OUTCOME REPORT

COST-EFFECTIVENESS OF PRADHAN MANTRI BHARTIYA JANAUSHADHI PARIYOJANA and ITS IMPACT ON FINANCIAL RISK PROTECTION IN INDIA

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Executive Summary

The Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) was launched by the Government of India to ensure the availability of quality generic medicines at affordable prices, thereby reducing the financial burden on patients and enhancing access to essential medications. The program, however, faced challenges in its early years, including supply chain issues, limited drug coverage, and low penetration and public awareness. The present study was conducted to assess the scheme's impact on alleviating the financial burden on the patients. This study was conducted with the objective of evaluating the impact of the PMBJP on financial risk protection, particularly by examining out-of-pocket expenditure (OOPE) on medicines, catastrophic health expenditure (CHE), and impoverishment rates. As the PMBJP primarily relies on provision of generic drugs to the patients, the study also attempted to assess the cost-effectiveness of using generic drugs in comparison to the branded drugs for the treatment of selected ailments.

The analyses were conducted incorporating both primary and secondary data. The primary data were collected through exit interviews with patients from outpatient departments (OPD), inpatient departments (IPD), and Jan Aushadhi Kendras (PMBJP outlets) as well as private pharmacies. The research was conducted across nine states in India, selected based on variations in household OOPE on medicines. The states were divided into two categories, those with high OOPE on medicines and those with low OOPE on medicines, using data from the National Sample Survey Office. In each state, two districts were chosen based on a Multi-Dimensional Poverty Index, ensuring geographic and socio-economic diversity. Patient recruitment took place in both secondary and tertiary care public health facilities.

The study covered a sample of 11,916 patients, with approximately 4,600 recruited from health facilities and 7,300 from pharmacies. The patients with specific health conditions, such as hypertension, diabetes, cancer, and respiratory diseases, were included in the study, as these are the conditions either having higher prevalence, or are associated with significant OOPE on medicines.

Data collection involved assessing the availability of generic medicines at PMBJP outlets, the prescription patterns of physicians, and the financial burden borne by patients. The key indicators of financial risk protection, including OOPE, CHE, and impoverishment rates, were calculated using a combination of face-to-face interviews and follow-up surveys conducted at 15 and 30 days after initial recruitment. Health-related quality of life (HRQoL) was also assessed using the EQ-5D-5L tool, which measures patients' health across five dimensions, producing a utility score ranging from 0 (death) to 1 (perfect health). The Indian EQ-5D-5L value set was used to convert patients' responses into utility scores for analysis.

The study found significant differences in the indicators of financial risk protection between the patients who obtained their medications from PMBJP outlets as compared to private pharmacies. Patients who visited PMBJP outlets incurred significantly lower OOPE on medicines compared to those who visited private pharmacies, for instance, the mean OOPE for OPD patients who visited PMBJP outlets was ₹172, compared to ₹1,085 for those who visited private pharmacies. The findings demonstrated similar trends for IPD patients and those recruited from pharmacies. For IPD patients, the mean OOPE for those who obtained their medicines from PMBJP outlets was ₹183, compared to ₹1,212 for those who visited private pharmacies. Patients who purchased medicines from both

PMBJP and private pharmacies had a mean OOPE of ₹1,015. Among patients recruited from pharmacies, the mean OOPE was lower for patients who used only PMBJP outlets, at ₹142, compared to ₹1,127 for those who relied on private pharmacies. Those who obtained medicines from both PMBJP and private pharmacies incurred a mean OOPE of ₹965. The availability of generic medicines at PMBJP outlets was a crucial factor in reducing OOPE, as patients who were unable to obtain all prescribed medicines at PMBJP outlets had to purchase them from private pharmacies, increasing their OOPE.

Financial risk protection was assessed through the prevalence of catastrophic health expenditure and impoverishment rates. Among OPD patients, 9.2% experienced CHE, and 5.7% were impoverished due to their healthcare costs. The study found that none of the patients who obtained their medicines solely from PMBJP outlets experienced CHE, compared to 17.1% of those who obtained their medicines from private pharmacies. Similarly, the impoverishment rate was significantly lower among patients who used PMBJP outlets (0%) compared to those who used private pharmacies (9.4%). CHE and impoverishment rates were higher among patients from rural areas, lower-income quintiles, and those with more severe diseases or higher prescription drug needs.

Among IPD patients, it was found that 12.6% of the patients experienced CHE. Among those who obtained their medicines solely from PMBJP outlets, none experienced CHE, while 21.9% of patients who purchased medicines from both PMBJP and private pharmacies encountered CHE. Additionally, impoverishment rates were considerably lower among patients using PMBJP outlets (0%) compared to those relying on private pharmacies (19.8%). Higher rates of CHE and impoverishment were observed among IPD patients from rural areas, those in lower-income quintiles, and those with severe diseases

requiring more extensive prescriptions. Likewise, among the patients recruited from pharmacy, it was observed that 9.4% of the patients experienced CHE, with 6.5% facing impoverishment. Patients who obtained their medications exclusively from PMBJP outlets had no incidence of CHE, while 17.1% of those who used private pharmacies encountered CHE. As with OPD and IPD patients, the prevalence of CHE and impoverishment was higher among those from rural areas, individuals in lower wealth quintiles, and those requiring a greater number of medications or managing severe health conditions.

The study also examined the prescription patterns of physicians in both OPD and IPD settings. On average, OPD patients were prescribed 4.85 medicines, of which only 30.5% were generic. This indicates that physicians were still prescribing branded medicines, contributing to higher OOPE for patients. The lack of awareness about PMBJP outlets among the patients and the non-availability of generic medicines at the PMBJP outlet were cited as a significant barrier, with 54.8% of OPD patients reporting that they were unaware of the scheme.

The cost-effectiveness analysis compared the use of generic medicines versus branded medicines for the treatment of hospital acquired pneumonia (HAP). This health condition was selected for assessment as the estimates of comparative effectiveness of generic and branded counterparts were available only for the drugs used in treatment of HAP. A mathematical Markov model was used to estimate the incremental cost-effectiveness ratio (ICER) of using generic imipenem/cilastatin compared to its branded counterpart for the treatment of HAP. The analysis found that the use of generic medicines was cost-effective, with an ICER below the willingness-to-pay threshold, indicating that the use of

generic medicines could result in cost savings for the health system while maintaining similar health outcomes.

The study concluded that PMBJP has a significant positive impact on financial risk protection by reducing OOPE, CHE, and impoverishment rates. However, the scheme's full potential remains untapped due to low public awareness and limited availability of generic medicines at PMBJP outlets. The findings suggest that increasing the coverage of PMBJP outlets, enhancing public awareness campaigns, and encouraging physicians to prescribe generic medicines could further reduce the financial burden on patients and improve access to essential medicines. The cost-effectiveness analysis demonstrated that the use of generic medicines is a viable and cost-effective alternative to branded medicines, particularly for the treatment of high-cost conditions like hospital-acquired pneumonia. The study provides insights for policymakers aiming to improve the reach and effectiveness of PMBJP and similar programs aimed at reducing healthcare costs and promoting universal health coverage in India.

Introduction

"*Jan Aushadhi*" is the novel project launched by Government of India in the year 2008 for provision of quality medicines at affordable prices through sale of generic medicines in exclusive outlets namely "*Pradhan Mantri Jan Aushadhi Kendra*" (PMJAK).[1] Pharmaceuticals & Medical Devices Bureau of India (PMBI) is the implementing agency of Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP). PMBI was established in December 2008 under the Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India. The Bureau has been registered as an independent society under the Societies Registration Act, 1860 as a separate independent legal entity in April 2010.[1] As on 30.06.2024, 12616 Janaushadhi Kendras are functional across the country. Product basket of PMBJP comprises 2047 generic drugs and 300 surgical items.

The main objectives of the scheme are, first, to ensure access to quality medicines for all sections of the population, especially the poor and the deprived ones. The second objective is to create awareness about generic medicines through education and publicity to counter the perception that quality is synonymous with high price only. The third objective is to generate employment by engaging individual entrepreneurs in the opening of PMJAK.

The Pradhan Mantri Bhartiya Janaushadhi Kendras (PMJAKs) initiative is an effort aimed at ensuring the availability of affordable generic medicines to the masses. To achieve this, the government has set forth several guidelines and support mechanisms. State Governments, reputed NGOs, Trusts, Private hospitals, Charitable institutions, Doctors, Unemployed pharmacists, and individual entrepreneurs are all eligible to apply for the

establishment of new PMJAKs. A prerequisite for these stores is the employment of at least one B. Pharma. or D. Pharma. degree/ diploma holder as the pharmacist. These Kendras can be strategically located within Government and Private hospital premises, or anywhere outside, ensuring wide accessibility. In addition to the medicines and surgical items supplied by the Pharmaceuticals & Medical Devices Bureau of India (PMBI), these Kendras are allowed to sell allied medical products commonly found in chemist shops, enhancing the viability of running the store.

PMBI sources medicines from both Pharma Public Sector Undertakings (PSUs) and Private companies, prioritizing PSUs for the products they manufacture. Private manufacturers are selected through a stringent, transparent e-tendering process to ensure only reputed organizations participate. Upon receipt of goods at the central warehouse, PMBI sends samples to NABL accredited laboratories for quality inspection. Only after receiving quality certification are the goods dispatched to Carrying & Forwarding (C&F) agents and Distributors. To raise awareness about generic medicines, PMBI also undertakes suitable media activities aligned with the objectives of the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP).

Moreover, financial support is provided to applicants establishing PMJAKs in Government hospital premises, where space is provided free of cost, with an incentive of Rs. 2.5 lakhs. A similar incentive is extended to PMJAKs established elsewhere by private entities, provided they are linked with PMBI headquarters via the internet. A trade margin of 20% is included in the Maximum Retail Price (MRP) for retailers, and 10% for distributors. PMJAKs and Distributors are compensated with 2% of total sales or actual loss, whichever is lower, against the expiry of medicines, with expired goods not needing

to be returned to PMBI. Stocks expiring at the C&F level will be entirely borne by PMBI. Additionally, a credit facility of 30 days is extended to PMJAKs against postdated cheques, and distributors receive a 60-day credit period. PMBI also arranges suitable training programs for entrepreneurs lacking experience in running medicine shops. Lastly, institutions, charitable organizations, and NGOs procuring medicines for their own consumption or free distribution to the needy are allowed to procure medicines from PMBI CFA agents. This cohesive approach aims to ensure that PMJAKs not only provide affordable medicines but also remain viable and sustainable, contributing to the broader goal of accessible healthcare for all.

The PMBJP has initially struggled to meet its objectives due to several challenges.[1]Key issues included an overreliance on support from State Governments, poor supply chain management leading to frequent stock outs, and a limited and non-comprehensive drug basket that resulted in poor public response and disproportionate expiries. Furthermore, only 85 medicines across 11 therapeutic categories were supplied, and there was a significant lack of awareness among patients regarding the scheme. Given these limitations, this research project was initiated to assess the impact of PMBJP. Our research aims to evaluate the coverage and impact of PMBJP in achieving financial risk protection and ensuring universal health coverage from the patient's perspective. Specifically, we seek to assess the impact of PMBJP on out-of-pocket expenditure (OOPE), catastrophic health expenditure (CHE), and the impoverishment rate (IR) attributed to medicines. Additionally, we will compare the cost-effectiveness of using generic drugs versus branded drugs in treatment regimens. This research aspires to provide insights and recommendations to enhance the efficacy and reach of PMBJP, ultimately contributing to better health outcomes and financial protection for the Indian population.

Research Questions

1. What is the coverage and impact of Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) in achieving financial risk protection and ensuring universal health coverage in India? (Patient's perspective)

2. What is the cost-effectiveness of using generic drugs as compared to branded drugs in the treatment regimens?

Study Objectives

1. To assess the coverage of PMBJP in India.

2. To assess the impact of PMBJP on the out-of-pocket expenditure (OOPE), catastrophic health expenditure (CHE) and impoverishment rate (IR) attributed to medicines.

3. To assess the incremental cost per quality adjusted life year gained as a result of using branded medicines as compared to generic drugs in the treatment regimens of the selected diseases.

Methodology

Study population

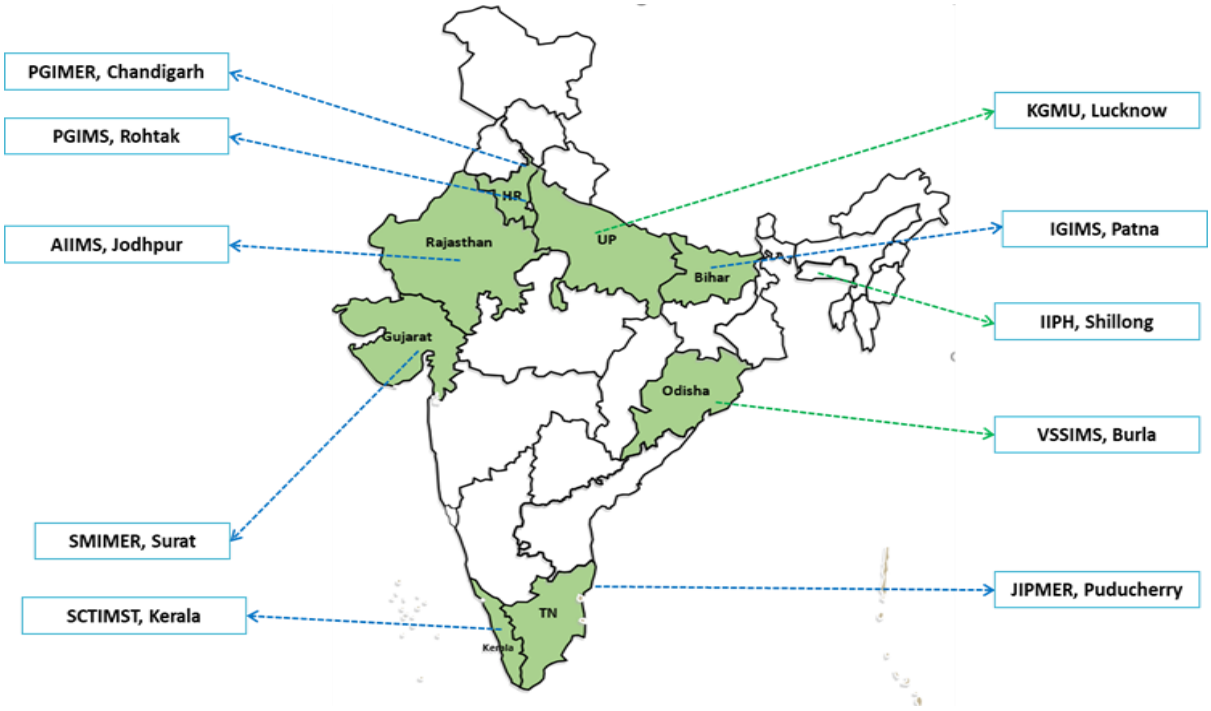
Patients of specified diseases visiting OPD, admitted in IPD, or visiting pharmacies to purchase medicines were comprised of study population. The participants were recruited from two places, first from the outpatient departments (OPDs) and inpatient departments (IPDs) of the selected health facilities, and second from Jan Aushadhi Kendra and private pharmacies.

Study settings

The study included primary as well as secondary data analysis. To select the healthcare institutions for the data collection, all the states of India were classified into two categories (low and high) on the basis of household out-of-pocket expenditure (OOPE) on medicines using Consumer Expenditure Survey (CES) data of National Sample Survey Office (NSSO) 75th round.[2] The states having OOPE on medicines less than 70% were categorized as low, whereas states having OOPE on medicines more than 70% were categorized as high status of OOP on drug expenditure, respectively. In order to guarantee geographic representation throughout the nation, health facilities were chosen from these two groups of states. The states that made up the low-OOPE group were Uttar Pradesh, Gujarat, Tamil Nadu, and Kerala; the high-OOPE group included Haryana, Rajasthan, Bihar, and Odisha. Assam was chosen as an additional state due to differences in health system functioning in the North-eastern part of India. The primary data collection was conducted in 9 states, selected on the basis of the OOPE share of medicines.

These states were Haryana, Rajasthan, Bihar, Odisha, Tamil Nadu, Gujarat, Kerala, Uttar Pradesh, and Assam (Figure 1).

Figure 1: Sites of data collection for assessment of impact of PMBJP in India



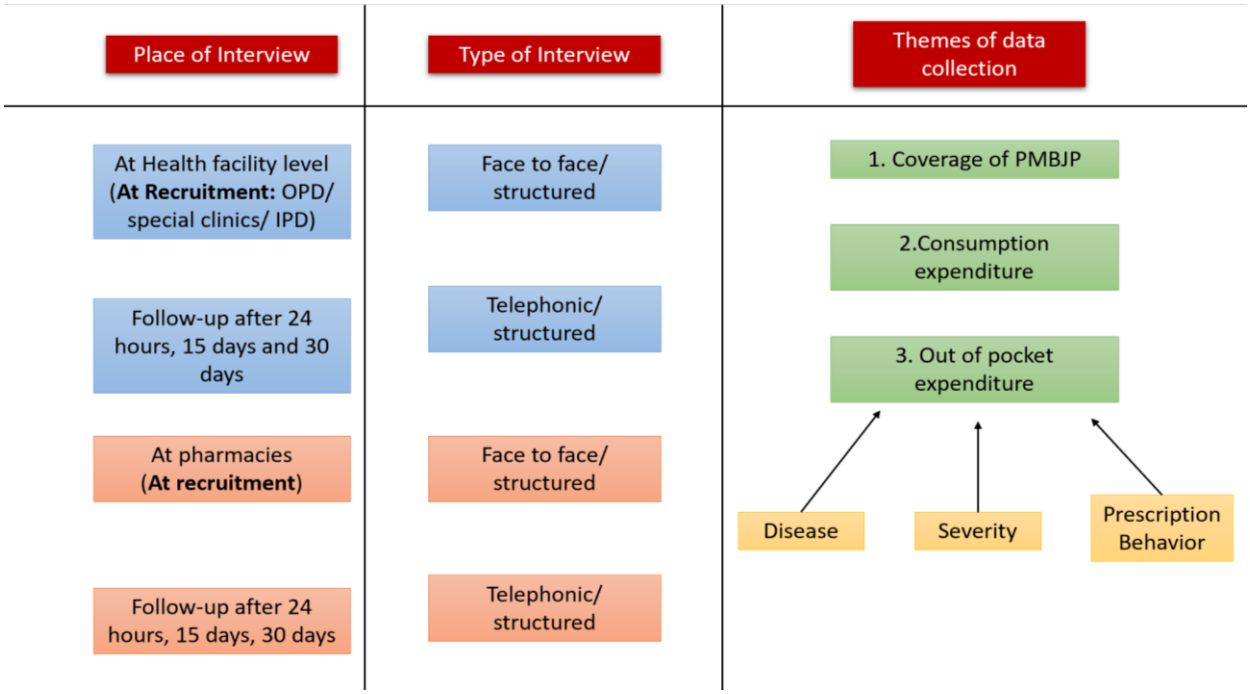
In the second stage, two districts having PMBJP outlets were selected from each state using stratified random sampling approach. The stratification of the districts was done based on Multi-Dimensional Poverty Index (MDPI), which comprised of three indicators- education, health and living standards.[3] All the districts having PMBJP outlets have been divided into two strata- high MDPI and low MDPI districts. One district was selected randomly from each stratum using a simple random sampling approach. In the next-stage, one secondary-care and one tertiary-care public health facility was selected from each district.

Thereafter, the data collection was conducted through patient exit interviews in OPD as well as IPD settings at district hospitals and government medical colleges and interviews at PMBJP and private pharmacies. Whereas PGIMER Chandigarh served as the nodal center to carry-out the study activities, the recruitment, training and data-collection at the respective states were undertaken by the partner institutes in these states. PGIMS Rohtak served as the coordinating institute for Haryana, KGMU Lucknow served for Uttar Pradesh, AIIMS Jodhpur served as the coordinating institute for Rajasthan, IGIMS Patna served as the coordinating institute for Bihar, VSSIMSR Sambalpur served for Odisha, SCTIMST Trivandrum served as the coordinating institute for Kerala, JIPMER Pondicherry served as the coordinating institute for Tamil Nadu, SMIMER Surat served for Gujarat, and IIPH Shillong served as the coordinating institute for Assam.

