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Original Article

What is the out-of-pocket expenditure on medicines in India? An empirical assessment using a novel methodology

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Abstract

The share of expenditure on medicines as part of the total out-of-pocket (OOP) expenditure on healthcare services has been reported to be much higher in India than in other countries. This study was conducted to ascertain the extent of this share of medicine expenditure using a novel methodology. OOP expenditure data were collected through exit interviews with 5252 out-patient department patients in three states of India. Follow-up interviews were conducted after Days 1 and 15 of the baseline to identify any additional expenditure incurred. In addition, medicine prescription data were collected from the patients through prescription audits. Self-reported expenditure on medicines was compared with the amount imputed using local market prices based on prescription data. The results were also compared with the mean expenditure on medicines per spell of ailment among non-hospitalized cases from the National Sample Survey (NSS) 75th round for the corresponding states and districts, which is based on household survey methodology. The share of medicines in OOP expenditure did not change significantly for organized private hospitals using the patient-reported vs imputation-based methods (30.74–29.61%). Large reductions were observed for single-doctor clinics, especially in the case of 'Ayurvedic' (64.51–36.51%) and homeopathic (57.53–42.74%) practitioners. After adjustment for socio-demographic factors and types of ailments, we found that household data collection as per NSS methodology leads to an increase of 25% and 26% in the reported share of medicines for public- and private-sector out-patient consultations respectively, as compared with facility-based exit interviews with the imputation of expenditure for medicines as per actual quantity and price data. The nature of healthcare transactions at single-doctor clinics in rural India leads to an over-reporting of expenditure on medicines by patients. While household surveys are valid to provide total expenditure, these are less likely to correctly estimate the share of medicine expenditure.

Keywords: Out-of-pocket expenditure, healthcare financing, medicines, National Health Accounts, universal health coverage

Introduction

Providing affordable good quality healthcare is a major challenge in low- and middle-income countries. Like other countries in this category, households in India bear significant financial burden on account of medical treatment, with about two-thirds (65%) of all healthcare payments being paid out-of-pocket (OOP) at the point of service delivery (National Health Systems Resource Centre, 2019). These payments refer to direct payments for services (including informal payments), usually made by the user at the time of accessing services, from household primary income or savings without the involvement of a third-party payer (Agorinya *et al.*, 2021a). OOP payments not only have negative consequences on households' ability to spend on other basic needs, in which case they may lead to catastrophic health expenditures, but also have lower living standards, which can lead to impoverishment (Wagstaff *et al.*, 2018a; 2018b). According to estimates, between 39 and 50 million households are pushed below the poverty line in India due to OOP expenditure on healthcare every year (Hooda, 2017; Selvaraj *et al.*, 2018b).

The single largest determinant of these OOP payments is considered to be medicines. Nearly 70% of the total OOP payments are reported to be attributable to medicines in India. Since OOP expenditure is the major share of the total health expenditure (THE), medicines are also estimated to account for 36.8% of the THE (National Health Systems Resource Centre, 2019). Previous studies have reported this to be responsible for >60% of financial catastrophe that occurs due to healthcare expenses (Selvaraj *et al.*, 2018a). Several reasons have been outlined for this, the foremost being the inadequate availability of medicines at government health facilities, forcing households to access private facilities where they end up incurring significant OOP payments (Prinja *et al.*, 2015). The Indian Government has formulated

Key messages

- More than two-thirds (65%) of all healthcare payments are borne out-of-pocket (OOP) in India, of which 70% is reported to be attributable to medicines.
- We obtained the mean expenditure and the share of expenditure on medicines out of the total OOP expenditure reported by 5252 patients at their exit from the healthcare facilities in three states of India and compared it with the cost of medicines imputed using local market prices based on their prescription data. The results were also compared with the mean expenditure on medicines per spell of ailment among non-hospitalized cases from the National Sample Survey (NSS) 75th round for the corresponding states and districts, which is based on household survey methodology.
- We observed that the extent of patient's understanding in stratifying OOP expenditure was reasonable. However, the discordance between the patient-reported vs imputation-based methods was much higher among those utilizing single-doctor private clinics as compared with public- and private-sector organized hospitals.
- Household data collection as per NSS methodology, however, led to an increase of 25% and 26% in the reported share of medicines for public- and private-sector out-patient consultations, respectively, as compared with facility-based exit interviews with the imputation of expenditure for medicines as per actual quantity and price data. Thus, there is a need to review the traditional methods employed for the collection of data on OOP expenditures in national surveys and other studies.

several strategies to reduce the share of OOP on medicines, including introducing reforms to improve procurement and distribution of medicines, establishing low-cost subsidized-medicine stores and making efforts to promote prescription of generic medicines at healthcare facilities (Mukherjee, 2017; Roy and Rana, 2018; Joshi *et al.*, 2019). In contrast, several costing studies that have estimated the health system cost of providing services report the share of medicines at primary, secondary and tertiary care facilities in the range of 11.3–21.8% (Prinja *et al.*, 2016; 2017; 2018; 2020; Chauhan *et al.*, 2018). It is very unlikely that this cost share would differ very significantly between public and private providers (Prinja, 2021). This probably points to the fact that the high share of medicines in THE is not due to supply-side factors.

This brings us to investigate other factors as well, several of which, such as the type of morbidities or prescription practices in India, could be responsible for the reportedly high share of medicines in the total OOP expenditure. The share of spending on medicines as a proportion of THE in India is 2–5 times of what is reported in developed countries (7–15%) (Shahrawat and Rao, 2012; OECD, 2020). This difference may be potentially attributed to either one or multiple of the following three reasons: higher prescription or consumption rate of medicines in India, high medicine prices or high burden of diseases that require more and expensive medicines, such as non-communicable diseases (NCDs). However, there is no evidence in the published literature to support either of these reasons. The medicine prescription rate in India is 16.0 DID (defined daily dose per 1000 inhabitants per day), which is less than the European Surveillance of Antimicrobial Consumption Network countries (21.5 DID) (Farooqui *et al.*, 2018). Other studies on medicine prescription patterns for specific diseases have also reported similar findings (Neubert *et al.*, 2010; Pichetti *et al.*, 2013; Chauthankar *et al.*, 2017; Aparna *et al.*, 2021). Secondly, the prices of medicines in India are less than the developed countries. For example, the nominal price of a new medicine for hepatitis C for a 12-week course was ∼I$1821 (I$ = International Dollar) in India in 2016, ∼35 times less than the price in the USA (I$64 680) (Goldstein *et al.*, 2016; OECD, 2022b). These prices must have been further reduced in India after National Pharmaceutical Pricing Authority brought the drug 'Sofosbuvir', prescribed for patients with hepatitis C, under price control. Other studies report that the global median price for medicine (generic or branded) is 25–75% lower in India when compared with other high- and medium-income countries (Iyengar *et al.*, 2016; Medbelle, 2020). The median prices of the patented drug have also been reported to be minimum in India (US$1515) and maximum in the USA (US$8694) (Medbelle, 2020). On the other hand, while the pharmaceutical spending as a proportion of the total health spending in the USA was just 12.7% in 2017, it was 37% in India in the same year (OECD, 2022a). Lastly, although India is facing a dual burden of disease, the burden of NCDs, which could be a reason for higher spending on medicines, is lower in India as compared with other countries. The share of mortality due to NCDs in India stands at 63%, compared with 86–91% among countries that have a much lower share of spending on medicines (WHO, 2018).

