patients. These differences highlight potential gaps in private sector engagement with broader public health strategies like family screening and preventive care.

Another policy implication such as the Frontline health workers intervention during treatment is notably higher among public-sector hospital patients, with an 80% intervention rate, compared to 35% among private-sector patients. This significant involvement in the public sector aligns with health policy efforts prioritizing community-based interventions and support structures that are essential for comprehensive TB management.

Table 5.2: Medical characteristics of the study participants, service utilization and policy measures among public and private hospital patients (Oct 2022-Mar 2023), Agra District, Uttar Pradesh, India (n=2244)

Variables	Type of Hospital for Availing Health Service	
	Public N (%), n=886	**Private N (%), n=1358**
Category of Hospital		
Primary Health Care	223 (25.2)	283 (20.8)
Community Health Care	447 (50.4)	360 (26.5)
Medical College Hospital/Tertiary Care	36 (4.1)	619 (45.6)
District Hospital/Quaternary Care	180 (20.3)	96 (7.1)
Active TB Stage		
Primary Infection	23 (2.6)	47 (3.5)
Pulmonary Infection	657 (74.2)	1110 (81.7)
Extra Pulmonary	146 (16.5)	197 (14.5)
MDR TB	57 (6.4)	4 (0.3)
Active TB with Comorbidities	3 (0.3)	0 (0)
Family Screening		
Yes	703 (79.3)	336 (24.7)
No	183 (20.7)	1022 (75.3)

TB Cases in the Family after Screening (Public n=703, Private n=336)		
0 Case	556 (79.1)	250 (74.4)
1 Case	100 (14.2)	77 (22.9)
2 Cases	29 (4.1)	8 (2.4)
3 Cases	6 (0.9)	1 (0.3)
4 Cases	12 (1.7)	0 (0)
Preventive Treatment to Family		
Yes	631 (71.2)	137 (10.1)
No	255 (28.8)	1221 (89.9)
No. of Monthly Hospital Visits		
One	415 (46.8)	336 (24.7)
Two	294 (33.2)	911 (67.1)
Three	83 (9.4)	106 (7.8)
Four & above	94 (10.6)	5 (0.4)
Frontline Health Worker (ASHA/AWW) contacted during the Treatment Period		
Yes	709 (80)	480 (35.3)
No	177 (20)	878 (64.7)
Frontline Health Worker Visit to Patient Home		
None Visited	188 (21.2)	878 (64.7)
TB Health Visitor	323 (36.5)	336 (24.7)
Asha Worker	104 (11.7)	64 (4.7)
Senior Treatment Supervisor	205 (23.1)	19 (1.4)
Any Other from the Health Department	66 (7.4)	61 (4.5)

N-Frequency, %-Percentage, n-total respondents in the respective category, MDR TB-Multidrug-resistant tuberculosis, ASHA-Accredited Social Health Activist, AWW-Anganwadi worker.

5.3.1.3 Availability, Accessibility, Affordability, OOPE on Medicines, and Health Policy Benefits

The out-of-pocket expenditures (OOPE) among people living with TB are assessed and the effectiveness of policy measures related to the availability, accessibility, and affordability of medicines are evaluated. These findings are shown in **Table 5.3**.

In the context of public hospitals, it is well-established that consultations and diagnostic services are provided free of charge. However, all patients utilizing private hospitals faced charges for these services, which varied depending on the hospital type and nature of the diagnosis. This unpreventable imposition of fees in the private sector presents significant financial barriers for patients and underscores a critical difference in the economic impact of healthcare access between the sectors.

Table 5.3: OOPE of the study participants, and policy measures among public and private hospital patients (Oct 2022-Mar 2023), Agra District, Uttar Pradesh, India (n=2244)

Variables	Type of Hospital for Availing Health Service	
	Public N (%), n=886	Private N (%), n=1358
OPD Visits/Consultation Charges Per Visit		
Free of Charge	872 (98.4)	0 (0)
<500 INR	12 (1.4)	885 (65.2)
501-1000 INR	2 (0.2)	426 (31.4)
>1000 INR	0 (0)	47 (3.5)
Diagnosis Expenses		
Free of Charge	854 (96.4)	0 (0)

<500 INR	16 (1.8)	531 (39.1)
501-1000 INR	8 (0.9)	369 (27.2)
1001-2000 INR	1 (0.1)	288 (21.2)
>2000 INR	7 (0.8)	170 (12.5)
Medicine Availability in the Treating Hospital		
Yes	867 (97.9)	647 (47.6)
No	19 (2.1)	711 (52.4)
Affordability on Medicines		
Yes	816 (92.1)	123 (9.1)
No	70 (7.9)	1235 (90.9)
Monthly Medicine Expenses		
Free of Charge	796 (89.8)	0 (0)
<500 INR	41 (4.6)	106 (7.8)
501-1000 INR	5 (0.6)	528 (38.9)
1001-2000 INR	22 (2.5)	321 (23.6)
>2000 INR	22 (2.5)	403 (29.7)
Expenses of Vitamins & Supplements		
Free of Charge	636 (71.8)	0 (0)
<2000 INR	228 (25.7)	911 (67.1)
2001-4000 INR	20 (2.3)	319 (23.5)
4001-10000 INR	2 (0.2)	114 (8.4)
>10000 INR	0 (0)	14 (1.0)
Expenditure on Hospitalization on MDR TB		
Free of Charge	875 (98.8)	0 (0)

<3000 INR	7 (0.8)	543 (40.0)
3001-5000 INR	2 (0.2)	306 (22.5)
>5000 INR	2 (0.2)	509 (37.5)
Other Expenses		
<500 INR	755 (85.2)	851 (62.7)
500-1000 INR	118 (13.3)	317 (23.3)
1001-2000 INR	9 (1.0)	157 (11.6)
>2000 INR	4 (0.5)	33 (2.4)
Patients Received 500 INR/Month for Nutrition from the Government as Aid		
Yes	819 (92.4)	289 (21.3)
No	67 (7.6)	1069 (78.7)
Source of Money on Expenditure		
Daily Wages	46 (5.2)	104 (7.7)
Family Dependent	101 (11.4)	15 (1.1)
Farming	35 (4.0)	36 (2.7)
Government Aid	169 (19.1)	4 (0.3)
Insurance	3 (0.3)	3 (0.2)
Loan	2 (0.2)	2 (0.1)
Salary	289 (32.6)	967 (71.2)
Savings	241 (27.2)	215 (15.8)
Business	0 (0)	12 (0.9)

N-Frequency, %-Percentage, n-total respondents in the respective category, INR-Indian Rupee currency, OPD-Out Patient Department, MDR TB-Multidrug-resistant tuberculosis.

In the case of medicine availability in the treating hospital, around 98% (n = 886) of patients from public hospitals reported the availability, whereas 48% (n = 1358) only reported the availability in private hospitals. This significant disparity highlights ongoing challenges in pharmaceutical supply chain management and accessibility in private healthcare settings.

In terms of affordability, almost 91% (n = 1358) of private-sector patients could not afford the medicines. Furthermore, about 30% of these patients reported monthly spending on medicines exceeding 2000 INR, highlighting a substantial economic burden that threatens their ability to sustain essential treatment regimens.

Government Policy and Nutritional Aid

Government policy aimed at mitigating these financial constraints includes provisions such as the Central government's nutritional aid of 500 INR per month for people living with TB. This benefit is effectively extended to 92% of patients within the public healthcare sector. However, access is notably restricted in the private sector, reaching only 21% of patients. The limited reach of this aid into private care sectors highlights a potential policy review/enhancement to ensure equitable support for all people with TB, regardless of their healthcare provider choice.

Sources of OOPE

The study also reveals that patients predominantly rely on personal resources to cover their healthcare expenses. Specifically, 60% of patients in the public sector and 87% in the private sector report their source of expenditure as their salary and savings. This reliance not only underscores the prevalent financial burden faced by people with TB but also reflects the issues in healthcare financing and the need for policies aimed at reducing OOPE through enhanced insurance coverage and subsidies.

5.3.2 Qualitative Findings

5.3.2.1 Socio-Demographic Characteristics of Respondents

In total, 49 participants aged between 20 and 62 years are engaged as respondents in this qualitative study. The diverse roles of these respondents are carefully selected to provide comprehensive insights into the study objectives. Among the 49 respondents, respondent's roles such as treating doctors, and health officers are engaged in providing valuable perspectives on the intricacies of TB treatment, healthcare service delivery, and the implementation of health policies. For the remaining participants, which include people with TB and their relatives, the focus is primarily on their experiences and interactions with healthcare services. The length of service in the respondent's role is also gathered, except for the patients and their relatives. The inclusion of various respondent roles enriches the data and contributes to a multifaceted understanding of the factors impacting TB care and support in the Agra district.

The demographic characteristics of the qualitative study participants are summarized in **Table 5.4**. This table presents important data, allowing for a clearer understanding of the diversity and backgrounds of those involved in this qualitative component study.

Table 5.4: Socio-demographic characteristics of health professionals, patients, and patient relatives around the study facilities for the qualitative findings (Oct 2022-Mar 2023), Agra District, Uttar Pradesh, India (n=49)

Variables	N (%), n=49
Sex	
Male	34 (69.4)
Female	15 (30.6)

Age	
20-30 Years	6 (12.3)
31-40 Years	22 (44.9)
41-50 Years	13 (26.5)
>50 Years	8 (16.3)
Respondent's Role	
Doctor	14 (28.5)
Health Officer	5 (10.2)
Store Manager	4 (8.1)
Pharmacist	8 (16.3)
Frontline Health Worker	6 (12.3)
Patient Relatives	6 (12.3)
Patients	6 (12.3)
Length of Service on Respondent's Role (n=37)	
<5 Years	3 (8.1)
5-15 Years	26 (70.3)
16-25 Years	6 (16.2)
>25 Years	2 (5.4)

N-Frequency, %-Percentage, n-total respondents in the respective category

5.3.2.2 Perceived factors contributing to the impaired public service utilization and OOPE on medicines

In this study, a total of 17 factors are identified as potentially influential in determining service utilization and the out-of-pocket expenditure (OOPE) burden associated with tuberculosis (TB) therapy. These factors are circulated as questionnaires administered to all respondents, whose

insights are evaluated using a 5-point Likert scale to quantify perceptions regarding their impact.

Among the factors assessed, several factors are found to be particularly significant in the context of TB therapy. The most commonly perceived contributors are as follows,

- **Delayed Diagnosis and Poor Treatment Adherence**: Respondents indicated that delays in diagnosis and non-adherence to prescribed treatment plans significantly exacerbate both the disease burden and OOPE. This factor received a mean score of 3.76 ± 1.15 (Mean ± Standard Deviation), highlighting its critical role in influencing patient outcomes.
- **Low Monthly Disposable Income**: Another key factor identified is the limited real monthly disposable income per patient, which is rated with a mean score of 3.71 ± 1.18 (Mean ± Standard Deviation). This underscores the financial challenges faced by the patients, which can hinder their ability to access necessary treatments.
- **Lack of Health Insurance**: The majority of patients do not possess health insurance. This factor is rated with a mean score of 3.69 ± 1.33 (Mean ± Standard Deviation), indicating that insufficient insurance coverage is a significant barrier to financial protection and access to healthcare services.
- **Insufficient Government Incentives**: Respondents also expressed concern over the insufficient government incentives. This factor is rated with a mean score of 3.61 ± 1.16 (Mean ± Standard Deviation).

The mean scores of all responses concerning the various contributing factors are presented in **Table 5.5**.

Table 5.5: Perceived factors contributing to the impaired public service utilization and OOPE on medicines by the health professionals, patients, and patient relatives in the study facilities (Oct 2022-Mar 2023), Agra District, Uttar Pradesh, India (n=49)

S. No	Contributing Factors	Frequency (%)						Mean	SD*
		NA	SD	D	N	A	SA		
1	TB disease prevalence or incidence itself is a major cause	0 (3)	1 (5)	2 (3)	3 (3)	4 (24)	5 (11)	**3.49**	1.47
2	Rising drug prices on medicines	0 (0)	1 (14)	2 (1)	3 (8)	4 (21)	5 (5)	3.04	1.41
3	Rising inflation	0 (1)	1 (8)	2 (4)	3 (13)	4 (22)	5 (1)	3.02	1.20
4	Govt spending on medicines is low	0 (4)	1 (13)	2 (7)	3 (6)	4 (9)	5 (10)	2.67	1.68
5	Govt not providing medicines free of cost in govt facilities	0 (7)	1 (16)	2 (8)	3 (4)	4 (10)	5 (4)	2.12	1.59
6	Medicines availability in govt hospitals is low	0 (4)	1 (17)	2 (6)	3 (4)	4 (8)	5 (10)	2.51	1.73
7	High-cost branded drugs are prescribed	0 (0)	1 (10)	2 (8)	3 (10)	4 (11)	5 (10)	3.06	1.42
8	Govt medical service utilization by the public is poor	0 (3)	1 (14)	2 (6)	3 (10)	4 (12)	5 (4)	2.53	1.47
9	Govt facility/infrastructure is poor & patients depend on private	0 (2)	1 (11)	2 (6)	3 (3)	4 (21)	5 (6)	2.98	1.52
10	Govt schemes in addressing OOPE are not adequate	0 (1)	1 (14)	2 (8)	3 (6)	4 (10)	5 (10)	2.82	1.57
11	Govt schemes in addressing OOPE are not reaching the public	0 (0)	1 (13)	2 (8)	3 (4)	4 (12)	5 (12)	3.04	1.56
12	Govt incentives on people living with TB are not sufficient	0 (0)	1 (5)	2 (4)	3 (4)	4 (28)	5 (8)	**3.61**	1.16
13	The majority of patients have not taken health insurance	0 (0)	1 (5)	2 (6)	3 (5)	4 (16)	5 (17)	**3.69**	1.33
14	Private medical service is good	0 (2)	1 (8)	2 (3)	3 (16)	4 (12)	5 (8)	3.06	1.41
15	Private medical service/Private medical store is the only cause	0 (0)	1 (6)	2 (15)	3 (13)	4 (11)	5 (4)	2.84	1.15
16	Real monthly disposable income per patient is very low	0 (0)	1 (3)	2 (8)	3 (1)	4 (25)	5 (12)	**3.71**	1.18
17	Delayed diagnosis and patient not following treatment plan lead to the increased burden on disease and OOPE	0 (1)	1 (2)	2 (5)	3 (3)	4 (27)	5 (11)	**3.76**	1.15

NA-Not Applicable, SD-Strongly Disagree, D-Disagree, N-Neutral, A-Agree, SA-Strongly Agree.
Response scores-Strongly Disagree (1), Disagree (2), Neutral (3), Agree (4), Strongly Agree (5), and Not Applicable (0).
TB-Tuberculosis, Govt-Government, OOPE-Out-of-Pocket Expenditure, SD-Standard deviation.*

5.3.3 Qualitative Semi-Structured In-Depth Interview Findings

In-depth interviews are conducted with all 49 study participants, to explore their perspectives based on their specific roles within the healthcare framework. The interviews are structured around three primary patterns of responses, such as

- ✓ Factors that contribute to impaired public service utilization
- ✓ Self-strategies for improving the burden of OOPE on medicines
- ✓ Suggestions to the government/policymakers for improving service utilization and reducing OOPE

5.3.3.1 Factors that Contribute to Impaired Public Service Utilization

The key informants mentioned several critical factors that contribute to impaired public healthcare service utilization among the people living with TB in the Agra district.

Identified Factors

- ➢ **Long Wait Times**: The long waiting periods at the OPD and medication counters are among the most common issues mentioned by the key informants. They mention that "these delays cause frustration and discourage people from seeking timely care", which underscores the high patient volumes and inadequate staffing.

- ➢ **Centralization of TB Treatment Services**: Key informants mention that the centralization of TB treatment services in specific facilities creates accessibility challenges for those in rural areas. They say that "have to travel considerable distances to specific treatment centres", which can also contribute to non-adherence to treatment regimens.

- **Poor Infrastructure**: The infrastructure of government hospitals is another concern mentioned by the key informants. They say that "Inadequate facility, lack of essential medical equipment, and lack of hygienic condition", as factors challenging the quality of care.

- **Lack of Branded Medicines**: Informants say that "branded medicines are not available in government hospitals", leading to the perceptions of poor treatment options and loss of trust in public health services.

- **Misconceptions about Public Health Services**: Majority of the key informants pointed about the misconception of the quality of services in public health facilities. Many patients perceive these services as subpar compared to private options, which can deter them from utilizing available resources. This stigma, combined with the above factors, creates an impaired public health services utilization within the community.

5.3.3.2 Self-Strategies for Improving the Burden of OOPE on Medicines

Key informants in the study are asked for their opinions on the effective strategies that could be implemented at the facility level to alleviate the burden of out-of-pocket expenditures (OOPE) on medications for tuberculosis (TB) treatment. Their insights highlight several key approaches that may significantly enhance patient access to treatment and reduce financial constraints.

Recommended Strategies

- **Orientation and Awareness Programs**: A predominant recommendation from key informants is to conduct orientation and awareness programs about the services provided by the government. These initiatives should focus on informing the

public/patients about the services available in the government healthcare facilities through the following modes,

- ✓ **Frontline Health Workers**: Utilizing community health workers to engage directly with the public, providing information and support regarding available services and navigating the healthcare system.

- ✓ **Media Outreach**: Campaigns such as television advertisements and local newspapers could be instrumental in raising awareness about TB treatment options, eligibility for support programs, and the availability of essential medications.

- ✓ **Community Engagement**: Collaborating with religious leaders and community preachers to incorporate health education in community gatherings. This approach can effectively communicate critical health messages and encourage individuals to seek services without stigma.

- ➢ **Availability of Branded Medications**: Some key informants raised the issue of the availability of branded drugs in public sector hospitals. They suggested that making these medications accessible could improve the quality of care and enhance patient trust in government facilities.

- ➢ **Direct Benefit Transfers (DBT)**: Majority of key informants recommended the timely provision of direct benefit transfers (DBT) to patients. They said that timely DBT would not only enhance the affordability but also encourage adherence to prescribed regimens.

5.3.3.3 Suggestions to the Government/Policymakers for Improving Service Utilization and Reducing OOPE

Key informants are asked for their suggestions to the government and the policymakers to enhance service utilization and mitigate out-of-pocket expenditure (OOPE). Their insights reveal a comprehensive set of proposed strategies in addressing existing challenges of the healthcare system.

Key Recommendations

1. **Employment of Additional Health Professionals**: A common suggestion made is to increase the number of health professionals across all healthcare settings. This would not only alleviate the burden on existing staff but also improve patient care and reduce wait times.

2. **Decentralization of TB Treatment Services**: Respondents strongly support the decentralization of TB treatment services. By making these services more accessible at the community level, patients would not face barriers to receiving care, ultimately leading to improved adherence to treatment and better health outcomes.

3. **Extension of Free Medicine Schemes**: There is a strong suggestion for extending free medicine schemes to private hospitals. This measure aligns with the vision of completely eradicating TB by reducing financial burdens on patients, which is believed to be a critical step towards ensuring that all individuals have access to effective treatment options.

4. **Compensability of Tuberculosis**: Respondents made suggestions that tuberculosis could be classified as a compensable disease. Implementing such a policy could provide additional financial support for those affected, helping to cover the costs associated with treatment and care.

5. **Public Insurance Coverage for Private Treatment**: Another notable recommendation made is for the establishment of public insurance programs that include coverage for all treatments in private hospitals. This could enhance patient choice and access to a broader range of treatment options, ensuring that individuals do not face financial hardship when seeking necessary care.

6. **Travel Allowance for people living with TB**: Respondents suggest the travel allowance of 300 INR for all people living with TB. Currently, this allowance is provided only to people with multi-drug resistant (MDR) TB. Extending this support to all people with TB would address the travel-related challenges and could facilitate better access to necessary care.

7. **Full Implementation of Current Policies**: All respondents suggest the necessity of fully implementing existing health policies. There is an urgent need to ensure that policies intended to improve healthcare access and TB support programs are executed effectively, optimizing their intended impact.

5.4 Discussion

In this study, around 61% of the people living with TB avail private sector healthcare facilities in the study area. This result is in line with the study by Guy Stallworthy et al. 2020, in which they compare the private TB treatment coverage in 10 countries by using the WHO data, which shows India at 74%, Indonesia at 74%, and Philipines 70%, Pakistan 85%, Nigeria 67%, Bangladesh 84%, and Myanmar 74% (Stallworthy et al., 2020). The same study also reports the private TB drug sales of 54% and a private % of total health expenditure (2017) of 72% in India.

There is growing evidence that the private sector's TB care falls short of international standards and needs urgent improvement (Cazabon et al., 2017). Private healthcare providers have low

tuberculosis (TB) testing rates, rarely send patients to the national TB program, and prefer empirical antibiotic treatment. Chest radiography is used often, sputum testing seldom, and medication susceptibility testing rarely. A "know-do gap" exists between healthcare providers' knowledge and actions. They also struggle with patients' poor compliance and high care expenditures, with 50% of these costs incur before a medical diagnosis (Cazabon et al., 2017; Daniels et al., 2017; Hanson et al., 2017; Tanimura et al., 2014). A study from Mumbai and Patna cities of India by Kwan et 2018 shows that only 37% of symptomatic people living with TB are correctly managed by private healthcare providers, and only 15% are referred to the national TB program (Kwan et al., 2018).

Around 70% of the private patient's monthly income falls below 10000 INR, irrespective of the financial burden the patients choose the private healthcare sector may be due to a lack of awareness of public schemes regarding national TB programs. This can be well addressed by creating health campaigns, advertising, and orientation to the public by the government and the same is supported by the current qualitative findings. TB treatment often requires long-term drug therapy, which can impose a significant financial burden on patients and their families. Public hospitals generally offer TB treatment at subsidized or free rates, but these facilities are overburdened and may lack adequate resources. Private hospitals, on the other hand, charge high fees for consultations, diagnostics, and medications, making TB treatment unaffordable for many patients (Viney et al., 2019).

Regarding the non-availability of medicines, 2% of patients in public sector hospitals and 52.4% of patients in private sector hospitals report the non-availability of medicines, respectively. This shows that the private hospitals are not well prepared for TB treatment services, irrespective of having branded costly medicines on their premises. Inadequate drug supply and stockouts can hinder patients access to crucial TB medications. This issue is more prevalent in public hospitals that often struggle with procurement and distribution

inefficiencies. Private hospitals face drug shortages, particularly if they do not have robust supply chains or if the drugs are expensive (Shukar et al., 2021). When it comes to affordability around 8% of public sector patients reported unaffordable, which could be a reason for some unavailable medicines in the public sector hospitals and force the patients to obtain from private medical stores. In the case of private sector patients, around 91% of them reported the unaffordability of the medicines, this is believed to be a major impact on achieving the vision of TB eradication at the country level.