Data collection

The following approach (Figure-2) followed in the data-collection, the detail of which is provided in the subsequent sections:

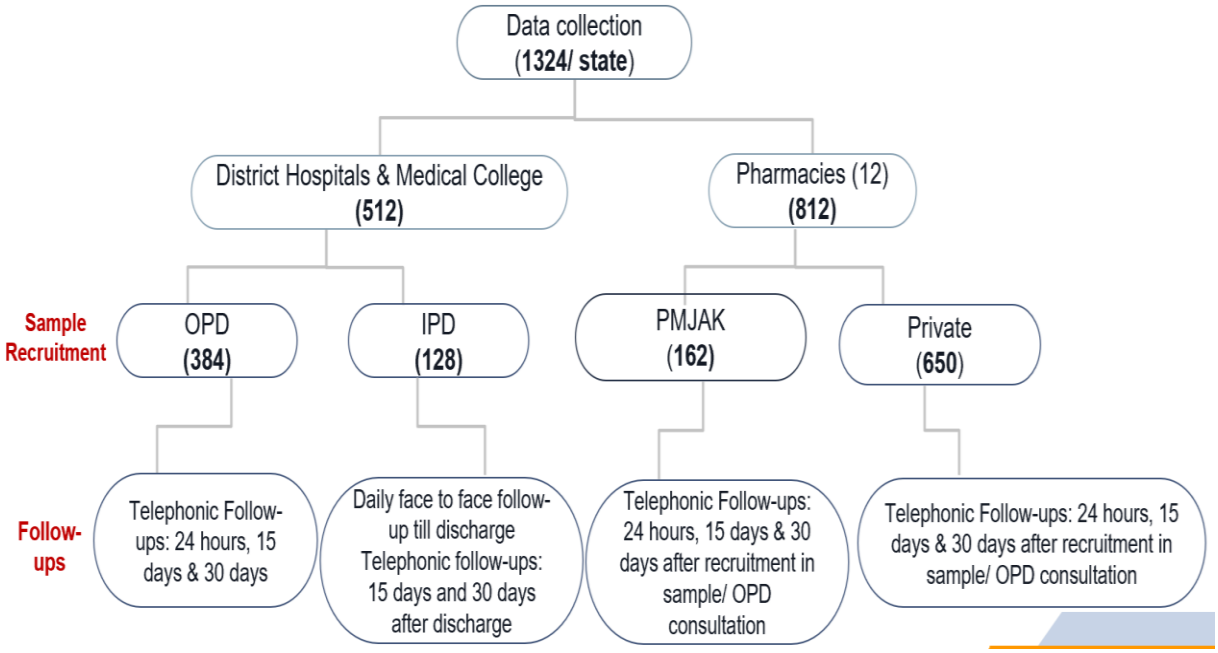
Figure 2: Approach of data-collection followed in the study



Sample size

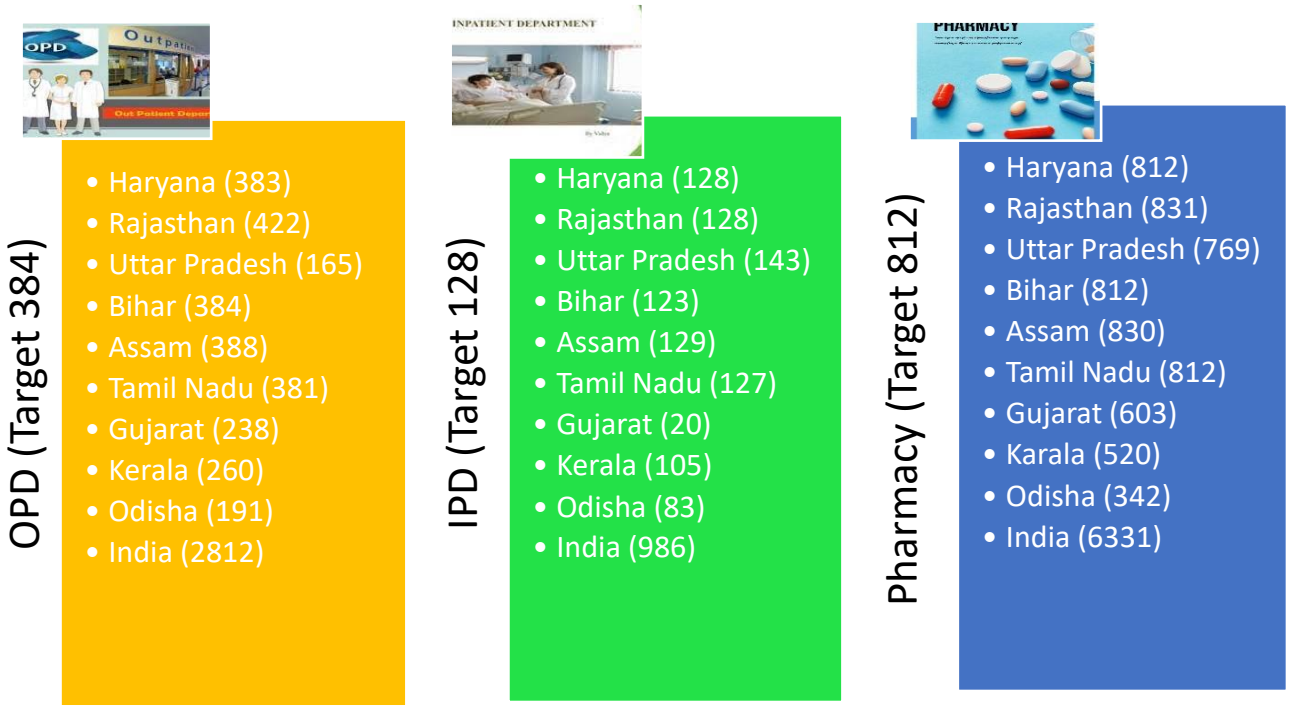
In order to estimate the required sample size to detect the extent of change in OOPE, the assumed level of significance as 5%, power of study as 80% and error margin as 5% was used. The sample was estimated individually for the health facilities and the pharmacies. Considering the change in catastrophic expenditure from 12% to 9%, and a non-response of 10%, the total sample size for health facilities was 4606.[4] Therefore, a total of 4606 patients were proposed to collect data on OOPE from nine sites. A sample size of 7294, after considering 10% non-response was calculated for the pharmacies. Therefore, a sample size of 11916 [4608 at hospitals and 7308 at pharmacies] has been computed based on impoverishment rate. Figure 3 presents the data collection plan in each state.

Figure 3. Data collection plan in each state



The final status of data collection across all the study sites has been summarized in figure 4.

Figure 4: Summary of data collection at selected sites



Selection of health conditions

One of the most important determinants of the out-of-pocket expenditure on medicines is the type/severity of the disease. Therefore, it was important to enroll patients who fall under some predefined diseases/ health conditions, so that the extent of reduction in the OOPE within the selected sample can be assessed clearly. Because of this reason, some health conditions were shortlisted, and only those patients have been considered for inclusion in which any of these conditions were present. The selection of health conditions has been done on the basis of four different criteria such as the prevalence of the selected health condition should be high in the population, so that enough patients are available for enrolment; the health condition should have a clear case definition, and a smaller number of possible differential diagnoses; the health conditions for which medicines and consumables at available at Jan Aushadhi Kendras; and the selected health

conditions should represent a good mix of communicable and non-communicable diseases, as well as acute and chronic conditions. Based on these criteria, diabetes mellitus, hypertension, congestive heart failure, osteoarthritis, cervical cancer, breast cancer, schizophrenia, chronic obstructive pulmonary disease and pneumonia had been selected.

Assessment of coverage of PMBJP

The coverage of PMBJP has been assessed by face-to-face interviews as well as telephonic interviews of the patients visiting the out-patient departments and the in-patient departments of the selected health facilities. The respondents interviewed telephonically to assess the type of pharmacy (PMBJP outlets or other) from where they would have obtained the medicines prescribed to them after their discharge/ consultation.

Assessment of prescription pattern

As only generic drugs are available under PMBJP outlets, the extent and pattern of prescribing generic drugs was required. Prescription audit of the patients visiting pharmacies (PMBJP outlets and other) had been undertaken for this assessment.

Assessment of indicators of financial risk protection

Exit interviews had been conducted among the patients visiting pharmacies (PMBJP outlets and other). The assessment of OOPE and CHE was done with the help of these interviews. 'Cost of illness' approach followed in determining OOPE. The recruited patients were interviewed based on a pre-tested semi-structured interview scheduled, adapted from previous studies done in similar settings.[5-7] It included information on socio-demographic characteristics, duration of treatment, consumption expenditure,

insurance status, OOP expenditure incurred on treatment, and coping mechanisms for dealing with the same. Payment receipts and bills have been checked where available from the participants to validate the reported expenditure. The follow-up interviews after 24 hours, 15 days, and 30 days of recruitment in the sample aided in estimation of cost of treatment and cost on medicines monthly.

Assessment of health-related quality of life

Although only the patients of selected health conditions were included in the study, the severity of each of these conditions can vary from patient to patient. This difference in the severity could have an implication on the type and dosage of the drugs being prescribed, there by impacting the OOPE on medicines. This necessitates the measurement of the severity of the disease in every patient, so that at the time of analysis, the patients of similar severity can be compared against each other for the OOPE incurred. The health-related quality of life of these patients was assessed during the exit interviews using the EuroQol 5- dimensions 5- level (EQ-5D-5L) instrument.[8]

EQ-5D-5L is a generic questionnaire intending to cover the crucial aspects of health significant to patients consisting of five attributes.[9] The EQ-5D-5L descriptive system covers these five dimensions: mobility, self-care, usual activity, pain/discomfort and anxiety/depression, and each dimension has five levels of severity: no problems, slight problems, moderate problems, severe problems, and extreme problems. An EQ-5D-5L health state is a set of responses to the five dimensions and is represented as a five-digit number (11111, 12111, 11112, etc.) with each digit representing the level of problem in respective dimension.[10, 11] EQ-5D-5L used to produce a single utility score between <0 and 1 based on individuals' response to questions. Utility score of 1 means perfect health

and 0 implies death. The Indian EQ-5D-5L value-set was used to convert the health profiles of the patients to respective utility scores.[12, 13]

Assessment of availability of medicines at PMBJP outlets

It was a possibility that the patients visiting PMBJP outlets might not get all the prescribed medicines at these outlets, and some of these medicines had been bought from pharmacies other than the PMBJP outlets. Therefore, in order to assess the true extent of OOPE incurred by the patient despite visiting a PMBJP outlet, it was important to assess that how many of the prescribed medicines were available at the PMBJP outlets and how many were to be bought from other pharmacies. To assess this, the patients whose exit interviews were undertaken at PMBJP outlets contacted again telephonically the next day to collect the data on OOPE incurred on purchasing medicine from other pharmacies.

Data analysis

Assessment of Financial Risk Protection

The tools for data collection for OPD patients, IPD patients, and pharmacy interviews consisted of seven sections: background information, details of illness and quality of life, prescription audit, place of acquiring medicines and expenditures, details of healthcare utilization, and expenditure follow-up at 24 hours, 15 days, and 30 days after the recruitment in sample. The Redcap software tools were used in multilingual formats, which were developed with assistance from Shree Chitra Tirunal Institute of Medical Sciences and Technology, Trivandrum, Kerala.

Data was analyzed using SPSS (SPSS Inc., Chicago, IL, USA), Stata 13 and MS- Excel (Microsoft Corporation, Washington, USA). Descriptive analyses were conducted to assess data characteristics of OPD, IPD and pharmacy respondents, separately. The sociodemographic characteristics of a patient's age, gender, education level, occupation, religion, place of residence, marital status, caste, type of health insurance and type of family were analyzed descriptively. The mean out-of-pocket expenditure incurred on medicine along with standard error was computed with respect to presence of co-morbidity (hypertension & diabetes mellitus, cancer, other and multiple), type of facility (medical college & hospital and district hospital), number of drugs prescribed, and diseases severity using clinical information obtained. The utility values for each descriptive health state of a given patient using EQ-5D-5L was derived using the Indian EQ-5D-5L value set.[12] This value set comprised of the index value which has been assigned to each of the 3125 possible health states which can be obtained using the EQ-5D-5L system. The OOP expenditure is reported in Indian National Rupee (INR).

This was followed by multiple linear regression model using ordinary least square method for estimation of parameters. Multivariable regression was employed for OPD, IPD and pharmacy respondents, separately. The log form of continuous variables to address skewness in the data was used. Nominal variables were transformed into dummy variables. The multiple linear models are assumed to be

$$Y = b_0 + b_1X_1 + b_2X_2 + \cdots + b_kX_k + e \quad (1)$$

where Y is the outcome variable, X_i is the value of the i^{th} predictor, and e is the error. We used medicine expenditure as a dependent variable, while remaining variables of patient's age, gender, education level, occupation, religion, place of residence, marital

status, caste, type of health insurance, type of family, presence of co-morbidity, type of facility, number of drugs prescribed, and diseases severity were used as predictors to understand their influence on the response variable. Normality of regress and error term for all models has been checked using "Kolmogorov Smirnov Test" with insignificant p-values as 0.883 and 0.586 (OPD patients), 0.785 and 0.891(IPD patients) and 0.854 and 0.712, (pharmacy). While the presence of homoscedasticity is checked using "Breusch-Pagan Test" with insignificance p-values as 0.098 (OPD patients), 0.188 (IPD patients) and 0.265, (pharmacy), which fails to reject the null hypothesis of homoscedasticity. Thus, the assumptions of normality of regress and, the error term and presence of homoscedasticity were fulfilled for all of the models. There is no multicollinearity with Variance Inflation values in between 1 and 4.

Financial risk has been assessed in terms of catastrophic health expenditure and impoverishment rate in both the patient groups. Expenditure on medicines which exceeds the threshold of 40% of non-food household consumption expenditure was considered as catastrophic health care expenditure (CHE).[14, 15] Multiple logistic regression analysis was performed to examine the risk of catastrophic health expenditure with covariates including age, sex, income status, health condition, insurance status, etc. Impoverishment was also calculated in terms of relative increase in poverty headcount.

Assessment of cost-effectiveness of using generic drugs in place of their branded counterparts

Economic evaluation has been conducted to ascertain the incremental cost of per QALY gained as a result of using generic drugs as compared to their branded counterpart. For this, first a thorough literature search was conducted to identify the drugs for which the evidence of effectiveness is available for both branded and generic variants. The literature search returned that such evidence is available for only for Cilastatin/Imipenem for the treatment of Hospital Acquired Pneumonia.

A mathematical markov model was parameterized on an MS Excel spreadsheet to estimate the incremental cost-effectiveness of using generic imipenem/cilastatin as compared to branded imipenem/cilastatin for the treatment of HAP in India. The health consequences were valued in terms of LYs and QALY in both intervention and comparator scenarios. Clinical, cost and effectiveness parameters were used to model the 3 months costs and consequences for a hypothetical cohort of 1000 HAP patients, who could be treated by either of the treatment regimens, using a health system perspective. We used 3 months of time horizon, based on the fact that the average length of stay was 50.1 and 81 days for patients receiving generic and branded drugs respectively. It assumed that this time period is sufficient to capture all the health effects and costs in a HAP patient [16]. Cost-effectiveness was assessed in terms of incremental cost-effectiveness ratio (ICER) per QALY gained with treatment using generic imipenem/cilastatin against branded imipenem/cilastatin.

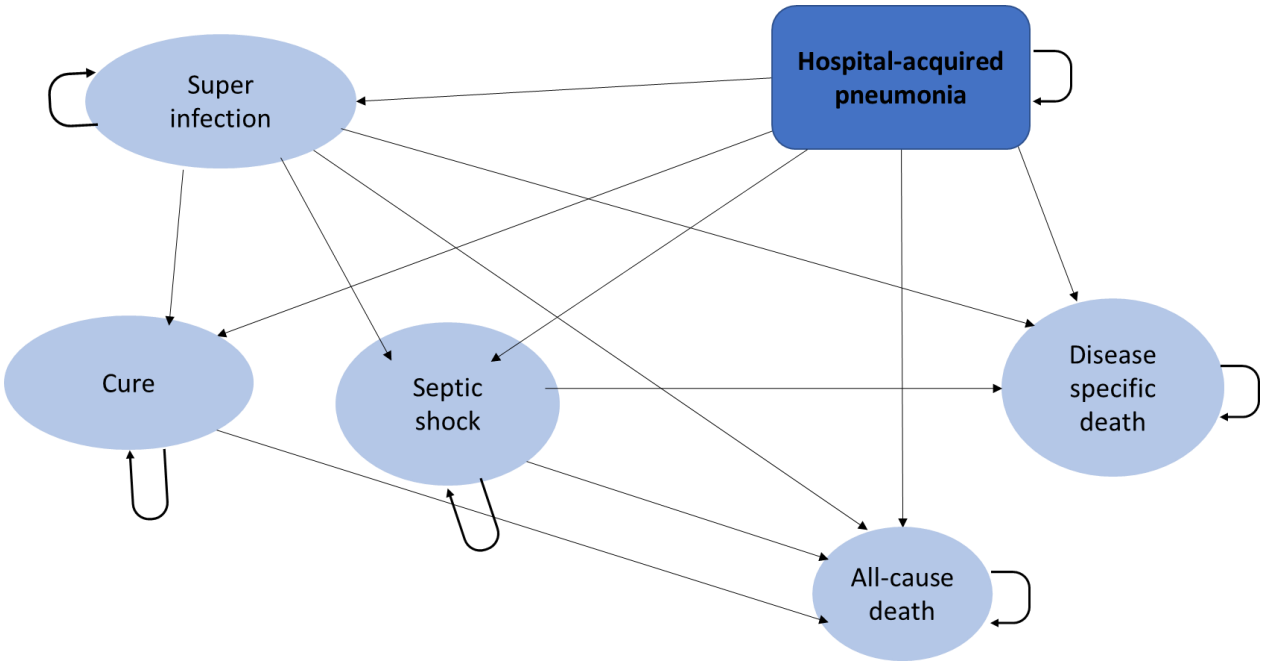
The markov model is comprised of number of health states to represent the progression of disease and death. All the future costs and consequences were discounted at the rate

of 3% for time preferences of cost and utility [17]. The patient's clinical progression was divided into distinct health states and the transition of patients among these health states over a week cycle was modeled (Figure 1). The cycle length of the model was assumed to be weekly, considering the fact that the average duration (7-8 days) is recommended for the treatment of HAP [18-20].

As the mean age of occurrence of HAP is 56 years [21], the incidence was assumed at this age, and the health effects were modeled till either the patient was cured or died. After the development of the disease, the patient was first assumed to be in the health state of HAP. During the subsequent week, some patients might resolve the infection and were cured, whereas a proportion of patients were assumed to have developed septic shock. As this is a reversible event, a certain proportion of the patients who progressed to septic shock were assumed to return to HAP once the septic shock is resolved. Similarly, depending on the weekly transition probability, some patients of HAP were assumed to develop superinfection. In the patients with superinfection, either the superinfection is resolved (return to HAP), or the complication of septic shock is developed, or the condition is cured. In patients where the superinfection was not resolved but no complication had developed, they were assumed to remain in the health state of superinfection. Additionally, two absorbing health states were also considered, i.e., disease-specific death and death from natural causes. Whereas a patient was assumed to encounter disease-specific death from the health states of HAP, superinfection, and septic shock, death from natural causes was assumed to happen from all the diseased and cured health states. A conceptual framework of markov model used in economic modeling is depicted in Figure 5. The model starts with the median (56 years) age at diagnosis [21]. Based on the clinical evidence, we assessed all health states after the completion of every

week of treatment cycles. The treatment of the disease was assumed as per the standard treatment guidelines [18-20].

Figure 5: Markov model depicting different health states of hospital acquired pneumonia



Costs of Treatment

Based on the standard or recommended treatment guidelines, all the diagnostics and treatments were assumed for different health states [18-20]. For HAP, the treatment comprised imipenem/cilastatin 0.5 gm IV QID [22], and added vancomycin 1g IV BD for patients developed with super-infection [23]. Patients in septic shock received different treatments- norepinephrine 0.5-3.5 µg/kg/min [24], phenylephrine 0.5-8.5 µg/kg/min [24], dopamine 10-25 µg/kg/min [25, 26], hydrocortisone 50 mg/QID [27], and vasopressin 0.04 units/min [26, 28]. The health system cost included only cost per bed day hospitalization. Since the cost of drugs and diagnostics were not considered as part of the health system cost, we separately calculated diagnostics and drug costs. We did not include the patient-

level OOPE and indirect cost. The unit health system cost of hospitalization was derived using the primary data of the 'National Health System Cost Database from India [7]'. The diagnostics costs were obtained from Central Government Health Scheme (CGHS) Rate List [29]. The cost for generic drugs was acquired from the price list of Jan Aushadhi Kendras [30], and for branded drugs, the average cost was obtained from market survey as well the prices available on online pharmacies like 1mg.com, pharmeasy, etc., [31]. All costs are reported in Indian National Rupee (INR). The clinical and cost parameters are presented in Table 1.