As none of these explanations justify the high share of medicine in THE in India, it also becomes important to look into the methodological processes employed to collect data through household surveys, which are the main source of this information in India (GBD 2015 SDG Collaborators, 2016). As is the case with other developing countries, India relies upon sample household surveys to determine the extent of healthcare utilization and OOP expenditures. In these national sample surveys (NSSs), individuals in households are interviewed to recall any illness or hospitalization, type of healthcare sought and its consequent OOP expenditures. These data, collected on OOP expenditures for both out-patient setting (OPD) and in-patient hospitalization (IPD), are further disaggregated into its constituents, such as expenses on doctor's consultation, medicines, diagnostic procedures, travel, food, boarding or lodging. There are several issues reported with this approach in the published literature, especially in the context of the structure of the data collection instruments and the recall bias due to the time gap between the date of the actual expenditure and the date of the survey (Ayhan and Işiksal, 2005; Le *et al.*, 2020; Agorinya *et al.*, 2021b). In order to estimate the THE for National Health Accounts (NHA), the OOP expenditure values reported in NSS are annualized. The expenses on in-patient care are taken as is, as they are reported for a reference (recall) period for the last 365 days and therefore no adjustment is needed for obtaining annual estimates. The OOP spending for out-patient care is reported for a reference (recall) period for the last 15 days, and therefore adjustment is needed for obtaining annual estimates. Annual estimates for out-patient expenditures are obtained by multiplying the 15-day estimates by

365/15 (Secretariat NHAT, 2016; National Health Systems Resource Centre, 2019). Thus, together with the large frequency of out-patient consultations, the contribution of out-patient expenditures is significantly large in the THE reported as part of NHA.

The problem of accurately eliciting the constituents of OOP expenditure, such as medicine, occurs since the healthcare providers do not divulge complete details of their charges for individual services. Nearly 45.7% of patients in rural India access out-patient care at private clinics or from informal providers (GBD 2015 SDG Collaborators, 2016). The services during such a transaction usually include a doctor consultation, prescription, provision of all or some medicines by the healthcare provider and occasionally a few diagnostic tests. While the patient makes OOP payment for such a service provision, break-up into costs for each service rendered is usually not provided by the provider. For the patient, the tangible service obtained is medicine. In such a situation, when an individual is interviewed during the survey regarding break-up of OOP expenditure, he or she is likely to report medicines as the basis of OOP expenditure. Thus, the inability of the patients receiving services at the single-doctor clinics to correctly estimate the share of medicines may also be responsible for a disproportionately high share of medicines in THE in India, as these clinics cater to a significant proportion of the Indian population.

Since this entire issue has a direct bearing on the ability of the country to achieve universal health coverage (UHC), the assessment of the true extent of expenditure on medicines and its proportion in the total OOP expenditure on healthcare was identified as an important area of research by the Government of India (Planning Commission, 2011; Prinja *et al.*, 2012; Gupta *et al.*, 2017; Sharma and Prinja, 2018). The Ministry of Health and Family Welfare had established a National Knowledge Platform (NKP) under National Health Systems Resource Centre in 2016 in order to facilitate linkages for knowledge translation between policymakers and researchers working in the health sector (Sriram *et al.*, 2018). The mandate of NKP is to generate scientific evidence on topics of relevance for health system improvements, as well as counter the lack of demand among decision makers for such research (Sheikh *et al.*, 2016). The NKP thus commissioned the current study to develop a novel methodology and investigate the share of medicines in the overall OOP expenditure.

Methodology

Study framework

Before initiation of the study, two potential sources were identified which could lead to a possible inaccurate representation of the share of medicines in the total OOP expenditure. Either the patients do not actually know the true extent of the share of medicines in the total OOP expenditure and under-report or over-report it (understanding issues), or they know this at the time of purchase of services but tend to forget it by the time data are collected in household surveys (recall issues) (Figure 1). A potential contributory factor in reporting of medicine expenditure could be the setting of service delivery—which seems to be the case in single-doctor private clinics or informal providers in a large majority of the rural area.