The government of India's National Tuberculosis Elimination Programme (NTEP) initiative, ensures the direct benefit transfer scheme "Nikshay Poshan Yojana" to all people with active TB for their nutritional benefits by providing 500 INR every month until the disease progression irrespective of both public and private sector patients. This study shows that there are around 8% and 79% of public and private sector patients, respectively not receiving the said amount. This gap needs to be urgently addressed by the program administration to ensure the DBT reaches 100%. The large number of private patients who are not receiving the amount may be also due to non-registration of patient profiles by the private sector hospital administration in the Ni-Kshay (End Tb) web portal. This is supported by a qualitative TB care study by Guy Stalworthy et al. 2020, in which non-reporting to the national TB programs is evidenced (Stallworthy et al., 2020). The government should ensure the identification of people living with TB and ensure the standards and policies maintained for TB eradication.

According to the WHO Global TB Report data, in India alone, there are 696 thousand missing patients from private TB providers (Stallworthy et al., 2020). The qualitative component of this study also recognized that delayed diagnosis and patients not following treatment plans can lead to an increased burden on disease and OOPE as a major perceived contributing factor. Also, this study identifies that real monthly disposable income per patient is very low, indicating the mandate of a cost-effective approach to treating TB disease. Economic research

reports the costs and cost-effectiveness of two Indian prototype Public-Private Mix (PPM) projects using public-sector DOTS and private-sector non-DOTS treatment. Public sector DOTS and PPM DOTS cost about half as much as non-DOTS private therapy (Floyd et al., 2006). Therefore, it is evident that the public-private mix could be more appropriate when it comes to including private sectors in national TB programs.

Access to healthcare facilities, including hospitals, is not evenly distributed across India. Rural areas and economically disadvantaged regions have limited access to quality healthcare facilities, including hospitals providing TB treatment. This lack of accessibility affects patients' ability to access drug therapy conveniently. Moreover, India's healthcare system is fragmented, with a mix of public and private hospitals providing TB treatment. This fragmentation poses challenges in coordinated efforts for identifying, treating, and monitoring TB cases. Lack of coordination between public and private sectors can result in gaps in treatment, difficulties in monitoring adherence to drug therapy, and uneven distribution of resources.

In terms of health insurance, the quantitative and qualitative findings of this study show a very low portion of patients on health insurance, which is 3% in both healthcare sectors and it is a notorious perceived contributing factor in escalating the OOPE issues. The government should prioritize advancing the promotion of comprehensive health insurance schemes and advocate to reduce disparities in reimbursement for TB care (Pan et al., 2016).

The key informants highlight the lack of awareness regarding the availability and quality of services in government hospitals. This unawareness and misconception in quality, diverts general public to seek healthcare services from private facilities, resulting in a strain on their financial resources. Additionally, the key informants mention that the perception of inadequate medical staffs and long waiting times causes frustration and discourages individuals from utilizing public health facilities. This gap should be addressed and adequate human resources

are to be ensured. The need for efficient and transparent mechanisms to ensure the timely delivery of direct benefit transfer (DBT) to the intended beneficiaries should also be deemed necessary.

There is an urgent need to address the challenges related to the infrastructure and the logistics to improve the accessibility and availability of government services in remote areas. The study noted the importance of increasing awareness campaigns and education programs to promote early detection and treatment of TB. Moreover, it is well known that TB is associated with social stigma in many communities, impacting patient willingness to seek treatment or disclose their condition. This can further hinder access or delays in seeking healthcare or opting for private hospitals over public facilities to avoid social stigma (Tadesse, 2016).

5.5 Limitations and Strengths of this Study

The limitations of this study include that it covered only service utilization and OOPE burden on TB medicines in public and private sector hospitals. This study did not assess the quality and outcome of the private sector hospitals. The strength of this study include the use of both quantitative and qualitative methods to supplement each other.

5.6 Conclusions

This study finds a high extent of TB service utilization in private sector hospitals in the Agra district. Among the sampled patients, around 61% avail of private sector healthcare services both in rural and urban areas of Agra. Several socio-economic and health policy challenges impact the availability, accessibility, and affordability of drug therapy among TB treatment in India. These challenges include limited availability of drugs, unequal distribution of healthcare system, finance, limited health insurance, and fragmented healthcare. Addressing these challenges requires a multi-faceted approach, including increased investment in healthcare

infrastructure, strengthening drug supply chains, expanding health insurance coverage, reducing out-of-pocket expenses for patients, and improving coordination between public and private healthcare providers. Additionally, awareness campaigns aimed at reducing stigma and discrimination can help encourage more people living with TB to seek timely treatment.

Similar issues regarding TB treatment are also prevalent in various regions across India. Therefore, while direct applicability may not be guaranteed due to regional differences in demographics and policies, the study's findings may serve as a reference for understanding broader trends in TB management both nationally and potentially in similar contexts internationally.

5.7 Ethical Considerations

The study complies with the declaration of Agra district hospitals. The Chief Medical Officer (CMO) of the Agra district administration has given approval for the study protocol, and the permissions are obtained from all the study facilities to conduct the study. Participants are informed that their personal information will remain confidential and will only be used for the study purpose. The consent process includes a clear explanation of the study's objectives, and the participants are given the privilege to withdraw from the study at any time. Written informed consent is obtained from each study participant for their participation and publication of the results. All data collected from participants is kept confidential by not using personal identifiers. For confidentiality and ethical considerations, the names of sampled health facilities are identified only by codes throughout the study.

CHAPTER 6

FINANCIAL CONSIDERATIONS IN PREGNANCY OUTCOMES

This study discusses the demographic and socioeconomic factors influencing out-of-pocket expenditure related to pregnancy and childbirth in the Agra district of Uttar Pradesh in India. The data is collected across diverse groups of women in various delivery settings using a cross-sectional mixed methods design using surveys and semi-structured interviews. This study explores the financial burdens of expectant mothers associated with income, education, geographic location, etc. Additionally, the study also identifies the patterns of healthcare utilization, particularly observing home deliveries associated with lower expenses, but with limited access to quality healthcare. Overall, this research attempts to identify the critical factors that determine OOPE and offer insights to enhance maternal healthcare by reducing OOPEs related to pregnancy and childbirth.

6.1 Background of the Study

Pregnancy and childbirth are important life events that can be expensive for some households. There are several factors associated with the financial burden in pregnancy and related healthcare, including health expenditure patterns and socioeconomic conditions. In India, the financial consequences of pregnancy is surrounded by the socioeconomic status and the choice of healthcare access. According to the OECD 2021 report, health expenditure is approximately 3.2% of GDP and there is considerable dependence on out-of-pocket expenditure for maternity care (OECD, 2021). Along with the prenatal and postnatal care costs, medications and nutrition costs are also contributing to the significant OOPE burden on low-income mothers (K. Taylor et al., 2021). Financial burden may impact access to essential healthcare, which can pose challenges to maternal health outcomes.

Geographical disparity is a significant issue that can lead to financial challenges for pregnant women. It is obvious that people living in rural and remote regions will encounter greater challenges in accessing quality healthcare and have a greater likelihood of OOPE burden (Backes et al., 2020). Delayed care and limited prenatal visits, can affect the health-seeking behavior and pregnancy outcomes negatively (Borde et al., 2020).

Providing equal access to healthcare services is the responsibility of the government. Minimum service standards and regulatory frameworks are designed to protect against the denial of care by any public or private healthcare provider (Maqbool et al., 2019). In contrast, majority of the expectant mothers are under additional financial strain, especially in the private healthcare sector where expenses are often significantly higher (Sarowar et al., 2010).

Effective interventions to reduce the disparities require a detailed understanding of socioeconomic and demographic factors that contribute to the financial burdens during pregnancy. Exploring the out-of-pocket expenses related to prenatal and postnatal care, including medicine and nutrition costs can give clear insights into the financial needs of the expectant mothers (Rahman et al., 2022). In addition, expanding comprehensive insurance coverage and support services like subsidized childcare and transportation assistance in vulnerable population groups can reduce OOP costs (Jeong et al., 2016). In the view of socioeconomic and demographic insights, and the OOP cost implications, this study aims to evaluate the impact of financial challenges associated with pregnancy and related healthcare outcomes.

6.2 Methodology

6.2.1 Study Design

Using a mixed-methods approach (both quantitative and qualitative), this study focuses at the demographic, socioeconomic, and reproductive characteristics of women who gave live births.

It investigates the extent and factors influencing out-of-pocket expenditures related to pregnancy and childbirth.

6.2.2 Study Duration and Setting

The study is conducted from January 2023 to December 2023. During this time frame, women with post-partum periods, with various socio-economic strata, are recruited from healthcare facilities and community settings of Agra district, Uttar Pradesh, India.

6.2.3 Data Collection Methods

The quantitative aspect of the research is undertaken by a cross-sectional survey study with structured questionnaires. Complementing the quantitative study, the qualitative part again uses a facility-based cross-sectional survey study with self-administered questionnaires and semi-structured in-depth interviews to explore the contributing factors for the OOPE on pregnancy and related health care.

6.2.4 Study Population

A total population of 76,350 women who gave live births were found in the study setting during the period between January 2023 to December 2023. Upon conducting an initial survey for sample recruitment (consent to participate), 804 participants showed a willingness to participate. All the health facilities providing prenatal and childbirth services in the Agra district, as well as home deliveries (home), are considered to be the potential source facilities, while women who gave birth are considered sources of information. The women who gave live birth within one month during the timeframe from January 2023 to December 2023 in the sampled facilities are contemplated as the study population. The facility administration that showed unwillingness to conduct the study is excluded. Additionally, women with specific medical conditions that could potentially confound the results and those unwilling to participate are also excluded from the study.

6.2.5 Sampling Methodology

This study is conducted in both rural and urban areas for a comprehensive analysis of the disparities in health expenditure among pregnant women (Sanogo & Yaya, 2020). A total of 804 participants, who showed a willingness to participate are considered for the quantitative study.

Using the standard sampling formula, the total sample size (n) is calculated for the desired confidence level, margin of error and the estimated proportion of live births. Stratified random sampling method is used to make representation across diverse socioeconomic, and demographic groups. The sampling method comprises the participants across three strata such as home deliveries, private hospital deliveries, and public hospital deliveries. The allocation of sample size to different strata is done in proportion to their sizes (Emori et al., 2014).

A stratified random sampling for the proportional allocation is done by using the following formula:

$$n_h = \frac{N_h}{N} . n \qquad ---------- (1)$$

Where,

nh - Sample size required for stratum h.

Nh - Population size of stratum h (the total number of live births in that stratum).

N - Total population size across all strata.

n - Total sample size required for the entire population.

The total sample size is distributed among the strata according to the proportion of the population within that stratum (Cochran, 1977; Levy & Lemeshow, 2013).

Among the 804 participants, 125 women delivered at home, 308 women delivered in private hospitals and 371 in public hospitals. After adjusting for the total sample size based on standard sampling formula and proportional allocation formula, the total adjusted sample size is 428 and it is then allocated to each cluster as 67 samples to home deliveries; 164 and 197 samples to private and public hospital deliveries respectively. The sample size for each cluster is a proportional allocation based on the proportion of live births in each setting (Goli et al., 2018).

For the qualitative part of the study, a subset of 50 participants is chosen using the purposive sampling technique. Additionally, they are also purposively designated as key informants for the qualitative semi-structured in-depth interviews.

6.2.6 Questionnaire Development

To effectively address the research objectives of this study, an in-house questionnaire is developed for both quantitative and qualitative components based on the extensive research needs assessment and with valuable inputs from various experts, including government health officials, administrative officials, hospital administration, and public health officers.

The quantitative study questionnaires are designed with clear research objectives in mind and aim to gather specific observations and insights that are crucial for informing decision-making processes.

The Likert scale questions and interview questions in the questionnaire for qualitative study are thoughtfully designed and developed, ensuring their relevance in capturing the targeted qualitative aspects that this study aims to explore. Careful consideration is given to the response options to offer participants a sufficient level of granularity in expressing their opinions, experiences, or attitudes. It is firmly believed that the in-house questionnaires are the most appropriate and effective approach for this study's objective. The English version of

questionnaires used for both quantitative and qualitative studies are included as supplemental material (**Appendix C**).

6.2.7 Pre-testing and Validation

Each questionnaire (both quantitative and qualitative) is subjected to pre-testing and quality checks in 10% of the sample population to ensure reliability and effectiveness and is not included in the main study. This approach allowed to validation and refinement of the questionnaire, ensuring its optimal performance before implementing it in the main study.

The expertise and diverse perspectives of various professionals have greatly contributed to the questionnaire's content and design, ensuring that it elicits the necessary information accurately and comprehensively. In testing the questionnaire, the responses from the sample facilities are analyzed and critically examined for their performance in terms of clarity, relevance, and data reliability. Through this improvement and quality check process, potential ambiguities or issues are identified and necessary adjustments are made to enhance the questionnaire's validity and consistency. By following this rigorous scientific approach, a robust foundation is established for the data collection. Moreover, using an in-house questionnaire provides several benefits, as it allows to maintain the control over the research process, customizes the questionnaire to specific research needs, and ensures a higher level of consistency and reliability compared to using third-party questionnaires.

6.2.8 Data Collection Process

The authors/data collectors collected the data using data abstraction formats and self-administered questionnaires, and the principal investigator conducted the qualitative semi-structured in-depth interviews. Self-administered questionnaires data collection sheet includes questions related to demographics, income level, insurance coverage and healthcare utilization patterns. Moreover, questionnaires on their out-of-pocket expenses covering prenatal care like

healthcare bills, medications, transportation, and indirect costs like lost wages are included (Jeong et al., 2016). In addition, the questionnaires on the health seeking behaviour, insurance coverage and healthcare utilization patterns are also included (Yang & Yu, 2023).

Key informants are interviewed using a semi-structured approach designed to elicit their views/perspectives on the problem's causes and present initiatives to address them. Data collectors are trained for four days on the data collection instruments and processes before data collection. Two experts from the health department of the district administration are invited to review the interview guide for an in-depth interview to ensure its face and content validity.

6.2.9 Analysis and Statistics

Socioeconomic and demographic variables of the study participants, service utilization, and policy measures among the women who gave live births are the critical components of the analysis. The analysis is performed in aggregate and descriptive parameters such as Frequency, Mean, and Standard Deviation (SD) are calculated for different variables. To investigate the potential association between socioeconomic, and demographic variables and the choice of availing healthcare services from either public or private providers, or at home, a chi-square test is conducted using GraphPad Prism® Version 5.01 statistical software. The socioeconomic, demographic, and geographic variables considered in this analysis included residence, age, gravida, level of education, marital status, occupation of husband/guardian, self-occupation, monthly family income, distance to health facility, and number of hospital visits during pregnancy. The associated *p-value* is reported and the *p-value* ≤ 0.05 is considered statistically significant.

In the Likert scale method employed in the qualitative study, respondents are asked to rate their level of agreement or disagreement with each statement (total of 13 factors) using a 5-point scale from 1 to 5. The scale ranged from “1 - Strongly Disagree” to “5 - Strongly Agree”.

Participants are instructed to select the response option that best represents their viewpoint. Based on the specific values of each response, the mean scores and standard deviation for each factor are computed based on the provided ratings. The analysis and interpretation of participant responses are used to evaluate the factors contributing to impaired public service utilization and out-of-pocket expenditure.

Data from an in-depth interview is subjected to a thematic analysis approach. Key themes such as contributing factors, and suggestions for improving service utilization and reducing the OOPE are manually reviewed and handled.

6.3 Results

6.3.1 Quantitative Findings

6.3.1.1 Socioeconomic, Demographic, and Geographic Variables

In this study, pregnant women are recruited from urban and rural locations for geographical diversity. Participants were 18–40 years old and varied in education, occupation, and wealth status. The experiences of married, single, and divorced women are also considered by including pregnant women with different marital statuses. Additionally, a range of parity and gestational ages are allowed for a comprehensive analysis of reproductive characteristics.

The Chi-square tests conducted on various socioeconomic, demographic, and geographic variables across three clusters of delivery locations (Home, Private Hospital, and Public Hospital) aim at understanding its association with the financial burdens of pregnancy and related healthcare. The socioeconomic, demographic, and geographic variables across three clusters of delivery locations are shown in **Table 6.1**, along with the *p values* for differences.

The study assessed 67 home deliveries, 164 private hospital deliveries, and 194 public hospital deliveries. This study finds that there are no statistically significant differences in marital status

and self-occupation regarding the choice of availing services from the healthcare sector for childbirth. However, factors such as residence, age, gravida, level of education, occupation of husband/guardian, monthly family income, distance to the health facility, and the number of hospital visits during pregnancy are significantly associated with differences in the choice of availing maternity-related healthcare services between the private sector, public sector, and non-healthcare sector (home).

Table 6.1: Descriptive Statistics on the Socioeconomic, Demographic, and Geographic factors across three clusters of women who gave live births in the study setting (January 2023 to December 2023), Agra District, Uttar Pradesh, India

Variable	Home N (%) n=67	Private N (%) n=164	Public N (%) n=197	Chi-square statistic (χ^2) & P value*
Residence				
Urban	3 (4.5)	143 (87.2)	111 (56.3)	**137.7 & <0.0001**
Rural	64 (95.5)	21 (12.8)	86 (43.7)	
Age				
18-25	35 (52.2)	109 (66.5)	122 (62)	**19.53 & 0.0034**
26-35	28 (41.8)	55 (33.5)	73 (37)	
36-45	4 (6)	0 (0)	1 (0.5)	
>45	0 (0)	0 (0)	1 (0.5)	
Gravida				
Primigravida	8 (12)	77 (47)	48 (24.4)	**34.89 & <0.0001**
Multigravida	59 (88)	87 (53)	149 (75.6)	
Level of Education				
None	14 (20.9)	15 (9.2)	13 (6.6)	**21.64 &**
High School or Below	33 (49.3)	63 (38.4)	104 (52.8)	

Higher Secondary or Diploma	18 (26.8)	75 (45.7)	73 (37)	**0.0014**
Degree/Graduates or Above	2 (3)	11 (6.7)	7 (3.6)	
Marital Status				
Married	66 (98.5)	163 (99.4)	195 (99)	1.90 & 0.7541^{ns}
Widowed	1 (1.5)	1 (0.6)	1 (0.5)	
Divorced	0 (0)	0 (0)	1 (0.5)	
Occupation of Husband/Guardian				
Casual Labour	19 (28.4)	12 (7.3)	70 (35.5)	**140.3 & <0.0001**
Cultivator	36 (53.7)	28 (17.1)	86 (43.7)	
Employed (Salaried)	0 (0)	66 (40.2)	18 (9.1)	
Employed (Self)	12 (17.9)	58 (35.4)	23 (11.7)	
Occupation (Self)				
Casual Labour	8 (11.9)	17 (10.4)	16 (8.1)	17.55 & 0.0631^{ns}
Cultivator	11 (16.4)	9 (5.5)	23 (11.7)	
Home Maker	48 (71.7)	123 (75)	147 (74.6)	
Employed (Salaried)	0 (0)	7 (4.3)	2 (1)	
Employed (Self)	0 (0)	3 (1.8)	2 (1)	
Student	0 (0)	5 (3)	7 (3.6)	
Monthly Family Income				
<5000 INR	39 (58.2)	24 (14.6)	57 (28.9)	**154.8 & <0.0001**
5001-10000 INR	18 (26.9)	18 (11)	99 (50.3)	
10001-15000 INR	8 (11.9)	65 (39.6)	18 (9.1)	
>15000 INR	2 (3)	57 (34.8)	23 (11.7)	
Distance to Health Facility				
Up to 5 KM	32 (47.8)	25 (15.2)	50 (25.4)	**26.85 & <0.0001**
More than 5 KM	35 (52.2)	139 (84.8)	147 (74.6)	
No. of Visits to Hospital During Pregnancy				

None	25 (37.3)	0 (0)	0 (0)	**201.3 &**
One or two	22 (32.8)	22 (13.4)	19 (9.6)	**<0.0001**
Three	15 (22.4)	58 (35.4)	117 (59.4)	
Four and more	5 (7.5)	84 (51.2)	61 (31)	

**P value ≤ 0.05 was considered statistically significant, ns – non-significant*
N-Frequency, %-Percentage, n-total respondents in the respective category, INR-Indian Rupee currency

6.3.1.2 Financial and Healthcare Utilization Variables

The analysis of financial and healthcare utilization variables across the three clusters of women who gave live births within the study setting reveal significant variations in expenditures, and the data are shown in **Table 6.2**. It is well known that public hospitals have no charges for consultations, diagnostic aspects, and monthly medicine expenses, but private hospitals impose charges on 100% of the participants in different aggregates, which cannot be prevented.

The distribution of OPD visits/consultation charges per visit varies widely, with private hospitals incurring charges ranging from less than 500 INR to over 1000 INR. Lab and radiology expenditures similarly show a diverse range, with some private hospital-delivered participants incurring significant expenditures exceeding 10,000 INR for lab tests and up to 10,000 INR for radiology services. Moreover, newborn care expenditures, nutritional expenses, and other expenses vary significantly, especially for the women participants from private hospital deliveries.

Regarding healthcare support, the presence of ASHA (frontline healthcare workers) visits during pregnancy and the receipt of Janani Suraksha Yojana (JSY) benefits are documented with varying proportions of participants receiving these services. Lastly, the source of money for expenditure includes daily wages, farming, government aid, insurance, loans, salaries, savings, and business income. These findings highlight the significant financial burden and diverse healthcare utilization experiences among the women participants in the study.

The analysis reveals significant differences in financial burden among the participants who gave birth at home, in private hospitals, and public hospitals within the study setting. It is important to note that the participants who gave birth at home incur negligible financial expenses compared to those who delivered in public or private. However, the healthcare utilization aspects for home deliveries are considered significantly poor, with less OPD visits, minimum lab and radiology expenditures, and lower nutritional and medication costs. This lack of healthcare utilization is associated with increased risks for both the mother and newborn. Despite not facing considerable financial burdens, the absence of adequate medical support and supervision during home deliveries underscores the critical need for improving maternal healthcare and safe delivery practices. These findings emphasize the importance of enhancing healthcare utilization to mitigate associated risks and improve outcomes for mothers and newborns in home birth settings.