Table 1. Parameters used for assessing cost-effectiveness of generic and branded imipenem/cilastatin in hospital-acquired pneumonia

	Base value	Lower limit	Upper limit	Distribution	Source
Clinical parameters					
Utility scores					
HAP	0.7000	0.6300	0.7700	Beta	32
Superinfection	0.4000	0.3600	0.4400	Beta	33
Septic shock	0.3170	0.2853	0.3487	Beta	34
Cure	0.8480	0.7632	0.9328	Beta	33
Transition probabilities for branded drug					
HAP to superinfection	0.0166	0.0149	0.0183	Beta	16
HAP to Septic shock	0.0386	0.0347	0.0424	Beta	16
HAP to Cure	0.1354	0.1219	0.1489	Beta	16
HAP to all-cause death	0.0012	0.0011	0.0014	Beta	35
HAP to disease specific death	0.0344	0.0310	0.0379	Beta	16
Superinfection to disease specific death	0.0344	0.0149	0.0182	Beta	36

Superinfection to all-cause death	0.0012	0.0011	0.0014	Beta	35
Superinfection to cure	0.1210	0.1089	0.1331	Beta	36
Superinfection to Septic shock	0.0065	0.0059	0.0072	Beta	37
Septic shock to HAP	0.2684	0.2415	0.2952	Beta	38
Septic shock to disease specific death	0.0684	0.0616	0.0753	Beta	27
Septic shock to all-cause death	0.0012	0.0011	0.0014	Beta	35
Transition probabilities for generic drug					
HAP to superinfection	0.0377	0.0340	0.0415	Beta	16
HAP to Septic shock	0.0457	0.041	0.0503	Beta	16
HAP to Cure	0.0711	0.0640	0.0783	Beta	16
HAP to all-cause death	0.0012	0.0011	0.0014	Beta	35
HAP to disease specific death	0.0361	0.0324	0.0397	Beta	16
Superinfection to disease specificdeath	0.0003	0.0003	0.0003	Beta	36
Superinfection to all-cause death	0.0012	0.0011	0.0014	Beta	35
Superinfection to cure	0.1210	0.1089	0.1331	Beta	36
Superinfection to Septic shock	0.0065	0.0059	0.0072	Beta	37
Septic shock to HAP	0.2684	0.2415	0.2952	Beta	38
Septic shock to disease specific death	0.0684	0.0616	0.0753	Beta	27
Septic shock to all-cause death	0.0012	0.0011	0.0014	Beta	35
Cost parameters					
Drug costs					
Branded IMIPENEM/CILASTATIN 0.5 gm IV QID	1490.00	1117.50	1862.50	Gamma	39
Generic IMIPENEM/CILASTATIN 0.5 gm IV QID	330.00	247.50	412.50	Gamma	30

Branded Vancomycin (1g IV BD)	574.00	430.50	717.50	Gamma	[31]
Generic Vancomycin (1g IV BD)	270.00	202.50	337.50	Gamma	[30]
Norepinephrine 4mg	120.00	90.00	150.00	Gamma	[31]
Phenylephrine 10mg	210.00	157.50	262.50	Gamma	[31]
Dopamine 40mg	31.52	23.64	39.40	Gamma	[31]
Generic Hydrocortisone 100mg	20.00	15.00	25.00	Gamma	[30]
Branded Hydrocortisone 100mg	45.34	34.00	56.67	Gamma	[31]
Vasopressin 20 IU	180.87	135.65	226.08	Gamma	[31]
Diagnostics tests					
Chest x-ray	140.00	105.00	175.00	Gamma	[40]
CBC	138.00	103.50	172.50	Gamma	[40]
Bacterial culture and sensitivity	200.00	150.00	250.00	Gamma	[40]
CT chest	2875.00	2156.25	3593.75	Gamma	[40]
Ultrasound	300.00	225.00	375.00	Gamma	[40]
Health system costs					
Cost per bed day hospitalization	1671.00	1253.25	1838.10	Gamma	[7]

HAP: Hospital acquired pneumonia, IV: Intravenous, QID: Four times a day, BID: Twice a day, IU: International Unit, CBC: Complete blood count, CT: Computerized tomography

Valuation of health outcomes

Consequent to the model structure explained in the preceding paragraphs, both intermediate and long-term health outcomes for the patient of HAP were estimated. The incidence of occurrence of superinfection and development of septic shock were considered as intermediate outcomes, whereas, the number of LYs lived, QALYs lived, and mortality in the patients of HAP was considered as the final outcome. A review of the literature complemented with expert opinion was undertaken to determine the value of clinical parameters (Table 1). Weekly transition probabilities of HAP to superinfection, HAP to septic shock, HAP to cure, and HAP to disease-specific deaths for generic and

branded drugs for HAP treatment were derived from the reported estimates of a group of 368 HAP patients [16]. For both generic and branded drug groups, the weekly transition probabilities of superinfection to disease-specific death, and superinfection to cure were assumed as 0.34, and 0.12, which were obtained from the data of a cohort of 74 patients [36]. Transition probabilities for superinfection to septic shock were retrieved from a study conducted on 310 patients of which disease [37]. Transition probabilities for septic shock to HAP and septic shock to disease-specific deaths were taken from a cohort study carried out with 1041 patients with pneumococcal pneumonia [38], and a randomized controlled trial with 90 septic shock patients [27] respectively. All-cause, age-wise probability of death was obtained from the Census of India Sample Registration System life tables [35].

Each of the health states is assigned a utility score published in the literature (0= death and 1= full health). Utility values for HAP (0.70) were obtained from a cost-utility study in patients with HAP [32]. Utility value for bacteremia/sepsis considered as septic shock which was captured from a systematic review [33] and for super-infection, it was obtained by taking clinician opinion. Finally, the utility value for cure (0.84) is considered from the EQ-5D value set for a healthy individual in India [41]. Various parameters and assumptions used for analysis are mentioned below in Table 1.

QALYs lived by the patients of both the treatment and intervention groups were calculated as a product of duration spent in a particular health state, and the utility score of the corresponding health state. To estimate the additional amount of money required to generate one extra QALY using branded cilastatin/ imipenem as compared to their generic counterparts for the treatment of HAP, the ICER was estimated as the ratio of the

difference in costs and the difference in effectiveness between both the scenarios using the following formula:

$$ICER\ (QALY) = \frac{Cost\ (Branded\ drug) - Cost\ (Generic\ drug)}{QALY(Branded\ drug) - QALY(Generic\ drug)}$$

Sensitivity Analysis

A multivariate probabilistic sensitivity analysis (PSA) was performed to estimate the effect of joint parameter uncertainty [42]. All cost parameters were assigned as gamma distributions, whereas the utility values and probabilities/proportions were as beta distributions. The measure of variance was used to generate a distribution around the point estimate of a parameter. In cases measure of variance was not reported, the upper and lower bound were computed assuming a variation of 25% and 10% on either side of the base value was used for cost and clinical parameters, respectively. The Monte Carlo method was used for simulating the results over 999 times [43]. The median value of ICER was computed along the 2.5th and 97.5th percentile to estimate the 95% confidence interval (CI).

The probability of intervention to remain cost-effective at a different WTP (willingness to pay) threshold equal to per capita gross domestic product (GDP) and 3 times the GDP per capita was assessed. We also undertook to take much higher ranges of WTP as compared to one and 3-times per capita GDP to assess the probability of the intervention being cost-effective.

Results

Socio-demographic and clinical profile of patients

A total of 2812 OPD, 986 IPD and 6331 pharmacy visited patients were recruited in the study and data was collected on out-of-pocket expenditure (OOPE) incurred by patients on medicine in India. The sociodemographic profile of patients recruited in the study has been presented in Table 1. Patients in the OPD had an average age of 52.28 years, those in the IPD had an average age of 53.47 years, and pharmacies had an average age of 44.38 years. A total of 7.6 % OPD patients, 6.4% IPD patients and 23.1% patients who recruited at pharmacy were less than 30 years of age (Table-1).

In the OPD, 87.2% of patients were married, 82.1% were Hindu, 58.4% were unemployed, 57.9% were from rural areas, and 73.1 were literate. Nonetheless, 81.3% of the IPD patients were Hindu, 87.7% were married, 74% were from rural areas, 60.5% were unemployed, and 64.1% were literate. Patients who were recruited to the pharmacy included 62.2% literates, 62.2% unemployed people, 52.6% rural residents, 84.4% Hindus, and 80% married people.

Thirty percent of OPD and twenty-five percent of IPD patients visited district hospitals, while most of patients in both categories (70% and 74.2%) visited medical colleges and hospitals. Patients with hypertension comprised 69.9% of OPD patients, 50.1% of IPD patients, and 28.1% of patients recruited at the pharmacy. In OPD patients, there were 2.4%, in IPD patients, 7.5%, and 17.9% of patients who were recruited at the pharmacy had multiple co-morbidities. A small percentage of patients enrolled at the pharmacy, (16.3%), OPD, and IPD (2.4%) made a visit to Jan Aushadhi Kendra. 69.9% of patients

recruited at the pharmacy, 71.7% of IPD patients, and 85.8% of OPD patients visited another pharmacy besides Jan Aushadhi Kendra (Table-2). The majority of OPD patients (70.2%) were found to be uninsured under any health plans; 20.8% of patients were engaged in government-funded programs; 9% of patients had private health insurance. Among hospitalized cases, 61.5% of the patients were found not to be covered under any health insurance schemes- 25.5% patients were enrolled in government funded, and 13.1% were insured through private health insurance. Approximately 73% of patients enrolled at pharmacy had no health insurance coverage; 21.5% were engaged in government-funded programs, and 5.8% had private health insurance.

Table 1: Socio-demographic profile of patients

		OPD N (%)	IPD N (%)	Pharmacy N (%)
Gender	Male	1543 (54.9)	564 (57.2%)	3423 (54.1%)
	Female	1269 (45.1)	422 (42.8%)	2908 (45.9%)
State	Haryana	383 (13.6)	128 (13%)	812 (12.8%)
	Rajasthan	422 (15)	128 (13%)	831 (13.1%)
	Uttar Pradesh	165 (5.9)	143 (14.5%)	769 (12.2%)
	Bihar	384 (13.7)	123 (12.5%)	812 (12.8%)
	Assam	388 (13.8)	129 (13.1%)	830 (13.1%)
	Odisha	191 (6.8)	83 (8.4%)	342 (5.4%)
	Gujarat	238 (8.5)	20 (2%)	603 (9.5%)
	Kerala	260 (9.2)	105 (10.6%)	520 (8.2%)
	Tamil Nadu	381 (13.5)	127 (12.9%)	812 (12.8%)
Age of Patient	Up to 19	47 (1.7)	13 (1.3%)	545 (8.6%)
	20-29	166 (5.9)	50 (5.1%)	920 (14.5%)
	30-39	271 (9.6)	105 (10.6%)	984 (15.5%)
	40-49	593 (21.1)	186 (18.9%)	1183 (18.7%)
	50-59	733 (26.1)	243 (24.6%)	1220 (19.3%)
	60-69	691 (24.6)	250 (25.4%)	978 (15.4%)
	70+	311 (11.1)	139 (14.1%)	501 (7.9%)
Education Group	Illiterate	756 (26.9)	354 (35.9%)	1364 (21.5%)
	literate	2056 (73.1)	632 (64.1%)	4967 (78.5%)
Occupation Group	Employed	1169 (41.6)	389 (39.5%)	2390 (37.8%)
	Unemployed	1643 (58.4)	597 (60.5%)	3941 (62.2%)
Religion	Hindu	2310 (82.1)	802 (81.3%)	5346 (84.4%)
	Muslim	360 (12.8)	137 (13.9%)	782 (12.4%)

	Sikh	12 (0.4)	3 (0.3%)	16 (0.3%)
	Christian	130 (4.6)	44 (4.5%)	187 (3%)
Caste Group	SC/ST	402 (14.3)	206 (20.9%)	840 (13.3%)
	OBC	979 (34.8)	334 (33.9%)	2183 (34.5%)
	General	1431 (50.9)	446 (45.2%)	3308 (52.3%)
Marital Status	Never Married	181 (6.4)	56 (5.7%)	1104 (17.4%)
	Married	2507 (89.2)	865 (87.7%)	5064 (80%)
	Separated/Widow	124 (4.4)	65 (6.6%)	163 (2.6%)
Insurance Group	None	1974 (70.2)	606 (61.5%)	4604 (72.7%)
	Government Funded	586 (20.8)	251 (25.5%)	1362 (21.5%)
	Private	252 (9)	129 (13.1%)	365 (5.8%)
Type Family	Nuclear	1208 (43)	346 (35.1%)	2709 (42.8%)
	Joint	1604 (57)	640 (64.9%)	3622 (57.2%)
Wealth Quintile	Poorest	415 (14.8)	197 (20%)	1268 (20%)
	Poor	499 (17.7)	198 (20.1%)	1264 (20%)
	Middle	573 (20.4)	196 (19.9%)	1273 (20.1%)
	Rich	588 (20.9)	193 (19.6%)	1260 (19.9%)
	Richest	737 (26.2)	202 (20.5%)	1266 (20%)
Area of Residence	Rural	1656 (58.9)	730 (74%)	3329 (52.6%)
	Urban	1134 (40.3)	250 (25.4%)	2978 (47%)
	Slum	22 (0.8)	6 (0.6%)	24 (0.4%)
	Total	**2812**	**986**	**6331**

Table 2: Clinical characteristics of patients

		OPD N (%)	IPD N (%)	Pharmacy N (%)
Type of Health Facility Visited	Medical College & Hospital	1969 (70)	732 (74.2%)	
	District Hospital	843 (30)	254 (25.8%)	
Diseases Severity	Mild	1055 (37.5)	329 (33.4%)	2154 (34%)
	Moderate	836 (29.7)	339 (34.4%)	2123 (33.5%)
	Severe	921 (32.8)	318 (32.3%)	2054 (32.4%)
Number of Drugs Prescribed	<=4	1466 (52.1)	137 (13.9%)	4038 (63.8%)
	5-8	1082 (38.5)	432 (43.8%)	1971 (31.1%)
	>8	264 (9.4)	417 (42.3%)	322 (5.1%)
Type of Patient at Pharmacy	OPD			6062 (95.8%)
	IPD			269 (4.2%)
Type of Pharmacy Visited	PMBJP	93 (6)	17 (2.4%)	1033 (16.3%)
	Non-PMBJP	1336 (85.8)	515 (71.7%)	4426 (69.9%)
	Both	129 (8.3)	186 (25.9%)	872 (13.8%)
Total		**2812**	**986**	**6331**

Outpatient Department

Assessment of prescription pattern and coverage of PMBJP

On an average, OPD patients were prescribed 4.85 medicines, of which 30.5% (1.48) were generic and 69.5% (3.37) weren't (Table 3). OPD patients were prescribed pills or capsules in 97.5 percent of cases, syrup in 16.7%, lotion in 9.6%, and injections in 13.2% of cases. The district hospital dispensed 85.5% of the medicines, while the medical college & hospital dispensed 42.3%. Forty-five percent of the medicines were bought from pharmacies; of these, 4.8 percent were bought from Jan Aushadhi Kendra, 1.2% from Amrit Pharmacy, and 38.5% from private pharmacies (Table-5).

Of the OPD patients, 64.5 percent received at least one medicine from the health facility, and 35.9 percent received all medicines. Among OPD patients, Jan Aushadhi Kendra was visited by 11.6%, Amrit Pharmacy by 2.6%, private pharmacies by 78.7%, and both Amrit and private pharmacies by 81.3% (Table 6). A lack of awareness prevented 54.8% of OPD patients from visiting Jan Aushadhi Kendra, and 44.4% of OPD patients were unable to obtain medicine.

Table 3: Number and Types of Dosage forms prescribed in OPD

	Number of Drugs Prescribed Per Person (%)		
	Medical College & Hospital	**District Hospital**	**Overall**
Average Number of Medicine Prescribed	**4.94**	**4.63**	**4.85**
Generics	1.51 (30.5%)	1.44 (31.1%)	1.48 (30.5%)
Non-Generics	3.43 (69.5%)	3.19 (68.9%)	3.37 (69.5%)
Type of Dosage Form			
Number of Capsules /Tablets	4.34	3.88	4.21
Number of Injections	0.30	0.44	0.34
Number of Syrups	0.18	0.20	0.19
Number of Lotions	0.11	0.11	0.11

Figure 5: Analysis of OPD prescription according to dosage forms

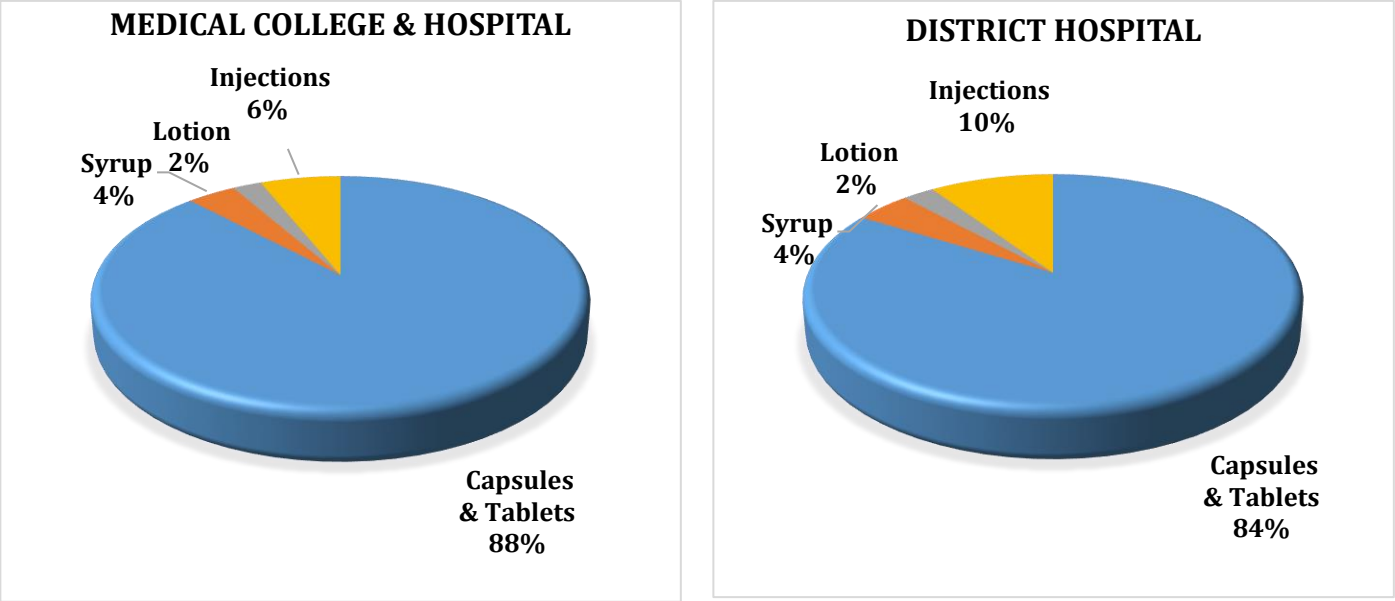


Table 4: Percentage of OPD patients as per the type of dosage form prescribed

Prescribed Medicine	Medical College & Hospital	District Hospital	Overall
Capsules / Tablets	1943 (98.7%)	799 (94.8%)	2742 (97.5%)
Syrup	323 (16.4%)	147 (17.4%)	470 (16.7%)
Lotion	188 (9.5%)	83 (9.8%)	271 (9.6%)
Injection	254 (12.9%)	118 (14%)	372 (13.2%)

Table 5: Proportion of medicines obtained at different type of pharmacies by OPD patients

	Medical College & Hospital	District Hospital	Overall
Dispensed within Health Facility	3471 (42.3%)	3063 (85.5%)	6534 (55.4%)
To be Purchased from Pharmacy	4733 (57.7%)	520 (14.5%)	5253 (44.6%)
Type of Pharmacy			
Jan Aushadhi Kendra	520 (6.3%)	51 (1.4%)	571 (4.8%)
Amrit Pharmacy	142 (1.7%)	0 (0%)	142 (1.2%)
Private Pharmacy	4071 (49.6%)	469 (13.1%)	4540 (38.5%)

Note: % of Medicines

Figure 6: Proportion of medicines obtained at different type of pharmacies by OPD patients