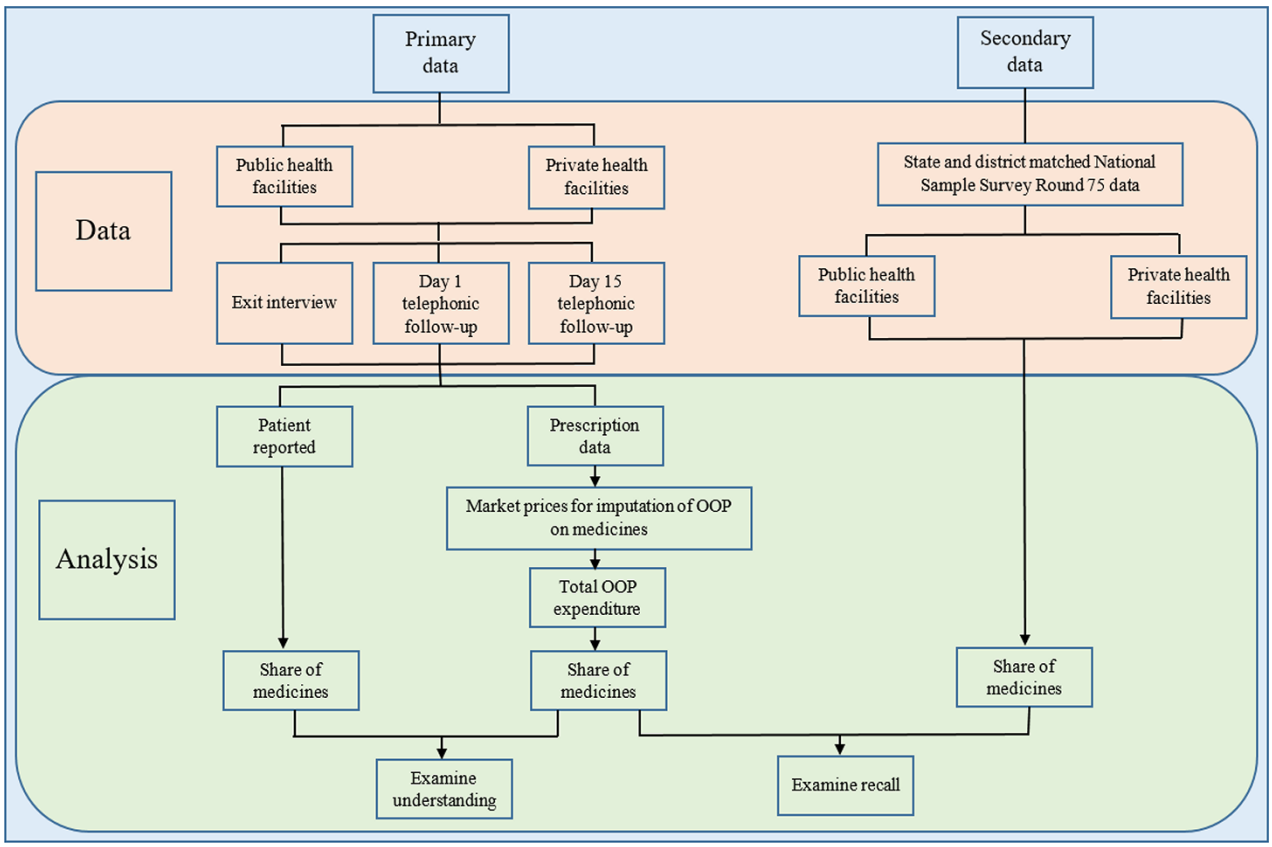

Figure 1. Study framework

To investigate the problem, patients were recruited for the collection of data related to OOP expenditure at their exit from the healthcare facility. Additionally, prescription audits of the patients were done to record the nature and quantity of medicines, and diagnostic tests prescribed. These were then used to impute estimates of the actual costs of these medicines using market prices of medicines collected from a survey of pharmacies in the study area. This share of medicines in the imputed OOP expenditure was then compared with (1) the share self-reported by the patients and (2) results from the individual-level NSS 75th round data for corresponding states and districts as was done in the present study.

Sample size

The share of medicines out of the total OOP expenditure reported by National Sample Survey Office (NSSO) in its 75th round ranged ~70% for non-hospitalized treatment (National Statistical Office, 2019). Expecting to find the proportion of expenditure on medicines to be 50% of the total OOP expenditure in the current study, with a design effect of 2 and an expected follow-up response rate of 90%, a sample size of 5200 individuals was computed which was required for estimating the share of medicine OOP expenditure, with 2% absolute precision and 95% confidence interval (CI). Detailed power calculations for the sample size used in the stratified analysis have been provided as Supplementary Material 1.

Sampling

A multi-stage stratified random sampling approach was followed for the selection of the states, districts and facilities (Supplementary Material 2). In the first stage, states were classified into three strata according to the share of medicines (low, medium and high) in the overall OOP expenditure as reported by the Government of India, and one state was randomly selected from each stratum (Central Statistical Office, 2016). The selected states were Haryana, Chhattisgarh and Tamil Nadu. Next, districts in each state were classified into three categories based on Human Development Index (HDI) scores, as HDI includes indicators that are reflective of important demand side characteristics which explain health status, care seeking and ability to pay for OOP expenditure. One district from each HDI category in each state was randomly selected for inclusion in the study.

Finally, public and private healthcare facilities were selected from each district for an accurate representation of the healthcare service delivery scenario. In the public sector, one District Hospital (DH), one Community Health Centre (CHC) and two Primary Health Centres (PHCs) were selected. While the CHCs were selected randomly, the two PHCs included were the ones geographically closest and farthest to the CHC. Additionally, a tertiary care teaching hospital (medical college) with the highest patient load was also selected from each state. Therefore, a total of 13 public healthcare facilities, including one tertiary care hospital, three DHs, three CHCs and six PHCs, were selected in each state. An equal number of facilities were selected from the private sector, with the selection determined by equivalency in the level of service provision as provided by the selected public healthcare facilities from the same district. This was done to ensure the comparability of infrastructure, resources and service outputs. In addition to this, six stand-alone pharmacies (from both rural and urban areas) were randomly selected from each district on the basis of the proportion of the rural and urban population. Thus, the overall study sample included 44 healthcare facilities (13 public, 13 private and 18 stand-alone pharmacies) in each state, adding up to 132 healthcare facilities in three selected states.

The sample size was divided equally among the three states and their nine districts. Within a district, the probability proportion to size principle was used to distribute the sample among the facilities (Medical College, DH, CHCs and PHCs in the public sector and equivalent facilities in the private sector), considering their share in service provision. Twenty respondents were selected for inclusion from each of the stand-alone private pharmacies included in the study. Patients were recruited at the pharmacy of the facility so that patients from all specialities could be captured at the time of their exit from the hospital. Patients were selected consecutively until the required sample size for that facility was achieved.

Data collection

Patients were interviewed to collect data on their socio-demographic and clinical characteristics over a period from January to November 2020. Data on both direct medical (consultation/hospital charges, medicine and diagnostics) and direct non-medical OOP expenditures were collected. Additionally, data on medicines were abstracted from prescription slips in terms of the name of medicine, dose, duration, route of administration and quantity of each medicine on a structured schedule. Each patient was also followed up telephonically twice: on Days 1 and 15 after the baseline data collection to record any additional OOP expenditure incurred. This 15-day period for subsequent follow-up was considered in order to standardize with existing surveys, which interview individuals for OOP expenditure for out-patient visits using a 15-day recall period. During the follow-up interviews, data were collected on any further consultations sought, type of healthcare provider and OOP expenditures incurred during this period.

For stand-alone pharmacies, patients were interviewed at the time of their visit to buy medicines. Data on details of the healthcare facility visited for consultation before coming to the pharmacy and OOP expenditures incurred on consultation, medicines, diagnostics, etc. were also collected. The rest of the data collection process and follow-up telephonic call on Day 15 was similar to the out-patient interviews at the health facilities.

The mean market prices of medicines and diagnostic tests were estimated from a survey of 10 pharmacies and 5 diagnostic centres in each study district. In addition, we collected data on prices listed on online pharmacy portals, diagnostic laboratory websites and documents of 'Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)', which were used as references for average market prices (Rajkumar and Swaroop, 2008).

Data analysis

The mean OOP expenditures were computed separately for public- and private-sector facilities. These expenditures were stratified for different determinants (such as medicines and diagnostics) as reported by the patients.

