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Financial burden of medicine out of pocket payments: Implications for living status of Indian households

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Financial burden of medicine out of pocket payments: Implications for living status of Indian households

Objective: The objective of this research is to generate new evidence on financial implications of medicine out of pocket (OOP) payments for households. We also report disease conditions separately in outpatient and inpatient care, which caused significant increase in OOP expenses.

Setting: All Indian States including Union Territories, 1993-94 to 2014 **Design:** Repeated cross section analysis

Data: Secondary data of nationwide Consumer Expenditure Surveys for the years 1993-94, 2004-05 and 2011-12 and one wave of Social Consumption: Health for the year 2014 from National Sample Survey Organisation.

Outcome measure : Total out-of-pocket expenditure on healthcare and medicine out-of-pocket expenditure on healthcare.

Results: Total and medicine out-of-pocket were estimated to be 6.77% [CI: 6.70%, 6.84%] and 4.49% [4.45%, 4.54%] of total consumption expenditure in the year 2011-12 which marked significant increase since 1993-94. These proportions were 11.46% [CI: 11.36%, 11.56%] and 7.60% [CI: 7.54%, 7.67%] respectively of non-food expenditure in the same year. Total and medicine OOP were catastrophic for 17.9% [CI: 17.7%, 18.2%] and 11.2% [11.0%, 11.4%] households respectively in 2011-12 at the 10% of total consumption expenditure threshold implying 29 million households incurred catastrophic out-of-pocket payments in the year 2011-12. Further medicine out-of-pocket pushed 3.09% [CI: 2.99%, 3.20%], implying 38 million, persons into poverty in the year 2011-12. Among the main diseases which caused major out-of-pocket payments are cancers, cardiac, geneto-urinary and metal disorder conditions. Average monthly medicine OOP was invariably higher in outpatient care compared to inpatient care.

Conclusions: Government intervention in terms of public provisioning of free medicine has potential to significantly reduce the medicine related OOP as well as total OOP.

Key words: India, out of payment, medicine, catastrophe, poverty

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1.	The study used multiple points of time and nationally representative data set to
2	highlight the burden of medicine out-ofpocket expenditure incurred by househol
Ζ.	This study is the first one to produces evidence on catastrophic and poverty impa of out-of-pocket payments for medicine
3.	The paper links medicine out-of-pocket payments by households with disease
5.	conditions and identify types of disease conditions which trigger medicine out-of
	pocket payments
4.	The study also highlights for the first time that out-of-pocket payments on medic
	in outpatient care is far greater burden for households than expenditure on
	hospitalisation care
5.	The study has limitations in terms of using arbitrary cut-off for measuring
	catastrophic payments
6.	Self-reported disease conditions and related out-of-pocket expenditure is an obv
	limitation of the study.
	limitation of the study.

Background

 Households' in India bear significant financial burden due to treatment, as prepayment and risk pooling mechanisms are inadequate. Since both government funding and social health insurance contributions are insufficient to meet health care needs of households, over three-fourth of overall health care payments are paid out-of-pocket (OOP) at the point of service delivery and medicine purchase account for the single largest component of these payments¹. Such spending has dominated over the years, which has pushed significant proportion of population impoverished while a higher proportion of households have incurred catastrophic spending due to OOP payments²⁻⁴.

The unpredictable and catastrophic nature of illness can throw households into the vortex of poverty. The predicament of high OOP could result in liquidation of assets, heavy borrowing, running down savings, etc. Evidence suggests that households' OOP expenditure pulls down a vast chunk of population below poverty line^{2 5-8}. Similarly, recent findings documented the burden of catastrophic spending of health care on households owing to high OOP share to total households' resources^{6 9 10}. In the Indian context, several studies in the past confirmed high OOP in general and OOP on medicine in particular. Estimates of impoverishment due to OOP vary widely depending upon the methods and year in which the estimates were made. The number of households falling below poverty line was in the range of 32-39 million per annum during the period 2004 ^{2 5-7}. Such evidence is no surprise given the fact that in India, OOP expenditures are approximately three quarters of total health expenditure ¹¹¹.

Available evidence reveals that large proportions of population belonging to poor households forego formal treatments owing to family budget constraint. Further, it confirms earlier findings that a substantial burden of OOP is due to outpatient care while the financial burden caused by inpatient care episodes are to the extent of little over one-fifth, and the remaining four-fifth due to outpatient care visits ⁵. Another study demonstrated that medicines purchase alone constituted over 70 percent of overall OOP payments. Further, it showed that by simply removing OOP payments for inpatient care resulted in a negligible decline in poverty headcount ratio and poverty gap. Interestingly, the research also demonstrated that by deducting OOPs payments for outpatient care or medicines, the percent of people falling below poverty worked out to just 0.5% ¹².

Using the method of impoverishment to measure affordability, one study assessed the impoverishment effect of medicines purchases by households in 16 low-and-middle income economies ¹³. Comparing four key medicine prices to household income in 16 nations, and using World Bank poverty levels of US\$ 1.25 or US\$ 2 per day, the study concluded that a substantial number of people are brought to bear financial burden due to unaffordability of medicines. In Philippines, it was pointed out that an originator brand atenolol purchase by individuals would push an additional 22% of population below the US\$ 1.25 per day

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measurement while even a generic equivalent of atenolol was likely to push about 7% of population below poverty levels ¹⁴.