Table 6.2: Financial and Healthcare Utilization variables across three clusters of women who gave live birth in the study setting (January 2023 to December 2023), Agra District, Uttar Pradesh, India

Variables	Type of Hospital for Availing Health Service		
	Home N (%) n=67	Private N (%) n=164	Public N (%) n=197
OPD Visits/Consultation Charges Per Visit			
Free of Charge/NA	25 (37.3)	0 (0)	173 (87.8)
<500 INR	42 (62.7)	103 (62.8)	16 (8.1)
501-1000 INR	0 (0)	42 (25.6)	8 (4.1)
>1000 INR	0 (0)	19 (11.6)	0 (0)
Lab Expenditure			
Free of Charge/NA	30 (44.8)	0 (0)	153 (77.7)
<1000 INR	28 (41.8)	45 (27.4)	31 (15.7)
1001-5000 INR	9 (13.4)	85 (51.8)	13 (6.6)

5001-10000 INR	0 (0)	28 (17.1)	0 (0)
>10000 INR	0 (0)	6 (3.7)	0 (0)
Radiology Expenditure			
Free of Charge/NA	29 (43.3)	0 (0)	149 (75.6)
<1000 INR	38 (56.7)	24 (14.6)	17 (8.6)
1001-5000 INR	0 (0)	125 (76.2)	24 (12.2)
5001-10000 INR	0 (0)	15 (9.2)	7 (3.6)
Transportation Expenditure			
Free of Charge/NA	49 (73.1)	0 (0)	27 (13.7)
<500 INR	13 (19.4)	56 (34.1)	152 (77.2)
501-1000 INR	5 (7.5)	67 (40.9)	8 (4.1)
1001-2000 INR	0 (0)	29 (17.7)	7 (3.5)
>2000 INR	0 (0)	12 (7.3)	3 (1.5)
Monthly Medicine Expenses			
Free of Charge	61 (91)	0 (0)	172 (87.3)
<500 INR	6 (9)	80 (48.8)	11 (5.6)
501-1000 INR	0 (0)	34 (20.7)	8 (4.1)
1001-2000 INR	0 (0)	22 (13.4)	6 (3)
>2000 INR	0 (0)	28 (17.1)	0 (0)
Newborn Care Expenditure			
Free of Charge	0 (0)	9 (5.5)	174 (88.3)
<1000 INR	0 (0)	91 (55.5)	11 (5.6)
1001-4000 INR	0 (0)	38 (23.1)	8 (4.1)
4001-10000 INR	0 (0)	26 (15.9)	3 (1.5)
>10000 INR	0 (0)	0 (0)	1 (0.5)
Nutrition Expenditure			
Free of Charge/NA	38 (56.7)	49 (29.9)	115 (58.4)
<1000 INR	15 (22.4)	24 (14.6)	56 (28.4)
1001-5000 INR	11 (16.4)	67 (40.9)	17 (8.6)
>5000 INR	3 (4.5)	24 (14.6)	9 (4.6)
Other Expenses			
NA	28 (41.8)	0 (0)	0 (0)

<500 INR	17 (25.4)	120 (73.2)	144 (73.1)
500-1000 INR	12 (17.9)	20 (12.2)	34 (17.3)
1001-2000 INR	10 (14.9)	17 (10.3)	13 (6.6)
>2000 INR	0 (0)	7 (4.3)	6 (3)
ASHA Visit during Pregnancy			
Yes	37 (55.2)	162 (98.8)	197 (100)
No	30 (44.8)	2 (1.2)	0 (0)
Janani Suraksha Yojana (JSY) Benefits			
Yes	0 (0)	86 (52.4)	170 (86.3)
No	67 (100)	78 (47.6)	27 (13.7)
Source of Money on Expenditure			
Daily Wages	27 (40.3)	15 (9.2)	16 (8.1)
Farming	30 (44.8)	28 (17.1)	32 (16.2)
Government Aid	0 (0)	45 (27.4)	124 (62.9)
Insurance	0 (0)	4 (2.4)	0 (0)
Loan	10 (14.9)	5 (3)	2 (1.1)
Salary	0 (0)	34 (20.7)	3 (1.5)
Savings	0 (0)	17 (10.4)	20 (10.2)
Business	0 (0)	16 (9.8)	0 (0)

N-Frequency, %-Percentage, n-total respondents in the respective category, INR-Indian Rupee currency, OPD-Out Patient Department, NA-Not Applicable

6.3.2 Qualitative Findings

6.3.2.1 Perceived factors contributing to the burden of OOPE on pregnancy and related healthcare expenses

A total of 13 factors, which are believed to influence service utilization and the OOPE burden, especially on pregnancy and related health care, are given as questionnaires to all the respondents, and the responses are assessed using a 5-point Likert scale.

Among the factors assessed, several factors are found to be particularly significant in the context of pregnancy and related health care. The most commonly perceived contributors are as follows,

- **Inadequate Government Maternity Care Facilities**: Respondents indicated that there is insufficiency in government related maternity care facilities, which leads to rely on more expensive private sector services, significantly increasing their OOPE. This factor received a mean score of 3.88 ± 1.18 (Mean ± Standard Deviation).
- **Rising Costs of Prenatal and Postnatal Care**: Another key factor identified is the escalating costs associated with prenatal and postnatal care services, allowing many families to allocate a larger portion of their income to ensure adequate maternal and child healthcare. This factor received a mean score of 3.76 ± 1.16 (Mean ± Standard Deviation).
- **Limited Availability of Essential Medicines and Supplies**: The limited availability of essential medicines and supplies in government hospitals identified as another critical factor, which force the individuals towards additional out-of-pocket costs to obtain necessary medicines from private sectors. This factor received a mean score of 3.70 ± 1.28 (Mean ± Standard Deviation).
- **Low Real Monthly Disposable Income**: Respondents also expressed concern about the impact of a low real monthly disposable income on worsening the financial problems associated with pregnancy. This factor is rated with a mean score of 3.64 ± 1.41 (Mean ± Standard Deviation).

The mean scores of all responses concerning the various contributing factors are presented in **Table 6.3**.

Table 6.3: Perceived factors contributing to the burden of OOPE on pregnancy and related healthcare expenses in the study setting (January 2023 to December 2023), Agra District, Uttar Pradesh, India (n=50)

S. No	Contributing Factors	Frequency (%)					Mean (SD)
		SD	D	N	A	SA	
1	Rising costs of prenatal and postnatal care services create a significant financial strain	1 (4)	2 (4)	3 (5)	4 (24)	5 (13)	**3.76 (1.16)**
2	Rising inflation increases the overall cost of pregnancy-related healthcare	1 (16)	2 (1)	3 (7)	4 (21)	5 (5)	2.96 (1.46)
3	Government spending on prenatal and postnatal care is insufficient	1 (10)	2 (4)	3 (12)	4 (20)	5 (4)	3.08 (1.26)
4	Prescriptions often include high-cost branded maternity drugs and supplies that are expensive	1 (16)	2 (8)	3 (7)	4 (10)	5 (9)	2.76 (1.52)
5	Limited availability of essential medicines and supplies in government hospitals leads to additional costs	1 (7)	2 (2)	3 (3)	4 (25)	5 (13)	**3.7 (1.28)**
6	Utilization of government maternity medical services is poor due to perceived inadequacies	1 (10)	2 (6)	3 (4)	4 (14)	5 (16)	3.4 (1.52)
7	Inadequate government maternity care facilities lead to a reliance on more expensive private services	1 (3)	2 (5)	3 (5)	4 (19)	5 (18)	**3.88 (1.18)**
8	Government schemes targeting the reduction of OOPE for maternity care are not sufficient	1 (15)	2 (6)	3 (10)	4 (12)	5 (7)	2.8 (1.44)
9	Government schemes for reducing OOPE in maternity care are not effectively reaching the target population	1 (10)	2 (6)	3 (3)	4 (21)	5 (10)	3.3 (1.43)
10	Most pregnant women do not have sufficient health insurance coverage to cover pregnancy-related expenses	1 (13)	2 (6)	3 (5)	4 (12)	5 (14)	3.16 (1.58)
11	Private maternity medical services are perceived to offer better quality of care compared to public services	1 (13)	2 (8)	3 (4)	4 (12)	5 (13)	3.08 (1.57)
12	Dependence on private maternity services, which are more costly, significantly contributes to OOPE	1 (23)	2 (8)	3 (4)	4 (10)	5 (5)	2.32 (1.46)
13	Low real monthly disposable income worsens the financial impact of pregnancy-related expenses	1 (8)	2 (3)	3 (5)	4 (17)	5 (17)	**3.64 (1.41)**

SD-Strongly Disagree, D-Disagree, N-Neutral, A-Agree, SA-Strongly Agree, Mean (SD)- Mean (Standard Deviation)
Response scores ranged from Strongly Agree (5) to Strongly Disagree (1)

6.3.3 Qualitative Semi-Structured In-Depth Interview Findings

In-depth interviews are conducted with all the qualitative study participants (n = 50), to explore their perspectives. The interviews are structured around three primary patterns of responses, such as

- ✓ Factors that contribute to impaired public service utilization
- ✓ Strategies for improving the burden of OOPE on pregnancy-related expenses
- ✓ Suggestions to the Government/policymakers in reducing the burden of OOPE on pregnancy-related expenses

6.3.3.1 Factors that Contribute to Impaired Public Service Utilization

The key informants mention several critical factors that contribute to the impaired public healthcare service utilization, such as:

- ✓ Prolonged wait times at OPD and drug counters
- ✓ Insufficient infrastructure in government hospitals
- ✓ The lack of branded medicines in government hospitals
- ✓ Misconceptions regarding the quality of services in government hospitals

6.3.3.2 Strategies for improving the burden of OOPE on pregnancy-related expenses

Key informants in the study are asked for their opinions on the effective strategies that could be implemented at the facility level to alleviate the burden of out-of-pocket expenditures (OOPE). The following suggestions are made by the key informants,

- ✓ Enhancing government facilities and infrastructure.
- ✓ Increasing the number of healthcare professionals.
- ✓ Decreasing long wait times.
- ✓ Providing financial counselling services to households.

- ✓ Creating awareness on government subsidies for pregnancy-related healthcare.

6.3.3.3 Suggestions to the Government/policymakers in reducing the burden of OOPE on pregnancy-related expenses

Key informants are asked for their suggestions to the government and policymakers on the strategies to improve service utilization and reduce OOPE. Their insights reveal a comprehensive set of proposed strategies in addressing existing challenges. They suggest for increased funding for maternal healthcare in public hospitals to ensure that all essential services and medications are available free of charge. They also suggest that policies should be implemented to regulate the costs of prenatal and postnatal care in private hospitals, that are affordable.

Some of the key informants mention that introducing government subsidies specially to the pregnancy-related healthcare costs can directly alleviate the financial burden on households. This targeted financial support could make a substantial difference in ensuring equitable access to quality maternity care.

6.4 Discussion

In this study, the quantitative analysis uncovered significant correlations between various socioeconomic, demographic, geographic factors and out-of-pocket costs on pregnancy-related healthcare (Krishnamoorthy et al., 2020). It is found that factors such as education, income, and geographic location are closely associated with the level of financial burden experienced by pregnant women (A. K. Taylor et al., 2006). A lower OOPE burden is linked with educational qualification and high income, which underscores the influence of socioeconomic status on health expenditure during pregnancy. In addition, this study reveals the gaps associated with OOP costs in urban and rural areas, which highlights the need for the targeted

interventions to address the financial challenges faced by pregnant women (Ouedraogo et al., 2021; Simkhada et al., 2014).

Out-of-pocket expenditure (OOPE) in India accounts for 63% of the total health spending, which is significantly above the global trends. The burden on public healthcare infrastructure often drives the general public towards private clinics, where the charges are significantly higher. On the other hand, individuals pay out-of-pocket due to the limited health insurance coverage. Additionally, the cost of medicines and diagnostic services remains high due to inefficient government regulations, which further increases the financial burden on households (Sriram & Khan, 2020).

Expanding public healthcare infrastructure, increasing awareness of government health insurance schemes like Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (PM-JAY), and regulating the cost of essential medicines and diagnostics could reduce OOPE burden. Additionally, the initiatives by the government of India to distribute generic medicines at affordable prices and by making essential medications more accessible align with the goal of lowering healthcare costs for the general public (Rejikumar et al., 2018).

This study also shows the intricate relationship between socioeconomic, demographic, and geographical factors and the choice of delivery location. Age, gravida status, education level, occupation of husband/guardian, distance to health facilities, and the number of hospital visits during pregnancy are significant determinants in the financial decision-making process for delivery locations. These factors influence not only the direct costs, such as fees for delivery services, but also indirect costs, including transportation and additional hospital visits. The absence of significant associations with marital status and the respondent's occupation suggests that the direct costs of delivery and related healthcare services might be more universally challenging, regardless of these factors.

The significant association between delivery location choice and distance to health facilities, as well as the number of hospital visits, underlines the critical role of accessibility and the need for frequent healthcare interventions in shaping the financial burdens of pregnancy. This points towards a need for policy interventions that could include improving transportation, reducing travel costs for pregnant women, and enhancing insurance coverage or financial support for those requiring frequent medical attention. In terms of health insurance, this quantitative and qualitative finding shows a very low number of individuals on health insurance, which is overall 2.4% in whole sampled participants, and it is one of the significant perceived contributing factors in escalating the OOPE issues. Concerning the issue of financial inequality, pregnant women who has lower household incomes are subject to higher financial burdens. The government should prioritize advancing the promotion of comprehensive health insurance schemes. Understanding all these dynamics is crucial for designing effective policies and interventions aimed at minimizing the financial burdens of pregnancy.

The financial variables analyzed in this study underscore the diverse and significant financial burdens associated with pregnancy, reflecting both direct healthcare costs and broader socioeconomic and demographic factors influencing out-of-pocket expenses. Public hospitals play a crucial role in alleviating financial burdens through free or subsidized services, including JSY benefits, radiology, and newborn care. However, the presence of significant out-of-pocket cost in private hospitals highlights disparities in access to affordable care. In terms of socioeconomic and demographic correlations, variations in financial burdens across different types of expenditures suggest that the factors such as income, education, and geographic location significantly influence healthcare choices and the associated costs.

The qualitative analysis provided rich insights into the nuanced experiences of pregnant women with out-of-pocket expenditures. It complemented the quantitative results by providing a deeper understanding of the financial challenges faced during pregnancy (Sekandari et al.,

2024; Tura et al., 2022). Inadequate government maternity care makes expectant mothers to rely on costly private healthcare services and thus further adds to the financial burden. Also, the rising costs associated with prenatal and postnatal care services further compound the financial strain on families, particularly those with limited resources, which can significantly impact the financial well-being of individuals and families. Moreover, the low real monthly disposable income among the individuals with pregnancy-related expenses magnifies the economic challenges.

Key informants mention several critical factors that contribute to the impaired public healthcare services. They emphasize the urgent need for infrastructure improvements to enhance service delivery. Additionally, addressing misconceptions about the quality of care provided in public health facilities is deemed essential. Strategies proposed by informants aims at strengthening the capabilities of government healthcare facilities, offering financial counselling, and advocating for more comprehensive government subsidies to alleviate the burden of out-of-pocket expenses on pregnancy-related healthcare costs. Overall, the integrated analysis of both quantitative and qualitative data allowed for a comprehensive exploration of the determinants of out-of-pocket costs during pregnancy. The findings underscore the complexity of factors influencing health expenditure and highlight the critical need for targeted interventions to alleviate the financial burden on expectant mothers, ultimately improving maternal and child health outcomes (Sriram & Khan, 2020).

6.5 Limitations and Strengths of this Study

The study is limited by self-reporting bias and geographical focus, which pose limitations despite its valuable insights. Further, the study covered only service utilization and OOPE burden in public and private hospitals, and did not assess the quality and outcome of the private

sector hospitals. The strength of this study includes the use of both quantitative and qualitative methods to supplement each other.

6.6 Conclusions

A comprehensive analysis of both quantitative and qualitative data lead to insights of the determinants of out-of-pocket costs incurred during pregnancy and childbirth, and the financial burden of out-of-pocket cost borne by expectant mothers of varied socio-economic and demographic profiles. These results reveal notable trends and correlations between various socioeconomic and demographical factors to the pregnancy and related healthcare expenditure, and a greater understanding of the factors that contribute to health expenditure during pregnancy. Structured questionnaires and semi structured interviews are integrated together to explore the emotional and practical implications of financial strain on pregnant women in different location. Further, the outcome of the study provides a critical need for targeted interventions to help reduce the financial burden of expectant mothers and improve maternal and child health outcomes. This research leverages the financial burden of pregnancy to highlight the need of comprehensive policy measures in addressing the gaps for equitable access.

6.7 Ethical Considerations

The study complies with the declaration of Agra district health department. The Chief Medical Officer (CMO) of the Agra district administration has given approval for the study protocol, and the permissions are obtained from all the study facilities to conduct the study. Participants are informed that their personal information will remain confidential and will only be used for the study purpose. The consent process includes a clear explanation of the study's objectives, and the participants are given the privilege to withdraw from the study at any time. Written informed consent is obtained from each study participant for their participation and publication

of the results. All data collected from participants is kept confidential by not using personal identifiers. For confidentiality and ethical considerations, the names of sampled health facilities are identified only by codes throughout the study.

CHAPTER 7

PUBLIC DRUG PROCUREMENT PERFORMANCE

This study discusses the performance of public drug procurement systems across seven states in India. The study looks at various challenges faced by India in ensuring availability and accessibility to essential medicines on account of the rapid growth of its pharmaceutical sector. Although, government being a major purchaser of drugs, its public procurement processes are often overwhelmed by inefficiencies, inadequate regulation, and a lack of transparency. The methodology used in this research is quantitative, and the data collection is done using predetermined performance indicators related to efficiency, cost effectiveness and quality that are self-developed. The study finds large disparities in procurement outcomes and underscores the importance of controlling for geographic and financial factors when assessing procurement systems. At the same time, it identifies weaknesses and strengths of public drug procurement systems to help policymakers design appropriate reforms and collaborative strategies in ensuring drug availability, accessibility, quality, and public trust.

7.1 Background of the Study

India faces significant challenges in providing access to basic healthcare and necessary medications to its large population, despite the remarkable expansion of the country's pharmaceutical sector over the last few decades (Singh et al., 2013; Thombare et al., 2024). Furthermore, lack of access to essential medicines affects about 2 billion people globally, exacerbating suffering, extending illness, causing unnecessary disabilities, and preventable deaths (Chan, 2017).

Medicine access is defined as “having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour walk from the homes of the people”, according to the United Nations Development Group (United Nations

Development Group, 2003). India is positioned 179th out of 189 countries in terms of the importance given to health in its government budgets, which includes both the union and state levels (Kulshreshth, 2021). Healthcare spending varies significantly between states and cannot be entirely attributed to the state's income level.

Public drug procurement in India is an important process that ensures availability of essential drugs at a quality standard (Kaur et al., 2021). Procurement inefficiencies, rooted in poor regulatory frameworks and fragmented legal systems, however, have caused up to 20 percent of drugs that have proven to be substandard to fail quality control tests (Weir et al., 2005). This problem is aggravated by heavy reliance on the private healthcare sector and branded medicines which further aggravates financial burden on the economically weak population pushing them into the poverty (Khanday, 2019; Verma, 2019).

Drug procurement and distribution in India is extremely complex varying from state to state with regards to demographic, economic and geographic factors. The challenges to achieve medical and legal complexity necessitate that these variations need tailored strategies that engage with the local health needs and administrative capacities (Jadhav et al., 2020; Nikam et al., 2019). However, the success of drug procurement policies primarily depends upon state specific legal frameworks and procurement models, and good practices may lead to learning about better regulatory frameworks at the state level (Evenett & Hoekman, 2005; Lewis & Pettersson Gelander, 2009).

In spite of the extensive research on issues of drug availability and accessibility, there are gaps in evaluation of ability to procure drugs, with unreliable data on the availability and accessibility of drugs to hinder effective policy decision (Singh et al., 2013). To increase equity of health outcomes and improve service delivery, Fiszbein et al. in 2011 propose a state level framework of performance indicators and accountability measures (Fiszbein et al., 2011). This

study formulates specific performance indicators aimed at assessing procurement efficacy, cost-effectiveness, and quality across seven Indian states: Tamil Nadu, Andhra Pradesh, Rajasthan, Chhattisgarh, Uttar Pradesh, Odisha, Kerala. This study assigns weighted values to these indicators to account for the multidimensional nature of public drug procurement and help stakeholders to locate best practices and areas for improvement in enhancing efficacy, cost-effectiveness, quality, and public confidence (Bradley, 2021).

7.2 Methodology

7.2.1 Study Design and Selection of Sample States

A quantitative study is conducted to evaluate and compare the performance of public drug procurement systems across seven Indian states during the period of 2021-2022. To reflect geographic diversity, states from southern, southeastern, northwestern, central, northern, eastern, southwestern regions along with different socioeconomic factors by varying levels of their population size, health budget and per capita health budget are chosen. Accordingly, Tamil Nadu, Andhra Pradesh, Rajasthan, Chhattisgarh, Uttar Pradesh, Odisha, and Kerala are chosen. This selection strategy ensures a comprehensive representation of the varied healthcare systems across India. The sampling methodology is shown in **Table 7.1**.

Table 7.1: Sample States for the Study (Period of the Study: 2021-2022)

Sampling Attribute	Tamil Nadu	Andhra Pradesh	Rajasthan	Chhattisgarh	Uttar Pradesh	Odisha	Kerala
Population (in Millions)	72.15	49.63	68.55	25.54	199.81	41.97	33.4
Total Health Budget (in Millions - INR)	200800	139400	170780	76220	263280	113830	120980
Per capita Health Budget (in INR)	2783.09	2808.78	2491.32	2984.33	1317.65	2712.17	3622.15
Geography	South	Southeast	Northwest	Central	North	East	Southwest

7.2.2 Development of Performance Indicators

Initially, a set of 45 key performance indicator parameters is developed, leveraging insights from some previous studies on public procurement practices (Kaur et al., 2021), with a particular focus on the need for transparent procurement processes and strong quality assurance systems. Further, this initial set is refined to 22 parameters, and a solid scoring framework is developed. The final set of 22 predetermined parameters and their scoring criteria are were based on the extensive research needs assessment and with valuable inputs from various stakeholders and experts, including government health officials, administrative officials, and key personnel from various state medical corporations (including procurement and quality managers), etc. The study design not only underscores the role of stakeholder participation in the formulation of indicators but also ensures validation through expert consultations, thereby enhancing the reliability of the results.

7.2.3 Data Collection Methods

The data collection tool is developed, stating the objective of the study, and distributed as applications to the concerned key personnel of respective medical corporations to seek drug procurement and process data. However, owing to some missing data and limitations in available open-source information, semi structured telephonic interviews with the executive leadership teams of the drug procurement cells in the sample states are conducted. Additionally, the website of respective medical corporation to acquire some drug procurement and process data are also referred. The data collection tool is included as supplemental material (**Appendix D**).

7.2.4 Scoring Framework and Validation

A comprehensive validation process is necessary to ensure that a scoring framework is reliable and applicable in various types of contexts. In this study, the scoring framework includes three

essential metrics: efficiency, cost-effectiveness, and quality, each assigned a weight to denote its comparative significance in evaluating procurement practices. The overall weightage allocated to efficiency performance indicators is 30%, while cost-effectiveness and quality performance indicators are each allocated 35%, resulting in a total weightage of 100%. This method of weightage is adopted from a published study (Kaur et al., 2021), with slight modifications as per the needs assessment of the current study.

7.2.5 Validation and Comprehensive Evaluation

In order to validate and improve the key performance indicators, a pilot study is conducted in two of the seven sample states. Kerala and Chhattisgarh are strategically chosen for the pilot study for their diverse healthcare systems. Kerala has an effective public health system, as seen by its strong community health programs and remarkable health metrics. However, Chhattisgarh has interesting problems with healthcare access and resource distribution that are commonly seen in emerging healthcare systems.

Following the improvement in scoring methodology and performance indicator parameters by pilot study, a complete evaluation of the public drug procurement systems is conducted in each of the seven states. The key performance indicators (KPIs), its parameters, and the scoring criteria are shown in **Table 7.2**.