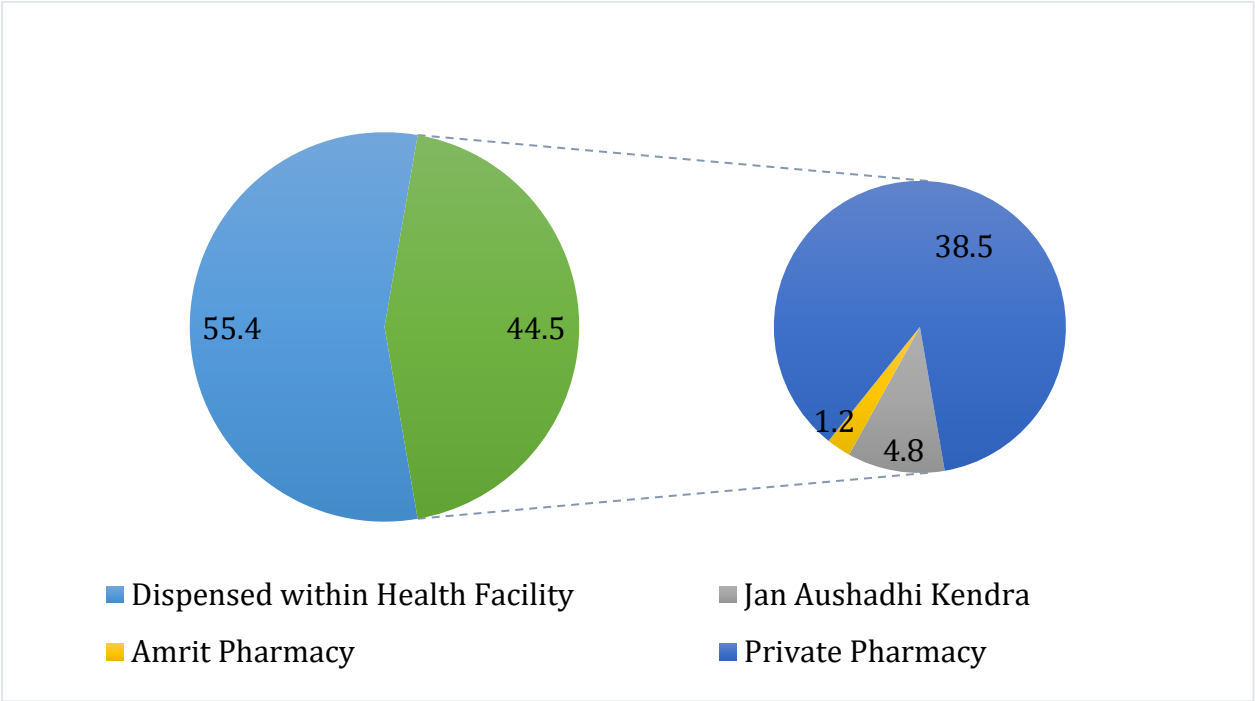


Table 6: Proportion of OPD patients visiting different type of pharmacies

	Medical College & Hospital	District Hospital	Overall
Patients getting at Least One Medicine from Health Facility	1012 (51.4%)	802 (95.1%)	1814 (64.5%)
Patients getting all Medicine from Health Facility	481 (24.4%)	528 (62.6%)	1009 (35.9%)
Type of Pharmacy			
Jan Aushadhi Kendra	183 (12.3%)	27 (8.6%)	210 (11.6%)
Amrit Pharmacy	46 (3.1%)	0 (0%)	46 (2.6%)
Private Pharmacy	1193 (80.2%)	226 (71.7%)	1419 (78.7%)
Non-JAK (Amrit & Private)	1239 (83.3%)	226 (71.7%)	1465 (81.3%)

*% of Respondents

Figure 7: OPD Patients visiting different type of pharmacies as per disease status

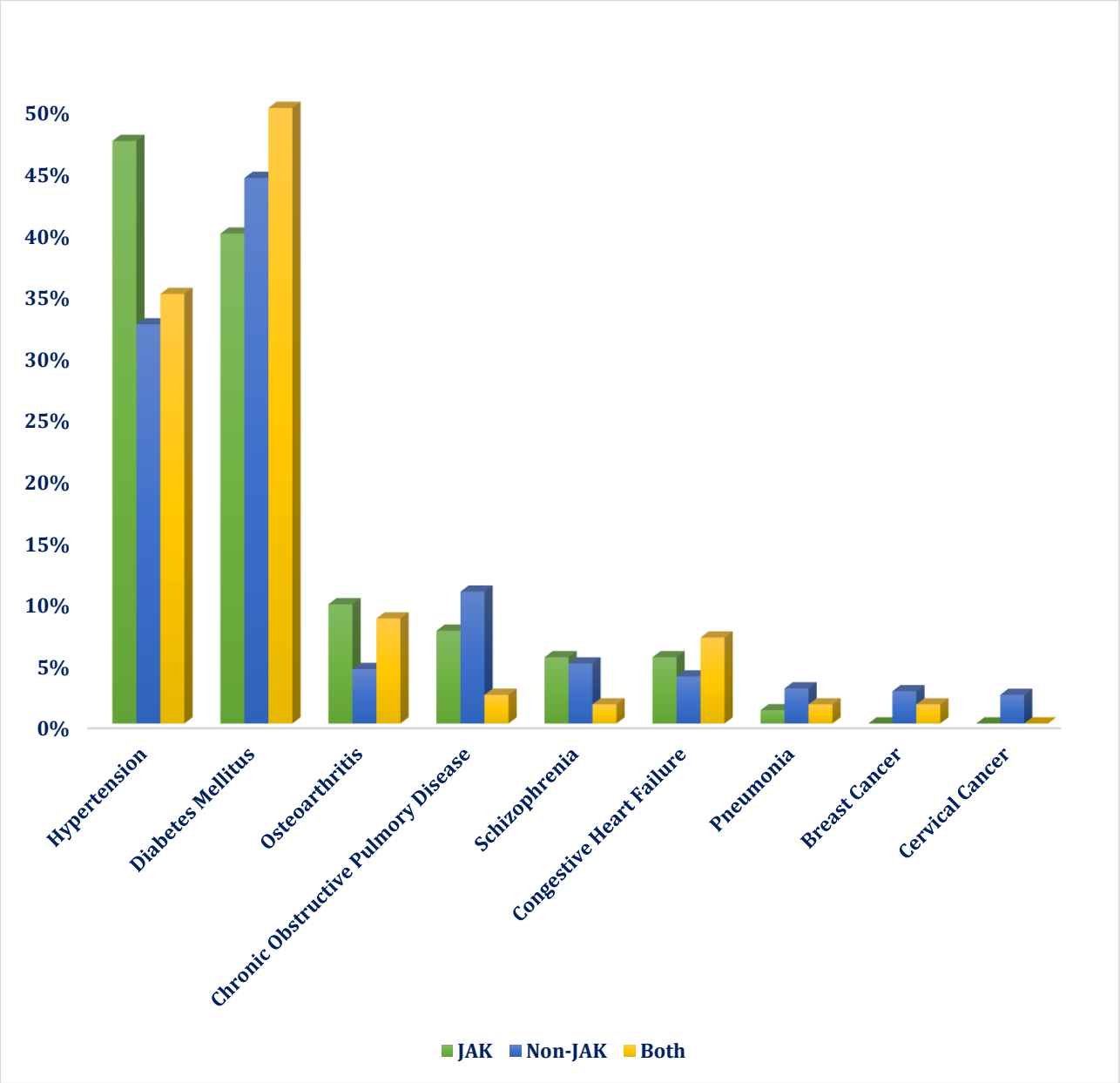


Figure 8: Reasons for not acquiring medicines from Jan Aushadhi Kendra by OPD patients visiting JAK

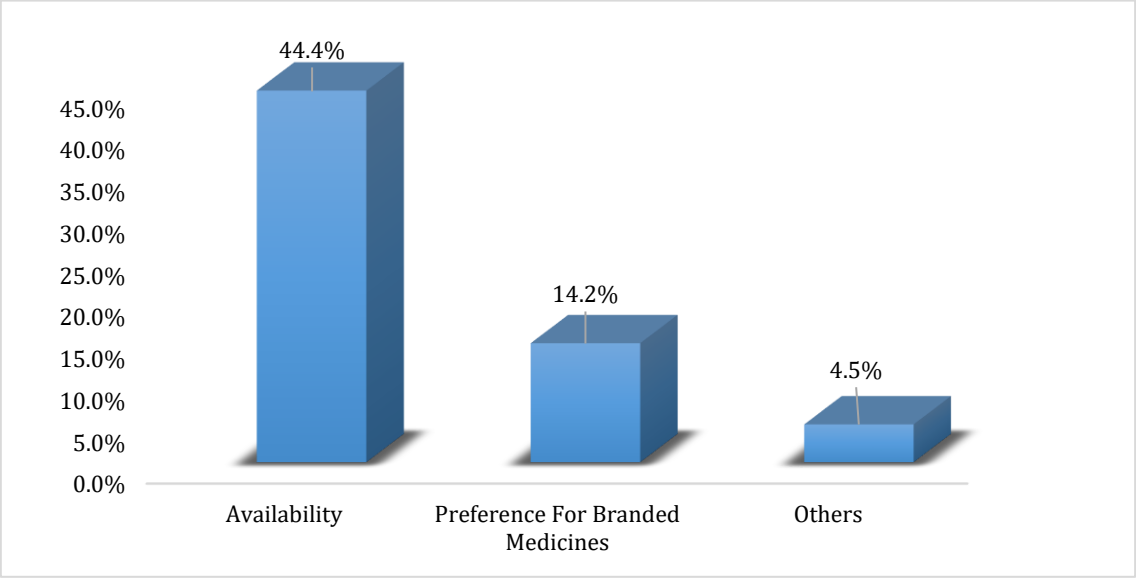
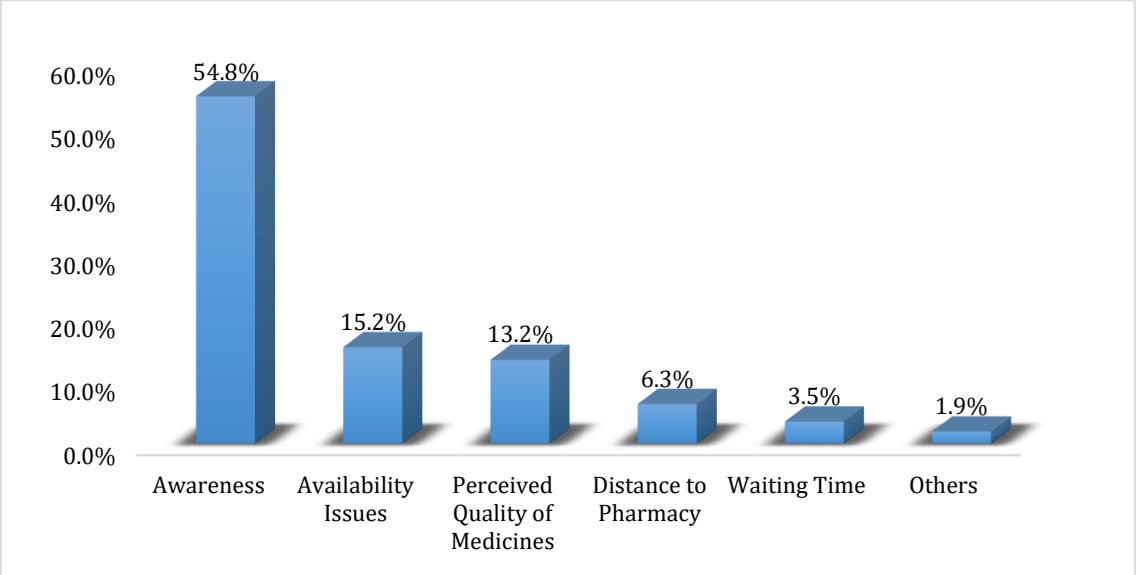


Figure 9: Reasons for not visiting Jan Aushadhi Kendra by OPD patients



Assessment of financial risk protection

Out-of-pocket expenditure on medicines by OPD patients

Mean OOPE incurred was found to be the lowest among OPD patients who visited PMBJP [INR 172 (236.7)] followed by those who visited both PMBJP and other pharmacies [INR 1,005 (956)], and those who visited only other pharmacies [INR 1,085 (2033.4)]. OOPE was also found to be higher among males [INR 611 (1527.3)] as compared to females [INR 441 (1467.1). The OOPE was found to be increasing with increase in level of diseases severity [INR 277 (702.5) for mild, INR 465 (1759.1) for moderate and INR 891 (1821.2) for severe. Considering the type of hospital, OPD patients incurred a significantly higher OOPE in medical college and hospitals [INR 736 (1753.2)] than in district hospitals [INR 62 (186.1)]. The highest OOPE was incurred by cancer patients [INR 1,013 (4302)] followed by hypertension & diabetes [INR 547 (1002.8)], and other [INR 439 (1837.6)]. It was observed that OOPE increased with increasing purchasing of drugs; the highest OOPE [INR 715 (2948.8)] was incurred by patients who purchased more than 8 drugs.

Age of patient, education level, and area of residence did not show any significant association ($p>0.05$) with OOPE on medicines, but the difference in OOPE estimates for the outpatient department was found to be statistically significant ($p<0.05$) for a number of parameters, including pharmacy type, facility, disease, gender, occupational status, religion, caste, marital status, family type, wealth quintile, number of drugs, disease severity, and health insurance status.

Table 7: Out of pocket expenditure on medicines by OPD patients

		N (%)	Mean (SD)	F-value	p-value
Type of Pharmacy Visited	PMBJP	93 (6)	172 (236.7)	8.62	<0.001**
	Non-PMBJP	1336 (85.8)	1085 (2033.4)		
	Both	129 (8.3)	1005 (956)		
Type of Facility	Medical College & Hospital	1969 (70)	736 (1753.2)	11.127	<0.001**
	District Hospital	843 (30)	62 (186.1)		
Type of Disease	Hypertension/Diabetes	1966 (69.9)	547 (1002.8)	5.138	0.002**
	Cancer	111 (3.9)	1013 (4302)		
	Other	669 (23.8)	439 (1837.6)		
	Multiple	68 (2.4)	334 (833.2)		
Age of Patient	Up to 19	47 (1.7)	435 (601.7)	1.986	0.064
	20-29	166 (5.9)	495 (1228.1)		
	30-39	271 (9.6)	515 (913.9)		
	40-49	593 (21.1)	655 (2171.1)		
	50-59	733 (26.1)	613 (1777.7)		
	60-69	691 (24.6)	418 (839)		
	70+	311 (11.1)	428 (878.1)		
Gender	Male	1543 (54.9)	611 (1527.3)	3.003	0.003**
	Female	1269 (45.1)	441 (1467.1)		
Education Group	Illiterate	756 (26.9)	516 (907.2)	0.388	0.698
	literate	2056 (73.1)	541 (1669)		
Occupation Group	Employed	1169 (41.6)	624 (1772.5)	2.677	0.007**
	Unemployed	1643 (58.4)	470 (1272.9)		
Religion	Hindu	2310 (82.1)	579 (1605.5)	5.206	0.001**
	Muslim	360 (12.8)	409 (970.6)		
	Sikh	12 (0.4)	260 (490.9)		
	Christian	130 (4.6)	105 (377)		
	Other				
Caste Group	SC/ST	402 (14.3)	487 (984)	13.948	<0.001**
	OBC	979 (34.8)	735 (2165.7)		
	General	1431 (50.9)	410 (956.7)		
Marital Status	Never Married	181 (6.4)	445 (715.1)	7.365	<0.001**
	Married	2507 (89.2)	516 (1348.1)		
	Separated/Widow	124 (4.4)	1033 (3681)		
Insurance Group	None	1974 (70.2)	611 (1700.3)	9.031	<0.001**
	Government Funded	586 (20.8)	252 (702.3)		
	Private	252 (9)	597 (1107.1)		
Type Family	Nuclear	1208 (43)	437 (1521.6)	2.975	0.003**
	Joint	1604 (57)	607 (1484.3)		
Wealth Quintile	Poorest	415 (14.8)	353 (2073.6)	4.042	0.003**
	Poor	499 (17.7)	419 (935.7)		
	Middle	573 (20.4)	693 (2191)		
	Rich	588 (20.9)	548 (898.6)		
	Richest	737 (26.2)	579 (1089.8)		
Area of Residence	Rural	1656 (58.9)	521 (1742.2)	0.826	0.438
	Urban	1134 (40.3)	560 (1078.5)		
	Slum	22 (0.8)	182 (240.3)		

Number of Drugs	<=4	1466 (52.1)	376 (739.7)	17.21	<0.001**
	5-8	1082 (38.5)	705 (1715.4)		
	>8	264 (9.4)	715 (2948.8)		
Diseases Severity	Mild	1055 (37.5)	277 (702.5)	43.593	<0.001**
	Moderate	836 (29.7)	465 (1759.1)		
	Severe	921 (32.8)	891 (1821.2)		
Overall		**2812**	**534 (1502.6)**	**(478.54, 589.66)**	

*Significant at 0.05, **Significant at 0.01

Determinants of Out-of-pocket expenditure on medicines by OPD patients

The study also determined the parameters influencing OOPE on drugs taken by individuals with OPD. The results of the regression analysis showed that type of pharmacy, state, type of facility, number of drugs purchased, type of diseases, diseases severity and type of family significantly impacted out-of-pocket expenditure on drugs by OPD patients (Table 8). The OOPE incurred by only other pharmacy 's patients (172.1%) or both PMBJP and other pharmacy's patients (95.6%) were found to be significantly higher ($p<0.01$) as compared to those who purchased drugs from PMBJP only. In addition, OOPE incurred by medical college and hospital patients (190.1%, $p<0.01$) was significantly higher as compared to district hospital's patients. Significant increase in OOPE was found with increase in number of drugs (68.2%). Further, patients having mild diseases severity were found to have lower OOPE as compared to those who were had moderate (16.2%; $p<0.01$) and severe (41.1%; $p<0.01$).

Table 8: Determinants of Out-of-pocket expenditure on medicines by OPD patients

		Coef.	Std. Err.	t	P>t	[95% Confidence Interval]	
Type of Pharmacy Ref. PMBJP	Non-PMBJP	1.001	0.104	9.620	<0.001**	0.797	1.205
	Both	0.671	0.135	4.960	<0.001**	0.405	0.936
State Ref Haryana	Rajasthan	0.945	0.122	7.750	<0.001**	0.706	1.184
	Uttar Pradesh	1.091	0.130	8.390	<0.001**	0.836	1.346
	Bihar	1.251	0.118	10.580	<0.001**	1.019	1.483
	Assam	-0.001	0.121	0.000	0.996	-0.238	0.236
	Odisha	-0.076	0.300	-0.250	0.801	-0.664	0.513
	Gujarat	-0.125	0.133	-0.940	0.348	-0.385	0.136
	Kerala	0.418	0.168	2.490	0.013*	0.088	0.747
	Tamil Nadu	1.041	0.171	6.100	<0.001**	0.706	1.376
Type of facility Ref. DH	Medical Hospital	1.065	0.081	13.120	<0.001**	0.906	1.225
Number of Drugs Purchased		0.520	0.044	11.720	<0.001**	0.433	0.607
Gender Ref. Male	Female	-0.018	0.058	-0.320	0.753	-0.133	0.096
Type of Disease Ref. Hyp & Dia	Cancer	-0.355	0.121	-2.930	0.003**	-0.592	-0.117
	Other	-0.277	0.061	-4.550	<0.001**	-0.397	-0.158
	Multiple	-0.293	0.177	-1.650	0.099	-0.641	0.055
Occupation Ref. Employed	Unemployed	-0.052	0.058	-0.900	0.369	-0.167	0.062
Religion Ref. Hindu	Muslim	-0.121	0.073	-1.660	0.098	-0.265	0.022
	Sikh	-0.482	0.305	-1.580	0.114	-1.080	0.115
	Christian	-0.441	0.204	-2.160	0.031*	-0.841	-0.041
Caste Ref SC/ST	OBC	0.032	0.071	0.450	0.652	-0.107	0.171
	General	0.023	0.071	0.330	0.745	-0.117	0.163
Type of Family Ref. Nuclear	Joint	-0.120	0.051	-2.340	0.020*	-0.220	-0.019
Health Insurance Ref. None	Government Funded	0.025	0.087	0.290	0.774	-0.145	0.195
	Private	-0.163	0.103	-1.590	0.112	-0.364	0.038
Marital Status Ref. Unmarried	Married	0.191	0.095	2.000	0.045*	0.004	0.378
	Separated/Widow	0.263	0.142	1.850	0.064	-0.016	0.542
Wealth Quintile Ref. Poorest	Poor	0.091	0.093	0.980	0.327	-0.091	0.274
	Middle	0.129	0.097	1.340	0.182	-0.060	0.318
	Rich	0.022	0.098	0.230	0.820	-0.170	0.215
	Richest	0.180	0.100	1.790	0.073	-0.017	0.377
Diseases Severity Ref. Mild	Moderate	0.150	0.066	2.280	0.023*	0.021	0.279
	Severe	0.344	0.071	4.850	<0.001**	0.205	0.483
Constant		2.738	0.195	14.030	<0.001**	2.355	3.121
R Square		0.5202					
Adjusted R Square		0.5095					

*Significant at 0.05, **Significant at 0.01

Catastrophic health expenditure and impoverishment rate among OPD patients

The overall prevalence of catastrophic health expenditure among OPD patients was found to be 9.2% and 5.7% were impoverished. The prevalence of CHE was found to lie in the range of 7.1% to 17.8% among different age groups of OPD patients. None of OPD patient who purchased drugs from PMBJP had catastrophic health expenses, followed by 17.1% who purchased drugs from other pharmacies and 21.9% who purchased drugs from both PMBJP and other pharmacies. CHE was found be more among males (9.6%) than females (8.7%). Furthermore, the prevalence of CHE was highest among outpatients belonging to rural areas (11.8%) followed by urban areas (5.7%). The prevalence of CHE among patients who got treatment from medical college and hospital was highest (12.6%) versus (1.2%) district hospital patients. The prevalence of CHE among non-hospitalised patients was highest (11.4%) among poorest income group (versus 1.1% among richest quintile). The prevalence of CHE also increased with increase in the number of drugs prescribed; 6.2% for less than 5 drugs, and 12.9% for 5-8 drugs. The prevalence of CHE increased as the level of disease's severity increased (range: 3.9% to 16.2%).