In view of the system of provider payments, especially in private facilities, which leaves the patients unable to accurately recall the break-up of OOP expenditure (recall issues), a

second set of estimations were made (Figure 1). In this alternative scenario, a revised estimate of break-up of OOP expenditure was generated after imputing the prices based on the type and quantity of medicines prescribed, as well as accounting for any medicine provided by the provider along with the lump sum fee charged (Figure 2). In the case of a branded medicine prescription, its maximum retail price was used. For generic drugs, an average of the market price was used. The imputation was done for patients availing OPD services at private healthcare facilities. If the overall estimated OOP expenditure on medicines was less than the patient-reported value, the balance amount was adjusted by inflating the doctor consultation fee. Thus, the overall OOP expenditure remained the same as had been reported by the patient in this imputation scenario. Then the differences in the share of medicines in OOP expenditures between the patient self-reported and imputation scenarios were estimated. The Mann–Whitney *U* test and the chi-squared test were used to determine the statistical significance (with 5% type 1 error) of the difference in the mean reported expenditures on medicines, and the share

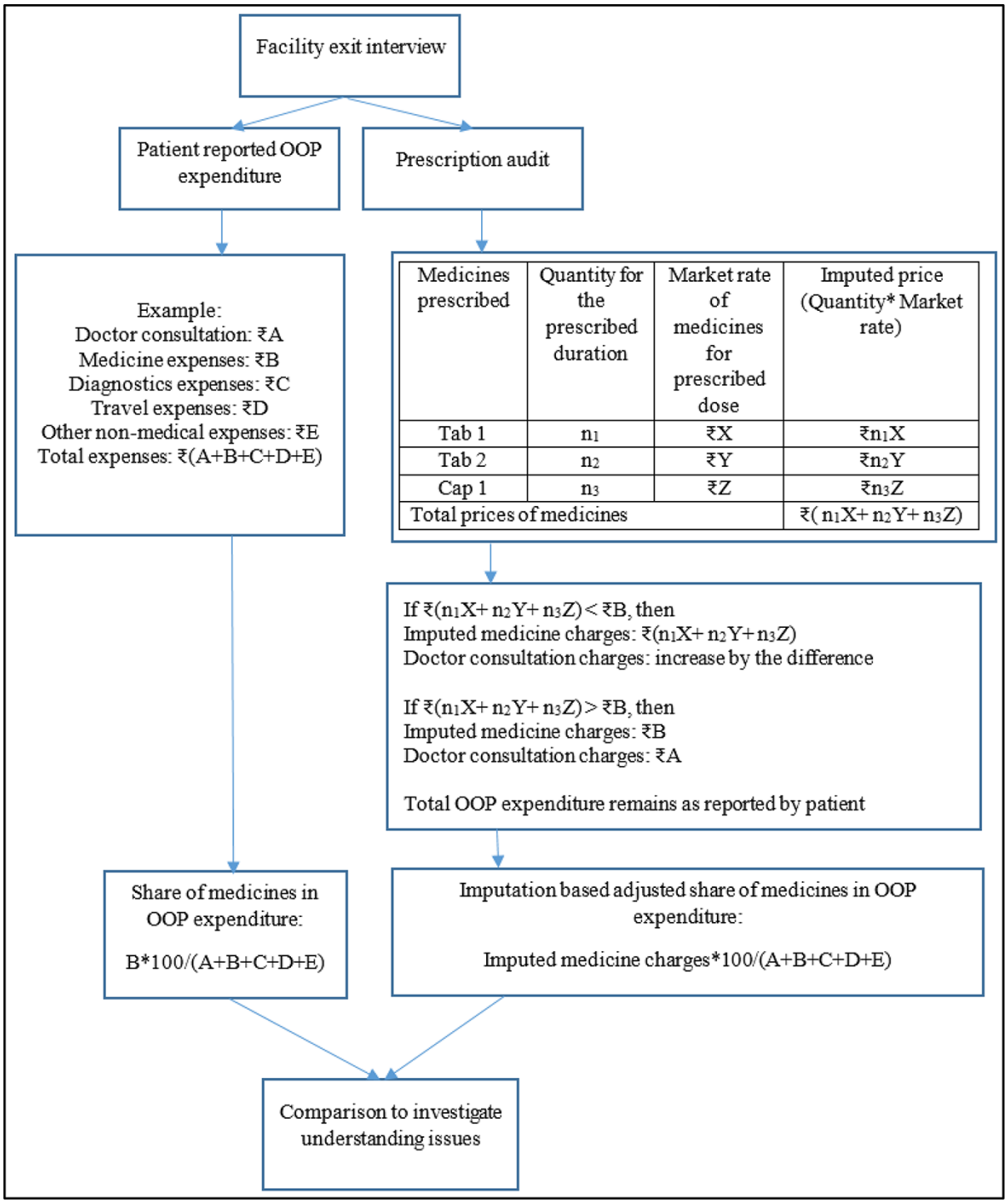

Figure 2. Imputation approach to investigate patients' understanding of the share of medicines in the total OOP expenditure

of OOP expenditure on medicines assessed based on the two approaches.

Secondary data analysis

NSS 75th round individual-level data for out-patient OOP expenditures were obtained for the three selected states and analysed for comparison with the results of the current study. The NSS 75th round was a nationwide household survey conducted between July 2017 and June 2018, where a random sample of 113 823 households from rural and urban areas of all districts in the country were included (National Statistical Office, 2019). The aim of the survey was to generate basic quantitative information on the morbidity levels, patients' healthcare-seeking behaviour and OOP expenditures. Individuals were interviewed for any morbidity during the last 15 days, out-patient care utilized, nature of provider and the OOP expenditure incurred. The statistical significance of the difference in findings between the current study and NSS survey findings was determined using the aforementioned bivariate analytical tests.

Finally, a cross-sectional multivariable linear regression modelling approach was employed to estimate the association between the share of medicines in the total OOP expenditure and the data collection approach. The outcome indicator was a normally distributed ratio scale indicator (one-sample Kolmogorov–Smirnov test P-value >0.05). The primary explanatory variable was a binary variable comparing community-based household surveys (as in NSS 75th round) with facility-based client exit interviews (as in our study) to assess the relationship of survey methodology with the outcome. Individual-level data from our study and NSS 75th round for selected districts and states were pooled and analysed. Nine personal- and household-level socio-demographic–economic variables were identified on the basis of their importance to the outcome of interest and adjusted for by inclusion in the models. Household consumption expenditure was used to segregate the households into wealth quintiles. Two models were thus generated, one each for OPD care at public- and private-sector facilities. Details of the variables employed in the model have been provided in Table 1. The regression coefficients obtained from the multivariable analysis were then used to derive multiplication factors for public- and private-sector facilities using a reverse calculation approach. Since the regression coefficients represented a percentage increase in the reported share of medicines as a result of the data collection methodology, the following formula was used to derive the correction factor:

$$Multiplication\ Factor = \frac{100}{100 + \beta(\%)} \quad (1)$$

where $\beta(\%)$ represented the effect of the data collection methodology, obtained as the regression coefficient in the model.