Table 7.2: Public Drug Procurement – Key Performance Indicators and Scoring Criteria (Period of the Study: 2021-2022)

S. No	Performance Indicators Categories	Indicators (Score)				
		5	4	3	2	1
Efficiency Performance Indicators (Total Weight: 30%)						
1	**Purchase/Procedure**	Open Tender System	Centralized Online E-tender System	Limited Tender System	Single-Source Procurement	Direct Procurement
2	**Procurement Responsibility**	Centralized by Nodal Agency	State-Owned Agency with Independent Autonomy	Centralized by State-Owned Agency	Decentralized by District Health Departments	Public-Private Partnership for Procurement
3	**Distribution Process**	Centralized from State Warehouses to Districts	Decentralized from District Warehouses to Local	Mixed Centralized and Decentralized	State-Specific Distribution Mechanisms	Decentralized Distribution Without Warehouses
4	**Need of Pharmacist**	Required for Procurement and Technical Evaluation	Required for Technical Evaluation	Optional but recommended	Not Required	Not Specified
5	**Sample Test for Technical Bid**	Samples Tested for Every Batch After Purchase	Sample Evaluation Not Required	Samples Tested for Specific Circumstances	Sample Testing Performed Occasionally	Sample Testing Not Specified
6	**Medicine Disposal Process**	Through Biomedical Waste Management Approved by PCB	By Central or State Approved Agencies	Through Open e-Tender to Qualified Disposal Firms	Open Tender Process for Disposal Services	Disposal Method Not Specified or Non-compliant

Cost-Effectiveness Performance Indicators (Total Weight: 35%)						
7	**Budget Allocation**	High Allocation & Above 4% of Total Health Budget	Above Average Allocation & 3-4% of Total Health Budget	Moderate Allocation & 2-3% of Total Health Budget	Data Not Mentioned or Below 2% of Total Health Budget	Low Allocation & Below 1% of Total Health Budget
8	**Tender Fees**	Low Tender Fees	Moderate Tender Fees with Exceptions for MSMEs	Moderate Tender Fees	High Tender Fees	Varied Tender Fees Based on Contract Value
9	**Supplier Eligibility**	Manufacturers and Importers Allowed	Manufacturers, Importers, Loan Licensees Allowed	Manufacturers Only	Importers Allowed with Restrictions	Eligibility for Specific License Holders
10	**Time for Tender Submission**	Usually, 30 days with Extendable Option	30 days after Tender is Live	30 days without Extendable Option	Less than 30 days with Extendable Option	Less than 30 days without Extendable Option
11	**Market Standing**	Explicit Requirement for 5 or More Years	Explicit Requirement for 3 to 4 Years	Explicit Requirement for 1 to 2 Years	Duration Not Specified	No Requirement
12	**Two Bid System**	Two Bid System Followed	Two Bid System Partially Followed	No Clear Information on Bid System	No Two Bid System Followed	Bid System Not Applicable
13	**Annual Turnover**	Highly Inclusive, Strong Local MSME Support	Moderately Inclusive,	Balanced Threshold,	High Threshold, Lower Inclusivity	Very High Threshold,

			Moderate MSME Support	Limited MSME Support		Exclusivity to Large Entities
14	**Earnest Money Deposit (EMD)**	Very Low EMD	Low EMD	Moderate EMD	High EMD	Very High EMD
15	**Management Cost**	No Management Cost	Low Fixed Management Cost	Variable Management Cost	Undisclosed but Acknowledged Cost	No Information Provided
16	**Limit of Expiry Percentage**	Very Strict Limit	Moderate Limit	Lenient Limit	No Specific Limit but Acknowledged	No Information Provided
Quality Performance Indicators (Total Weight: 35%)						
17	**Availability at PHC Level**	Extensive Range	Comprehensive Coverage	Adequate for Essential Health Needs	Basic but Limited	Insufficient Information
18	**Availability at District Hospital**	Exceptionally Comprehensive	Highly Comprehensive	Comprehensive	Adequate	Limited or Insufficient Information
19	**Generic Medicines Usage**	All EML are Generic with Few Specialty Drugs	Majority (90%) of EML and AML Drugs are Generic	All EML are Generic with Few NHM Program Drugs	Most of the Medicines are Generic	No Information Provided
20	**GMP (Good Manufacturing Practices)**	Required cGMP	Required GMP/WHO GMP	Required GMP	Other Quality Standards	No Specific GMP Requirement

21	**Quality Control Parameters**	Stringent Quality Control Parameters with Penalty Clause	Comprehensive Quality Control Parameters as Per Pharmacopoeia Standards	Defined Quality Control Parameters Covering Multiple Parameters	Quality Control Parameters Specified Without Penalty Clause	No Information Provided
22	**Penalty Clause for Quality Default**	Stringent Penalty Clause with Blacklisting and Financial Deduction	Financial Penalty for Quality Default	Blacklisting as Penalty for Quality Default	Yes, Penalty Clause Specified	No Information Provided

PCB – Pollution Control Board, MSME - Micro, Small, and Medium Enterprises, EMD - Earnest Money Deposit, EML - Essential Medicines List, AML - Additional Medicines List, NHM - National Health Mission, cGMP – Current Good Manufacturing Practices, GMP - Good Manufacturing Practices

7.3 Findings

The evaluation of public drug procurement performance across the different states for the period of 2021-2022 reveal specific strengths and weaknesses for each region. The responsible bodies for public drug procurement in the selected study states are as follows,

- ✓ Tamil Nadu - Tamil Nadu Medical Services Corporation (TNMSC)
- ✓ Andhra Pradesh - Andhra Pradesh Medical Services & Infrastructure Development Corporation (APMSIDC)
- ✓ Rajasthan - Rajasthan Medical Services Corporation Limited (RMSCL)
- ✓ Chhattisgarh - Chhattisgarh Medical Services Corporation Limited (CGMSCL)
- ✓ Uttar Pradesh - Uttar Pradesh Medical Supplies Corporation Limited (UPMSCL)
- ✓ Odisha - Odisha State Medical Corporation Limited (OSMCL)
- ✓ Kerala - Kerala Medical Services Corporation Limited (KMSCL)

The results for each state, as determined by a variety of performance indicators in the categories of efficiency, cost-effectiveness, and quality, are presented in the **Tables 7.3 to 7.9**. The tables highlight the specific scores that are achieved in each category of the key performance indicators as described in **Table 7.2**, as well as the overall performance of the procurement systems in the sampled study states.

Table 7.3: Public Drug Procurement – Key Performance Indicators Evaluation of Tamil Nadu (Period of the Study: 2021-2022)

S. No	Parameter	Levels of Performance	Scoring (Out of 5)	Total
Efficiency Performance Indicators (Total Weight: 30%)				
1.	Process/Procedure of Purchase of Medicines	Open Tender System	5	**29.00 out of 30**
2.	Responsibility of Medicine Procurement & Autonomy	Centralized Procurement by Nodal Agency Registered under Companies Act	5	
3.	Distribution Process	Centralized Distribution from State-Level Warehouses to Districts	5	
4.	Need of Pharmacist	Required for Technical Evaluation	4	
5.	Sample Test for Evaluation of Technical Bid	Samples Tested for Every Batch After Purchase	5	
6.	Process of Dispose of Medicine	Through Biomedical Waste Management Service Providers Approved by Pollution Control Board	5	
Cost-Effectiveness Performance Indicators (Total Weight: 35%)				
7.	Budget Allocation for Medicines supplies	Moderate Allocation & 2-3% of Total Health Budget (Per Capita Allocation: 75.09 INR, Percentage of Health Budget: 2.7%)	3	**27.30 out of 35**
8.	Tender Fees	Moderate Tender Fees	3	
9.	Types of Suppliers Eligible	Manufacturers and Importers only Allowed	5	
10.	Time for Submission of Tender	Usually, 30 days with Extendable Option	5	
11.	Market Standing Requirement	Explicit Requirement for 3 to 4 Years of Market Standing	4	
12.	Two Bid System Followed	Yes	5	
13.	Annual Turnover Requirement	Moderately Inclusive, Moderate MSME/Home State Support	4	
14.	Earnest Money Deposit	EMD as a Percentage of the Contract Value	1	
15.	Management Cost	No Management Cost	5	
16.	Limit of Expiry Percentage	Moderate Limit - Permitted up to 2% on the procurement value	4	
Quality Performance Indicators (Total Weight: 35%)				
17.	Availability of Medicines at Primary Health Care level	Adequate for Essential Health Needs – (348 Nos)	3	**29.16 out of 35**
18.	Availability of Medicines at District Hospital level	Comprehensive – (649 Nos including Specialty Drugs)	3	
19.	Percentage of Generic Medicines used	All Essential Drugs are Generic with Few Specialty Drugs	5	
20.	GMP (Good Manufacturing Practices)	Required cGMP	5	
21.	Quality Control Parameters Defined	Comprehensive Quality Control Parameters as Per Pharmacopoeia Standards	4	
22.	Penalty Clause for Quality Default	Stringent Penalty Clause with Blacklisting and Financial Deduction	5	
Total Score based on the Performance Indicators Evaluation of Tamil Nadu				**85.46**

INR – Indian Rupees, MSME – Micro, Small, and Medium Enterprises, EMD - Earnest Money Deposit, Nos – Numbers, cGMP - Current Good Manufacturing. Practices

Table 7.4: Public Drug Procurement – Key Performance Indicators Evaluation of Andhra Pradesh (Period of the Study: 2021-2022)

S. No	Parameter	Levels of Performance	Scoring (Out of 5)	Total
Efficiency Performance Indicators (Total Weight: 30%)				
1.	Process/Procedure of Purchase of Medicines	Open Tender System	5	**29.00 out of 30**
2.	Responsibility of Medicine Procurement & Autonomy	Centralized Procurement by Nodal Agency Registered under Companies Act	5	
3.	Distribution Process	Centralized Distribution from State-Level Warehouses to Districts	5	
4.	Need of Pharmacist	Required for Technical Evaluation	4	
5.	Sample Test for Evaluation of Technical Bid	Samples Tested for Every Batch After Purchase	5	
6.	Process of Dispose of Medicine	Through Biomedical Waste Management Service Providers Approved by Pollution Control Board	5	
Cost-Effectiveness Performance Indicators (Total Weight: 35%)				
7.	Budget Allocation for Medicines supplies	Above Average Allocation & 3-4% of Total Health Budget (Per Capita Allocation: 100.75 INR, Percentage of Health Budget: 3.59%)	4	**23.80 out of 35**
8.	Tender Fees	High Tender Fees	2	
9.	Types of Suppliers Eligible	Manufacturers and Importers only Allowed	5	
10.	Time for Submission of Tender	Usually, 30 days with Extendable Option	5	
11.	Market Standing Requirement	No Mention of Market Standing	1	
12.	Two Bid System Followed	No	2	
13.	Annual Turnover Requirement	Balanced Threshold, Limited MSME/Home State Support	3	
14.	Earnest Money Deposit	High EMD	2	
15.	Management Cost	No Management Cost	5	
16.	Limit of Expiry Percentage	Very Strict Limit - Permitted up to 0.5% on the procurement value	5	
Quality Performance Indicators (Total Weight: 35%)				
17.	Availability of Medicines at Primary Health Care level	Basic but Limited – (215 Nos)	2	**25.66 out of 35**
18.	Availability of Medicines at District Hospital level	Comprehensive – (608 Nos)	3	
19.	Percentage of Generic Medicines used	Majority (90%)	4	
20.	GMP (Good Manufacturing Practices)	Required GMP/WHO GMP	4	
21.	Quality Control Parameters Defined	Comprehensive Quality Control Parameters as Per Pharmacopoeia Standards	4	
22.	Penalty Clause for Quality Default	Stringent Penalty Clause with Blacklisting and Financial Deduction	5	
Total Score based on the Performance Indicators Evaluation of Andhra Pradesh				**78.46**

INR – Indian Rupees, MSME – Micro, Small, and Medium Enterprises, EMD - Earnest Money Deposit, Nos – Numbers, WHO – World Health Organization

Table 7.5: Public Drug Procurement – Key Performance Indicators Evaluation of Rajasthan (Period of the Study: 2021-2022)

S. No	Parameter	Levels of Performance	Scoring (Out of 5)	Total
Efficiency Performance Indicators (Total Weight: 30%)				
1.	Process/Procedure of Purchase of Medicines	Open Tender System	5	**25.00 out of 30**
2.	Responsibility of Medicine Procurement & Autonomy	Centralized Procurement by State-Owned Agency	3	
3.	Distribution Process	Decentralized Distribution from District Warehouses to Local Facilities	4	
4.	Need of Pharmacist	Required for Technical Evaluation	4	
5.	Sample Test for Evaluation of Technical Bid	Sample Evaluation Not Required	4	
6.	Process of Dispose of Medicine	Through Biomedical Waste Management Service Providers Approved by Pollution Control Board	5	
Cost-Effectiveness Performance Indicators (Total Weight: 35%)				
7.	Budget Allocation for Medicines supplies	Data Not Mentioned	2	**23.80 out of 35**
8.	Tender Fees	Low Tender Fees	5	
9.	Types of Suppliers Eligible	Manufacturers, Importers, Loan Licensees Allowed	4	
10.	Time for Submission of Tender	Less than 30 days with Extendable Option	2	
11.	Market Standing Requirement	Explicit Requirement for 3 to 4 Years of Market Standing	4	
12.	Two Bid System Followed	Yes	5	
13.	Annual Turnover Requirement	Highly Inclusive (Lower Threshold)	5	
14.	Earnest Money Deposit	High EMD	2	
15.	Management Cost	Low Fixed Management Cost	4	
16.	Limit of Expiry Percentage	No Information Provided	1	
Quality Performance Indicators (Total Weight: 35%)				
17.	Availability of Medicines at Primary Health Care level	Comprehensive Coverage – (>350 Nos)	4	**29.16 out of 35**
18.	Availability of Medicines at District Hospital level	Comprehensive – (around 696 Nos)	3	
19.	Percentage of Generic Medicines used	All Essential Drugs are Generic with Few Specialty Drugs	5	
20.	GMP (Good Manufacturing Practices)	Required WHO GMP	4	
21.	Quality Control Parameters Defined	Comprehensive Quality Control Parameters as Per Pharmacopoeia Standards	4	
22.	Penalty Clause for Quality Default	Stringent Penalty Clause with Blacklisting and Financial Deduction	5	
Total Score based on the Performance Indicators Evaluation of Rajasthan				**77.96**

INR – Indian Rupees, MSME – Micro, Small, and Medium Enterprises, EMD - Earnest Money Deposit, Nos – Numbers, WHO – World Health Organization

Table 7.6: Public Drug Procurement – Key Performance Indicators Evaluation of Chhattisgarh (Period of the Study: 2021-2022)

S. No	Parameter	Levels of Performance	Scoring (Out of 5)	Total
Efficiency Performance Indicators (Total Weight: 30%)				
1.	Process/Procedure of Purchase of Medicines	Open Tender System	5	**20.00 out of 30**
2.	Responsibility of Medicine Procurement & Autonomy	Centralized Procurement by State-Owned Agency	3	
3.	Distribution Process	Decentralized Distribution from District Warehouses to Local Facilities	4	
4.	Need of Pharmacist	Required for Technical Evaluation	4	
5.	Sample Test for Evaluation of Technical Bid	Sample Testing Information Not Specified	1	
6.	Process of Dispose of Medicine	Through Open e-Tender to Qualified Disposal Firms	3	
Cost-Effectiveness Performance Indicators (Total Weight: 35%)				
7.	Budget Allocation for Medicines supplies	Data Not Mentioned	2	**23.10 out of 35**
8.	Tender Fees	Moderate Tender Fees	3	
9.	Types of Suppliers Eligible	Manufacturers and Importers only Allowed	5	
10.	Time for Submission of Tender	30 days after Tender is Live	4	
11.	Market Standing Requirement	Market Standing Mentioned but Duration Not Specified	2	
12.	Two Bid System Followed	Yes	5	
13.	Annual Turnover Requirement	High Threshold, Lower Inclusivity	2	
14.	Earnest Money Deposit	Moderate EMD	3	
15.	Management Cost	Low Fixed Management Cost	4	
16.	Limit of Expiry Percentage	Lenient Limit	3	
Quality Performance Indicators (Total Weight: 35%)				
17.	Availability of Medicines at Primary Health Care level	Extensive Range – (1437 Nos)	5	**29.16 out of 35**
18.	Availability of Medicines at District Hospital level	Exceptionally Comprehensive – (1797 Nos)	5	
19.	Percentage of Generic Medicines used	Majority (90%)	4	
20.	GMP (Good Manufacturing Practices)	Required GMP	3	
21.	Quality Control Parameters Defined	Defined Quality Control Parameters Covering Multiple Parameters	3	
22.	Penalty Clause for Quality Default	Stringent Penalty Clause with Blacklisting and Financial Deduction	5	
Total Score based on the Performance Indicators Evaluation of Chhattisgarh				**72.26**

INR – Indian Rupees, MSME – Micro, Small, and Medium Enterprises, EMD - Earnest Money Deposit, Nos – Numbers

Table 7.7: Public Drug Procurement – Key Performance Indicators Evaluation of Uttar Pradesh (Period of the Study: 2021-2022)

S. No	Parameter	Levels of Performance	Scoring (Out of 5)	Total
Efficiency Performance Indicators (Total Weight: 30%)				
1.	Process/Procedure of Purchase of Medicines	Open Tender System	5	**25.00 out of 30**
2.	Responsibility of Medicine Procurement & Autonomy	Centralized Procurement by State-Owned Agency with Independent Autonomy	4	
3.	Distribution Process	Mixed Distribution Model - Both Centralized and Decentralized Components	3	
4.	Need of Pharmacist	Required for Technical Evaluation	4	
5.	Sample Test for Evaluation of Technical Bid	Sample Evaluation Not Required	4	
6.	Process of Dispose of Medicine	Through Biomedical Waste Management Service Providers Approved by Pollution Control Board	5	
Cost-Effectiveness Performance Indicators (Total Weight: 35%)				
7.	Budget Allocation for Medicines supplies	Moderate Allocation & 2-3% of Total Health Budget (Per Capita Allocation: 35.22 INR, Percentage of Health Budget: 2.67%)	3	**20.30 out of 35**
8.	Tender Fees	Moderate Tender Fees with Exceptions for MSMEs	4	
9.	Types of Suppliers Eligible	Manufacturers and Importers only Allowed	5	
10.	Time for Submission of Tender	Less than 30 days with Extendable Option	2	
11.	Market Standing Requirement	Explicit Requirement for 3 to 4 Years of Market Standing	4	
12.	Two Bid System Followed	No	2	
13.	Annual Turnover Requirement	Very High Threshold, Exclusivity to Large Entities	1	
14.	Earnest Money Deposit	High EMD	2	
15.	Management Cost	No Information Provided	1	
16.	Limit of Expiry Percentage	Very Strict Limit	5	
Quality Performance Indicators (Total Weight: 35%)				
17.	Availability of Medicines at Primary Health Care level	Adequate for Essential Health Needs – (350 Nos)	3	**22.16 out of 35**
18.	Availability of Medicines at District Hospital level	Limited – (350 Nos)	1	
19.	Percentage of Generic Medicines used	All Essential Drugs are Generic with Few Specialty Drugs	3	
20.	GMP (Good Manufacturing Practices)	Required GMP	3	
21.	Quality Control Parameters Defined	Comprehensive Quality Control Parameters as Per Pharmacopoeia Standards	4	
22.	Penalty Clause for Quality Default	Stringent Penalty Clause with Blacklisting and Financial Deduction	5	
Total Score based on the Performance Indicators Evaluation of Uttar Pradesh				**67.46**

INR – Indian Rupees, MSME – Micro, Small, and Medium Enterprises, EMD - Earnest Money Deposit, Nos – Numbers

Table 7.8: Public Drug Procurement – Key Performance Indicators Evaluation of Odisha (Period of the Study: 2021-2022)

S. No	Parameter	Levels of Performance	Scoring (Out of 5)	Total
Efficiency Performance Indicators (Total Weight: 30%)				
1.	Process/Procedure of Purchase of Medicines	Centralized Online E-tender System	4	**21.99 out of 30**
2.	Responsibility of Medicine Procurement & Autonomy	Centralized Procurement by State-Owned Agency with Independent Autonomy	4	
3.	Distribution Process	State-Specific Distribution Mechanisms	2	
4.	Need of Pharmacist	Required for Technical Evaluation	4	
5.	Sample Test for Evaluation of Technical Bid	Samples Tested for Every Batch After Purchase	5	
6.	Process of Dispose of Medicine	Through Open e-Tender to Qualified Disposal Firms	3	
Cost-Effectiveness Performance Indicators (Total Weight: 35%)				
7.	Budget Allocation for Medicines supplies	Data Not Mentioned	2	**23.10 out of 35**
8.	Tender Fees	Moderate Tender Fees	3	
9.	Types of Suppliers Eligible	Manufacturers, Importers, Loan Licensees Allowed	4	
10.	Time for Submission of Tender	Usually, 30 days with Extendable Option	5	
11.	Market Standing Requirement	Explicit Requirement for 3 to 4 Years of Market Standing	4	
12.	Two Bid System Followed	Yes	5	
13.	Annual Turnover Requirement	Very High Threshold, Exclusivity to Large Entities	1	
14.	Earnest Money Deposit	Very High EMD	1	
15.	Management Cost	Variable Management Cost	3	
16.	Limit of Expiry Percentage	Very Strict Limit	5	
Quality Performance Indicators (Total Weight: 35%)				
17.	Availability of Medicines at Primary Health Care level	Basic but Limited – (216 Nos)	2	**24.5 out of 35**
18.	Availability of Medicines at District Hospital level	Comprehensive – (555 Nos)	3	
19.	Percentage of Generic Medicines used	All Essential Drugs are Generic with Few Specialty Drugs	3	
20.	GMP (Good Manufacturing Practices)	Required WHO GMP	4	
21.	Quality Control Parameters Defined	Comprehensive Quality Control Parameters as Per Pharmacopoeia Standards	4	
22.	Penalty Clause for Quality Default	Stringent Penalty Clause with Blacklisting and Financial Deduction	5	
Total Score based on the Performance Indicators Evaluation of Odisha				**69.59**

INR – Indian Rupees, MSME – Micro, Small, and Medium Enterprises, EMD - Earnest Money Deposit, Nos – Numbers, WHO – World Health Organization

Table 7.9: Public Drug Procurement – Key Performance Indicators Evaluation of Kerala (Period of the Study: 2021-2022)

S. No	Parameter	Levels of Performance	Scoring (Out of 5)	Total
Efficiency Performance Indicators (Total Weight: 30%)				
1.	Process/Procedure of Purchase of Medicines	Open Tender System	5	**27.00 out of 30**
2.	Responsibility of Medicine Procurement & Autonomy	Centralized Procurement by Nodal Agency Registered under Companies Act	5	
3.	Distribution Process	Decentralized Distribution from District Warehouses to Local Facilities	4	
4.	Need of Pharmacist	Required for Technical Evaluation	4	
5.	Sample Test for Evaluation of Technical Bid	Samples Tested for Every Batch After Purchase	5	
6.	Process of Dispose of Medicine	By Central or State Approved Agencies	4	
Cost-Effectiveness Performance Indicators (Total Weight: 35%)				
7.	Budget Allocation for Medicines supplies	High Allocation & Above 4% of Total Health Budget (Per Capita Allocation: 150.90 INR, Percentage of Health Budget: 4.17%)	5	**28.70 out of 35**
8.	Tender Fees	Varied Tender Fees Based on Contract Value	1	
9.	Types of Suppliers Eligible	Manufacturers and Importers only Allowed	5	
10.	Time for Submission of Tender	Usually, 30 days with Extendable Option	5	
11.	Market Standing Requirement	Explicit Requirement for 3 to 4 Years of Market Standing	4	
12.	Two Bid System Followed	Yes	5	
13.	Annual Turnover Requirement	Highly Inclusive, Strong Local MSME Support	5	
14.	Earnest Money Deposit	Very Low EMD	5	
15.	Management Cost	No Management Cost	5	
16.	Limit of Expiry Percentage	No Information Provided	1	
Quality Performance Indicators (Total Weight: 35%)				
17.	Availability of Medicines at Primary Health Care level	Comprehensive Coverage – (400 plus Nos)	4	**29.16 out of 35**
18.	Availability of Medicines at District Hospital level	Highly Comprehensive – (800 Nos plus Specialty Drugs)	4	
19.	Percentage of Generic Medicines used	Majority (90%)	4	
20.	GMP (Good Manufacturing Practices)	Required GMP/ WHO GMP	4	
21.	Quality Control Parameters Defined	Comprehensive Quality Control Parameters as Per Pharmacopoeia Standards	4	
22.	Penalty Clause for Quality Default	Stringent Penalty Clause with Blacklisting and Financial Deduction	5	
Total Score based on the Performance Indicators Evaluation of Kerala				**84.86**

INR – Indian Rupees, MSME – Micro, Small, and Medium Enterprises, EMD - Earnest Money Deposit, Nos – Numbers, WHO – World Health Organization

Overall scores from the evaluation of public drug procurement performance for each sample state are shown in **Table 7.10**. The scores represent the procurement systems effectiveness and efficiency in the respective regions, with the highest to lowest rank. Tamil Nadu (85.46) is the top most performer with Kerala (84.86) followed closely, demonstrating an excellent procurement practices and efficient management. Andhra Pradesh (78.46) and Rajasthan (77.96) placing them in the middle. However, Chhattisgarh (72.26) followed by Uttar Pradesh (67.46) and Odisha (69.59) got the least overall scores, indicating need for improvements. These scores are intended to rank the effectiveness and quality of public drug procurement of the states, and to demonstrate the need to focus on interventions to improve procurement practices in low scoring states.