The prevalence of impoverishment ranged from 2.3% to 31.1% across different diseases groups among OPD patients. Impoverishment was found to be concentrated more among patients who visited other pharmacies except PMBJP (9.4%) than those who visited only PMBJP (0%). Patients belonging to rural areas faced the greatest impact of impoverishment (9.1%). However, impoverishment was found to be more concentrated among medical college and hospital patients (7.7%) as compared to district hospital's patients (0.4%). The prevalence of impoverishment increases with increase in the level

of diseases severity, from mild to severe groups (2% to 11.7%) as well as number of drubs prescribed.

Logistic regression analysis was run to determine the factors influencing catastrophic health expenditure on medicine and impoverishment. The results of the analysis showed that the likelihood of CHE was significantly about three times higher for patients who purchased medicines form other pharmacies ($\beta = 3.113$, $p<0.01$) as compared to those who purchased drugs from PMBJP. Patients from medical college and hospitals had a significantly twenty-one times higher likelihood of experiencing CHE than those from district hospitals. The odds of CHE were 69.2%, 92%, and 99.1% lower for middle, rich and richest income quintiles respectively and were found to be statistically significant ($p<0.01$). The likelihood of CHE was significantly the highest among patients in the poorest wealth quintile as compared to richest income groups. Number of drugs purchased were significantly associated with higher odds of CHE ($\beta=1.133$; $p<0.05$). As compared to patients with mild diseases severity, the likelihood of CHE was approximately 2 and 2.6 times higher among those who had moderate and severe diseases severity, respectively.

The results of the analysis showed that the likelihood of impoverishment was about 9.5% higher for patients who purchased medicines only from private pharmacies ($\beta=1.095$) as compared to those who purchased drugs form PMBJP; however, the odds were found to be statistically insignificant ($p>0.05$). The odds of impoverishment were also found to be significantly higher ($\beta=15.738$, $p<0.01$) for medical college and hospital patients than that of district hospital patients. The odds of impoverishment were found to be 97.2%, 99.7%, and 100% lower for the middle, rich and the richest wealth quintile as compared to the poorest wealth quintile, respectively ($p<0.01$). Those with moderate and severe disease

severity were around 35.6% and three times more likely to be impoverished, respectively, than those with mild disease severity. The quantity of drugs bought was substantially linked to increased chances of poverty (β=1.255; p<0.01).

Table 9: Catastrophic health expenditure and impoverishment rate among OPD patients

		CHE			IR		
		N (%)	Odds Ratio	p-value	N (%)	Odds Ratio	p-value
Facility Level	PMBJP	0 (0)	**Reference**		0 (0)	**Reference**	
	Non-PMBJP	220 (17.1)	3.113	<0.001**	95 (9.4)	1.095	0.850
	Both	28 (21.9)	1		16 (19.8)	1	
Type of Facility	District Hospital	10 (1.2)	**Reference**		2 (0.4)	**Reference**	
	Medical College & Hospital	238 (12.6)	21.208	<0.001**	109 (7.7)	15.738	0.001**
Age of Patient	Up to 19	8 (17.8)	0.983	0.016*	2 (5.9)	0.967	0.013*
	20-29	22 (13.7)			5 (4.5)		
	30-39	19 (7.4)			6 (3.1)		
	40-49	56 (9.9)			31 (7.5)		
	50-59	70 (9.9)			38 (7)		
	60-69	47 (7.1)			19 (4.1)		
	70+	26 (8.6)			10 (5)		
Gender	Male	142 (9.6)	**Reference**		67 (6.1)	**Reference**	
	Female	106 (8.7)	1.027	0.909	44 (5.2)	0.621	0.244
Type of Disease	Hypertension/Diabetes	181 (9.5)	**Reference**		84 (5.9)	**Reference**	
	Cancer	20 (21.1)	0.686	0.300	14 (31.1)	0.568	0.294
	Other	46 (7.2)	0.373	<0.001**	10 (2.3)	0.141	<0.001**
	Multiple	1 (1.6)	0.145	0.075	3 (6.5)	1.916	0.509
Area of Residence	Rural	185 (11.8)	**Reference**		90 (9.1)	**Reference**	
	Urban	63 (5.7)	0.900	0.602	20 (2.1)	0.392	0.007**
	Slum	0 (0)	1		1 (5)	0.24	0.657
Religion	Hindu	229 (10.4)	**Reference**		102 (6.5)	**Reference**	
	Muslim	14 (4)	0.290	<0.001**	7 (2.4)	0.177	0.002**
	Sikh	1 (11.1)	0.448	0.507	0 (0)	1	
	Christian	4 (3.1)	0.564	0.366	2 (2.1)	0.577	0.627
Education Group	Illiterate	88 (12.2)	**Reference**		37 (9.2)	**Reference**	
	literate	160 (8.1)	0.636	0.030*	74 (4.8)	0.692	0.302
Occupation Group	Employed	110 (9.8)	**Reference**		45 (5.4)	**Reference**	
	Unemployed	138 (8.8)	0.674	0.085	66 (6)	1.357	0.438
Caste Group	SC/ST	42 (11.4)	**Reference**		10 (4.9)	**Reference**	
	OBC	127 (13.7)	0.954	0.852	63 (9.9)	1.714	0.259
	General	79 (5.6)	0.613	0.064	38 (3.4)	1.070	0.895
Marital Status	Never Married	22 (12.9)	**Reference**		4 (3.4)	**Reference**	
	Married	204 (8.5)	0.983	0.963	95 (5.5)	3.610	0.110
	Separated/Widow	22 (18.6)	4.581	0.006**	12 (11.7)	11.054	0.018*
Type Family	Nuclear	72 (6.1)	**Reference**		27 (2.8)	**Reference**	
	Joint	176 (11.5)	1.497	0.034*	84 (8.6)	16.068	<0.001**
Insurance Group	None	207 (11.1)	**Reference**		93 (7.3)	**Reference**	
	Government Funded	15 (2.6)	0.685	0.263	7 (1.5)	0.778	0.648
	Private	26 (10.7)	0.742	0.292	11 (5.9)	1.024	0.962
Wealth Quintile	Poorest	38 (11.4)	**Reference**		3 (33.3)	**Reference**	

	Poor	63 (13.3)	0.392	0.003	25 (20)	0.499	0.577
	Middle	101 (17.6)	0.308	<0.001**	66 (13.3)	0.028	0.005**
	Rich	38 (6.5)	0.080	<0.001**	16 (2.8)	0.003	<0.001**
	Richest	8 (1.1)	0.009	<0.001**	1 (0.1)	0.000	<0.001**
Number of Drugs Prescribed	Up to 4	88 (6.2)	1.133	<0.001**	29 (2.7)	1.255	<0.001**
	5-8	134 (12.9)			64 (9.1)		
	>8	26 (10.4)			18 (10.5)		
Diseases Severity	Mild	40 (3.9)	**Reference**		16 (2)	**Reference**	
	Moderate	68 (8.5)	1.977	0.011*	23 (4.3)	1.356	0.519
	Severe	140 (16.2)	2.603	<0.001**	72 (11.7)	3.049	0.010**
Overall		**248 (9.2)**			**111 (5.7)**		

*Significant at 0.05, **Significant at 0.01

Inpatient Department

Assessment of prescription pattern and coverage of PMBJP among IPD patients

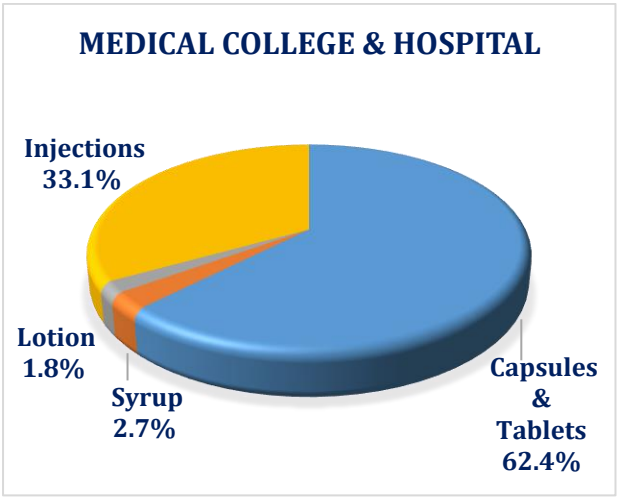
On average, IPD patients were prescribed 9.16 medicines, of which 16% (1.47) were generic and 84% (7.69) weren't (Table 10). IPD patients were prescribed pills or capsules in 95.5 percent of cases, syrup in 21.6%, lotion in 18.2%, and injections in 73.8% of cases. The district hospital dispensed 75.2% of the medicines, and the medical college & hospital dispensed 44.5%. Forty eight percent of the medicines were bought from pharmacies; of these, 8.7 percent were bought from Jan Aushadhi Kendra, 4.7% from Amrit Pharmacy, and 34.9% from private pharmacies (Table-12).

Of the IPD patients, 70.4 percent received at least one medicine from the health facility, and 27.8 percent received all medicines. Among IPD patients, Jan Aushadhi Kendra was visited by 19.9%, Amrit Pharmacy by 10.9%, private pharmacies by 65.1%, and both Amrit and private pharmacies by 76% (Table 13). A lack of awareness prevented 49.7% of IPD patients from visiting Jan Aushadhi Kendra, and 60.6% of IPD patients were unable to obtain medicines due to unavailability.

Table 10: Number and Types of Dosage forms prescribed in IPD

	Number of Drugs Prescribed Per Person (%)		
	Medical College & Hospital	**District Hospital**	**Overall**
Average Number of Medicine Prescribed	**9.42**	**8.39**	**9.16**
Generics	1.41 (15%)	1.62 (19.3%)	1.47 (16%)
Non-Generics	8.01 (85%)	6.77 (80.7%)	7.69 (84%)
Type of Dosage Form			
Number of Capsules /Tablets	5.88	4.71	5.58
Number of Injections	3.12	2.99	3.09
Number of Syrups	0.25	0.24	0.25
Number of Lotions	0.17	0.44	0.24

Figure 10: Analysis of IPD prescription according to dosage forms



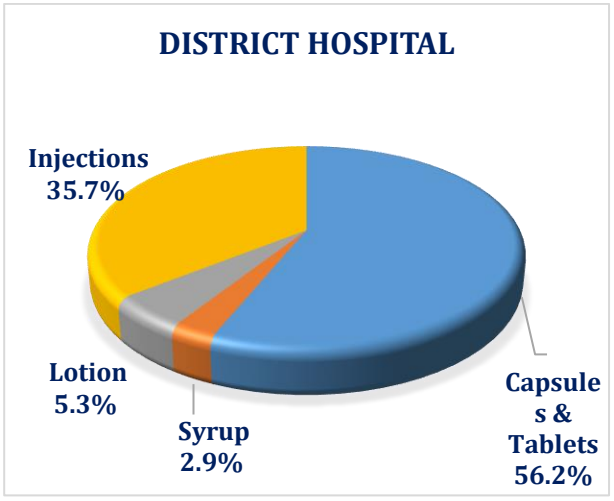


Table 11: Percentage of IPD patients as per the type of dosage form prescribed

Prescribed Medicine	Medical College & Hospital	District Hospital	Overall
Capsules / Tablets	705 (96.3%)	237 (93.3%)	942 (95.5%)
Syrup	163 (22.3%)	50 (19.7%)	213 (21.6%)
Lotion	107 (14.6%)	72 (28.3%)	179 (18.2%)
Injection	531 (72.5%)	197 (77.6%)	728 (73.8%)

Table 12: Proportion of medicines obtained at different type of pharmacies by IPD patients

	Medical College & Hospital	District Hospital	Overall
Dispensed within Health Facility	3067 (44.5%)	1602 (75.2%)	4669 (51.7%)
To be Purchased from Pharmacy	3830 (55.5%)	529 (24.8%)	4359 (48.3%)
Type of Pharmacy			
Jan Aushadhi Kendra	740 (10.7%)	45 (2.1%)	785 (8.7%)
Amrit Pharmacy	411 (6%)	11 (0.5%)	422 (4.7%)
Private Pharmacy	2679 (38.8%)	473 (22.2%)	3152(34.9%)

Note % of Medicines

Figure 11: Proportion of medicines obtained at different type of pharmacies by IPD patients

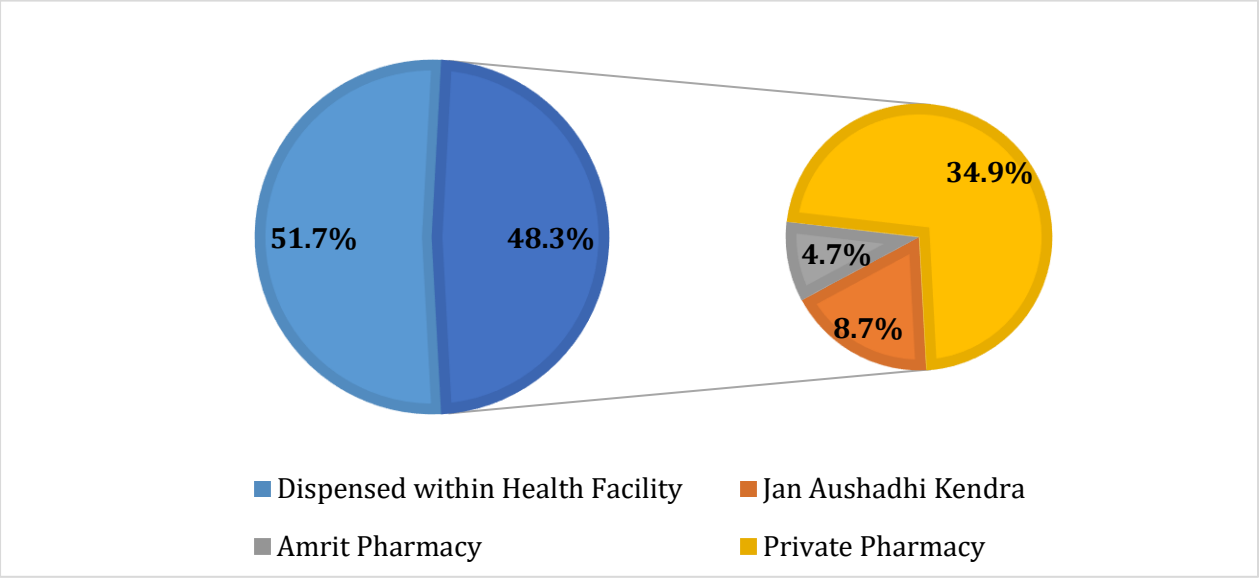


Table 13: Proportion of IPD patients visiting different type of pharmacies

	Medical College & Hospital	District Hospital	Overall
Patients getting at Least One Medicine from Health Facility	453 (61.9%)	241 (94.9%)	694 (70.4%)
Patients getting all Medicine from Health Facility	193 (26.4%)	81 (31.9%)	274 (27.8%)
Type of Pharmacy			
Jan Aushadhi Kendra	180 (24.6%)	16 (6.3%)	196 (19.9%)
Amrit Pharmacy	102 (13.9%)	5 (1.9%)	107 (10.9%)
Private Pharmacy	476 (65%)	166 (65.4%)	642 (65.1%)
Non-JAK (Amrit & Private)	578 (79%)	171 (67.3%)	749 (76%)

* % of Respondents

Figure 12: IPD Patients visiting different type of pharmacies as per disease status

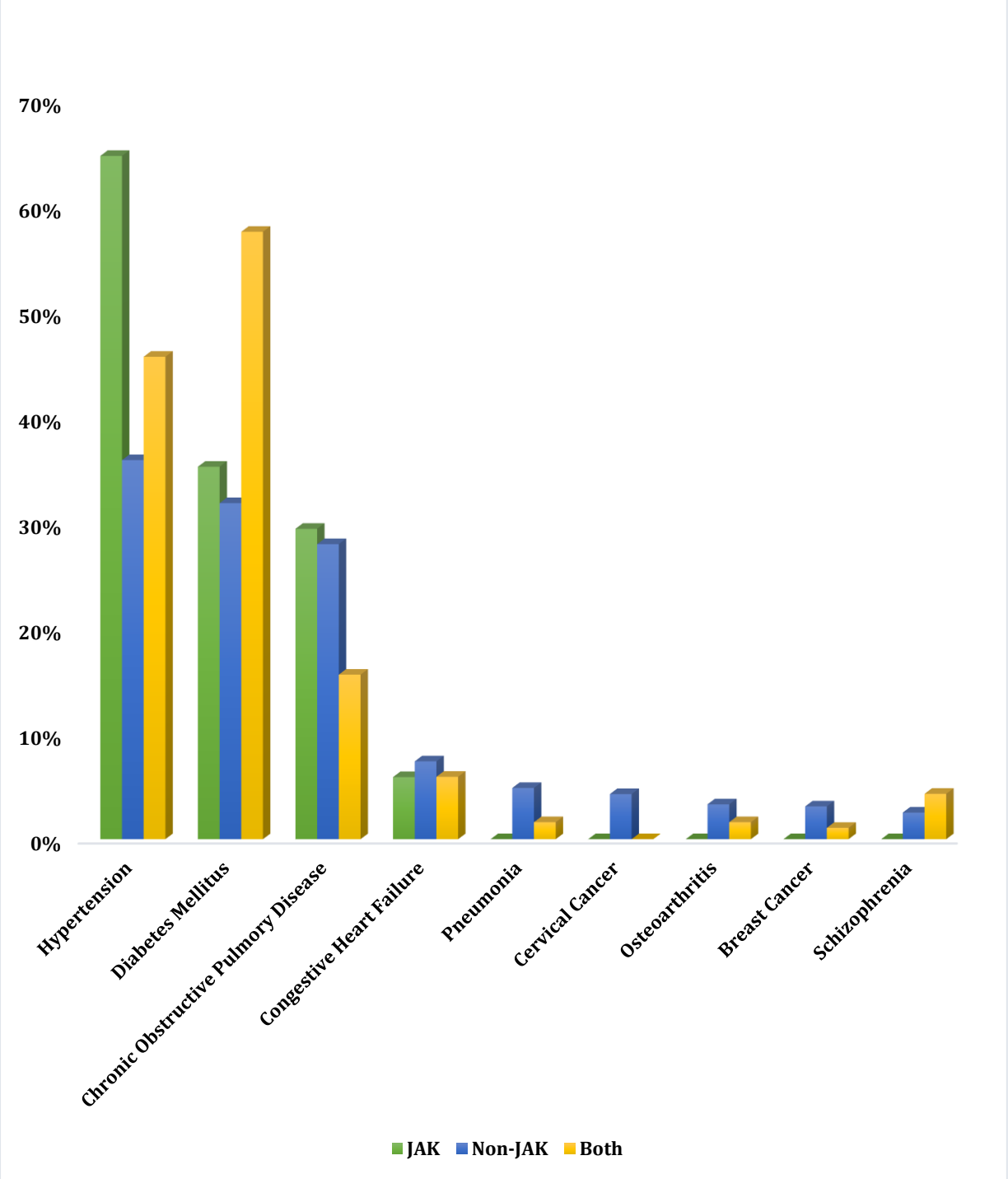


Figure 13: Reasons for not acquiring medicines from Jan Aushadhi Kendra by IPD patients