Results

A total of 5252 patients were recruited under the study in the three states; however, data collection till the second follow-up call could be completed from 4618 patients. The 12% patients lost to follow up were not found to be significantly different in their sample characteristics from the patients who continued to participate. Around 45% of the initial recruitment was at public health facilities (Table 2). More than 50% of patients belonged to 15–45 years' age group and were literate and employed, and 53% did not have any insurance coverage. The majority of those insured was covered under publicly financed health insurance schemes, sponsored by the central or state governments.

The mean OOP expenditures per out-patient consultation reported by patients at public and private healthcare facilities were ₹340.9 [standard error (SE): ₹37.1] and ₹1212.1 (SE: ₹31.5), respectively (Table 3). Patients recruited at pharmacies reported a mean expenditure of ₹132 on medicines, out of a total expenditure of ₹165.

Figure 3 presents the proportional distribution of overall OOP expenditures. Medicines constitute ∼28% and 33% of

Table 1. Variables employed in the model to predict the association of the reported proportion of medicines in the total OOP expenditure and the data collection approach

S. No.	Variable	Type	Characteristic	Categories
1.	Proportion of medicines in the total OOP expenditure (%)	Outcome	Proportion	–
2.	Data collection approach	Explanatory variable	Binary	0—Facility-based 1—Community-based
3.	Age (years)	Explanatory variable	Continuous	–
4.	Sex	Explanatory variable	Binary	0—Male 1—Female
5.	Education	Explanatory variable	Binary	0—Illiterate 1—Literate
6.	Employment	Explanatory variable	Binary	0—Unemployed 1—Employed
7.	Residence	Explanatory variable	Binary	0—Rural 1—Urban
8.	Socio-economic status (Wealth quintile)	Explanatory variable	Ordinal	1—Poorest 2—Poor 3—Medium 4—Rich 5—Richest
9.	Type of ailment	Explanatory variable	Binary	0—CD/infections 1—NCD/trauma
10.	Insurance coverage	Explanatory variable	Binary	0—Non-insured 1—Insured

Table 2. Characteristics of the patients initially enrolled in the study

Characteristics	Categories	*N* (%)
Age	0–14	438 (8.3)
	15–45	2990 (56.9)
	46–60	1180 (22.5)
	>60	644 (12.3)
Sex	Male	2497 (47.5)
	Female	2755 (52.5)
Residence	Rural	3215 (61.2)
	Urban	2037 (38.8)
Education	Illiterate	1078 (20.5)
	Up to primary	157 (3)
	Up to middle	1320 (25.1)
	Up to matric	816 (15.5)
	Higher secondary	850 (16.2)
	Graduate and above	1031 (19.6)
Employment	Self-employed	977 (18.6)
	Casual labour	369 (7)
	Formal sector	979 (18.6)
	Unemployed	2927 (55.7)
Insurance coverage	Publically financed health insurance	2131 (40.6)
	Employer-supported voluntary health protection	20 (0.4)
	Individual voluntary public insurance	248 (4.7)
	Individual voluntary private insurance	25 (0.5)
	Others	47 (0.9)
	Not covered	2781 (53)
Healthcare provider	Public	1935 (36.8)
	Private	2936 (55.9)
	Stand-alone pharmacy	389 (7.2)
Total		5252 (100.0)

the total expenditure on out-patient services at public and private healthcare facilities, respectively, which was found to be statistically significant (*P*-value < 0.01). Non-medical expenses and expenditure on diagnostics were found to be other major constituents. Tabulated comparisons have been provided as Supplementary Material 3.

After imputation, this share of expenditure for medicines marginally reduced to 30.7% (Figure 4). In terms of absolute levels, OOP expenditure on medicines decreased from ₹352.8 to ₹337.8 (*P*-value < 0.01) after adjustment as per the alternative imputation-based method. While the mean reduction was statistically significant, the percentage change was not statistically different.

While the share of medicines does not reduce much for organized private hospitals (from 30.74% to 29.61%, *P*-value = 0.39), large reductions were observed for 'Ayurvedic' (traditional Indian medicine) (from 64.51% to 36.51%, *P*-value = 0.08) and homeopathic (from 57.53% to 42.74%, *P*-value = 0.33) clinics. None of these reductions, however, were observed to be statistically significant (Figure 4).

Table 4 presents a comparison of the results of the current study with those reported by NSS 75th round for the corresponding three states and districts. The overall OOP expenditure per OPD consultation in private facilities is very similar in our study (₹1212) and NSS survey (₹1156). The overall OOP expenditure in public-sector OPD visit was 1.7 times higher in NSS survey. The expenditure on medicines in our study was less, as compared with NSSO, at both public (₹97.1 vs ₹218; *P*-value < 0.01) and private health facilities (₹408 vs ₹603; *P*-value < 0.01).

In terms of proportions, NSS 75th round reported a higher share of expenditure on medicines (Figure 5). The difference in share was much more for private facilities (33% vs 52%, *P*-value < 0.01) than the public facilities (28% vs 37%, *P*-value = 0.02). A stratification of the private-sector facilities into private hospitals and single-doctor clinics revealed a much higher reported share of medicines by patients receiving services at the single-doctor facilities (45%) as compared with the larger private hospitals (31%). Similar results were generated from NSS 75th round data. While NSS reports 51% share of medicines (in comparison with 31% in the current study, *P*-value < 0.01) at private hospitals, the same increases to 56% (in comparison with our 45%, *P*-value = 0.02) at single-doctor clinics.

After adjustment for age, gender, area of residence, education, employment, wealth status, insurance coverage and type of ailment, the reported share of medicines for public- and private-sector out-patient consultations was observed to be 25% and 26% higher for the household data collection (as per NSS methodology) as compared with the facility-based exit interviews and imputation of expenditure for medicines as per actual quantity and price data. These results are in the same direction as the difference in estimates

Table 3. OOP expenditures incurred by patients for out-patient services at public and private healthcare facilities

	OOP expenditures, mean (95% CI LL, UL)		
Categories	Public	Private	Pharmacy
Medical expenses			
Hospital charges[a]	22.1 (0.1, 46.2)	211.4 (203.4, 219.4)	3.1 (0.6, 5.6)
Medicines	97.1 (67.7, 126.5)	408.3 (383.8, 432.8)	132.4 (111.2, 153.6)
Diagnostics	65.1 (42.4, 87.8)	295.2 (268.5, 321.9)	0.3 (0.1, 0.9)
Consumables	10.5 (0.1, 26.2)	16.8 (9.9, 23.7)	0.8 (0.1, 2.4)
Others	0 (0,0)	86.6 (73.5, 99.7)	0 (0,0)
Total medical expenses	194.9 (133.1, 256.8)	1018.2 (970.6, 1065.8)	136.5 (114.9, 158.1)
Non-medical expenses[b]	146 (114.8, 177.2)	193.9 (165.7, 222.1)	29.2 (26.1, 32.3)
Total	340.9 (268.2, 413.6)	1212.1 (1150.4, 1273.8)	165.8 (143.7, 187.9)

LL: lower limit; UL: upper limit.
[a]Hospital charges include consultation fee and registration fee at public-sector facilities.
[b]Non-medical expenditures include transport, stay, food and others.