Table 7.10: Total Scores based on the Performance Indicators Evaluation on Sample States for the Study (Period of the Study: 2021-2022)

State	Responsible Body	EPI Score (out of 30)	CPI Score (out of 35)	QPI Score (out of 35)	Grand Total (out of 100)	Rank
Tamil Nadu	Tamil Nadu Medical Services Corporation (TNMSC)	29.0	27.30	29.16	**85.46**	**1**
Kerala	Kerala Medical Services Corporation Limited (KMSCL)	27.0	28.70	29.16	**84.86**	**2**
Andhra Pradesh	Andhra Pradesh Medical Services & Infrastructure Development Corporation (APMSIDC)	29.0	23.80	25.66	**78.46**	**3**
Rajasthan	Rajasthan Medical Services Corporation Limited (RMSCL)	25.0	23.80	29.16	**77.96**	**4**
Chhattisgarh	Chhattisgarh Medical Services Corporation Limited (CGMSCL)	20.0	23.10	29.16	**72.26**	**5**
Odisha	Odisha State Medical Corporation Limited (OSMCL)	21.99	23.10	24.50	**69.59**	**6**
Uttar Pradesh	Uttar Pradesh Medical Supplies Corporation Limited (UPMSCL)	25.0	20.30	22.16	**67.46**	**7**

7.4 Discussion

A comprehensive assessment of public drug procurement in seven Indian states reveals significant differences in performance, especially with regard to efficiency, cost-effectiveness, and drug quality. The data obtained from studied procurement systems suggests that states with independent procurement agencies, such as Tamil Nadu and Kerala, demonstrate increased efficiency in the management of inventory and the payment of suppliers, which in turn contributes in improving access to essential medicines (Singh et al., 2013). In contrast, states like Odisha and Chhattisgarh are lacking in budget allocation and compliance with procurement standards (Kaur et al., 2021). The study highlights the discrepancies and directly influence the policy suggestions for improving procurement systems.

Efficiency in Procurement Systems

Tamil Nadu, Andhra Pradesh, and Kerala states perform better as their scores are 29.0/30, 29.0/30, and 27.0/30, respectively. This performance is attributed to their effective centralized procurement frameworks and rigorous quality oversight. In contrast, Odissa and Chhattisgarh exhibit lower performance, having an efficiency aggregate of approximately 20-21, which suggests that there are deficiencies in the distribution mechanisms and procurement responsibilities. These are consistent with earlier studies which emphasize the importance of transparent and accountable procurement frameworks, particularly during the stage of development (Evenett & Hoekman, 2005). Therefore, promoting the exchange of knowledge across states can facilitate the adoption of best practices and enhance the efficient drug procurement process at a national level (Saaida, 2023).

Cost-Effectiveness Strategies, Quality Control and Drug Availability

Cost-efficiency and quality are the essential aspect of effective public drug procurement and supply systems. Cost-effectiveness aspect with 35% of total weightage, highlights Kerala and

Tamil Nadu as top performers with the scores of 28.70/35 and 27.30/35, respectively. This is attributed to strategic budget allocations, efficient tender processes, and comprehensive management of market standing and tender submission times. Andhra Pradesh, Rajasthan, and Chhattisgarh obtain moderate scores of about 23, indicating moderate allocation approaches and flexibility in supplier eligibility criteria. In contrast, Uttar Pradesh achieves a score of 20.30, highlighting the necessity for enhancements in budget allocation and cost strategies, particularly in terms of contract fees and annual turnover requirements.

The quality parameters, which carry a weightage of 35%, show that Tamil Nadu, Rajasthan, Chhattisgarh, and Kerala have all achieves scores of 29.16. This might be due to the widespread availability of drugs at primary health centres (PHCs) and district levels, adherence to good manufacturing practices, and the implementation of stringent quality control standards. Andhra Pradesh and Odisha have lower scores (25.66 and 24:50, respectively) indicating inadequacies in implementation of quality guidelines and availability of drugs. It also reveals that the states that adopt very strict quality control parameters adheres not only to good manufacturing practices, but also mitigate procurement inefficiencies (Lewis & Pettersson Gelander, 2009). The assessments provide valuable insights into key factors for enhancing public drug procurement systems across India, highlighting significant strengths as well as areas that may benefit from improvement (Evenett & Hoekman, 2005).

Geographic and Economic Influences

Knowing the complex relationships between economic and geographical conditions is crucial to evaluate public drug procurement across the diverse states of India. The logistic capabilities and resource allocation within public health infrastructure is influenced by the geographical characteristics. The study finds the variations in per capita health expenditures across the sampled states. The per capita allocation is high in Kerala with ₹3,622.15, but in Uttar Pradesh it is only ₹1,317.65. These differences create unique challenges for procurement, which have

to be tackled with personalized approaches, that take into consideration both the financial constraints and the geographical specificities. The present study emphasizes that the states with stronger economic resources and geographic advantages tend to perform better in drug procurement (Evenett & Hoekman, 2005). In contrast, states with resource constraints witness a decrease in the efficiency of their procurement processes, indicating that long term financial inequality reduces the total effectiveness in representing public health programs (Manning & Soon, 2014).

The efficiency of public drug supply chain is greatly influenced by geographic diversity. Certain states like Tamil Nadu and Kerala, which have highly developed and centralized e-tender systems and centralized procurement processes are able to score higher compared to those using decentralized models like Uttar Pradesh and Chhattisgarh. Furthermore, differences in outcomes across states reflects the importance of budgetary decision for public health systems. The performance metrics in states like Tamil Nadu and Kerala reveal a strong association between higher health budget allocations and better results. Tamil Nadu allocates ₹2,00,800 million as its health budget and obtained 85.46 out of 100 in the procurement efficiency category. However, Uttar Pradesh has a greater allocation of ₹263280 million, and ended with a lower score of 67.46. The discrepancy could be due to differences in per capita health budget. Uttar Pradesh has a larger population of about 199 million and as a result the per capita health budget is much lower. In contrast, Tamil Nadu has smaller population of about 72 million and allows a higher per capita expenditure of ₹2,783.09. Therefore, it is evident that the states with strong health funding frameworks consistently demonstrate superior performance, underscoring the necessity to meticulously evaluate budgetary strategies (Acharya, 2004).

Overall Performance

The combined scores from all indicators to a total of 100, Tamil Nadu and Kerala topped the list with a score of 85.46 and 84.86, respectively. Therefore, these state models could function as benchmark models for procurement strategies that are effective in achieving a balance of operational efficiency, quality, and cost. Competitive scores of 72.26 to 78.46 are obtained by Andhra Pradesh, Rajasthan, and Chhattisgarh, which indicate that the frameworks are robust but also indicate that there are areas that require improvement. On the other hand, the scores of Odisha and Uttar Pradesh are the lowest, at 69.59 and 67.46, respectively. This suggests that there is a critical need for policy reform and enhancements in procurement practices to enhance drug accessibility and reliability. Although some states establish high standards in public drug procurement through efficient, cost-effective, and quality-focused methodologies, others require strategic enhancements to align their procurement practices with best practices, ensuring timely and equitable access to essential medications.

7.5 Limitations and Strengths of this Study

The limitations of this study include that it focused on only seven selected states, making it difficult to generalize the findings to the wide socio-economic phenomenon of the country. It is also noteworthy that the indicators are based on known standards and an overreliance of quantitative data, which underscores the need of future qualitative research to better understand complicated inefficiencies in procurement processes. The strengths of this study include the use of a robust self-developed key performance indicators and solid coring framework, which can be serving as reference model in similar studies.

7.6 Conclusions

This study uncovers the strengths and weaknesses of the public drug procurement process in seven states. Policy reforms are suggested in order to implement at regional level with states

of Tamil Nadu and Kerala considered as benchmark models supporting effective procurement strategy. Improved integrity of drug procurement requires coordination among stakeholders, and institutional reforms. Conclusively this study recommends that the perspectives of all stakeholders involved can be used to enhance understanding of procurement dynamics.

7.7 Strategic Recommendations

- ✓ Implementing a holistic approach that emphasize efficiency, cost savings, and quality in public drug procurement and distribution.
- ✓ Establishing a centralized online tendering system, as shown by the benchmark states in this research.
- ✓ Reviewing health budget allocation for medication purchase holistically would help to build a more sustainable financial framework.
- ✓ Strict quality control policies with penalties for non-compliance help to preserve the quality.
- ✓ Focusing on initiatives that enhance public trust in healthcare services through transparency and accountability in drug procurement practices.

CHAPTER 8

SUMMARY AND CONCLUSION

This chapter provides a comprehensive summary and conclusion of the integrated study, which focuses on the challenges associated with healthcare access, medication distribution, and out-of-pocket expenditures (OOPE) in India. The study employs a mixed-methods approach, integrating quantitative and qualitative research to explore various dimensions of healthcare financing and delivery. Through the examination of financial burdens related to medicines, the specific challenges of tuberculosis drug therapy, the financial impacts faced by pregnant women, and an evaluation of public drug procurement systems, the study aims to highlight the pressing need for effective policy interventions and improvements in healthcare infrastructure.

8.1 Summary of this Integrated Study

8.1.1 Study 1 - Financial Burden of Medicines

This systematic review synthesizes data from published evidence to evaluate the effectiveness of government policies implemented over the past 20 years that aim to reduce out-of-pocket expenditures (OOPE) related to medications. The review encompasses relevant articles, literature, policy documents, and secondary data, with a specific focus on OOPE within the context of healthcare financing in India.

- **Article Screening Process**
  - ✓ ***Initial Articles Identified:*** 1,597
  - ✓ ***Duplicates Removed:*** 383
  - ✓ ***Ineligibility Flagged:*** 327
  - ✓ ***Remaining Articles for Screening:*** 887

- ✓ ***Exclusions:*** 820 based on titles/abstracts
- ✓ ***Final Assessments Conducted:*** 66 articles assessed; 10 met inclusion criteria

➢ **Overview of Included Studies**

- ✓ ***Publication Years:*** 2006 - 2022
- ✓ ***Primary Data Collection:*** 5 studies gathered data via questionnaires/interviews
- ✓ ***Secondary Data Collection:*** 5 studies used national datasets (e.g., NSSO)
- ✓ ***Study Types:*** 3 cross-sectional studies, 1 prospective observational study
- ✓ ***Sample Populations:*** Ranged from 77 to 420 patients; 600 to 125,000 households

➢ **Key Findings on Out-of-Pocket Expenditures (OOPE)**

- ✓ ***Healthcare Costs:*** All studies reported OOPE, including medicine costs
- ✓ ***Socio-Economic Status:*** 6 studies linked OOPE to socio-economic factors
- ✓ ***Significant OOPE Findings:*** 7 studies reported substantial OOPE, with or without financial catastrophe

➢ **Disease-Specific OOPE Insights**

- ✓ ***Visceral Leishmaniasis (VL):*** Total cost per episode was ₹15,400 (58% of annual household income), with ₹2,334 (15%) spent on medicines
- ✓ ***Diabetes Patients:*** Nearly half paid OOP for medications; patients with lower socio-economic status missed fewer appointments
- ✓ ***Rheumatic Heart Disease (RHD):*** Costs breakdown included 30% for medication, 22% for administration, and 48% for travel

- **Surgical and Non-Surgical OOPE**
  - ✓ ***Rout 2016 Study Findings:***
    - ❖ *Nonsurgical Hospitalization:* Medicines accounted for 20.6% of the overall mean OOPE (Rs 374 out of Rs 1,814)
    - ❖ *Surgery-Related Hospitalization:* Medicines accounted for 12.4% of the overall mean OOPE (Rs 382 out of Rs 3,081)
    - ❖ *Financial Protection*: 45% of households lacked financial protection; 61% resorted to borrowing for expenses
- **Healthcare Inequities and OOPE**
  - ✓ ***Prinja 2012 Study:*** Found higher hospitalization frequency among the affluent, with medicines accounting for a significant portion of public sector OOPE
  - ✓ ***Bose 2018 Study:*** Assessed the effectiveness of policies aimed at achieving Universal Health Coverage
- **Financial Implications of OOPE**
  - ✓ ***Selvaraj 2018 Study:***
    - ❖ Noted that OOP spending on medicines increased from 20.86% to 36.1% between 1993 and 2012
    - ❖ Indicated that 18% of households faced financial catastrophe due to OOP spending
  - ✓ ***La 2022 Study:*** Demonstrated that multimorbidity resulted in a 20.9% increase in medicines OOPE; specific conditions, such as stroke, led to a 131.6% increase, and diabetes resulted in a 91.5% increase in medicines OOPE

- **Subnational Health Accounts and OOPE**
  - ✓ ***Bahuguna 2018 Study:*** Reported that 76.64% of healthcare expenses were covered by households, with 52% of OOPE attributed to medicines
- **Indirect Costs of Vaccine Delivery**
  - ✓ ***Mogasale 2015 Study:*** Identified that 24.6% to 38.0% of total vaccine delivery costs were due to productivity loss, which impacted vaccine uptake despite vaccines being free.

8.1.2 Study 2 - TB Drug Therapy Challenges

This segment of the study utilized a mixed-methods approach, combining both quantitative and qualitative techniques to investigate healthcare service utilization among individuals living with tuberculosis (TB) in the Agra district of Uttar Pradesh, India. The quantitative aspect involved the distribution of structured questionnaires to both patients with TB and healthcare providers, aiming to collect data on service utilization patterns, access to medications, and related costs. The qualitative aspect included in-depth interviews with patients and healthcare professionals, providing valuable insights into the experiences and challenges encountered in accessing TB treatment.

- **Quantitative Findings - Sample Characteristics**
  - ✓ ***Participants:*** 2,244 individuals; 61% accessed services in the private healthcare sector.
  - ✓ ***Demographics:*** No significant differences in residence area, age, or sex; significant differences in education, occupation, and income between sectors.

- **Healthcare Service Utilization**
  - ✓ ***Hospital Usage:*** 50.4% utilized community health centers; 45.6% utilized tertiary care hospitals.
  - ✓ ***Active TB Stage:*** 74.2% in the public sector and 81.7% in the private sector had pulmonary infections.
  - ✓ ***Family Screening:*** 79% in the public sector vs. 25% in the private sector.
  - ✓ ***Preventive Treatments:*** 71% in the public sector received treatment vs. 10% in the private sector.
- **Out-of-Pocket Expenditures (OOPE) and Health Policy Benefits**
  - ✓ ***Consultation Costs:*** Public hospitals have no consultation charges, while private hospitals charge all patients.
  - ✓ ***Medicine Availability:*** 98% in public hospitals vs. 48% in private hospitals.
  - ✓ ***Affordability:*** 91% of private patients are unable to afford medicines; 30% spend over 2000 INR monthly.
  - ✓ ***Government Aid:*** 92% of public sector patients receive 500 INR monthly for nutrition, compared to only 21% of private sector patients.
- **Qualitative Findings - Respondent Characteristics**
  - ✓ ***Participants:*** 49 respondents, primarily consisting of doctors, health officers, patients, and patient relatives, aged 20–62.
  - ✓ ***Roles:*** Key informants provided insights on service utilization and OOPE.

- **Factors Influencing Service Utilization and OOPE**
  - ✓ ***Perceived Contributing Factors (Mean ± SD):***
    - ❖ Delayed diagnosis and treatment adherence (3.76 ± 1.15)
    - ❖ Low disposable income (3.71 ± 1.18)
    - ❖ Lack of health insurance (3.69 ± 1.33)
    - ❖ Insufficient government incentives (3.61 ± 1.16)
- **Impaired Public Service Utilization**
  - ✓ ***Key Informant Responses:***
    - ❖ Long waits, centralization of TB services, and poor hospital infrastructure.
    - ❖ Misconceptions about low service quality in public health facilities impact utilization.
- **Self-Strategies for Reducing OOPE**
  - ✓ ***Suggested Strategies:***
    - ❖ Awareness programs through health workers, media, and community leaders.
    - ❖ Availability of branded medicines in public hospitals.
    - ❖ Ensuring timely direct benefit transfers for patients.
  - ✓ ***Policy Recommendations:***
    - ❖ Hiring more health professionals.
    - ❖ Decentralizing TB treatment services.

- ❖ Extending free medicine schemes to private hospitals.
- ❖ Enhancing public insurance to include private treatment.
- ❖ Increasing travel allowance for all individuals living with TB (currently applicable for MDR TB cases only).
- ❖ Full implementation of existing policies.

8.1.3 Study 3 - Financial Considerations in Pregnancy Outcomes

This component of the study examined the financial burdens experienced by women during pregnancy and childbirth through a combination of cross-sectional surveys and in-depth interviews. Surveys were administered to pregnant women in both urban and rural areas, collecting data on socioeconomic status, healthcare utilization, and out-of-pocket expenditures (OOPE) related to prenatal and postnatal care. Additionally, a subset of participants took part in semi-structured interviews to delve into their personal experiences regarding financial pressures during pregnancy, the affordability of services, and their perceptions of the quality of care received.

- ➢ **Quantitative Findings - Participant Characteristics**
  - ✓ ***Sample Size:*** 428 participants; diverse representation by geographical area, age, education, income, employment, marital status, and reproductive history.
  - ✓ ***Demographics:***
    - ❖ Age range: 18 to 40 years
    - ❖ Varied levels of education and income
    - ❖ Employment status included a variety of occupational roles

- **Out-of-Pocket Expenditures (OOPE) and Healthcare Support**
  - ✓ ***OOPE Patterns:***
    - ❖ Negligible expenses for home deliveries compared to public/private deliveries.
    - ❖ Limited healthcare utilization for home deliveries posed risks to mothers and newborns.
  - ✓ ***Government Programs:***
    - ❖ Notable gains from ASHA; varied receipt of Janani Suraksha Yojana (JSY) benefits.
    - ❖ Expenditures often sourced from salaries and savings (60% in the public sector, 87% in the private sector).
- **Financial and Healthcare Utilization Variables**
  - ✓ ***Healthcare Utilization:***
    - ❖ Delivery Locations: 67 home deliveries, 164 private hospital deliveries, 194 public hospital deliveries.
    - ❖ No significant differences in marital status and occupation (self) for healthcare choice; significant factors included residence, age, education, family income, and healthcare visits.
  - ✓ ***Expenditures:***
    - ❖ Public hospitals: No charges for consultations; private hospitals charge participants variably (e.g., ₹500 to ₹10,000+ for services).
    - ❖ Major financial burdens associated with private hospital deliveries, including outpatient department (OPD) visits and laboratory tests.

- **Qualitative Findings - Perceived Factors**
  - ✓ ***Key Factors Influencing OOPE (Mean ± SD):***
    - ❖ "Inadequate government maternity care leads to reliance on private services" – 3.88 (1.18)
    - ❖ "Rising costs of prenatal and postnatal care create financial strain" – 3.76 (1.16)
    - ❖ "Limited availability of essential medicines in government hospitals leads to additional costs" – 3.70 (1.28)
    - ❖ "Low disposable income exacerbates financial impact" – 3.64 (1.41)
- **Qualitative Insights from Interviews**
  - ✓ ***Factors Contributing to Service Utilization Issues:***
    - ❖ Long wait times and inadequate infrastructure in government hospitals.
    - ❖ Misconceptions about the quality of services.
  - ✓ ***Strategies for Improvement:***
    - ❖ Enhancing infrastructure and staffing in public facilities.
    - ❖ Providing financial counselling for navigating medical expenses and available subsidies.
- **Suggestions for Government/Policymakers**
  - ✓ ***Funding Increase:*** More funding for maternal healthcare in public hospitals to ensure free access to essential services and medications.
  - ✓ ***Regulations:*** Implement policies to control prices of prenatal and postnatal services in private hospitals.

- ✓ ***Targeted Subsidies:*** Introduce government subsidies specifically for pregnancy-related healthcare costs to alleviate financial burdens, including medicine costs.

8.1.4 Study 4 - Public Drug Procurement Performance

This study aimed to evaluate public drug procurement processes across seven Indian states by utilizing 22 key performance indicators (KPIs). The selected states were chosen to ensure geographic diversity and to represent varying levels of access to healthcare resources. A comprehensive set of 22 KPIs was developed, categorized into efficiency, cost-effectiveness, and quality performance indicators, each representing essential aspects of public drug procurement. Data collection involved distributing structured questionnaires to key personnel within medical corporations to obtain information on drug procurement and associated processes. To address gaps in information and limitations of open-source data, semi-structured telephonic interviews were conducted with the executive leadership teams of drug procurement cells in the selected states. The scoring framework included three principal metrics: efficiency, cost-effectiveness, and quality, each assigned a weight that reflected its relative importance in evaluating procurement practices.