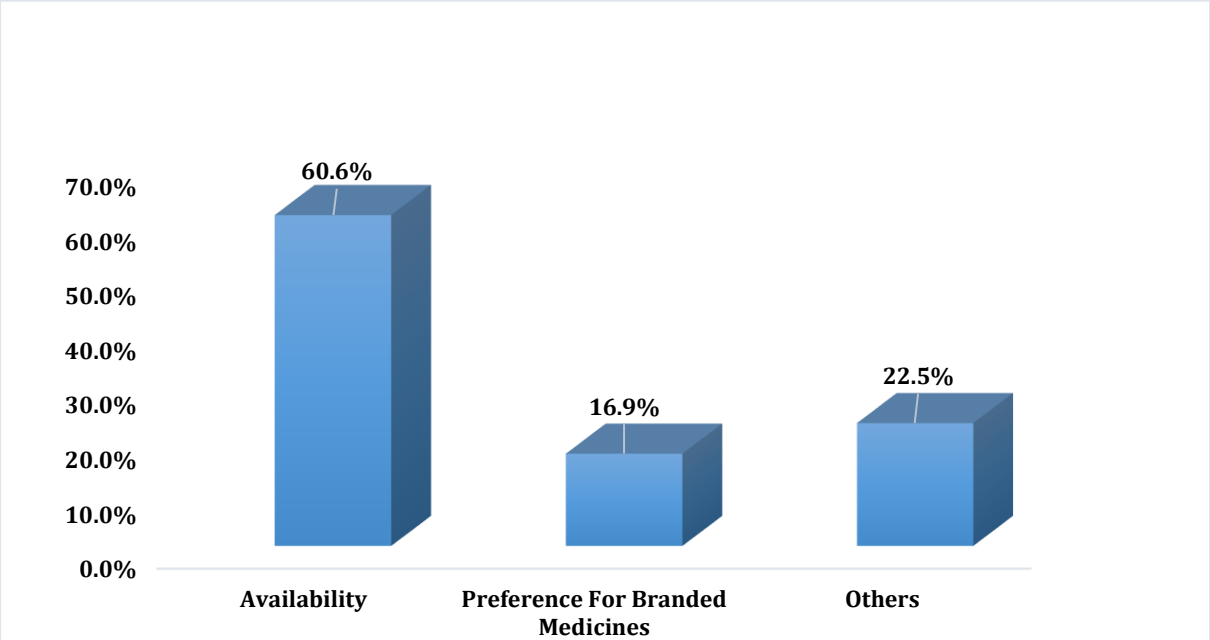
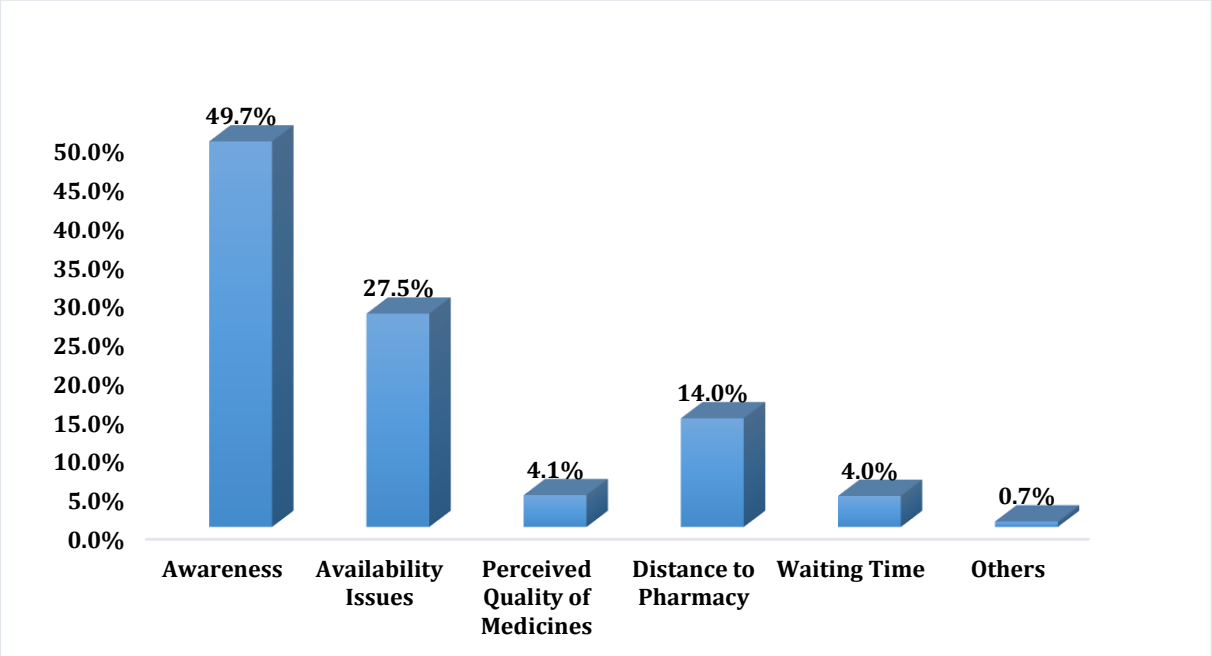


Figure 14: Reasons for not visiting Jan Aushadhi Kendra by IPD patients



Assessment of financial risk protection among IPD patients

Out of pocket expenditure on medicines by IPD patients

The IPD patients who visited PMBJP had the lowest mean out-of-pocket expenses (OOPE) at INR 275 (254.8). These patients were followed by those who visited PMBJP and other pharmacies [INR 3,038 (3557)] and those who visited other pharmacies alone [INR 3,165 (4440.4)]. Considering the type of hospital, IPD patients incurred a significantly higher OOPE in medical college and hospitals [INR 2,599 (4272.2)] than in district hospitals [INR 1,169 (1684.7)]. The highest OOPE was incurred by cancer patients [INR 2,489 (3844.2)] followed by other [INR 2,044 (3278.5)] and hypertension & diabetes [INR 1,654 (5020.8)]. It was observed that OOPE increased with increasing purchasing of drugs; the highest OOPE [INR 3,418 (5309.7)] was incurred by patients who purchased more than 8 drugs. The OOPE was found to be increasing with increase in level of diseases severity [INR 1,355 (2489.8) for mild, INR 2,552 (3943.5) for moderate and INR 2,795 (4620.3) for severe. Age of patient, type of disease, gender, occupational status, religion, caste, marital status, and area of residence did not show any significant association ($p>0.05$) with OOPE on medicines, but the difference in OOPE estimates for the outpatient department was found to be statistically significant ($p<0.05$) for a number of parameters, including pharmacy type, facility, education level, disease, family type, wealth quintile, number of drugs, disease severity, and health insurance status.

Table 14: Out of pocket expenditure on medicines by IPD patients

		N (%)	Mean (SD)	F-value	p-value
Type of Pharmacy Visited	PMBJP	17 (2.4%)	275 (254.8)	3.944	0.020*
	Non-PMBJP	515 (71.7%)	3165 (4440.4)		
	Both	186 (25.9%)	3038 (3557)		
Type of Facility	Medical College & Hospital	732 (74.2%)	2599 (4272.2)	7.525	<0.001**
	District Hospital	254 (25.8%)	1169 (1684.7)		
Type of Disease	Hypertension/Diabetes	493 (50.1%)	1654 (5020.8)	1.878	0.132
	Cancer	118 (12%)	2489 (3844.2)		
	Other	300 (30.5%)	2044 (3278.5)		
	Multiple	74 (7.5%)	2208 (3565.1)		
Age of Patient	Up to 19	13 (1.3%)	1893 (2020.9)	0.771	0.593
	20-29	50 (5.1%)	1632 (1552.6)		
	30-39	105 (10.6%)	2637 (5098.7)		
	40-49	186 (18.9%)	1930 (2787)		
	50-59	243 (24.6%)	2150 (4135)		
	60-69	250 (25.4%)	2442 (4182.6)		
	70+	139 (14.1%)	2336 (3379.5)		
Gender	Male	564 (57.2%)	2304 (3465.8)	0.695	0.487
	Female	422 (42.8%)	2133 (4270)		
Education Group	Illiterate	354 (35.9%)	2557 (4425.6)	2.005	0.045*
	literate	632 (64.1%)	2048 (3441.3)		
Occupation Group	Employed	389 (39.5%)	2317 (3620.3)	0.569	0.569
	Unemployed	597 (60.5%)	2175 (3961.9)		
Religion	Hindu	802 (81.3%)	2180 (3687.7)	2.249	0.081
	Muslim	137 (13.9%)	2384 (4476)		
	Sikh	3 (0.3%)	7800 (10612.7)		
	Christian	44 (4.5%)	2306 (3424.3)		
Caste Group	SC/ST	206 (20.9%)	2226 (4195.4)	1.354	0.259
	OBC	334 (33.9%)	2493 (3929)		
	General	446 (45.2%)	2037 (3565.4)		
Marital Status	Never Married	56 (5.7%)	2059 (3357.1)	0.301	0.740
	Married	865 (87.7%)	2265 (3867.3)		
	Separated/Widow	65 (6.6%)	1923 (3739.3)		
Insurance Group	None	606 (61.5%)	1421 (3247.1)	12.228	<0.001**
	Government Funded	251 (25.5%)	2701 (4219)		
	Private	129 (13.1%)	1596 (2321.6)		
Type Family	Nuclear	346 (35.1%)	1688 (3239.8)	3.52	<0.001**
	Joint	640 (64.9%)	2524 (4085.8)		
Wealth Quintile	Poorest	197 (20%)	2563 (4507.1)	2.998	0.018*
	Poor	198 (20.1%)	2653 (3282.5)		
	Middle	196 (19.9%)	2488 (4428.8)		
	Rich	193 (19.6%)	1624 (2420)		

	Richest	202 (20.5%)	1825 (4001.1)		
Area of Residence	Rural	730 (74%)	2392 (3842)	2.721	0.066
	Urban	250 (25.4%)	1795 (3803.7)		
	Slum	6 (0.6%)	755 (752.2)		
number of Drugs	<=4	137 (13.9%)	701 (790.4)	40.396	<0.001**
	5-8	432 (43.8%)	1570 (1887.5)		
	>8	417 (42.3%)	3418 (5309.7)		
Diseases Severity	Mild	329 (33.4%)	1355 (2489.8)	13.597	<0.001**
	Moderate	339 (34.4%)	2552 (3943.5)		
	Severe	318 (32.3%)	2795 (4620.3)		
Overall		**986**	**2231 (3829.6)**		

*Significant at 0.05, **Significant at 0.01

Determinants of Out-of-pocket expenditure on medicines by IPD patients

The factors influencing OOPE on medicines by IPD patients were also identified by the study. Out-of-pocket expenditure on drugs by IPD patients was found to be significantly impacted by the type of pharmacy, state, type of facility, and number of drugs purchased (Table 15). Patients who purchased drugs from PMBJP alone incurred significantly lesser OOPE as compared to those who purchased drugs from other pharmacies or both PMBJP & other pharmacies; and patients from medical colleges and hospitals (21.4%, $p<0.01$) incurred significantly higher OOPE than the patients from district hospitals. Significant increase in OOPE was found with increase in number of drugs (101%).

Table 15: Determinants of Out-of-pocket expenditure on medicines by IPD patients

		Medicine Expenditure with Log					
		Coef.	**Std. Err.**	**t**	**P>t**	**[95% Conf.**	**Interval]**
Number of Drugs Prescribed		0.698	0.051	13.640	<0.001**	0.598	0.798
Type of Pharmacy Ref. PMBJP	Non-PMBJP	2.231	0.179	12.480	<0.001**	1.880	2.582
	Both	1.643	0.183	8.990	<0.001**	1.284	2.001
State Ref Haryana	Rajasthan	0.823	0.155	5.330	<0.001**	0.520	1.127
	Uttar Pradesh	0.999	0.110	9.110	<0.001**	0.784	1.215
	Bihar	1.383	0.118	11.710	<0.001**	1.151	1.615
	Assam	0.315	0.117	2.680	0.007**	0.084	0.545
	Odisha	0.637	0.142	4.470	<0.001**	0.357	0.916
	Gujarat	-0.381	0.329	-1.160	0.248	-1.028	0.266
	Kerala	0.426	0.133	3.200	0.001**	0.165	0.688
	Tamil Nadu	0.888	0.313	2.830	0.005**	0.272	1.503
Type of facility Ref. DH	Medical Hospital	0.194	0.080	2.440	0.015*	0.038	0.351
Type of Family Ref. Nuclear	Joint	-0.094	0.064	-1.450	0.146	-0.220	0.033
Education Ref Illiterate	literate	-0.018	0.062	-0.290	0.771	-0.141	0.104
Health Insurance Ref. None	Government Funded	-0.115	0.096	-1.200	0.232	-0.304	0.074
	Private	-0.143	0.140	-1.020	0.307	-0.417	0.132
Wealth Quintile Ref Poorest	Poor	0.067	0.082	0.820	0.414	-0.094	0.228
	Middle	-0.043	0.086	-0.490	0.623	-0.212	0.127
	Rich	-0.173	0.090	-1.920	0.055	-0.350	0.004
	Richest	-0.072	0.096	-0.750	0.453	-0.261	0.117
Diseases Severity Ref Mild	Moderate	-0.035	0.070	-0.500	0.617	-0.173	0.103
	Severe	-0.108	0.083	-1.300	0.194	-0.270	0.055
Constant		3.443	0.229	15.050	<0.001**	2.993	3.892
R Square		0.5153					
Adjusted R Square		0.4981					

*Significant at 0.05, **Significant at 0.01

Catastrophic health expenditure and impoverishment rate among IPD patients

The overall prevalence of catastrophic health expenditure among IPD patients was found to be 35.4% and 21.9% were impoverished. 5.9% of IPD patient who purchased drugs from PMBJP had catastrophic health expenses, followed by 45.4% who purchased drugs from both PMBJP and other pharmacies and 50% who purchased drugs from other pharmacies. Furthermore, the prevalence of CHE was highest among inpatients belonging to rural areas (41.3%) followed by urban areas (18%) and slum area (16.7%). The prevalence of CHE among patients who got treatment from medical college and hospital

was highest (39.8%) versus (23.1%) district hospital patients. The prevalence of CHE among hospitalised patients was highest (69.4%) among poorest income group (versus 8.4% among richest quintile). The prevalence of CHE also increased with increase in the number of drugs prescribed; 16.3% for less than 5 drugs, 31% for 5-8 and 46.9% more than 8 drugs. The prevalence of CHE increased as the level of disease's severity increased (range: 24.8% to 42.6%).

Impoverishment was found to be concentrated more among patients who visited other pharmacies except PMBJP (31.1%) than those who visited only PMBJP (0%). The prevalence of impoverishment ranged from 7.2% to 26.6% across different diseases groups among IPD patients. Patients belonging to rural areas faced the greatest impact of impoverishment (27.2%). However, impoverishment was found to be more concentrated among medical college and hospital patients (24%) as compared to district hospital's patients (16.1%). The prevalence of impoverishment increases with increase in the level of diseases severity, from mild to severe groups (13.1% to 28.3%) as well as number of drugs prescribed (5.7% to 33.2%).

A logistic regression analysis was performed to ascertain the variables affecting impoverishment and catastrophic health expenditure. The analysis's findings indicated that patients who bought their medicines from other pharmacies had a considerably higher chance of developing CHE (β = 47.134, $p<0.01$) than those who bought their medicines from PMBJP. Patients from medical college and hospitals had a significantly 4 times higher likelihood of experiencing CHE than those from district hospitals. The odds of CHE were 60.8%, 87%, 95.5%, and 97.3% lower for poor, middle, rich and richest income quintiles respectively and were found to be statistically significant ($p<0.01$).

Number of drugs purchased were significantly associated with higher odds of CHE (β=1.102; p<0.05). As compared to patients with mild diseases severity, the likelihood of CHE was approximately 31% and 78.7% higher among those who had moderate and severe diseases severity, respectively.

The results of the analysis showed that the likelihood of impoverishment was about 45.2% higher for patients who purchased medicines only from private pharmacies (β=1.452) as compared to those who purchased drugs form PMBJP; however, the odds were found to be statistically insignificant (p>0.05). The odds of impoverishment were also found to be significantly higher (β=3.015, p<0.01) for medical college and hospital patients than that of district hospital patients. The odds of impoverishment were found significantly to be 93.7%, 99.3%, 99.9%, and 99.9% lower for the middle, rich and the richest wealth quintile as compared to the poorest wealth quintile, respectively (p<0.01). Those with severe disease severity were around three times more likely to be impoverished, respectively, than those with mild disease severity. The quantity of drugs bought was substantially linked to increased chances of poverty (β=1.157; p<0.01).

Table 16: Catastrophic health expenditure and impoverishment rate among IPD patients

		Catastrophic			Impoverishment		
		N (%)	Odds Ratio	p-value	N (%)	Odds Ratio	p-value
Facility Level	PMBJP	1 (5.9%)	**Reference**		0 (0%)	**Reference**	
	Non-PMBJP	252 (50%)	47.134	0.001**	126 (31.1%)	1.452	0.283
	Both	83 (45.4%)	20.215	0.007**	50 (32.1%)		
Type of Facility	District Hospital	58 (23.1%)	**Reference**		35 (16.1%)	**Reference**	
	Medical College and Hospital	278 (39.8%)	3.830	<0.001**	141 (24%)	3.015	0.009**
Age of Patient	Up to 19	6 (46.2%)	1	0.959	2 (18.2%)	1.005	0.679
	20-29	21 (43.8%)			11 (24.4%)		
	30-39	39 (39%)			15 (17.9%)		
	40-49	53 (29.3%)			25 (15.9%)		
	50-59	80 (33.8%)			43 (21.1%)		
	60-69	81 (34.2%)			54 (27.7%)		
	70+	56 (42.1%)			26 (23.9%)		
Type of Disease	Hypertension/Diabetes	179 (38.2%)	**Reference**		99 (24.7%)	**Reference**	
	Cancer	17 (15.6%)	0.560	0.220	7 (7.2%)	0.955	0.947
	Other	115 (38.7%)	1.144	0.563	53 (21.9%)	0.947	0.874
	Multiple	25 (34.2%)	0.919	0.829	17 (26.6%)	1.694	0.319
Religion	Hindu	274 (35.6%)	**Reference**		144 (22.6%)	**Reference**	
	Muslim	48 (36.4%)	1.285	0.383	25 (20.3%)	0.846	0.688
	Sikh	2 (66.7%)	0.841	0.927	0 (0%)	1.000	
	Christian	12 (27.3%)	1.008	0.988	7 (16.3%)	0.899	0.873
Area of Residence	Rural	293 (41.3%)	**Reference**		158 (27.2%)	**Reference**	
	Urban	42 (18%)	0.64	0.097	17 (7.8%)	0.52	0.118
	Slum	1 (16.7%)	1.698	0.685	1 (16.7%)	8.057	0.157
Caste Group	SC/ST	76 (38.2%)	**Reference**		42 (28.2%)	**Reference**	
	OBC	122 (39.4%)	0.905	0.718	65 (25.3%)	0.614	0.227
	General	138 (31.4%)	1.241	0.453	69 (17.3%)	0.927	0.861
Education Group	Illiterate	133 (39.7%)	**Reference**		75 (30.4%)	**Reference**	
	literate	203 (33.1%)	1.057	0.817	101 (18.1%)	0.391	0.008**
Type Family	Nuclear	101 (29.4%)	**Reference**		51 (16.1%)	**Reference**	

	Joint	235 (38.8%)	1.133	0.591	125 (25.6%)	5.802	<0.001**
Insurance Group	None	247 (43.4%)	**Reference**		132 (28.7%)	**Reference**	
	Government Funded	52 (20.7%)	0.836	0.532	22 (9.9%)	0.674	0.401
	Private	37 (28.7%)	1.093	0.782	22 (18%)	1.053	0.903
Occupation Group	Employed	152 (39.6%)	**Reference**		79 (24%)	**Reference**	
	Unemployed	184 (32.6%)	0.925	0.702	97 (20.4%)	1.029	0.923
Marital Status	Never Married	24 (43.6%)	**Reference**		8 (17%)	**Reference**	
	Married	295 (35.5%)	0.723	0.469	161 (23%)	1.364	0.641
	Separated/Widow	17 (26.6%)	1.032	0.961	7 (11.9%)	0.558	0.537
Wealth Quintile	Poorest	118 (69.4%)	**Reference**		29 (65.9%)	**Reference**	
	Poor	105 (55.6%)	0.392	0.002**	90 (52%)	0.063	<0.001**
	Middle	64 (32.7%)	0.130	<0.001**	41 (21.1%)	0.007	<0.001**
	Rich	32 (16.7%)	0.045	<0.001**	10 (5.2%)	0.001	<0.001**
	Richest	17 (8.4%)	0.027	<0.001**	6 (3%)	0.001	<0.001**
Number of Drugs Prescribed	Up to 4	22 (16.3%)	1.102	<0.001**	7 (5.7%)	1.157	<0.001**
	5-8	132 (31%)			66 (17.7%)		
	>8	182 (46.9%)			103 (33.2%)		
Diseases Severity Equal Proportion	Mild	81 (24.8%)	**Reference**		36 (13.1%)	**Reference**	
	Moderate	134 (39.5%)	1.310	0.276	70 (24.7%)	1.997	0.066
	Severe	121 (42.6%)	1.787	0.043*	70 (28.3%)	2.915	0.011*
Overall		**35.40%**			**21.90%**		

*Significant at 0.05, **Significant at 0.01

Pharmacy

Assessment of prescription pattern and coverage of PMBJP among patients recruited from pharmacies

On average, patients enrolled at pharmacy were prescribed 4.3 medicines, of which 14.9% (0.64) were generic and 85.1% (3.66) weren't (Table 17). Patients were prescribed pills or capsules in 98.2 percent of cases, syrup in 16.7%, lotion in 12.6%, and injections in 8.4% of cases. Patients in the OPD received 25.3% of the medicines, whereas patients in the IPD received 36.1%. Seventy four percent of the medicines were bought from pharmacies; of these, 18.6 percent were bought from Jan Aushadhi Kendra, 3.1% from Amrit Pharmacy, and 52.2% from private pharmacies (Table-19).