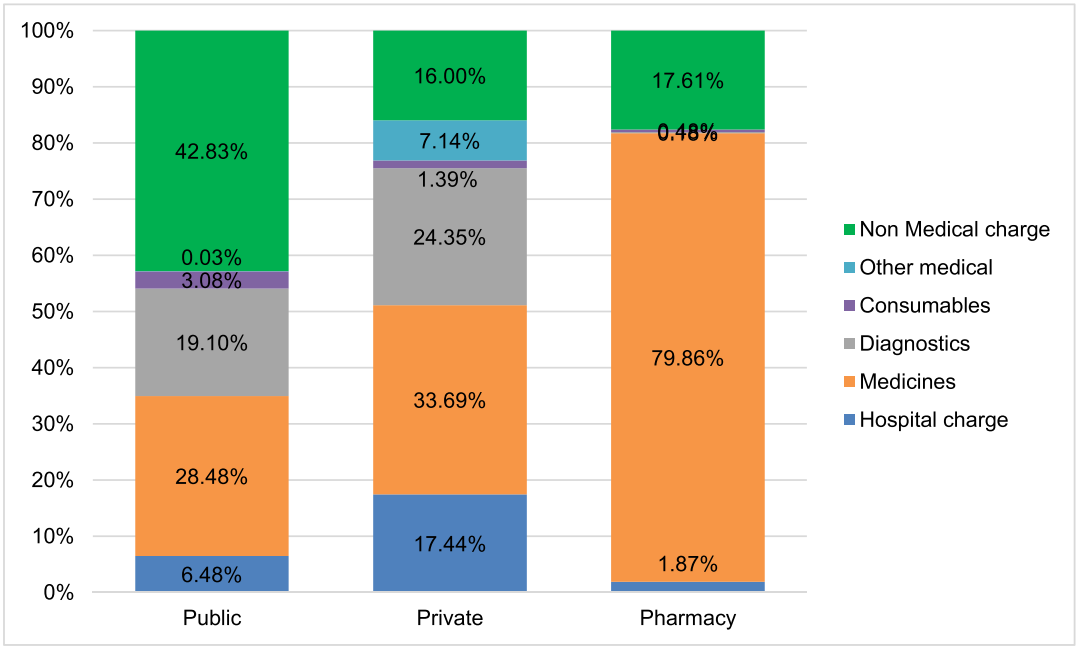

Figure 3. Distribution of self-reported OOP expenditure incurred at public and private health facilities for out-patient care services

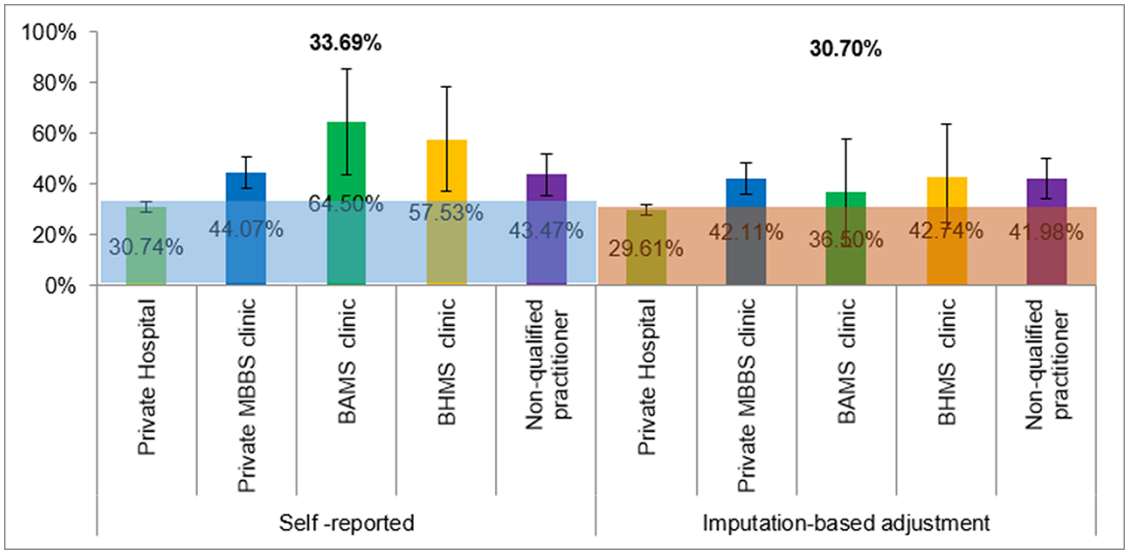

Figure 4. Proportional share of medicines in patient-reported OOP expenditure and after adjustment as per the imputation-based method for OPD services at private single-doctor stand-alone clinics and other private hospitals

Table 4. Comparison of study results with findings from NSS 75th round data on OOP expenditures for the three states

	Public-sector facilities, mean (95% CI)		Private-sector facilities, mean (95% CI)	
	Current study	NSS 75th round	Current study	NSS 75th round
Consultation	6.6 (5.6, 7.6)	4 (0.1, 28.1)	200.8 (196.3, 205.3)	183.3 (107.1, 259.5)
Medicine	97.1 (67.9, 126.3)	218 (124.5, 311.5)	408.3 (383.8, 432.8)	603 (489.5, 716.5)
Diagnostics	65.1 (42.4, 87.8)	119 (0.1, 302.7)	295.1 (268.6, 321.6)	146.3 (71.0, 221.6)
Transport	98 (73.5, 122.5)	114.1 (83.1, 145.1)	149.5 (133.0, 166.0)	73.4 (52.6, 94.2)
Others	24.8 (15.6, 34.0)	216 (154.5, 277.5)	23.2 (16.3, 30.1)	116.2 (81.9, 150.5)
Total	340 (267.3, 412.7)	582.5 (323.4, 841.6)	1212 (1150.3, 1273.7)	1156 (886.9, 1425.1)