- ➢ **Sample States for the Study (2021-2022)**
  - ✓ ***States Analyzed:*** Tamil Nadu, Andhra Pradesh, Rajasthan, Chhattisgarh, Uttar Pradesh, Odisha, Kerala.
  - ✓ ***Key Metrics:***
    - ❖ *Population:* Ranged from 25.54 million (Chhattisgarh) to 199.81 million (Uttar Pradesh).
    - ❖ *Total Health Budget:* Highest in Uttar Pradesh (263,280 million INR); lowest in Chhattisgarh (76,220 million INR).

- ❖ *Per Capita Health Budget:* Highest in Kerala (3,622.15 INR); lowest in Uttar Pradesh (1,317.65 INR).

- **Public Drug Procurement - KPIs Evaluation**

  - ✓ ***Efficiency Performance Indicators:***

    - ❖ *Top scoring states:* Tamil Nadu & Andhra Pradesh (scores of 29.0 out of 30).

    - ❖ Lower scores in Odisha and Chhattisgarh (20.0–21.0).

  - ✓ ***Cost-Effectiveness Indicators:***

    - ❖ Kerala (28.70) and Tamil Nadu (27.30) showed strong performance.

    - ❖ Uttar Pradesh scored lowest (20.30), indicating significant room for improvement.

  - ✓ ***Quality Performance Indicators:***

    - ❖ All top states achieved scores of 29.16, highlighting effective drug availability and adherence to quality standards.

- **Total Scores and Rankings**

  - ✓ ***Top Performers:***

    - ❖ Tamil Nadu: 85.46

    - ❖ Kerala: 84.86

  - ✓ ***Moderate Performers:*** Andhra Pradesh (78.46), Rajasthan (77.96), Chhattisgarh (72.26).

- ✓ ***Lowest Scores:*** Odisha (69.59) and Uttar Pradesh (67.46), indicating a critical need for policy reform.

- ➢ **Insights from the Procurement Evaluation**

  - ✓ ***Efficiency Insights:***

    - ❖ States with centralized procurement frameworks (Tamil Nadu, Kerala) exhibit higher efficiency and better access to medicines.

  - ✓ ***Cost-Effectiveness:***

    - ❖ Improved budget allocations and management strategies were observed in top-performing states.

    - ❖ Lower scores in Uttar Pradesh highlight inefficiencies in expenditure and procurement practices.

  - ✓ ***Quality Parameters Importance:***

    - ❖ States implementing stringent quality control measures reduced procurement inefficiencies and significantly improved health outcomes.

- ➢ **Geographic and Economic Factors**

  - ✓ ***Impact of Geography:***

    - ❖ States like Tamil Nadu and Kerala utilize advanced e-tender systems, reflecting better scores in efficiency.

  - ✓ ***Budget Allocations:***

    - ❖ Strong correlation between health budget allocations and performance metrics; Tamil Nadu yielded higher results with less population pressure compared to Uttar Pradesh.

- **Concluding Findings**

  - ✓ ***Benchmark Models:*** Tamil Nadu and Kerala serve as effective benchmarks for public drug procurement models.
  - ✓ ***Need for Improvement:*** States like Odisha and Uttar Pradesh require targeted strategies and reforms to enhance drug accessibility and reliability.
  - ✓ ***Impact on Policymaking:*** Findings underscore the necessity for policymakers to evaluate budgetary strategies meticulously to optimize healthcare service delivery.

8.2 Conclusion of this Integrated Study

Despite existing policies aimed at reducing healthcare costs, out-of-pocket expenditures for medicines remain a significant financial burden, particularly for poorer households, highlighting the necessity for increased government health spending. In Agra, the limited availability and high costs of tuberculosis (TB) medications in the private sector underscore the urgent need for enhanced public healthcare infrastructure and better integration with private providers to improve access to essential treatments. Additionally, maternal health expenses, including medicine costs, present substantial financial hardships, necessitating policy measures to alleviate these burdens and ensure equitable access to essential drugs. An evaluation of public drug procurement across seven states identified Tamil Nadu and Kerala as effective models, while emphasizing the need for reform in other regions to enhance drug quality and accessibility for all populations.

Moreover, leveraging data-driven AI tools in rural healthcare settings offers significant potential for enhancing decision-making and improving health outcomes. By utilizing data analytics to optimize resource allocation and engage communities, the efficiency and responsiveness of healthcare delivery can be improved in rural settings. Addressing social

determinants of health such as poverty, education, and housing is also crucial in reducing healthcare inequities. Targeted policy interventions, including universal health coverage, integrated social services, and accessible nutrition programs, can help marginalized populations overcome systemic barriers and foster long-term health improvements.

8.3 Addressing Social Determinants of Health to Reduce Healthcare Inequities

- **Universal Health Coverage:** Expanding access to health insurance will ensure that marginalized populations receive necessary healthcare services without financial strain.
- **Integrated Social Services:** Linking healthcare with social support programs can help low-income families overcome barriers related to poverty.
- **Affordable Housing Initiatives:** Promoting access to safe and affordable housing is critical for improving health outcomes and stability within communities.
- **Public-Private Partnerships in Housing and Health Services:** Fostering collaborations between public and private sectors to improve housing conditions linked to health services.
- **Educational Access and Health Literacy:** Investing in education and health literacy can empower individuals to make informed health choices, promoting preventive care and improving long-term health.
- **Conditional Cash Transfers:** Initiating conditional cash transfer programs that link financial support to healthcare utilization to incentivize preventive care among low-income families.

- **Nutrition and Food Security Programs:** Ensuring access to nutritious food through targeted programs can combat health disparities associated with poor dietary habits.
- **Targeted Nutritional Support:** Integrating nutritional support programs for vulnerable populations with maternal and child healthcare services.
- **Transportation Services:** Providing transportation assistance will enhance access to healthcare for those in rural and underserved areas.
- **Infrastructure and Accessibility Improvements:** Investing in rural infrastructure to bolster access to healthcare facilities and enhance service utilization.
- **Community Health Workers:** Training and deploying community health workers can bridge gaps in healthcare access, enhancing health education, disease prevention, and navigation of healthcare systems.
- **Data Collection and Monitoring:** Developing robust data systems to track the social determinants of health will enable targeted interventions and inform policy decisions.

8.4 Strategic Recommendations

- **Increasing Public Health Investment:** Boosting funds to reduce out-of-pocket expenditures on medicines, focusing on vulnerable populations.
- **Strengthening Public Drug Procurement:** Adopting best practices from Tamil Nadu and Kerala to centralize procurement and enforce quality controls.
- **Enhancing Public-Private Sector Coordination:** Improving collaboration to address disparities in medication availability and affordability, particularly for TB and maternal healthcare.

- **Expanding Health Insurance:** Broadening coverage to include essential medications, alleviating financial barriers for patients.
- **Promoting Awareness and Education:** Implementing campaigns to reduce stigma and encourage treatment in public sector hospitals for people living with TB.
- **Developing Targeted Maternal Health Policies:** Introducing subsidies and comprehensive programs to mitigate financial burdens related to pregnancy-related medicines.
- **Addressing Socioeconomic Disparities:** Tailoring policies to ensure equitable access to essential medicines across diverse socioeconomic and geographic groups.
- **Leveraging AI for Enhanced Rural Healthcare:** Integrating data-driven AI tools in rural healthcare can optimize decision-making and allocate resources effectively, ultimately improving patient outcomes.

8.5 Mechanisms for Implementing Policy Recommendations

- **Public-Private Partnerships (PPPs):** Forming partnerships to improve healthcare infrastructure and mobilizing resources in underserved areas.
- **Technology Transfer Initiatives:** Collaborating with research institutions to adopt technologies like telemedicine in rural healthcare.
- **Targeted Financial Incentives:** Offering incentives for healthcare providers operating in low-income areas to boost workforce availability.
- **Capacity Building for Community Health Workers:** Developing training programs for community health workers to enhance their skills in health education, disease prevention, and navigation of healthcare systems.
- **Monitoring and Evaluation Framework:** Establishing a comprehensive system for

tracking the effectiveness of implemented policies and interventions.

- **Stakeholder Engagement and Advocacy:** Involving local communities, healthcare providers, and policymakers in discussions about health needs and solutions.

8.6 Future Scope of the Integrated Study

The future scope of this integrated study highlights the importance of continuous research and assessment to understand the intricate relationships among health policy, healthcare expenses, and patient outcomes. By further exploring these aspects, this study can significantly contribute to the improvement of public health systems in India and beyond.

- **Longitudinal Studies:** Future research can focus on conducting long-term studies to assess the impact of implemented policy changes on out-of-pocket expenditures and healthcare access over time. This will provide insights into the sustainability of reforms and ongoing challenges.

- **Broader Geographic Analysis:** The study may be expanded to include a more extensive range of states or regions within India, or even comparisons with other countries, to develop a comprehensive understanding of healthcare financing and procurement practices.

- **Health Equity Focus:** Future investigations can explore disparities in healthcare access and expenditures among various demographic groups, particularly marginalized communities, to ensure more equitable health policies and practices.

- **Integration of Qualitative Research:** Further qualitative research can be conducted to explore patient experiences and perceptions in more depth, providing a richer understanding of the barriers they face in accessing healthcare.

- **Policy Impact Evaluation:** Developing frameworks for evaluating the effectiveness of specific government policies aimed at reducing healthcare costs and improving service delivery is essential for using robust performance indicators.
- **Technological Advancements:** Future studies may examine the role of technology in enhancing healthcare access and reducing costs, such as telemedicine, mobile health applications, and electronic procurement systems.
- **Public-Private Partnerships:** Investigating the potential for public-private partnerships to improve drug procurement processes and healthcare delivery should be a focus of future research, assessing models from various regions and sectors.
- **Economic Analysis:** A detailed economic analysis of the impacts of high out-of-pocket expenditures on household finances and the broader economy, including productivity losses and socioeconomic outcomes, can be performed in future studies.
- **Patient Empowerment and Education:** Exploring strategies for empowering patients through education about healthcare financing and their rights will help improve health literacy, enabling them to navigate the healthcare system more effectively.
- **Evaluation of Drug Quality and Safety:** Future research should investigate the implications of drug procurement practices on the quality and safety of medications available to the public, ensuring that policies prioritize patient safety alongside cost-effectiveness.

REFERENCES

Acharya, A. K. (2004). Toward establishing a universal basic health norm. *Ethics & International Affairs*, *18*(3), 65–78.

Aggarwal, V. (2023). Health Budget 2023: Highlights. *Indian Journal of Clinical Practice*, *33*(9), 5–6.

Aikins, M., Aryeetey, R., Dako-Gyeke, P., Adongo, P. B., & Mcgough, L. (2015). Socio-economic differences in cost of pregnancy-related health services in the peri-urban Accra, Ghana. *Journal of Public Health (United Kingdom)*, *37*(3), 540–546. https://doi.org/10.1093/pubmed/fdu072

Algharibi, E. D. A., Fadel, B. A., & Al-Hanawi, M. K. (2024). Assessment of Knowledge of Health Economics among Healthcare Professionals in the Kingdom of Saudi Arabia: A Cross-Sectional Study. *Healthcare (Basel, Switzerland)*, *12*(2). https://doi.org/10.3390/healthcare12020185

Ambade, M., Sarwal, R., Mor, N., Kim, R., & Subramanian, S. V. (2022). Components of out-of-pocket expenditure and their relative contribution to economic burden of diseases in India. *JAMA Network Open*, *5*(5), e2210040–e2210040.

Andrulis, D. P. (1998). Access to care is the centerpiece in the elimination of socioeconomic disparities in health. *Annals of Internal Medicine*, *129*(5), 412–416.

Anggriani, Y., Ramadaniati, H. U., Sarnianto, P., Pontoan, J., & Suryawati, S. (2020). The Impact of Pharmaceutical Policies on Medicine Procurement Pricing in Indonesia Under the Implementation of Indonesia's Social Health Insurance System. *Value in Health Regional Issues*, *21*, 1–8. https://doi.org/10.1016/j.vhri.2019.05.005

Archana, S. (2021). Prime minister Jan Aushdhi Pariyojna: Challenges in effective implementation. *International Journal of Advanced Research*, *8* (May). 960-964. http://dx.doi.org/10.21474/IJAR01/11005

Arvind, B., Saxena, A., Kazi, D. S., & Bolger, A. F. (2021). Out-of-pocket expenditure for administration of benzathine penicillin G injections for secondary prophylaxis in patients with rheumatic heart disease: A registry-based data from a tertiary care center in Northern India. *Indian Heart Journal*, *73*(2), 169–173. https://doi.org/10.1016/j.ihj.2020.11.151

Asante, A., Wasike, W. S. K., & Ataguba, J. E. (2020). Health financing in sub-Saharan Africa: from analytical frameworks to empirical evaluation. In *Applied Health Economics and Health Policy* (Vol. 18, pp. 743–746). Springer.

Assefa, D. G., Dememew, Z. G., Zeleke, E. D., Manyazewal, T., & Bedru, A. (2024). Financial burden of tuberculosis diagnosis and treatment for patients in Ethiopia: a systematic review and meta-analysis. *BMC Public Health*, *24*(1), 1–14. https://doi.org/10.1186/s12889-024-17713-9

Backes, E. P., Scrimshaw, S. C., & National Academies of Sciences and Medicine, E. (2020). Systemic Influences on Outcomes in Pregnancy and Childbirth. In *Birth Settings in America: Outcomes, Quality, Access, and Choice*. National Academies Press (US).

Bagcchi, S. (2023). WHO's global tuberculosis report 2022. *The Lancet Microbe*, *4*(1), e20.

Bahuguna, P., Mukhopadhyay, I., Chauhan, A. S., Rana, S. K., Selvaraj, S., & Prinja, S. (2018). Sub-national health accounts: Experience from Punjab State in India. *PloS One*, *13*(12), e0208298. https://doi.org/10.1371/journal.pone.0208298

Bansal, J. R., Singh, S. K., Garg, V., & Mittal, N. (2024). Availability of Standard Quality Drugs Ensured in India: Stringent Drug Regulations and Up Graded Regulatory Mechanism. *Research Journal of Pharmacy and Technology*, *17*(7), 3079–3083.

Bashir, S., Sarin, S., Chadha, S. S., Kalra, A., ThekkePurakkal, A. S., Duraisamy, K., Saacks, S., Gwaza, G. P., Ongarello, S., & Denkinger, C. M. (2022). Strengthening resistance testing for tuberculosis in India - Investment cost, throughput, and efficiency of new laboratories. *Tuberculosis*, *136*(August). https://doi.org/10.1016/j.tube.2022.102245

Basu, S., Garg, S., Sharma, N., Singh, M. M., Garg, S., & Asaria, M. (2020). The determinants of out-of-pocket health-care expenses for diabetes mellitus patients in India: An examination of a tertiary care government hospital in Delhi. *Perspectives in Clinical Research*, *11*(2), 86–91. https://doi.org/10.4103/picr.PICR_169_18

Beall, R. F., & Attaran, A. (2017). A method for understanding generic procurement of HIV medicines by developing countries with patent protection. *Social Science and Medicine*, *185*, 118–126. https://doi.org/10.1016/j.socscimed.2017.05.012

Bedado, D., Kaso, A. W., & Hailu, A. (2022). Magnitude and determinants of out of pocket health expenditure among patients visiting outpatients in public hospitals in East Shoa Zone, Ethiopia. *Clinical Epidemiology and Global Health*, *15*(April), 1–6. https://doi.org/10.1016/j.cegh.2022.101066

Bijlmakers, L., Wientjes, M., Mwapasa, G., Cornelissen, D., Borgstein, E., Broekhuizen, H., Brugha, R., & Gajewski, J. (2019). Out-of-pocket payments and catastrophic household expenditure to access essential surgery in Malawi - A cross-sectional patient survey. *Annals of Medicine and Surgery*, *43*(June), 85–90. https://doi.org/10.1016/j.amsu.2019.06.003

Boche, B., Mulugeta, T., & Gudeta, T. (2022). Procurement Practice of Program Drugs and Its Challenges at the Ethiopian Pharmaceuticals Supply Agency: A Mixed Methods Study. *Inquiry (United States)*, *59*. https://doi.org/10.1177/00469580221078514

Borde, M. T., Loha, E., Johansson, K. A., & Lindtjørn, B. (2020). Financial risk of seeking maternal and neonatal healthcare in southern Ethiopia: a cohort study of rural households. *International Journal for Equity in Health*, *19*, 1–16.

Borghi, J., Munthali, S., Million, L. B., & Martinez-Alvarez, M. (2018). Health financing at district level in Malawi: an analysis of the distribution of funds at two points in time. *Health Policy and Planning*, *33*(1), 59–69. https://doi.org/10.1093/heapol/czx130

Bose, M., & Dutta, A. (2018). Health financing strategies to reduce out-of-pocket burden in India: a comparative study of three states. *BMC Health Services Research*, *18*(1), 830. https://doi.org/10.1186/s12913-018-3633-5

Bradley, M. M. (2021). *Ironing Out Anemia: Assessing the Role of Marketplace Factors and Government Investment Incentives in Shaping East African Pharmaceutical Markets*.

Buchan, J., Couper, I. D., Tangcharoensathien, V., Thepannya, K., Jaskiewicz, W., Perfilieva, G., & Dolea, C. (2013). Early implementation of WHO recommendations for the retention of health workers in remote and rural areas. *Bulletin of the World Health Organization*, *91*, 834–840.

Callander, E. J., Shand, A., & Nassar, N. (2021). Inequality in out of pocket fees, government funding and utilisation of maternal health services in Australia. *Health Policy*, *125*(6), 701–708. https://doi.org/10.1016/j.healthpol.2021.04.009

Callejas, J., & Mohapatra, D. P. (2021). Welfare effects of public procurement of medicines: Evidence from Ecuador. *International Journal of Industrial Organization*, *75*. https://doi.org/10.1016/j.ijindorg.2020.102697

Cazabon, D., Alsdurf, H., Satyanarayana, S., Nathavitharana, R., Subbaraman, R., Daftary, A., & Pai, M. (2017). Quality of tuberculosis care in high burden countries: the urgent need to address gaps in the care cascade. *International Journal of Infectious Diseases: IJID: Official Publication of the International Society for Infectious Diseases*, *56*, 111–116. https://doi.org/10.1016/j.ijid.2016.10.016

Chadha, V. K., Praseeja, P., Srivastava, R., Shivashankar, B. A., Hemanth Kumar, N. K., Padmesha, R., Suganthi, P., Umadevi, G., Narayana, L., Magesh, V., Nagendra, N., Puttaswamy, G., Jaiswal, R., & Somashekar, N. (2022). Pre-treatment delay and out of pocket expenses by notified new tuberculosis patients in an Indian mega city. *Indian Journal of Tuberculosis*, *69*(4), 446–452. https://doi.org/10.1016/j.ijtb.2021.07.001

Chadhar, K., Madhappan, N., Chandra, A., Salve, H. R., Yadav, K., Misra, P., & Kumar, R. (2023). Coverage and utilization of Nikshay Poshan Yojana among patients with tuberculosis: Exploring patterns and influencing factors. *Indian Journal of Tuberculosis*, *xxxx*. https://doi.org/10.1016/j.ijtb.2023.09.005

Chan, M. (2017). Ten years in public health, 2007–2017: report by Dr Margaret Chan, Director-General. *World Health Organization*.

Chatterjee, S., Kotelchuck, M., & Sambamoorthi, U. (2008). Prevalence of Chronic Illness in Pregnancy, Access to Care, and Health Care Costs. Implications for Interconception Care. *Women's Health Issues*, *18*(6 SUPPL.). https://doi.org/10.1016/j.whi.2008.06.003

Chopra, K. K., Malik, A., Abha Indora, Pandey, P., & Pandey, S. (2023). To study the occurrence of risk factors for pulmonary tuberculosis in the homeless population in areas of Delhi,

India. *Indian Journal of Tuberculosis*, *70*(3), 356–360. https://doi.org/10.1016/j.ijtb.2022.11.001

Cochran, W. G. (1977). Sampling techniques. *Johan Wiley & Sons Inc*.

Cunningham, P. J. (2010). The growing financial burden of health care: national and state trends, 2001–2006. *Health Affairs*, *29*(5), 1037–1044.

Daniels, B., Dolinger, A., Bedoya, G., Rogo, K., Goicoechea, A., Coarasa, J., Wafula, F., Mwaura, N., Kimeu, R., & Das, J. (2017). Use of standardised patients to assess quality of healthcare in Nairobi, Kenya: a pilot, cross-sectional study with international comparisons. *BMJ Global Health*, *2*(2), e000333. https://doi.org/10.1136/bmjgh-2017-000333

Darrudi, A., Ketabchi Khoonsari, M. H., & Tajvar, M. (2022). Challenges to Achieving Universal Health Coverage Throughout the World: A Systematic Review. *Journal of Preventive Medicine and Public Health = Yebang Uihakhoe Chi*, *55*(2), 125–133. https://doi.org/10.3961/jpmph.21.542

Dash, A., & Mohanty, S. K. (2019). Do poor people in the poorer states pay more for healthcare in India? *BMC Public Health*, *19*(1), 1020. https://doi.org/10.1186/s12889-019-7342-8

Deb, R. M., Stanton, M. C., Foster, G. M., Gupta, R. K. Das, Roy, N., Das, P., Dhariwal, A. C., & Coleman, M. (2018). Visceral leishmaniasis cyclical trends in Bihar, India–implications for the elimination programme. *Gates Open Research*, *2*.

Department of Health and Human Services. (2019). Medicare and Medicaid Programs: CY 2020 hospital outpatient PPS policy changes and payment rates and ambulatory surgical center payment system policy changes and payment rates. Price transparency requirements for hospitals to make standard charges public. *Federal Register*.

Diener, E., & Seligman, M. E. P. (2004). Beyond money: Toward an economy of well-being. *Psychological Science in the Public Interest*, *5*(1), 1–31.

Dixit, A., Routroy, S., & Kumar Dubey, S. (2019). A strategy to improve resource utilization: Case study of generic drug distribution in Rajasthan. *Materials Today: Proceedings*, *28*, 562–567. https://doi.org/10.1016/j.matpr.2019.12.219

Dubois, P., Lefouili, Y., & Straub, S. (2021). Pooled procurement of drugs in low and middle income countries. *European Economic Review*, *132*. https://doi.org/10.1016/j.euroecorev.2021.103655

Dutta, A., Mandal, S., Taraphdar, P., & Das, S. (2024). Catastrophic cost and coping strategies of tuberculosis patients in a block of Purba Bardhaman District, West Bengal: A crossectional study. *Indian Journal of Tuberculosis*, *June*. https://doi.org/10.1016/j.ijtb.2024.08.012

Elliott, P. A., Hoffman, J., Abad-Santos, M., Herndon, C., Katz, P. P., & Smith, J. F. (2016). Out-of-Pocket Costs for Men Undergoing Infertility Care and Associated Financial Strain. *Urology Practice*, *3*(4), 256–261. https://doi.org/10.1016/j.urpr.2015.07.010

Emori, Y., Amagai, S., Koizumi, H., Murai, F., Kawano, A., & Sankai, C. (2014). Relationship of socioeconomic status with psychological state and the number of weeks of pregnancy at the time of a first prenatal examination among perinatal women. *General Medicine*, *15*(1), 34–42.