Out of the pharmacy patients, 41 percent had at least one medicine from the health facility; of these, 40.2% were OPD patients and 54.6% were IPD patients. Among pharmacy patients, Jan Aushadhi Kendra was visited by 29.4%, Amrit Pharmacy by 4.7%, private pharmacies by 79.3%, and both Amrit and private pharmacies by 84.1% (Table 20). A lack of awareness prevented 43.1% of patients from visiting Jan Aushadhi Kendra, and 62.6% of patients were unable to obtain medicines due to unavailability.

Table 17: Number and Types of Dosage forms prescribed to patients recruited at Pharmacy

Number of Drugs Prescribed Per Person (%)			
	OPD	**IPD**	**Overall**
Average Number of Medicine Prescribed	4.16	7.38	4.30
Generics	0.59 (14.3%)	1.67 (22.6%)	0.64 (14.9%)
Non-Generics	3.57 (85.7%)	5.71 (77.4%)	3.66 (85.1%)
Type of Dosage Form			
Number of Capsules /Tablets	3.72	4.27	3.74
Number of Injections	0.11	2.45	0.21
Number of Syrups	0.18	0.36	0.19
Number of Lotions	0.15	0.30	0.16

Figure 15: Analysis of prescription according to dosage forms

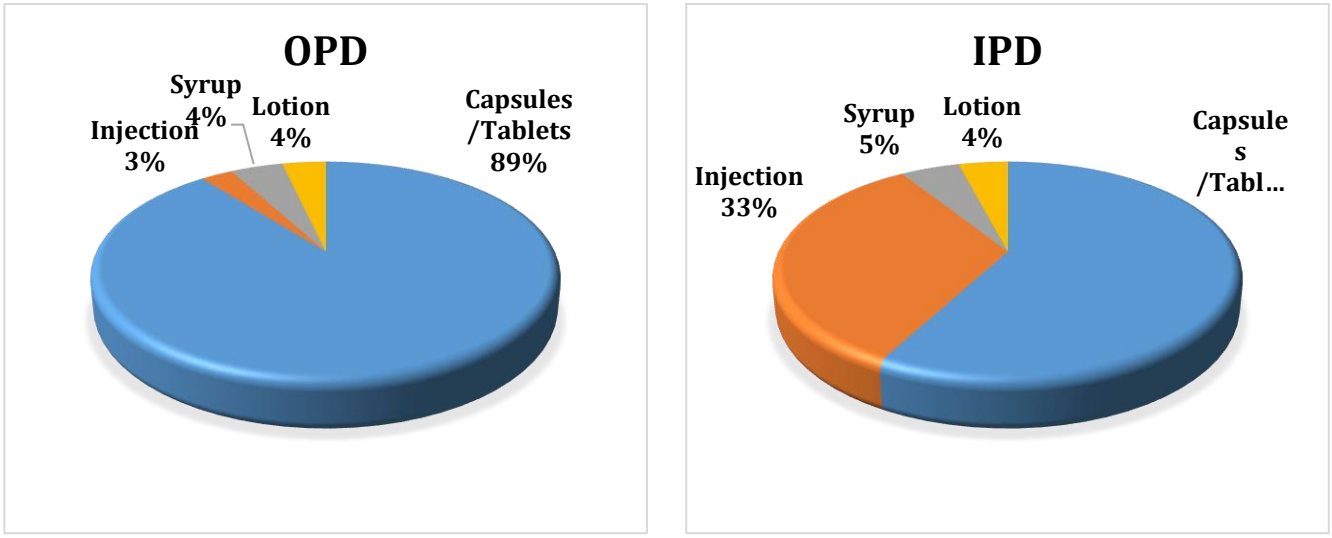


Table 18: Percentage of patients as per the type of dosage form prescribed in patients recruited at Pharmacy

Prescribed Medicine	OPD	IPD	Overall
Capsules / Tablets	5976 (98.6%)	243 (90.3%)	6219 (98.2%)
Syrup	973 (16.1%)	86 (32%)	1059 (16.7%)
Lotion	734 (12.1%)	64 (23.8%)	798 (12.6%)
Injection	374 (6.2%)	160 (59.5%)	534 (8.4%)

Table 19: Proportion of medicines obtained at different type of pharmacies by patients recruited at Pharmacy

	OPD	IPD	Overall
Dispensed within Health Facility	6390 (25.3%)	717 (36.1%)	7107 (26.1%)
To be Purchased from Pharmacy	18832 (74.7%)	1268 (63.9%)	20100 (73.9%)
Type of Pharmacy			
Jan Aushadhi Kendra	4858 (19.3%)	217 (10.9%)	5075 (18.6%)
Amrit Pharmacy	645 (2.6%)	186 (9.4%)	831 (3.1%)
Private Pharmacy	13329 (52.8%)	865 (43.6%)	14194 (52.2%)

Note % of Medicines

Figure 16: Proportion of medicines obtained at different type of pharmacies by patients recruited at Pharmacy

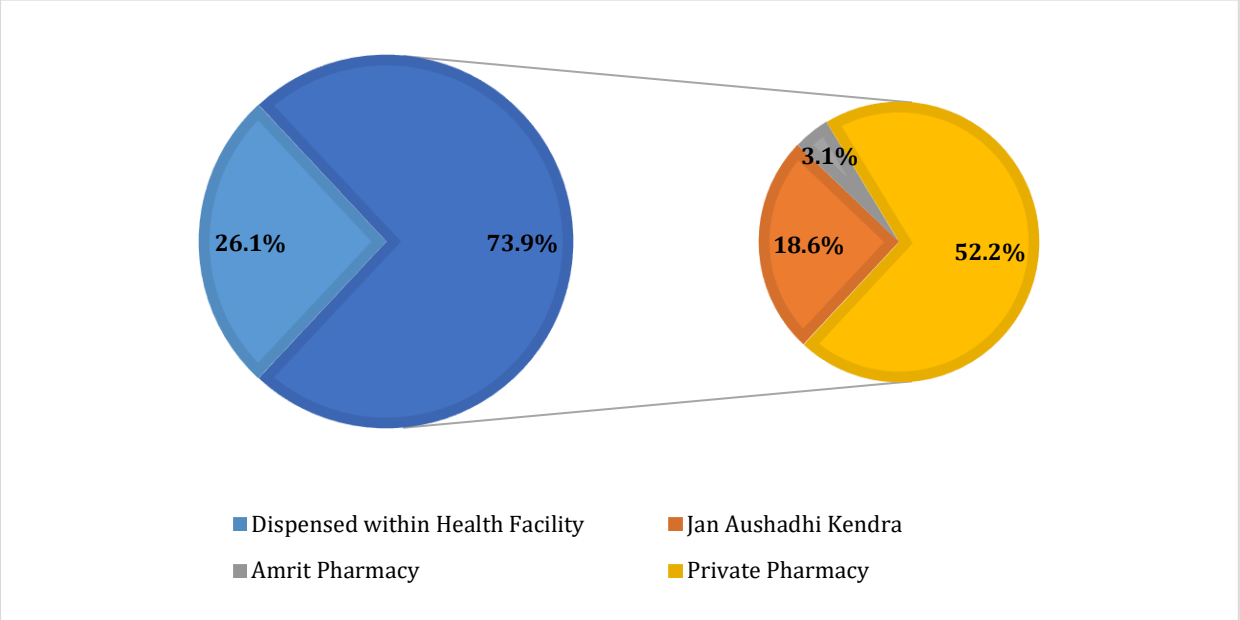


Table 20: Proportion of patients visiting different type of pharmacies

	OPD	IPD	Overall
Patients getting at Least One Medicine from Health Facility	2448 (40.2%)	147 (54.6%)	2595 (41%)
Type of Pharmacy			
Jan Aushadhi Kendra	1813 (29.9%)	48 (17.8%)	1861 (29.4%)
Amrit Pharmacy	260 (4.3%)	40 (14.9%)	300 (4.7%)
Private Pharmacy	4791 (79%)	231 (85.9%)	5022 (79.3%)
Non-JAK (Amrit & Private)	5051 (83.3%)	271 (100.7%)	5322 (84.1%)

Note % of Respondents

Figure 17: Patients visiting different type of pharmacies as per disease status

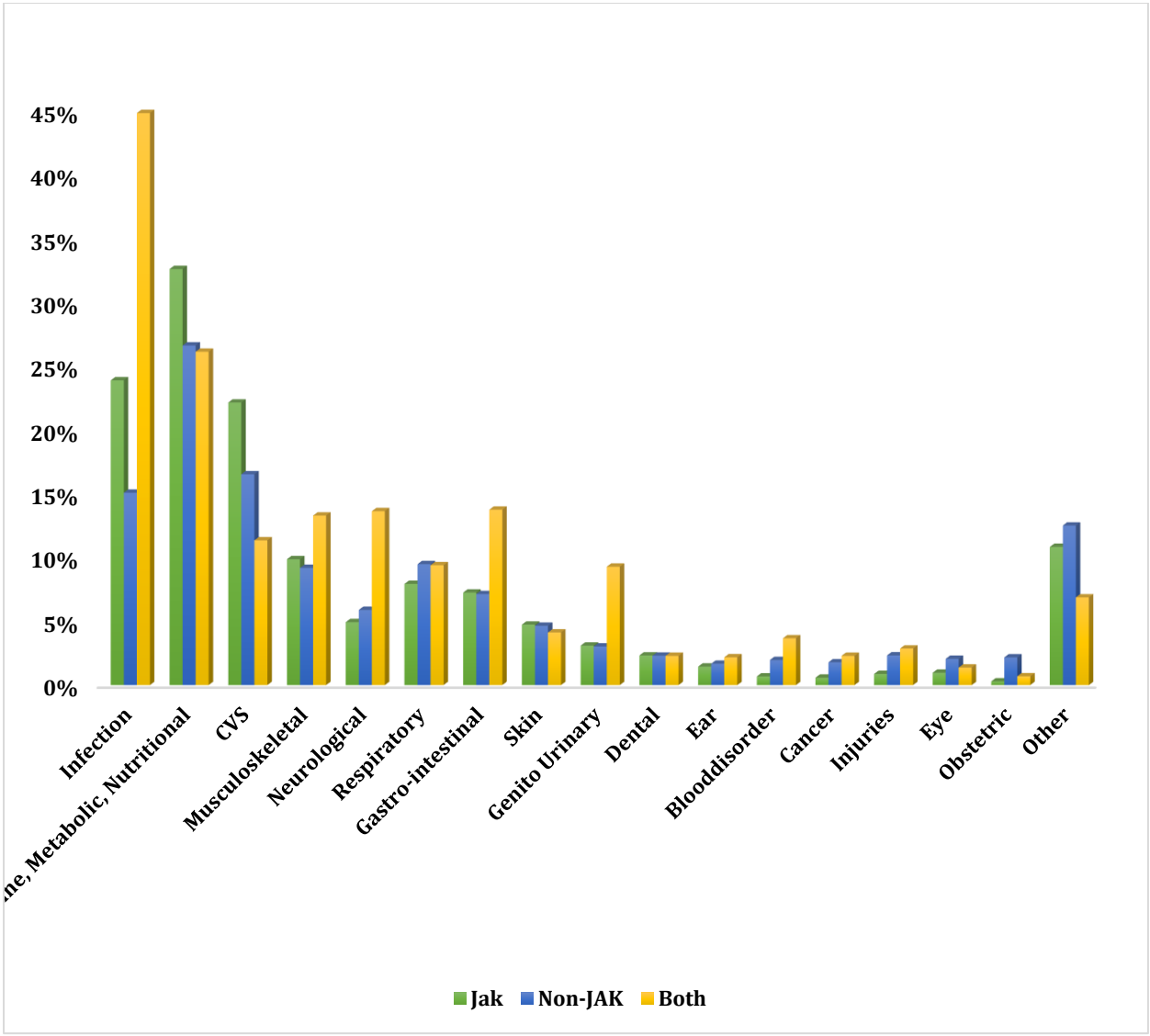


Figure 18: Reasons for not acquiring medicines from Jan Aushadhi Kendra by patients recruited at Pharmacy

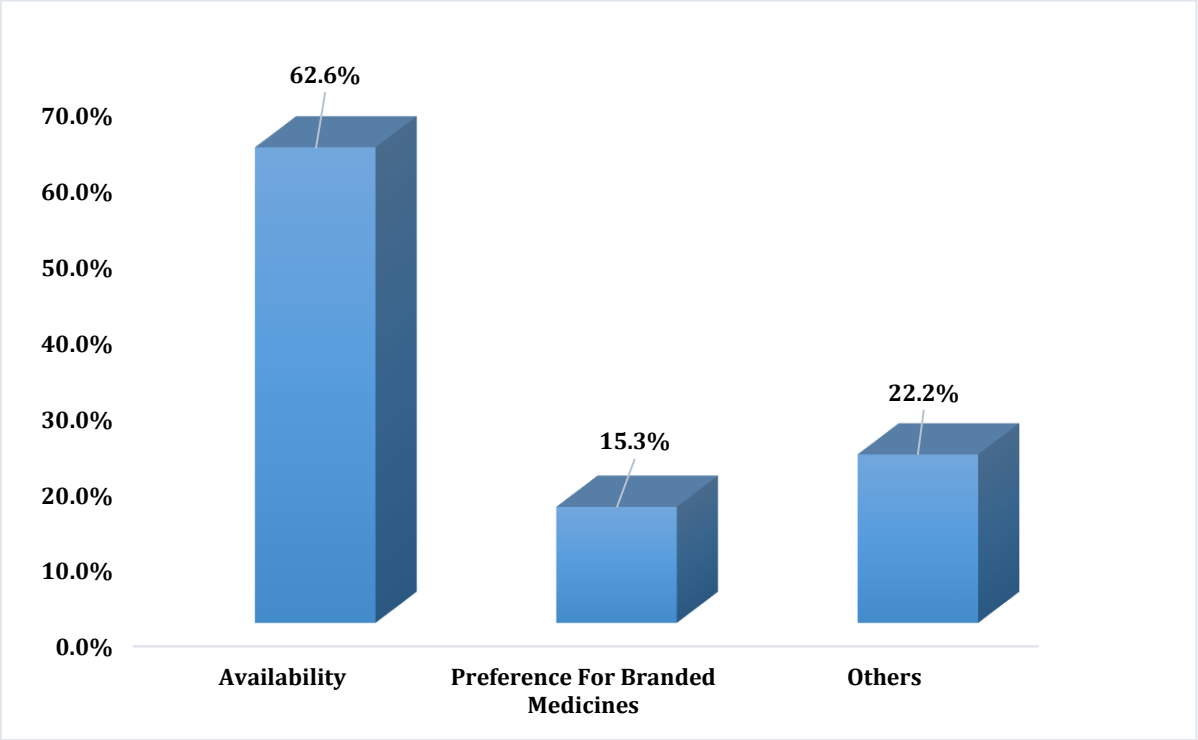
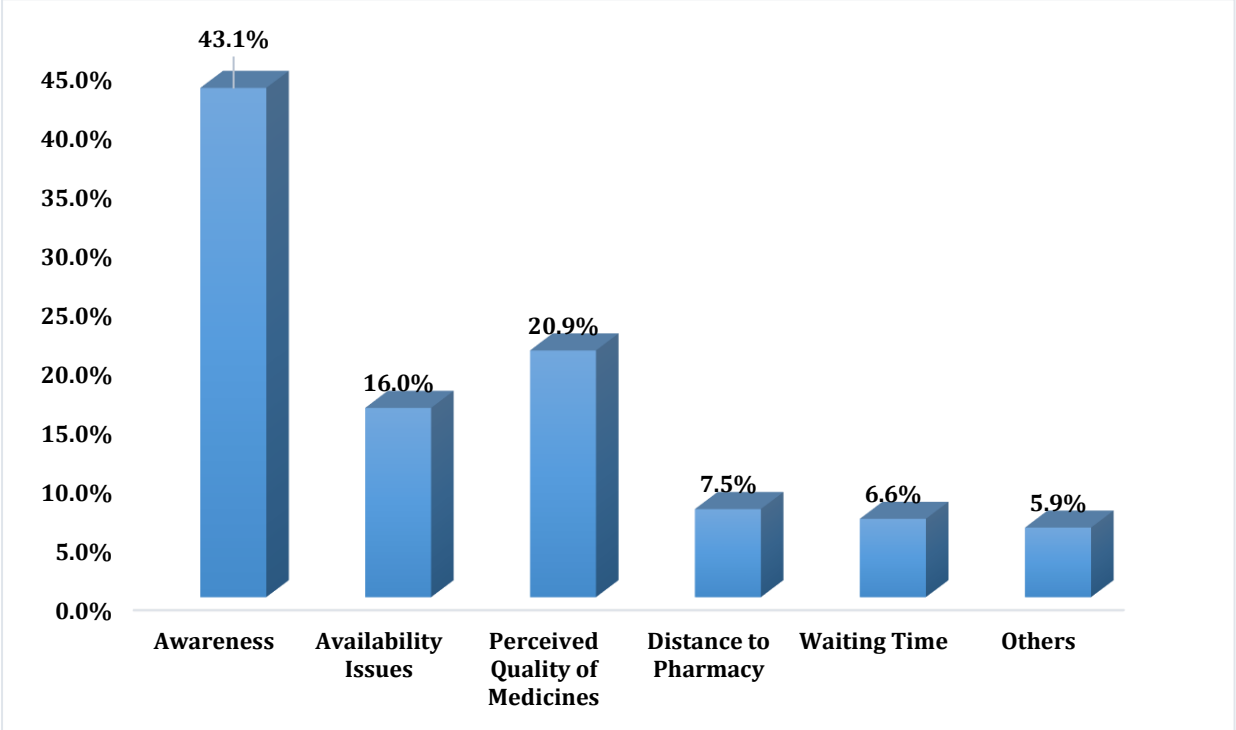


Figure 19: Reasons for not visiting Jan Aushadhi Kendra by patients recruited at Pharmacy



Assessment of financial risk protection

Out of pocket expenditure on medicines among patients recruited from pharmacies

The patients who visited PMBJP had mean out-of-pocket expenses (OOPE) of INR 307 (344.8), which was the lowest. These patients were followed by those who visited PMBJP and other pharmacies [INR 987 (1034.7)] and those who visited other pharmacies alone [INR 1,031 (2298.2)]. Compared to OPD patients [INR 842 (1803.6)], IPD patients saw a substantially greater OOPE [INR 2,369 (4123.1)]. Cancer patients had the highest OOPE [INR 1,889 (4661.1)], followed by multiple [INR 1,072 (1985.2)], diabetes & hypertension [INR 873 (1517)], and ENT [INR 684 (1424)]. It was shown that as the amount of pharmaceuticals purchased increased, so did the OOPE; patients who bought more than eight drugs incurred the highest OOPE [INR 2,233 (3891.7)]. With a rise in the severity of the disease, the OOPE was shown to be rising [INR 875 (1964.1) for mild, INR 853 (1867.8) for moderate, and INR 996 (2110) for severe].

