

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 (Kanthé, 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.