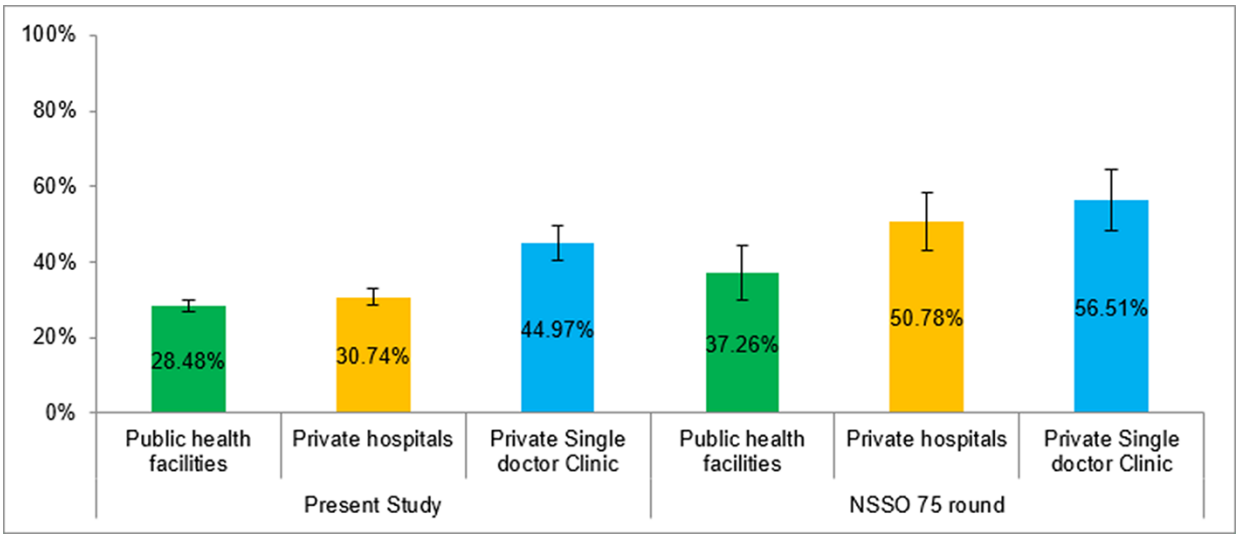

Figure 5. Comparison of share of expenditure on medicines reported by NSS 75th round with results of the current study

Table 5. Association of the data collection method with patient-reported proportion of medicines in the total OOP expenditure incurred on OPD consultations

	Public-sector facilities		Private-sector facilities	
	Reg. coeff. (SE)	*P*-value	Reg. coeff. (SE)	*P*-value
Constant	0.20 (0.05)	<0.01**	0.46 (0.03)	<0.01**
Data collection approach	0.25 (0.03)	<0.01**	0.26 (0.01)	<0.01**
Age	−0.01 (0.01)	<0.01**	0.01 (0.01)	0.04*
Sex	0.01 (0.02)	0.98	−0.01 (0.01)	0.27
Education	0.05 (0.02)	<0.01**	−0.01 (0.01)	0.29
Employment	−0.04 (0.02)	0.03*	−0.03 (0.01)	0.01**
Residence	−0.05 (0.02)	<0.01**	−0.04 (0.01)	<0.01**
Socio-economic status (wealth quintile)	0.02 (0.01)	<0.01**	−0.01 (0.01)	0.77
Type of ailment	−0.04 (0.02)	0.03*	0.02 (0.01)	0.12
Insurance coverage	0.17 (0.02)	<0.01**	−0.07 (0.01)	<0.01**
Model parameters				
Number of observations	2106		3248	
R	0.36		0.43	
R^2	0.13		0.19	
Adjusted R^2	0.12		0.18	
F-value	31.01		52.99	
P-value	<0.01		<0.01	

Dependent variable is the proportion of medicines in the total OOP expenditure (%).
Reg. coeff.: regression coefficient; R: correlation coefficient; R^2: coefficient of determination.
*Significant at $P \leq 0.05$.
**Significant at $P \leq 0.01$.

obtained from data from the two surveys (31% and 57% for public- and private-sector facilities, respectively) but are lower in magnitude due to adjustment for socio-economic factors (Table 5).

Replacing β(%) in Equation (1) with 25% and 26% for the effect of data collection approach on the public- and private-sector facilities, respectively, we obtained multiplication factors of 0.80 and 0.79. The multivariable analysis results, thus, imply that these adjustment factors of 0.80 and 0.79 should be used to arrive at correct non-inflated results for public- and private-sector facilities, respectively, if the household survey approach is used for data collection.

Discussion

As medicines form an indispensable part of both public and private healthcare system, no country can achieve UHC without making these available at affordable prices. The true extent of the share of medicines in the total OOP expenditure, however, remains a matter of debate. Many previous studies using standard methodology for collecting OOP expenditure data (with a recall period of 15 days for OPD care and 365 days for IPD care) have estimated this share to be ∼65–70% of the THE in India. We used a novel approach, by interviewing patients at their exit/discharge from the healthcare facilities in order to arrive at more accurate results, to reduce problems of recall bias. Furthermore, as a second part

of the analysis, the medicine expenditure was imputed using quantity from prescription data and actual prices. This was done to remove the effect of misclassification by patients as a result of the setting and nature of healthcare transactions.

We have compared our results against the findings published by NSSO, as it is widely considered the primary source for public data on healthcare utilization and associated OOP expenditures in India (Sharma *et al.*, 2020). The 75th round NSS survey (2017–18) used a stratified multi-stage design to collect data from rural households in 8077 randomly selected villages and the urban households in 6181 randomly selected urban blocks. For other spells of ailments requiring non-hospitalized treatment, the reference period for recall was restricted to last 15 days prior to the date of survey. To make our study methods (except for the settings of data collection) comparable to NSSO, we used two additional patient follow ups, on Days 1 and 15 after the baseline data collection, to adjust our results for any expenditure that the patient might have incurred after the exit from the healthcare facility. Also, the results were compared with the mean expenditure per treated spell of ailment in out-patient mode for the corresponding states and districts to make the comparisons meaningful.

The overall trends in OOP expenditure in our study were found to be similar to what have been previously observed and reported in the literature (Gupta *et al.*, 2016; Nandi *et al.*, 2017; Pandey *et al.*, 2018; Selvaraj *et al.*, 2018a). Our OOP expenditure for OPD care, in absolute terms, is comparable with those published by NSS. A major difference between our findings and that of NSS 75th round was related to the share of OOP expenditure on medicines. These differences were observed for OPD services, received at both public- and private-sector facilities. While the share of expenditure on medicines was found to range between 28% and 33% for public and private facilities, NSS reported these to be 37% and 52%, respectively. A share of OOP expenditure for medicines ranging from 65% to 72% of the total OOP expenditure has been reported by several other studies which are based on the methodology of household surveys and the recall of OOP expenditure incurred in the last 15 days (Bhojani *et al.*, 2012; Shahrawat and Rao, 2012; Selvaraj *et al.*, 2018a). These differences in our study observations with the previous literature could only be explained due to the differences in methodology—exit interview-based approach at healthcare facilities and imputation of medicine expenditure in our study vs household surveys and self-reporting in others.