Essue, B., Laba, T.-L., Knaul, F., Chu, A., Minh, H., Nguyen, T. K. P., & Jan, S. (2018). Economic Burden of Chronic Ill-Health and Injuries for Households in Low-and Middle-Income Countries. *Disease Control Priorities: Improving Health and Reducing Poverty*.

Evenett, S. J., & Hoekman, B. M. (2005). *International cooperation and the reform of public procurement policies* (Vol. 4663). World Bank Publications.

Fiszbein, A., Ringold, D., & Rogers, F. H. (2011). Making services work: indicators, assessments, and benchmarking of the quality and governance of public service delivery in the human development sectors. *World Bank Policy Research Working Paper*, *5690*.

Floyd, K., Arora, V. K., Murthy, K. J. R., Lonnroth, K., Singla, N., Akbar, Y., Zignol, M., & Uplekar, M. (2006). Cost and cost-effectiveness of PPM-DOTS for tuberculosis control: evidence from India. *Bulletin of the World Health Organization*, *84*(6), 437–445. https://doi.org/10.2471/blt.05.024109

Foster, D. G., Biggs, M. A., Phillips, K. A., Grindlay, K., & Grossman, D. (2015). Potential public sector cost-savings from over-the-counter access to oral contraceptives. *Contraception*, *91*(5), 373–379. https://doi.org/10.1016/j.contraception.2015.01.010

Garcia-Diaz, R., Prasad Sapkota, V., Prasad Sapkota, V., & Flores, G. (2024). Persistency of catastrophic out-of-pocket health expenditures: Measurement with evidence from three African countries - Malawi, Tanzania, and Uganda. *Social Science and Medicine*, *357*(November 2023). https://doi.org/10.1016/j.socscimed.2024.117156

Goli, S., Rammohan, A., & Moradhvaj. (2018). Out-of-pocket expenditure on maternity care for hospital births in Uttar Pradesh, India. *Health Economics Review*, *8*, 1–16.

Government of India. (2021). *Government of India. Economic Survey 2020-21*. https://prsindia.org/policy/report-summaries/economic-survey-2020-21

Gunarathne, S. P., Wickramasinghe, N. D., Agampodi, T. C., Prasanna, R. P. I. R., & Agampodi, S. B. (2022). Protocol for systematic review and meta-analysis: magnitude, reasons,

associated factors, and implications of the out-of-pocket expenditure during pregnancy. *Public Health*, *206*, 33–37. https://doi.org/10.1016/j.puhe.2022.02.018

Hailu, A., Gebreyes, R., & Norheim, O. F. (2021). Equity in public health spending in Ethiopia: a benefit incidence analysis. *Health Policy and Planning*, *36*(Supplement_1), i4–i13. https://doi.org/10.1093/heapol/czab060

Hanson, C., Osberg, M., Brown, J., Durham, G., & Chin, D. P. (2017). Finding the Missing Patients With Tuberculosis: Lessons Learned From Patient-Pathway Analyses in 5 Countries. *The Journal of Infectious Diseases*, *216*(suppl_7), S686–S695. https://doi.org/10.1093/infdis/jix388

Iragorri, N., de Oliveira, C., Fitzgerald, N., & Essue, B. (2021). The out-of-pocket cost burden of cancer care—a systematic literature review. *Current Oncology*, *28*(2), 1216–1248. https://doi.org/10.3390/curroncol28020117

Jadhav, C. A., Vikhe, D. N., & Jadhav, R. S. (2020). Global and domestic market of herbal medicines: A review. *Research Journal of Science and Technology*, *12*(4), 327–330.

Janaki, S., & Prabakar, S. (2024). Examining socioeconomic factors influencing maternal health in pregnancy. *Journal of Human Behavior in the Social Environment*. https://doi.org/10.1080/10911359.2024.2310272

Jeong, I., Kim, J., & Im, S. Bin. (2016). Development of Financial Support Program for High Risk Pregnant Women. *Osong Public Health and Research Perspectives*, *7*(3), 141–148.

Joe, W. (2015). Distressed financing of household out-of-pocket health care payments in India: Incidence and correlates. *Health Policy and Planning*, *30*(6), 728–741. https://doi.org/10.1093/heapol/czu050

Jones, G. L., Mitchell, C. A., Hirst, J. E., & Anumba, D. O. C. (2022). Understanding the relationship between social determinants of health and maternal mortality: Scientific Impact Paper No. 67. *BJOG: An International Journal of Obstetrics and Gynaecology*, *129*(7), 1211–1228. https://doi.org/10.1111/1471-0528.17044

Kaladharan, S., & Manayath, D. (2024). Out-of-pocket healthcare expenditure in emerging economies: Evidence from panel data analysis. *Journal of Medicine Access*, *8*. https://doi.org/10.1177/27550834241262108

Kanthe, R. (2010). Consumer Buying Behavior and Non-Prescriptive Drugs Shopping In Sangli. *Asian Journal of Management*, *1*(2), 55–60.

Kaur, H., Shah, A., & Srivastava, S. (2021). *How elements of the Indian state purchase drugs*.

Kaurav, Y., & Bharti, A. (2023). Catastrophic "costs": A hindrance to eliminate tuberculosis. In *Indian Journal of Tuberculosis* (Vol. 70, Issue 2, pp. 147–148). Tuberculosis Association of India. https://doi.org/10.1016/j.ijtb.2023.01.003

Ke, Z., Zhang, Y., & Duan, D. (2024). Effect of centralized volume-based procurement of drugs on business performance of listed pharmaceutical enterprises. *Heliyon*, *10*(12). https://doi.org/10.1016/j.heliyon.2024.e33198

Khan, Y., Gupta, P., Goswami, D., Bihari, B., & Verma, V. K. (2013). A Review on Marketing of OTC Drugs. *Asian Journal of Research in Pharmaceutical Science*, *3*(2), 72–78.

Khanday, S. A. (2019). Globalization: The Third Eye in Drug Marketing. *Research Journal of Humanities and Social Sciences*, *10*(2), 383–390.

Kim, M. K., Lee, S. M., Bae, S. H., Kim, H. J., Lim, N. G., Yoon, S. J., Lee, J. Y., & Jo, M. W. (2018). Socioeconomic status can affect pregnancy outcomes and complications, even

with a universal healthcare system. *International Journal for Equity in Health*, *17*(1), 2. https://doi.org/10.1186/s12939-017-0715-7

Kjos, A. L., Binh, N. T., Robertson, C., & Rovers, J. (2016). A drug procurement, storage and distribution model in public hospitals in a developing country. *Research in Social and Administrative Pharmacy*, *12*(3), 371–383. https://doi.org/10.1016/j.sapharm.2015.07.007

Krishnamoorthy, Y., Ganesh, K., Sakthivel, M., Priyan, S., Rehman, T., & Surendran, G. (2020). Costs incurred and determinants of out-of-pocket payments for child delivery care in India: Evidence from a nationally representative household survey. *The International Journal of Health Planning and Management*, *35*(1), e167–e177.

Kruk, M. E., Goldmann, E., & Galea, S. (2009). Borrowing and selling to pay for health care in low-and middle-income countries. *Health Affairs*, *28*(4), 1056–1066.

Kulshreshth, P. (2021). A Temporal Analysis of India's Public Health Expenditure. *Health*.

Kumar, D., & Prinja, S. (2023). Costing of services under National Tuberculosis Elimination Program at public health facilities of northern India. *Indian Journal of Tuberculosis*, *70*(2), 232–238. https://doi.org/10.1016/j.ijtb.2022.05.009

Kwan, A., Daniels, B., Saria, V., Satyanarayana, S., Subbaraman, R., McDowell, A., Bergkvist, S., Das, R. K., Das, V., Das, J., & Pai, M. (2018). Variations in the quality of tuberculosis care in urban India: A cross-sectional, standardized patient study in two cities. *PLoS Medicine*, *15*(9), e1002653. https://doi.org/10.1371/journal.pmed.1002653

La, D. T. V., Zhao, Y., Arokiasamy, P., Atun, R., Mercer, S., Marthias, T., McPake, B., Pati, S., Palladino, R., & Lee, J. T. (2022). Multimorbidity and out-of-pocket expenditure for

medicines in China and India. *BMJ Global Health*, *7*(11). https://doi.org/10.1136/bmjgh-2021-007724

Lambert, M. L., Delgado, R., Michaux, G., Volz, A., Speybroeck, N., & Van Der Stuyft, P. (2005). Delays to treatment and out-of-pocket medical expenditure for tuberculosis patients, in an urban area of South America. *Annals of Tropical Medicine and Parasitology*, *99*(8), 781–787. https://doi.org/10.1179/136485905X65152

Levy, P. S., & Lemeshow, S. (2013). *Sampling of populations: methods and applications*. John Wiley & Sons.

Lewis, M., & Pettersson Gelander, G. (2009). Governance in health care delivery: raising performance. *World Bank Policy Research Working Paper*, *5074*.

Manchanda, N. K., & Chaudhary, K. (2015). Dissecting OOP Health Expenditure in India: An Investigation of Trends Since 1999-2000. *Available at SSRN 2544802*.

Manikandan A, Noorulla KM, Yasir M, & Hemalatha S. (2022). 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. *PROSPERO 2022 CRD42022342755*. https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42022342755

Manimegalai, A. P. (2021). An Analysis of the Drug Distribution Model in the Public Health Services in Tamil Nadu. *Sch Acad J Pharm*, *12*, 206–212.

Manning, L., & Soon, J. M. (2014). Developing systems to control food adulteration. *Food Policy*, *49*, 23–32.

Maqbool, M., Dar, M. A., Rasool, S., Gani, I., & Geer, M. I. (2019). Universal health coverage policy and practice framework in India: a review. *Research Journal of Pharmacy and Technology*, *12*(8), 4045–4051.

Mathewos Oridanigo, E., Beyene Salgedo, W., & Gebissa Kebene, F. (2021). Affordability of essential medicines and associated factors in public health facilities of Jimma Zone, Southwest Ethiopia. *Advances in Pharmacological and Pharmaceutical Sciences*, *2021*, 1–9.

McIntyre, D., & Mills, A. (2012). Research to support universal coverage reforms in Africa: the SHIELD project. In *Health Policy and Planning* (Vol. 27, Issue suppl_1, pp. i1–i3). Oxford University Press.

McIntyre, D., Thiede, M., Dahlgren, G., & Whitehead, M. (2006). What are the economic consequences for households of illness and of paying for health care in low-and middle-income country contexts? *Social Science & Medicine*, *62*(4), 858–865.

Meessen, B. (2018). The role of digital strategies in financing health care for universal health coverage in low-and middle-income countries. *Global Health: Science and Practice*, *6*(Supplement 1), S29–S40.

Meheus, F., Boelaert, M., Baltussen, R., & Sundar, S. (2006). Costs of patient management of visceral leishmaniasis in Muzaffarpur, Bihar, India. *Tropical Medicine & International Health: TM & IH*, *11*(11), 1715–1724. https://doi.org/10.1111/j.1365-3156.2006.01732.x

Mekuria, G. A., & Ali, E. E. (2023). The financial burden of out of pocket payments on medicines among households in Ethiopia: analysis of trends and contributing factors. *BMC Public Health*, *23*(1). https://doi.org/10.1186/s12889-023-15751-3

Mirza, I., & Jenkins, R. (2004). Risk factors, prevalence, and treatment of anxiety and depressive disorders in Pakistan: systematic review. *BMJ (Clinical Research Ed.)*, *328*(7443), 794. https://doi.org/10.1136/bmj.328.7443.794

Mogasale, V., Kar, S. K., Kim, J.-H., Mogasale, V. V, Kerketta, A. S., Patnaik, B., Rath, S. B., Puri, M. K., You, Y. A., Khuntia, H. K., Maskery, B., Wierzba, T. F., & Sah, B. (2015). An Estimation of Private Household Costs to Receive Free Oral Cholera Vaccine in Odisha, India. *PLoS Neglected Tropical Diseases*, *9*(9), e0004072. https://doi.org/10.1371/journal.pntd.0004072

Moher, D., Liberati, A., Tetzlaff, J., & Altman, D. G. (2009). Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *PLoS Medicine*, *6*(7), e1000097. https://doi.org/10.1371/journal.pmed.1000097

Mukherjee, K. (2017). A Cost Analysis of the Jan Aushadhi Scheme in India. *International Journal of Health Policy and Management*, *6*(5), 253–256. https://doi.org/10.15171/ijhpm.2017.02

Muniyandi, M., & Ramachandran, R. (2019). No families affected by tuberculosis to face catastrophic costs by 2020: India's new strategic plan to eliminate tuberculosis. *Indian Journal of Tuberculosis*, *66*(2), 219–221. https://doi.org/10.1016/j.ijtb.2019.04.009

National Health Systems Resource Centre. (2012). *National Health Systems Resource Centre (NHSRC): Assessment Criteria for State Drug Procurement and Distribution System*.

National Health Systems Resource Centre. (2022). *National Health Accounts Estimates for India (2018-19). New Delhi: Ministry of Health and Family Welfare, Government of India*. https://nhsrcindia.org/national-health-accounts-records

Nazmul Islam, M., Rabbani, A., De Allegri, M., & Sarker, M. (2024). Medical treatment loans and their effects on health care utilization and out-of-pocket expenditure: Evidence from an experiment in northern Bangladesh. *World Development*, *184*(August). https://doi.org/10.1016/j.worlddev.2024.106757

Nethan, S., Sinha, D., & Mehrotra, R. (2017). Non Communicable Disease Risk Factors and their Trends in India. *Asian Pac J Cancer Prev*, *18*(7), 2005–2010. https://doi.org/10.22034/APJCP.2017.18.7.2005

NHSRC. (2015). *National Health Systems Resource Centre (NHSRC) work report 2014-15, Ministry of health and family welfare, Government of India*. https://nhsrcindia.org/about-us/annual-report

NHSRC. (2020). *National Health Systems Resource Centre (NHSRC) work report 2019-20, Ministry of health and family welfare, Government of India*. https://nhsrcindia.org/about-us/annual-report

Nikam, N. R., Vakhariya, R. R., & Magdum, C. S. (2019). Generic Vs. Brand Medicines: An Overview. *Asian Journal of Pharmaceutical Research*, *9*(2), 109–115.

OECD. (2021). *Health at a Glance 2021*. OECD. https://doi.org/10.1787/ae3016b9-en

Okediji, P. T., Ojo, A. O., Ojo, A. I., Ojo, A. S., Ojo, O. E., & Abioye-Kuteyi, E. A. (2017). The Economic Impacts of Chronic Illness on Households of Patients in Ile-Ife, South-Western Nigeria. *Cureus*, *9*(10), e1756. https://doi.org/10.7759/cureus.1756

Ouedraogo, C. T., Vosti, S. A., Wessells, K. R., Arnold, C. D., Faye, M. T., & Hess, S. Y. (2021). Out-of-pocket costs and time spent attending antenatal care services: a case study of pregnant women in selected rural communities in Zinder, Niger. *BMC Health Services Research*, *21*, 1–17.

Ozieh, M. N., Bishu, K. G., Dismuke, C. E., & Egede, L. E. (2019). Trends in Out-of-Pocket Burden in United States Adults with Kidney Disease: 2002–2011. *American Journal of the Medical Sciences*, *358*(2), 149–158. https://doi.org/10.1016/j.amjms.2019.05.005

Pan, Y., Chen, S., Chen, M., Zhang, P., Long, Q., Xiang, L., & Lucas, H. (2016). Disparity in reimbursement for tuberculosis care among different health insurance schemes: evidence from three counties in central China. *Infectious Diseases of Poverty*, *5*(1), 7. https://doi.org/10.1186/s40249-016-0102-4

Park, E. J., Kwon, J. W., Lee, E. K., Jung, Y. H., & Park, S. (2015). Out-of-pocket Medication Expenditure Burden of Elderly Koreans with Chronic Conditions. *International Journal of Gerontology*, *9*(3), 166–171. https://doi.org/10.1016/j.ijge.2014.06.005

Prabhakaran, D., Jeemon, P., Sharma, M., Roth, G. A., Johnson, C., Harikrishnan, S., Gupta, R., Pandian, J. D., Naik, N., Roy, A., Dhaliwal, R. S., Xavier, D., Kumar, R. K., Tandon, N., Mathur, P., Shukla, D. K., Mehrotra, R., Venugopal, K., Kumar, G. A., … Dandona, L. (2018). The changing patterns of cardiovascular diseases and their risk factors in the states of India: the Global Burden of Disease Study 1990–2016. *The Lancet Global Health*, *6*(12), e1339–e1351. https://doi.org/10.1016/S2214-109X(18)30407-8

Prasanna, T., Jeyashree, K., Chinnakali, P., Bahurupi, Y., Vasudevan, K., & Das, M. (2018). Catastrophic costs of tuberculosis care: a mixed methods study from Puducherry, India. *Global Health Action*, *11*(1). https://doi.org/10.1080/16549716.2018.1477493

Prinja, S., Kanavos, P., & Kumar, R. (2012). Health care inequities in north India: role of public sector in universalizing health care. *The Indian Journal of Medical Research*, *136*(3), 421–431.

Rahman, M., Chen, L., Daw, J., Wright, J. D., D'Alton, M. E., Wen, T., & Friedman, A. M. (2022). Pregnancy costs with commercial insurance. *The Journal of Maternal-Fetal & Neonatal Medicine*, *35*(25), 10143–10151.

Ranabhat, C. L., Jakovljevic, M., Dhimal, M., & Kim, C.-B. (2020). Structural factors responsible for universal health coverage in low-and middle-income countries: results from 118 countries. *Frontiers in Public Health*, *7*, 414.

Reghu, R., Vijayan, M., & Pr, R. (2013). 96-100 ©JK Welfare & Pharmascope Foundation. *International Journal of Research in Pharmaceutical Sciences*, *4*(1). www.tnmsc.com

Rejikumar, G., Asokan, A. A., & Kumar, V. G. (2018). Pharmaceutical marketing: Directions for customer orientation. *Research Journal of Pharmacy and Technology*, *11*(8), 3283–3289.

Remme, M., Vassall, A., Fernando, G., & Bloom, D. E. (2020). Investing in the health of girls and women: a best buy for sustainable development. *Bmj*, *369*.

Reuter, A., Seddon, J. A., Marais, B. J., & Furin, J. (2020). Preventing tuberculosis in children: A global health emergency. *Paediatric Respiratory Reviews*, *36*, 44–51. https://doi.org/10.1016/j.prrv.2020.02.004

Roberts, S. C. M., Gould, H., Kimport, K., Weitz, T. A., & Foster, D. G. (2014). Out-of-pocket costs and insurance coverage for abortion in the United States. *Women's Health Issues*, *24*(2). https://doi.org/10.1016/j.whi.2014.01.003

Rodney, A. M., & Hill, P. S. (2014). Achieving equity within universal health coverage: a narrative review of progress and resources for measuring success. *International Journal for Equity in Health*, *13*, 1–8.

Rout, S. K., Sahu, K. S., Swain, S., & Pati, S. (2016). Out of pocket expenditure on surgical and nonsurgical conditions in Odisha. *Journal of Family Medicine and Primary Care*, *5*(2), 367–372. https://doi.org/10.4103/2249-4863.192377

Rovers, J. P., & Mages, M. D. (2017). A model for a drug distribution system in remote Australia as a social determinant of health using event structure analysis. *BMC Health Services Research*, *17*(1). https://doi.org/10.1186/s12913-017-2629-x

Ryckman, T., Weiser, J., Gombe, M., Turner, K., Soni, P., Tarlton, D., Mazhidova, N., Churchyard, G., Chaisson, R. E., & Dowdy, D. W. (2023). Impact and cost-effectiveness of short-course tuberculosis preventive treatment for household contacts and people with HIV in 29 high-incidence countries: a modelling analysis. *The Lancet Global Health*, *11*(8), e1205–e1216. https://doi.org/10.1016/S2214-109X(23)00251-6

Saaida, M. (2023). *Collaborating for Change: The Power of Multilateral Cooperation in SDGs*. *1*, 1–26.

Sangar, S., Dutt, V., & Thakur, R. (2022). Burden of out-of-pocket health expenditure and its impoverishment impact in India: evidence from National Sample Survey. *Journal of Asian Public Policy*, *15*(1), 60–77. https://doi.org/10.1080/17516234.2019.1601065

Santos, V. S., Rodrigues, J., Holanda, C. De, Silveira, D., & Noia, L. (2024). *Articles Social and health factors associated with unfavourable treatment outcomes in children and adolescents with drug-sensitive tuberculosis in Brazil: a national retrospective cohort study*. *40*, 1–13.

Sarmiento, A., Ayala, N., Rojas, K. K., Pinilla-Roncancio, M., Rodriguez, N., Londoño, D., Gil, J. S., Zapata-Arango, A., Martinez, N., & Ruiz-Rios, J. D. (2023). Cost-effectiveness analysis of spontaneous vaginal delivery vs elective cesarean delivery for maternal outcomes in Colombia. *AJOG Global Reports*, *3*(3). https://doi.org/10.1016/j.xagr.2023.100196

Sarowar, M. G., Medin, E., Gazi, R., Koehlmoos, T. P., Rehnberg, C., Saifi, R., Bhuiya, A., & Khan, J. (2010). Calculation of costs of pregnancy-and puerperium-related care:

experience from a hospital in a low-income country. *Journal of Health, Population, and Nutrition*, *28*(3), 264.

Sekandari, M. O., Begloo, A. G., & Alimohammadzadeh, K. (2024). The Role of Pharmacists in Providing Pharmaceutical Services in Selected Government Hospitals in Kabul. *Research Journal of Pharmacy and Technology*, *17*(2), 820–826.

Selvaraj, S., Farooqui, H. H., & Karan, A. (2018). Quantifying the financial burden of households' out-of-pocket payments on medicines in India: a repeated cross-sectional analysis of National Sample Survey data, 1994-2014. *BMJ Open*, *8*(5), e018020. https://doi.org/10.1136/bmjopen-2017-018020

Sengupta, A., & Nundy, S. (2005). The private health sector in India. In *Bmj* (Vol. 331, Issue 7526, pp. 1157–1158). British Medical Journal Publishing Group.

Shahrawat, R., & Rao, K. D. (2012). Insured yet vulnerable: out-of-pocket payments and India's poor. *Health Policy and Planning*, *27*(3), 213–221.