The patient's age, gender, education level, occupation, caste, religion, marital status, health insurance status, family structure, and area of residence did not significantly associated ($p>0.05$) with the OOPE on medicines; however, the variation in OOPE estimates for several factors, such as patient type, pharmacy type, wealth quintile, number of drugs, and caste, was found to be statistically significant ($p<0.05$).

Table 21: Out of pocket expenditure of patients recruited at Pharmacy

		N (%)	Mean (SD)	F-value	p-value
Type Pharmacy Visited	PMBJP	1033 (16.3%)	307 (344.8)	57.787	<0.001**
	Non-PMBJP	4426 (69.9%)	1031 (2298.2)		
	Both	872 (13.8%)	987 (1034.7)		
Type of Patient	OPD	6062 (95.8%)	842 (1803.6)	6.049	<0.001**
	IPD	269 (4.2%)	2369 (4123.1)		
Type of Disease	None	664 (10.5%)	888 (1910.4)	8.353	<0.001**
	Hypertension & Diabetic	1776 (28.1%)	873 (1517)		
	Cancer	77 (1.2%)	1889 (4661.1)		
	Miscellaneous	1595 (25.2%)	941 (2492.3)		
	ENT	1088 (17.2%)	684 (1424)		
	Multiple	1131 (17.9%)	1072 (1985.2)		
Age of Patient	Up to 19	545 (8.6%)	784 (1900.7)	1.210	0.298
	20-29	920 (14.5%)	917 (1974)		
	30-39	984 (15.5%)	881 (2003.7)		
	40-49	1183 (18.7%)	953 (2323.2)		
	50-59	1220 (19.3%)	872 (1552.8)		
	60-69	978 (15.4%)	1020 (2232.9)		
	70+	501 (7.9%)	830 (1524)		
Education Group	Illiterate	1364 (21.5%)	977 (2213.4)	1.359	0.174
	literate	4967 (78.5%)	888 (1913.7)		
Occupation Group	Employed	2390 (37.8%)	899 (2180.7)	0.249	0.803
	Unemployed	3941 (62.2%)	912 (1851.8)		
Religion	Hindu	5346 (84.4%)	909 (1977.9)	0.101	0.959
	Muslim	782 (12.4%)	912 (2148.3)		
	Sikh	16 (0.3%)	744 (606.4)		
	Christian	187 (3%)	845 (1374.5)		
Caste Group	SC/ST	840 (13.3%)	842 (2074)	1.889	0.138
	OBC	2183 (34.5%)	863 (1931.6)		
	General	3308 (52.3%)	953 (1990.9)		
Marital Status	Never Married	1104 (17.4%)	843 (1992.7)	0.713	0.49
	Married	5064 (80%)	920 (1990.1)		
	Separated/Widow	163 (2.6%)	939 (1638.7)		
Insurance Group	None	4604 (72.7%)	906 (1977.1)	1.122	0.326
	Government Funded	1362 (21.5%)	947 (1538.8)		
	Private	365 (5.8%)	772 (3166.2)		
Type Family	Nuclear	2709 (42.8%)	904 (1907.2)	0.100	0.916
	Joint	3622 (57.2%)	909 (2036.8)		
Wealth Quintile	Poorest	1268 (20%)	781 (1434.8)	7.033	<0.001**
	Poor	1264 (20%)	825 (1800.1)		
	Middle	1273 (20.1%)	865 (1912.3)		
	Rich	1260 (19.9%)	907 (2170.9)		
	Richest	1266 (20%)	1157 (2431.1)		
Area of Residence	Rural	3329 (52.6%)	907 (1911.5)	0.279	0.757
	Urban	2978 (47%)	910 (2066.1)		
	Slum	24 (0.4%)	607 (327.5)		

number of Drugs	<=4	4038 (63.8%)	727 (1652.5)	97.220	<0.001**
	5-8	1971 (31.1%)	1058 (2045.8)		
	>8	322 (5.1%)	2233 (3891.7)		
Diseases Severity	Mild	2154 (34%)	875 (1964.1)	3.147	0.043*
	Moderate	2123 (33.5%)	853 (1867.8)		
	Severe	2054 (32.4%)	996 (2110)		
Gender	Male	3423 (54.1%)	924 (2183.6)	0.767	0.443
	Female	2908 (45.9%)	887 (1715.3)		

*Significant at 0.05, **Significant at 0.01

Determinants of Out-of-pocket expenditure on medicines among patients recruited from pharmacies

The study also determined the factors affecting OOPE on medicines by pharmacy patients. The results of the regression analysis showed that type of pharmacy, state, type of patients, wealth quintile, type of diseases, diseases severity and number of drugs purchased significantly impacted out-of-pocket expenditure on drugs by patients enrolled at pharmacy (Table 22). The OOPE incurred by only other pharmacy 's patients (185.8%) or both PMBJP and other pharmacy's patients (153.7) were found to be significantly higher ($p<0.01$) as compared to those who purchased drugs from PMBJP only. In addition, OOPE incurred by IPD patients (57%, $p<0.01$) was significantly higher as compared to OPD patients. Significant increase in OOPE was found with increase in number of drugs (127.7%). Further, patients having mild diseases severity were found to have lower OOPE as compared to those who were had moderate (6.5%; $p<0.01$). OOPE incurred by patients belonging to poor (10.2%), rich (9.1%), and richest (33.4%) wealth quintiles were significantly higher ($p<0.05$) as compared to those from the poorest income groups.

Table 22: Determinants of Out-of-pocket expenditure of patients recruited at Pharmacy

		Out of Pocket Expenditure					
		Coef.	Std. Err.	t	P>t	[95% Conf.	Interval]
Type of Pharmacy Ref. PMBJP	Non-JAK	1.050	0.043	24.490	<0.001**	0.966	1.134
	Both	0.931	0.030	31.310	<0.001**	0.873	0.989
State Ref Haryana	Rajasthan	0.674	0.047	14.230	<0.001**	0.581	0.767
	Uttar Pradesh	1.280	0.050	25.490	<0.001**	1.182	1.379
	Bihar	1.166	0.046	25.220	<0.001**	1.076	1.257
	Assam	0.497	0.048	10.430	<0.001**	0.404	0.590
	Odisha	1.382	0.067	20.760	<0.001**	1.251	1.512
	Gujarat	0.723	0.055	13.030	<0.001**	0.614	0.831
	Kerala	0.545	0.051	10.660	<0.001**	0.445	0.646
	Tamil Nadu	1.671	0.059	28.200	<0.001**	1.555	1.787
Type of patients Ref. OPD	IPD	0.451	0.055	8.120	<0.001**	0.342	0.559
Wealth Quintile Ref Poorest	Poor	0.097	0.035	2.770	0.006**	0.028	0.165
	Middle	0.043	0.036	1.210	0.228	-0.027	0.113
	Rich	0.087	0.040	2.190	0.028*	0.009	0.165
	Richest	0.288	0.043	6.690	<0.001**	0.203	0.372
Type of Diseases Ref. None	Hyp & Dia	0.188	0.047	4.000	<0.001**	0.096	0.280
	Cancer	0.479	0.106	4.510	<0.001**	0.271	0.686
	Misc	0.020	0.044	0.460	0.646	-0.066	0.107
	ENT	-0.160	0.048	-3.360	0.001**	-0.254	-0.067
	Multiple	0.108	0.051	2.120	0.034*	0.008	0.208
Number of Drugs Purchased		0.823	0.022	37.920	<0.001**	0.781	0.866
Diseases Severity Ref Mild	Moderate	0.063	0.031	2.060	0.039*	0.003	0.124
	Severe	0.070	0.036	1.930	0.054	-0.001	0.141
Constant		3.000	0.072	41.630	<0.001**	2.859	3.141
R Square		0.4545					
Adjusted R-Square		0.4525					

*Significant at 0.05, **Significant at 0.01

Catastrophic health expenditure and impoverishment rate among patients recruited from pharmacies

The overall prevalence of catastrophic health expenditure among patients enrolled at pharmacy was found to be 8.3% and 6.3% were impoverished. Only 2% of pharmacy patient who purchased drugs from PMBJP had catastrophic health expenses, followed by 5.5% who purchased drugs from both PMBJP and other pharmacies and 16.4% who

purchased drugs from other pharmacies. Furthermore, the prevalence of CHE was highest among inpatients belonging to rural areas (11.3%) followed by urban areas (2%). The prevalence of CHE among IPD patients was highest (22.8%) versus (5.6%) OPD patients. The prevalence of CHE among hospitalised patients was highest (34.4%) among poorest income group (versus 0% among richest quintile). The prevalence of CHE also increased with increase in the number of drugs prescribed; 4.1% for less than 5 drugs, 9.2% for 5-8 and 18.6% more than 8 drugs. The prevalence of CHE increased as the level of disease's severity increased (range: 8% to 16.7%).

Impoverishment was found to be concentrated more among patients who visited other pharmacies except PMBJP (18.3%) than those who visited only PMBJP (1.3%). Patients belonging to rural areas faced the greatest impact of impoverishment (12.8%). However, impoverishment was found to be more concentrated among IPD patients (27.9%) as compared to OPD patients (7.5%). The prevalence of impoverishment increases with increase in the level of diseases severity, from mild to severe groups (4.1% to 14%) as well as number of drugs prescribed (4.6% to 25%).

A logistic regression analysis was performed to ascertain the variables affecting impoverishment and catastrophic health expenditure. The analysis's findings indicated that patients who bought their medicines from other pharmacies had a considerably higher chance of developing CHE ($\beta = 9.458$, $p<0.01$) than those who bought their medicines from PMBJP. OPD Patients had a significantly 40.9% lesser likelihood of experiencing CHE than those from IPD patients. The odds of CHE were 41.6%, 65%, 94.1%, and 96.7% lower for poor, middle, rich and richest income quintiles respectively

and were found to be statistically significant (p<0.01). Number of drugs purchased were significantly associated with higher odds of CHE (β=1.246; p<0.01).

The results of the analysis showed that the likelihood of impoverishment was about 5 times higher for patients who purchased medicines only from private pharmacies (β=4.615) as compared to those who purchased drugs form PMBJP; however, the odds were found to be statistically insignificant (p>0.01). The odds of impoverishment were found significantly to be 82.8%, 96.6%, and 99.6% lower for the poor, middle, and rich wealth quintile as compared to the poorest wealth quintile, respectively (p<0.01). The quantity of drugs bought was substantially linked to increased chances of poverty (β=1.238; p<0.01).

Table 23: Catastrophic and impoverishment for patients recruited at Pharmacy

		CHE			IR		
		N (%)	**Odds Ratio**	**p-value**	**N (%)**	**Odds Ratio**	**p-value**
Type of Facility Visited	PMBJP	17 (2%)	**Reference**		13 (1.3%)	**Reference**	
	Non-PMBJP	107 (16.4%)	9.458	<0.001**	159 (18.3%)	4.615	0.001**
	Both	210 (5.5%)	7.451	<0.001**	350 (8%)	2.653	<0.001**
Type of Patient	OPD	287 (5.6%)	0.591	0.004**	448 (7.5%)	0.619	0.058
	IPD	47 (22.8%)	**Reference**		74 (27.9%)	**Reference**	
Age of Patient	Up to 19	33 (7%)	0.989	0.007**	41 (7.6%)	0.99	0.048*
	20-29	71 (9%)			102 (11.2%)		
	30-39	47 (5.6%)			72 (7.4%)		
	40-49	65 (6.4%)			102 (8.7%)		
	50-59	45 (4.4%)			88 (7.3%)		
	60-69	55 (6.9%)			81 (8.3%)		
	70+	18 (4.8%)			36 (7.3%)		
Education Group	Illiterate	115 (12.8%)	**Reference**		186 (13.9%)	**Reference**	
	literate	219 (5%)	0.800	0.073	336 (6.8%)	0.674	0.017*
Occupation Group	Employed	114 (5.6%)	**Reference**		177 (7.5%)	**Reference**	
	Unemployed	220 (6.8%)	1.078	0.572	345 (8.8%)	1.621	0.010*
Caste Group	SC/ST	49 (7.7%)	**Reference**		65 (7.8%)	**Reference**	
	OBC	128 (7.2%)	1.336	0.077	191 (8.8%)	0.766	0.231
	General	157 (5.4%)	1.836	<0.001**	266 (8.1%)	0.976	0.907
Marital Status	Never Married	64 (6.9%)	**Reference**		100 (9.1%)	**Reference**	
	Married	265 (6.3%)	1.163	0.365	411 (8.2%)	1.709	0.019
	Separated/Widow	5 (3.6%)	1.527	0.298	11 (7%)	1.607	0.426
Insurance Group	None	284 (7.8%)	**Reference**		439 (9.7%)	**Reference**	
	Government Funded	38 (2.9%)	1.25	0.216	60 (4.4%)	0.882	0.607

	Private	12 (3.7%)	1.402	0.175	23 (6.3%)	0.900	0.760
Family Type	Nuclear	106 (4.2%)	**Reference**		182 (6.8%)	**Reference**	
	Joint	228 (8.3%)	0.869	0.210	340 (9.5%)	3.611	<0.001**
Wealth Quintile	Poorest	128 (34.4%)	**Reference**		250 (20.6%)	**Reference**	
	Poor	157 (13.8%)	0.584	<0.001**	156 (12.4%)	0.172	<0.001**
	Middle	45 (3.6%)	0.35	<0.001**	93 (7.3%)	0.034	<0.001**
	Rich	4 (0.3%)	0.059	<0.001**	14 (1.1%)	0.004	<0.001**
	Richest	0 (0%)	0.033	<0.001**	9 (0.7%)	1	
Area of Residence	Rural	278 (11.3%)	**Reference**		420 (12.8%)	**Reference**	
	Urban	56 (2%)	0.546	<0.001**	101 (3.4%)	0.451	<0.001**
	Slum	0 (0%)	0.424	0.423	1 (4.3%)	1	
Number of Drugs Prescribed	Up to 4	145 (4.1%)	1.246	<0.001**	185 (4.6%)	1.238	<0.001**
	5-8	142 (9.2%)			257 (13.2%)		
	>8	47 (18.6%)			80 (25%)		
Diseases Severity	Mild	70 (3.4%)	**Reference**		89 (4.1%)	**Reference**	
	Moderate	82 (4.5%)	1.080	0.633	151 (7.2%)	0.775	0.218
	Severe	182 (12.8%)	1.167	0.356	282 (14%)	1.120	0.590
Religion	Hindu	295 (6.7%)	**Reference**		467 (8.8%)	**Reference**	
	Muslim	35 (5.1%)	0.57	0.002**	45 (5.8%)	0.755	0.200
	Sikh	0 (0%)	1		0 (0%)	1	
	Christian	4 (2.3%)	0.774	0.477	10 (5.3%)	0.479	0.186
Gender	Male	189 (6.6%)	**Reference**		280 (8.3%)	**Reference**	
	Female	145 (5.9%)	0.977	0.851	242 (8.4%)	0.588	0.004**
Type of Disease	None	51 (8.3%)	**Reference**		66 (10.1%)	**Reference**	
	Hyp & Dia	41 (2.5%)	0.500	0.001**	78 (4.4%)	0.515	0.017*
	Cancer	6 (14.3%)	0.686	0.303	15 (19.5%)	0.713	0.553
	Misc	77 (5.7%)	0.579	0.004**	109 (7%)	0.586	0.026*
	ENT	46 (5.2%)	0.459	<0.001**	75 (6.9%)	0.415	0.001**
	Multiple	113 (14%)	0.864	0.452	179 (15.9%)	0.933	0.785
Overall		**8.3**			**6.3**		

*Significant at 0.05, **Significant at 0.01

Cost effectiveness of using generic vs branded drugs

Cost of branded and generic imipenem/cilastatin

The total cost incurred in treating a patient of HAP using branded cilastatin/imipenem was estimated as INR 1,44,196. Likewise, when the generic variants of cilastatin/imipenem were used, the treatment cost incurred was INR 1,17,180 (Table 24).

Table 24. Economic outcomes of generic and branded imipenem/cilastatin in hospital-acquired pneumonia

	Discounted			*Incremental*		
	LY	**QALY**	**Total treatment costs (INR)**	**Cost**	**QALY**	**ICER/QALY**
Branded drug	0.21 (95% CI: 0.19-0.23)	0.15 (95% CI: 0.13-0.17)	1,44,196 (95% CI: 101934-211409)	27916.42 (95% CI: -15102.59-88874.74)	0.014 (95% CI: 0.0096-0.02)	1936555 (95% CI: -1017392-6750049)
Generic drug	0.20 (95% CI: 0.18-0.23)	0.13 (95% CI: 0.12-0.15)	1,17,180 (95% CI: 95875-144782)			

LY: Life Year, QALY: Quality Adjusted Life Year, INR: Indian rupee, ICER: Incremental Cost-Effectiveness Ratio, CI: Confidence Interval

Cost Effectiveness

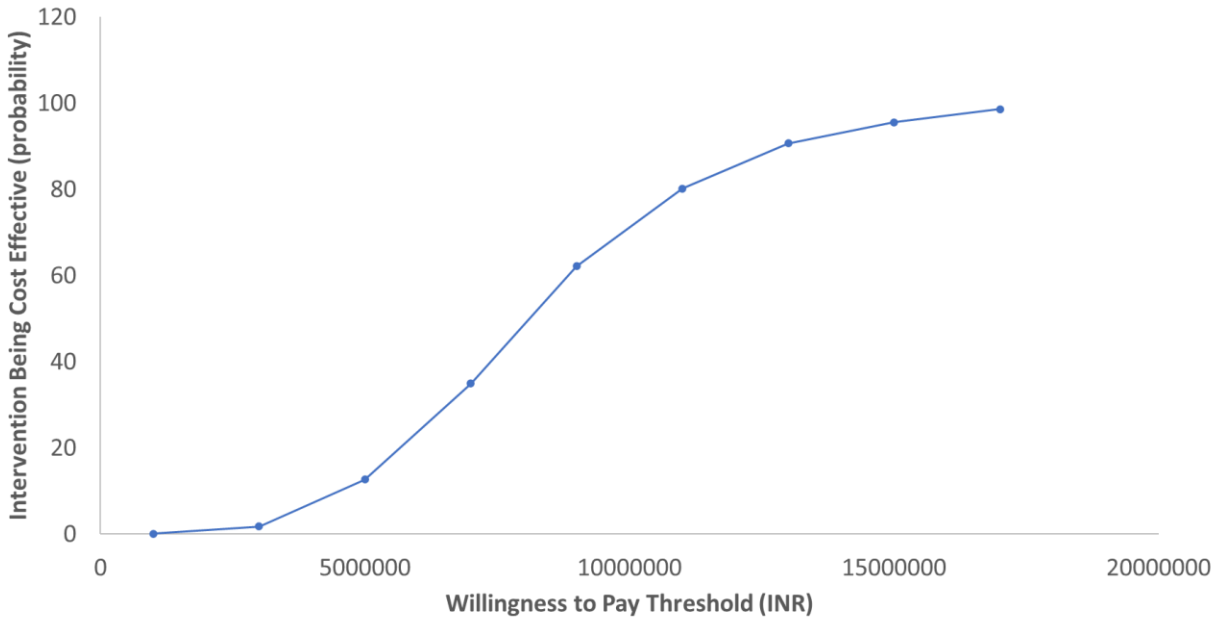
The number of LYs lived by a HAP patient receiving branded and generic imipenem/cilastatin, are 0.21, and 0.20 years, respectively. Further, the number of QALYs lived per HAP patient receiving branded and generic imipenem/cilastatin, are 0.154, and 0.134 years respectively (Table 2.). Over the 3 months of time horizon, a patient with HAP, treated with branded imipenem/cilastatin results in a gain of 0.014 QALY at an additional cost of INR 27,916 compared with generic imipenem/cilastatin. The incremental cost of using branded cilastatin/ imipenem as compared to the generic

variants for the treatment of HAP is INR 19,36,556 per QALY gained. As this value is much higher than the GDP-based cost-effectiveness threshold of INR 1,59,463, it implies that the use of branded imipenem/ cilastatin is not cost-effective for HAP treatment in India from a health system's perspective.

Sensitivity Analysis

The multivariate probabilistic sensitivity analysis showed that the probability of branded imipenem/cilastatin to be cost-effective at a threshold of per capita GDP and 3 times the per capita GDP was found to be 0% and 19.6% respectively.

Figure 20. Cost-effectiveness acceptability curve.



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