A potential limitation of our comparison with the NSS survey findings is the inability to control for the patients' clinical severity. However, we controlled for several known socio-economic factors which could influence the OOP expenditure. Secondly, we also controlled for the broad nature of illness. Moreover, our findings on the overall OOP expenditure per OPD visit in the private sector are very similar to those from the NSS survey, implying that the comparison is valid. The lower overall OOP expenditure in the public sector in our study could be a result of a difference in 2 years in the survey periods, during which there have been several initiatives to provide free medicines in the public sector.

The main finding of the study is the share of self-reported OOP on medicine and that derived by imputation is very similar in the public and organized formal private sectors. This implies that the extent of patient recall bias and understanding of the patient in stratifying OOP expenditure is reasonable. However, this discordance increases significantly in the informal private sector and single-doctor clinics where medicines are provided by the doctor as part of the consultation and a single price is levied. As a result, it is the setting and the nature of healthcare transactions that possibly lead to the over-reporting of medicine expenditures by patients.

As a result, we also believe that household surveys lead to inadvertent reporting of the majority of OOP expenditure under a single head of 'medicines', as that might be recognized as the predominant tangible service by patients. This appears to be more pronounced in single-doctor clinics, where the outpatient consultation results in a prescription slip as well as medicines provided by the doctor, and a lump sum charge or fee (Kanjilal *et al.*, 2007). These clinics, especially those run by practitioners of the traditional system of medicine or non-qualified practitioners, are also well known to be deeply integrated into the community and familiar with local traditions and customs (George *et al.*, 2011; Datta, 2013) Since these healthcare providers establish cordial relations with their customers, it is expected that the clients would not see the fee charged as consultation charges, rather it would be considered the cost of noticeable outputs of the process, such as injections or medicines provided to the patient. This leads to such patients reporting a disproportionately higher share of medicines in their OOP expenditure. Thus, the recall bias in reporting individual constituents of the OOP expenditure, especially medicines, tends to be enhanced in the private sector due to the nature of service provision. Hence, the researchers relying on household surveys to generate their results should stratify them by the provider and interpret the findings cautiously. The adjustment factors of 0.80 and 0.79, as generated in our study, can be used to multiply the results of medicine share for public- and private-sector facilities obtained through household surveys.

Our results have several implications for the process of evidence synthesis, which directly affects the development and execution of policies related to UHC. It was found that the approach of collecting data on OOP expenditures through exit interviews yielded more reliable disaggregated results in comparison with household surveys. There were also less recall issues and no inflation of the expenditures under the medicines. However, there are certain challenges associated with this approach. This process makes it arduous to obtain household-level information, whether on their socio-demographic–economic variables or on the purchase of healthcare services by other members of the household. There is also a possibility of losing data on services obtained (and expenses incurred) by the patients after the exit interviews, but this can be corrected using follow-up telephonic interviews, as was done in the present study.

A tangential approach to resolve this entire scenario could be to utilize data available with healthcare providers instead of relying on the patient-reported data. The public health system in India has a well-established health management information system (HMIS); however, lacunae in the availability and quality of data are frequently reported (Sharma *et al.*, 2016; Dehury and Chatterjee, 2018). Moreover, while these supply-side platforms concern themselves with the indicators related to the performance of the health system, they

do not capture and report the experiences and satisfaction of the patients with the system, personally, professionally and financially. Hence, strengthening the health system by incorporating these aspects in HMIS may help in generating an alternative resource for the expenditure data reported by the patients through household interviews. The Government of India has taken several initiatives in this direction. The Ministry of Health and Family Welfare has formulated the Ayushman Bharat Digital Mission (ABDM) to support a seamless online ecosystem for the provision of a wide range of data and information, ensuring the security, confidentiality and privacy of health-related personal information (Centre for Health Informatics, 2021). Along with developing a repository of verified hospitals, clinics and physicians, one of the objectives of ABDM is to create a unique health ID for Indians and to integrate all their health records onto a single platform (Jain, 2022). The claim management system of Ayushman Bharat Pradhan Mantri Jan Arogya Yojana insurance scheme is incorporating a section on patient-level information, including expenditure incurred OOP on medicines and diagnostics. Another pilot project is being planned in five states, wherein hospitals will provide details (quantity and prices) of all medicines, consumables, implants and diagnostic tests received by patients from the facility. These newer reforms may help establish a robust system for the estimation of the share of medicines in the overall healthcare spending in the coming future.

In the meantime, we strongly recommend the need to review the traditional methods employed for the collection of data on OOP expenditures in national surveys and other studies. These surveys should be cautiously designed, and their results carefully interpreted. More research needs to be undertaken to refine the processes and identify the best approach for collecting such data, as our results show significant effects of the settings and the nature of healthcare transactions, as well as recall bias on medicine expenditures reported by patients in household surveys. Once this has been established, research can be conducted to establish associations between the results obtained through different approaches and generate analytical weights to arrive at the correct results using either approach. The estimates of NSSO surveys are also used in preparing NHA, a better understanding of these concepts not only will have an impact on them but will also help to improve the policy design and implementation approach for achieving UHC in the country.

Supplementary data

Supplementary data is available at *Heath Policy and Planning* online.

Data availability

The data underlying this article will be shared on reasonable request to the corresponding author, subject to permission by the author's institute in New Delhi.

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Author contributions

Study conception and design: S.P., A.K.A., S.G., S.S.K., I.M., S.K., S.S., A.K. and N.D.
Data collection: S.P., S.K., N.T. and A.S.
Data analysis and interpretation of results: S.K., A.S and S.K.R.
Draft manuscript preparation: S.P., S.K. and A.S.
All authors involved in critical revision of article.
Final approval of article: S.P.

Reflexivity statement

The researchers include 11 males and 1 female with multiple levels of seniority: three of the authors specialize in health policy at the national and state level; three of them are established researchers in health policy, health systems and health economics; two of them are recognized researchers and four of them are first-stage researchers. The authors represent research institutes from the north, south and east-central part of India.

Ethical approval. Ethical approval for the study was obtained from the Institute Ethics Committee of the Postgraduate Institute of Medical Education and Research, Chandigarh and Jawaharlal Institute of Postgraduate Medical Education & Research, Puducherry. Written informed consent was obtained from all participants. Administrative approvals for data collection were obtained from the state health department in the three states.

Conflict of interest statement. The authors declare no conflict of interest.

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