Shukar, S., Zahoor, F., Hayat, K., Saeed, A., Gillani, A. H., Omer, S., Hu, S., Babar, Z.-U.-D., Fang, Y., & Yang, C. (2021). Drug Shortage: Causes, Impact, and Mitigation Strategies. *Frontiers in Pharmacology*, *12*, 693426. https://doi.org/10.3389/fphar.2021.693426

Simkhada, B., Van Teijlingen, E. R., Porter, M., Simkhada, P., & Wasti, S. P. (2014). Why do costs act as a barrier in maternity care for some, but not all women? A qualitative study in rural Nepal. *International Journal of Social Economics*, *41*(8), 705–713.

Singh, P. V., Tatambhotla, A., Kalvakuntla, R., & Chokshi, M. (2013). Understanding public drug procurement in India: a comparative qualitative study of five Indian states. *BMJ Open*, *3*(2), e001987.

Sisay, M., Amare, F., Hagos, B., & Edessa, D. (2021). Availability, pricing and affordability of essential medicines in Eastern Ethiopia: a comprehensive analysis using WHO/HAI methodology. *Journal of Pharmaceutical Policy and Practice*, *14*(1), 57. https://doi.org/10.1186/s40545-021-00339-2

Soares, C. M., Nascimento, B., Chaves, L. A., Silva, R. M., Oliveira, M. A., & Luiza, V. L. (2019). Public procurement of medicines: Scoping review of the scientific literature in South America. In *Journal of Pharmaceutical Policy and Practice* (Vol. 12, Issue 1). BioMed Central Ltd. https://doi.org/10.1186/s40545-019-0195-9

Sotgiu, G., Falzon, D., Castiglia, P., Migliori, G. B., & Raviglione, M. (2014). Tuberculosis and the strategy for the New Millennium: not simply "more of same." *Epidemiology, Biostatistics and Public Health*, *11*(2).

Srinadh, R., & Yadav, J. (2022). *Paying Out of One's Own Pocket: How the Poor in India Are Facing Hardship to Treat Their Kids.* Niti Ayog Annual Report 2020–21. https://www.niti.gov.in/paying-out-ones-own-pocket-how-poor-india-are-facing-hardship-treat-their-kids

Sriram, S., & Khan, M. M. (2020). Effect of health insurance program for the poor on out-of-pocket inpatient care cost in India: evidence from a nationally representative cross-sectional survey. *BMC Health Services Research*, *20*, 1–21.

Stallworthy, G., Dias, H. M., & Pai, M. (2020). Quality of tuberculosis care in the private health sector. *Journal of Clinical Tuberculosis and Other Mycobacterial Diseases*, *20*, 100171. https://doi.org/10.1016/j.jctube.2020.100171

Sulis, G., Roggi, A., Matteelli, A., & Raviglione, M. C. (2014). Tuberculosis: epidemiology and control. *Mediterranean Journal of Hematology and Infectious Diseases*, *6*(1).

Tadesse, S. (2016). Stigma against Tuberculosis Patients in Addis Ababa, Ethiopia. *PloS One*, *11*(4), e0152900. https://doi.org/10.1371/journal.pone.0152900

Tanimura, T., Jaramillo, E., Weil, D., Raviglione, M., & Lönnroth, K. (2014a). Financial burden for tuberculosis patients in low- and middle-income countries: a systematic review. *The European Respiratory Journal*, *43*(6), 1763–1775. https://doi.org/10.1183/09031936.00193413

Tanimura, T., Jaramillo, E., Weil, D., Raviglione, M., & Lönnroth, K. (2014b). Financial burden for tuberculosis patients in low- And middle-income countries: A systematic review. *European Respiratory Journal*, *43*(6), 1763–1775. https://doi.org/10.1183/09031936.00193413

Taylor, A. K., Larson, S., & Correa-de-Araujo, R. (2006). Women's health care utilization and expenditures. *Women's Health Issues*, *16*(2), 66–79.

Taylor, K., Compton, S., Kolenic, G. E., Scott, J., Becker, N., Dalton, V. K., & Moniz, M. H. (2021). Financial hardship among pregnant and postpartum women in the United States, 2013 to 2018. *JAMA Network Open*, *4*(10), e2132103–e2132103.

Taylor, S. I. (2020). The High Cost of Diabetes Drugs: Disparate Impact on the Most Vulnerable Patients. *Diabetes Care*, *43*(10), 2330–2332. https://doi.org/10.2337/dci20-0039

Tekulapally, K., Rao, GVK., & Prasanna V. (2024). Awareness, Attitude and Usage of Generic Medicines among Prescribers and Patients in a Tertiary Care Teaching Hospital; A Cross-Sectional Study. *SSR Institute of International Journal of Life Sciences*, *10*(3), 5595-5603. http://dx.doi.org/10.21276/SSR-IIJLS.2024.10.3.28

Thakur, R., & Sangar, S. (2022). Socioeconomic differentials in the burden of paying for healthcare in India: a disaggregated analysis. *Health Systems*, *11*(1), 48–58.

Thombare, S., Nashikkar, R., & Patil, R. (2024). Market Dynamics: Examining Drug Sales in Panvel. *Asian Journal of Management*, *15*(2), 2.

Tripathi, V. V. R., Tripathi, A., & Jaiswal, S. (2019). Health welfare system in modern India revitalizing Indian Healthcare-Its potential and challenges. *ZENITH International Journal of Multidisciplinary Research*, *9*(2), 178–193.

Tura, A. J., Dalecha, D. D., Yasir, M., Ketebo, T. A., & Noorulla, K. M. (2022). Expiry of medicine in public health facilities of Arsi Zone, Oromia Regional State, Ethiopia: a quantitative and qualitative study. *Current Issues in Pharmacy and Medical Sciences*, *35*(1), 27–33.

United Nations Development Group. (2003). *Indicators for monitoring the millennium development goals: definitions, rationale, concepts and sources* (Vol. 95). United Nations Publications.

United Nations General Assembly. (2015). Resolution adopted by the General Assembly on 11 September 2015. *New York: United Nations*.

Verma, D. R. K. (2019). Generic medicines: Core issues and legal mechanism. *International Journal of Reviews and Research in Social Sciences*, *7*(2), 405–414.

Vikram Singh, P., Tatambhotla, A., Kalvakuntla, R., & Chokshi, M. (2013). Understanding public drug procurement in India: a comparative qualitative study of five Indian states. *Open*, *3*, 1987. https://doi.org/10.1136/bmjopen-2012

Viney, K., Islam, T., Hoa, N. B., Morishita, F., & Lönnroth, K. (2019). The Financial Burden of Tuberculosis for Patients in the Western-Pacific Region. *Tropical Medicine and Infectious Disease*, *4*(2). https://doi.org/10.3390/tropicalmed4020094

Virk, A. K., & Atun, R. (2015). Towards universal health coverage in India: a historical examination of the genesis of Rashtriya Swasthya Bima Yojana–the health insurance scheme for low-income groups. *Public Health*, *129*(6), 810–817.

Vledder, M., Friedman, J., Sjöblom, M., Brown, T., & Yadav, P. (2019). Improving Supply Chain for Essential Drugs in Low-Income Countries: Results from a Large Scale Randomized Experiment in Zambia. *Health Systems and Reform*, *5*(2), 158–177. https://doi.org/10.1080/23288604.2019.1596050

Wagstaff, A., & Doorslaer, E. van. (2003). Catastrophe and impoverishment in paying for health care: with applications to Vietnam 1993–1998. *Health Economics*, *12*(11), 921–933.

Wagstaff, A., Eozenou, P., & Smitz, M. (2020). Out-of-pocket expenditures on health: a global stocktake. *The World Bank Research Observer*, *35*(2), 123–157.

Weir, R. E., Zaidi, F. H., Charteris, D. G., Bunce, C., Soltani, M., & Lovering, A. M. (2005). Variability in the content of Indian generic ciprofloxacin eye drops. *British Journal of Ophthalmology*, *89*(9), 1094–1096.

WHO. (2004). *World Health Organization. The world medicines situation report 2004. Geneva:* World Health Organization.

WHO. (2020). *World Health Organization (WHO). Health financing. Key policy messages.* https://www.who.int/health_financing/topics/financial-protection/key-policy-messages/en/.

WHO. (2022). *Global spending on health: rising to the pandemic's challenges*. World Health Organization.

Wollum, A., Trussell, J., Grossman, D., & Grindlay, K. (2020). Modeling the Impacts of Price of an Over-the-Counter Progestin-Only Pill on Use and Unintended Pregnancy among

U.S. Women. *Women's Health Issues*, *30*(3), 153–160. https://doi.org/10.1016/j.whi.2020.01.003

World Health Organization. (2024). To Meet the Unmet: Preparing for health equity Challenges in WHO South-East Asia Region. In *To Meet the Unmet: Preparing for health equity Challenges in WHO South-East Asia Region*.

Wu, A. K., Odisho, A. Y., Washington, S. L., Katz, P. P., & Smith, J. F. (2014). Out-of-pocket fertility patient expense: Data from a multicenter prospective infertility cohort. *Journal of Urology*, *191*(2), 427–432. https://doi.org/10.1016/j.juro.2013.08.083

Wuraola, F. O., Blackman, C., Olasehinde, O., Aderounmu, A. A., Adeleye, A., Omoyiola, O. Z., Kingham, T. P., Fodero, R. F., Adisa, A. O., Lumati, J., Dare, A., Alatise, O. I., & Knapp, G. (2024). The out-of-pocket cost of breast cancer care in Nigeria: A prospective analysis. *Journal of Cancer Policy*, *42*(November), 1–6. https://doi.org/10.1016/j.jcpo.2024.100518

Xu, K., Evans, D. B., Carrin, G., Aguilar-Rivera, A. M., Musgrove, P., & Evans, T. (2007). Protecting households from catastrophic health spending. *Health Affairs*, *26*(4), 972–983.

Yadav, J., John, D., & Menon, G. (2019). Out of pocket expenditure on tuberculosis in India: Do households face hardship financing? *Indian Journal of Tuberculosis*, *66*(4), 448–460. https://doi.org/10.1016/j.ijtb.2019.02.016

Yang, Y., & Yu, M. (2023). Disparities and determinants of maternal health services utilization among women in poverty-stricken rural areas of China: a cross-sectional study. *BMC Pregnancy and Childbirth*, *23*(1), 115.

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**

#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)

ID **Search**

#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 spents 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 Sub-continent".

#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. 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. 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. 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. 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. 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. 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. 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. 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. 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. 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. 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

S. No	Research Article – First Author	Reason for Exclusion
No Defined Outcome (n=20)		
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.
Articles Before 2000 (n=12) *		
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.
Outside India (n=17) **		
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
Review/Systematic Review (n=7)		
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)

1. Williams A, Mathai AS, Phillips AS. Antibiotic prescription patterns at admission into a tertiary level intensive care unit in Northern India. J Pharm Bioallied Sci. 2011; 3:531–6.
2. Roy V, Gupta U, Agarwal AK. Cost of medicines & their affordability in private pharmacies in Delhi (India). Indian J Med Res. 2012; 136:827–35.
3. Dror DM, Vellakkal S. Is RSBY India's platform to implementing universal hospital insurance? Indian J Med Res. 2012; 135:56–63.
4. Kotwani A. Where are we now: assessing the price, availability and affordability of essential medicines in Delhi as India plans free medicine for all. BMC Health Serv Res. 2013; 13:285.
5. Little KM, Pai M, Dowdy DW. Costs and Consequences of Using Interferon-γ Release Assays for the Diagnosis of Active Tuberculosis in India. PLoS One. 2014;10: e0124525.

6. Megiddo I, Chatterjee S, Nandi A, Laxminarayan R. Cost-effectiveness of treatment and secondary prevention of acute myocardial infarction in India: a modeling study. Glob Heart. 2014; 9:391-398.e3.
7. Abbas SS, Kakkar M, Rogawski ET. Costs analysis of a population level rabies control programme in Tamil Nadu, India. PLoS Negl Trop Dis. 2014;8: e2721.
8. Bose M, Dutta A. Inequity in hospitalization care: a study on utilization of healthcare services in West Bengal, India. Int J Health Policy Manag. 2015; 4:29–38.
9. Peasah SK, Purakayastha DR, Koul PA, Dawood FS, Saha S, Amarchand R, et al. The cost of acute respiratory infections in Northern India: a multi-site study. BMC Public Health. 2015; 15:330.
10. Dror DM, Chakraborty A, Majumdar A, Panda P, Koren R. Impact of community-based health insurance in rural India on self-medication & financial protection of the insured. Indian J Med Res. 2016; 143:809–20.
11. Megiddo I, Colson A, Chisholm D, Dua T, Nandi A, Laxminarayan R. Health and economic benefits of public financing of epilepsy treatment in India: An agent-based simulation model. Epilepsia. 2016; 57:464–74.
12. Sharma A, Kaplan WA. Challenges constraining access to insulin in the private-sector market of Delhi, India. BMJ Glob Health. 2016;1: e000112.
13. Mukherjee K. A Cost Analysis of the Jan Aushadhi Scheme in India. Int J Health Policy Manag. 2017; 6:253–6.
14. Gwatidzo SD, Stewart Williams J. Diabetes mellitus medication use and catastrophic healthcare expenditure among adults aged 50+ years in China and India: results from the WHO study on global AGEing and adult health (SAGE). BMC Geriatr. 2017; 17:14.

15. Prinja S, Bahuguna P, Faujdar DS, Jyani G, Srinivasan R, Ghoshal S, et al. Cost-effectiveness of human papillomavirus vaccination for adolescent girls in Punjab state: Implications for India's universal immunization program. Cancer. 2017; 123:3253–60.
16. Sarangi SC, Kaur N, Tripathi M, Gupta YK. Cost analysis study of neuropsychiatric drugs: Role of National List of Essential Medicines, India. Neurol India. 2018; 66:1427–33.
17. Chaillon A, Mehta SR, Hoenigl M, Solomon SS, Vickerman P, Hickman M, et al. Cost-effectiveness and budgetary impact of HCV treatment with direct-acting antivirals in India including the risk of reinfection. PLoS One. 2019;14: e0217964.
18. Rout SK, Mahapatra S. Has the Public Health System Provided Adequate Financial Risk Protection for Child Birth Conditions - Evidences from an Eastern Indian State. Int J Health Policy Manag. 2019; 8:145–9.
19. Sawers L, Stillwaggon E. Economic Costs and Benefits of Community-Based Lymphedema-Management Programs for Lymphatic Filariasis in India. Am J Trop Med Hyg. 2020; 103:295–302.
20. Behera S, Pradhan J. Uneven economic burden of non-communicable diseases among Indian households: A comparative analysis. PLoS One. 2021;16: e0260628-.
21. Ramaiah KD, Das PK, Michael E, Guyatt HL. The Economic Burden of Lymphatic Filariasis in India. Parasitology Today. 2000; 16:251–3.
22. Shobhana R, Rama Rao P, Lavanya A, Williams R, Vijay V, Ramachandran A. Expenditure on health care incurred by diabetic subjects in a developing country — a study from southern India. Diabetes Res Clin Pract. 2000; 48:37–42.
23. Singh AJ, Garner P, Floyd K. Cost-effectiveness of public-funded options for cataract surgery in Mysore, India. The Lancet. 2000; 355:180–4.

24. Shobhana R, Rao PR, Lavanya A, Vijay V, Ramachandran A. Cost burden to diabetic patients with foot complications--a study from southern India. J Assoc Physicians India. 2000; 48:1147–50.
25. Murthy KJ, Frieden TR, Yazdani A, Hreshikesh P. Public-private partnership in tuberculosis control: experience in Hyderabad, India. Int J Tuberc Lung Dis. 2001; 5:354–9.
26. Thomas S V., Sarma PS, Alexander M, Pandit L, Shekhar L, Trivedi C, et al. Economic Burden of Epilepsy in India. Epilepsia. 2001; 42:1052–60.
27. Garg CC. Financing of Health Care in India: Results of NHA from Karnataka. J Health Manag. 2001; 3:199–237.
28. Bhatia JC, Cleland J. Health-care seeking and expenditure by young Indian mothers in the public and private sectors. Health Policy Plan. 2001; 16:55–61.
29. Babu B V, Nayak AN, Dhal K, Acharya AS, Jangid PK, Mallick G. The economic loss due to treatment costs and work loss to individuals with chronic lymphatic filariasis in rural communities of Orissa, India. Acta Trop. 2002; 82:31–8.
30. Ray TK, Pandav CS, Anand K, Kapoor SK, Dwivedi SN. Out-of-pocket expenditure on healthcare in a north Indian village. Natl Med J India. 2002; 15:257–60.
31. Rajagopal MR, Venkateswaran C. Palliative care in India: successes and limitations. J Pain Palliat Care Pharmacother. 2003; 17:121–30.
32. Pandav CS. Economic evaluation of iodine deficiency disorder control program in Sikkim: a cost effectiveness study. Indian J Public Health. 2012; 56:37–43.
33. Marshall JK, Grootendorst P V, O'Brien BJ, Dolovich LR, Holbrook AM, Levy AR. Impact of reference-based pricing for histamine-2 receptor antagonists and restricted access for proton pump inhibitors in British Columbia. CMAJ: Canadian Medical Association journal. 2002; 166:1655-1662.

34. Hutchinson AB, Farnham PG, Dean HD, Ekwueme DU, del Rio C, Kamimoto L, et al. The economic burden of HIV in the United States in the era of highly active antiretroviral therapy: evidence of continuing racial and ethnic differences. J Acquir Immune Defic Syndr. 2006; 43:451–7.
35. Zarkin GA, Bray JW, Aldridge A, Mitra D, Mills MJ, Couper DJ, et al. Cost and cost-effectiveness of the COMBINE study in alcohol-dependent patients. Arch Gen Psychiatry. 2008; 65:1214-1221.
36. Wirtz VJ, Santa-Ana-Tellez Y, Servan-Mori E, Avila-Burgos L. Heterogeneous Effects of Health Insurance on Out-of-Pocket Expenditure on Medicines in Mexico. Value in Health. 2012; 15:593–603.
37. Mujinja PGM, Mackintosh M, Justin-Temu M, Wuyts M. Local production of pharmaceuticals in Africa and access to essential medicines: “urban bias” in access to imported medicines in Tanzania and its policy implications. Global Health. 2014; 10:12.
38. Jia J, Li F, Wei C, Chen S, Tang Y. Economic cost of Alzheimer’s disease in china: a cluster randomized observational study. Alzheimer’s & dementia. 2016;12: P255-P256.
39. Khan S, Mafara E, Geldsetzer P, Phanitsiri S, Wong C, Lejeune C, et al. No per-patient cost increase under immediate art for all: evidence from Swaziland. Top Antivir Med. 2017; 25:196s-.
40. Morgan A, Joshy G, Schaffer A, Laba TL, Litchfield M, Pearson S, et al. Rapid and substantial increases in anticoagulant use and expenditure in Australia following the introduction of new types of oral anticoagulants. PLoS One. 2018;13: e0208824.
41. He R, Ye T, Wang J, Zhang Y, Li Z, Niu Y, et al. Medical service quality, efficiency and cost control effectiveness of upgraded case payment in rural China: a retrospective study. Int J Environ Res Public Health. 2018;15.

42. Aljunid SM, Ali Jadoo SA. Factors Influencing the Total Inpatient Pharmacy Cost at a Tertiary Hospital in Malaysia: A Retrospective Study. Inquiry. 2018; 55:46958018755483.
43. Kuhl MJ, Ter Kuile F, Phiri K, Kwambai T, Dhabangi A, Robberstad B. Cost-effectiveness analysis of post-discharge malaria chemoprevention for severely anaemic children in Kenya and Uganda. Trans R Soc Trop Med Hyg. 2019;113: S112-S113.
44. Pisu M, Richman J, Szaflarski JP, Funkhouser E, Dai C, Juarez L, et al. High health care costs in minority groups of older US Medicare beneficiaries with epilepsy. Epilepsia. 2019; 60:1462–71.
45. Bodajko-Grochowska A, Bednarek A, Markut-Miotla E, Emeryk A. Costs of outpatient treatment of childhood asthma in Poland. Allergy. 2020; 75:152-.
46. Debellut F, Tang K, Clark A, Pecenka C, Assao B, Guindo O, et al. Impact and cost-effectiveness of rotavirus vaccination in Niger: a modelling study evaluating alternative rotavirus vaccines. BMJ Open. 2022;12: e061673.
47. Serván-Mori E, Islam MD, Kaplan WA, Thrasher R, Wirtz VJ. Out-of-pocket expenditure on medicines in Bangladesh: An analysis of the national household income and expenditure survey 2016–17. PLoS One. 2022;17: e0274671-.
48. Wirtz VJ, Servan-Mori E, Mungai J, Mboya J, Rockers PC, Onyango MA, et al. Probability and amount of medicines expenditure according to health insurance status in Kenya: A household survey in eight counties. Int J Health Plann Manage. 2022; 37:725–33.
49. Ismaïl S, Arfa C. Effects of Out-of-Pocket Medicine's Spending on Catastrophic Expenditure and Impoverishment in Tunisia. Value Health Reg Issues. 2022; 30:109–18.
50. Kumarasamy N, Venkatesh KK, Mayer KH, Freedberg K. Financial burden of health services for people with HIV/AIDS in India. Indian J Med Res. 2007; 126:509–17.

51. Azad R, Chandra P, Gupta R. The economic implications of the use of anti-vascular endothelial growth factor drugs in age-related macular degeneration. Indian J Ophthalmol. 2007; 55:441.
52. Green CJ, Maclure M, Fortin PM, Ramsay CR, Aaserud M, Bardal S. Pharmaceutical policies: effects of restrictions on reimbursement. Cochrane Database of Systematic Reviews. 2010; Available from: http://dx.doi.org/10.1002/14651858.CD008654
53. Acosta A, Ciapponi A, Aaserud M, Vietto V, Austvoll-Dahlgren A, Kösters JP, et al. Pharmaceutical policies: effects of reference pricing, other pricing, and purchasing policies. Cochrane Database of Systematic Reviews. 2014; Available from: http://dx.doi.org/10.1002/14651858.CD005979.pub2
54. Nandi A, Holtzman EP, Malani A, Laxminarayan R. The need for better evidence to evaluate the health & economic benefits of India's Rashtriya Swasthya Bima Yojana. Indian J Med Res. 2015; 142:383–90.
55. Gheorghe A, Griffiths U, Murphy A, Legido-Quigley H, Lamptey P, Perel P. The economic burden of cardiovascular disease and hypertension in low- and middle-income countries: a systematic review. BMC Public Health. 2018; 18:975.
56. Sum G, Hone T, Atun R, Millett C, Suhrcke M, Mahal A, et al. Multimorbidity and out-of-pocket expenditure on medicines: a systematic review. BMJ Glob Health. 2018;3: e000505.

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

_____

Date

_____

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

_____

Date

Background Information for Health Facility

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.

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

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.

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	**2020 - 2021**
5	Process/Procedure of Purchase of Medicines	
6	Responsibility of Medicine Procurement	
7	Autonomy of Procurement Agency	
8	Distribution Process	

Section II – Medicine Availability

S. No	Data Point	Value/Details
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

S. No	Data Point	Value/Details
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

S. No	Data Point	Value/Details
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).