Available evidence, both global and Indian, provides insights about the incidence of catastrophic payments and impoverishment impact of a high and rising households OOP. The literature on equity dimensions involving both catastrophe and impoverishment has attempted to address complex methodological and statistical approaches in measurements. The focus of this research, on the other hand, is to explore the consequences of high households' medicines spending, since a large share of households' OOP is often incurred on purchasing drugs. Further, we attempt to investigate which disease conditions are contributing to high financial burden on households' medicines spending. We attempted to answer - what is the contribution of medicine OOP by households in total OOP payments, catastrophic and poverty headcounts? And which disease conditions cause relatively higher financial disruption in the living status of households?

Materials and methods

Data

The study used secondary data from three waves of nationally representative 'Consumer Expenditure Surveys' (CES): 1993-94, 2004-05 and 2011-12, conducted by the National Sample Survey Organisation (NSSO). In addition, health and morbidity survey (HMS) 2014 of the NSSO was used for disease level classifications of OOP burden. While the sample of size of CES varied between 100,000 to 125,000 thousand households across different rounds, the sample size in HMS 2014 was approximately 72,000 households.

The CES collect socioeconomic and demographic information on households, but its key focus is on household spending on roughly 350 food and non-food items. Out-of-pocket medical expenses incurred by households are separately recorded for inpatient and outpatient services. The recall periods are one-year and 30-days for inpatient and outpatient expenses, respectively. HMS collects detailed information on morbidity types, utilisation pattern and expenditure by households incurred due to utilisation of healthcare. HMS too separately records expenditure for inpatient and outpatient. However, unlike in CES the recall period for outpatient in HMS is 15 days.

Both CES and are repeated cross-section surveys and are representative at the national and state levels. In most cases, all districts of a state are included for sampling purposes. Households in CES are sampled evenly in quarterly sub-rounds beginning on 1 July and ending on 30 June of the following year, with equal numbers of households allotted in each quarterly sub-round, to address seasonality. In HMS, survey was completed in only two sub-rounds starting January1 to June 30, 2014. All estimates in the present paper are sample weighted.

Outcome indicators

Using CES we estimated 4 household-level indicators of the financial burden of illness: i) per household member monthly OOP spending on medicines (inflation-adjusted), ii) OOP spending on medicines as a share of total household and non-food spending, and iii) percentage of households reporting catastrophic payments on medicines and iv) percentage of households slipping onto poverty after netting out medicines OOP from households' total consumption expenditure. Instead of sticking to a particular threshold, we considered a range of thresholds for assessing catastrophic expenditure ²⁴⁹¹⁵. We also considered a alternative thresholds as medicine OOP spending as a share of household non-food expenditure. For OOP induced poverty estimates we used two different poverty lines: i) Indian official state-specific poverty line¹⁶ and ii) international poverty line based on US \$ 1 per day per person adjusted to US \$ 1.9 purchasing power parity (PPP) per day per person for the year 2011-12¹⁷. Details of the method used for catastrophic and poverty estimates are presented in Appendix I.

In addition, we used NSSO 2014 HMS data for estimating disease level total and medicine OOP spending separately for inpatient and outpatient. Unlike CES, OOP spending in NSSO 2014 has not been recorded as part of the total household consumption expenditure and instead of estimating disease-wise catastrophic headcount, we present distribution of disease conditions based on incidence of occurrence and range of OOP spending separately for outpatient (15 days recall converted for 30 days) and inpatient (365 days recall converted for 30 days). This helped identifying disease conditions, separately for outpatient and inpatient, which are high frequency of occurrence and greater incidence of OOP spending.

Results

First, we present basic financial burden indicators for the years 1993-94, 2004-05 and 2011-12 in Table 1. Over 80 percent of populations are reportedly spending out-of-pocket while seeking treatment, during 2011-12. The proportion of population reporting any OOP payments have increased sharply from about 60 percent during 1993-94 to 80 percent in 2011-12. In respect to medicines spending, approximately every OOP spending is associated with expenditure on medicines. There was a significant increase (more than 50%) in household's total consumption expenditure in real terms from INR 517 in 1993-84 to INR 794 in 2011-12. However, during the same period total OOP increased by more than 100% from INR 26 in 1993-94 to INR 54 in 2011-12 in real terms. The increase in OOP on medicine has been more than 70% during the same period. Consequently, the share of spending on health from households' overall consumption expenditure have registered sharp increase during the past two decades, from a moderate 4.8 percent during 1993-94 to nearly seven percent in 2011-12. If we were to net out food expenditure from overall household spending, which are considered a necessity, the share of health spending remained stagnant

but as high as 11-12 percent during the period under consideration. It may be observed that in 2011-12 medicines alone contributed up to 67% of the total OOP.

Table 1: Financial burden indicators, India,	1993-94, 2004-0	5 and 2011-12	

Financial burden indicators	1993-94	2004-05	2011-12
Percentage households reporting oops			
	59.2 [58.9,	64.4 [64.2,	80.5 [80.2,
total oops	59.5]	64.7]	80.7]
	57.5 [57.3,	63.6 [63.3,	79.0 [78.8,
medicines oops	57.8]	63.8]	79.3]
Monthly per capita expenditure (INR)			
total consumption expenditure (current	317 [315,	712 [708,	1627 [1617,
prices)	318]	715]	1636]
total consumption expenditure (constant		619 [616,	794 [790,
1999-2000 prices)	517 []	622]	799]
total out-of-pocket expenditure (current	15.7 [15.4,	41.8 [41.1,	111.2 [109.1,
prices)	16.0]	42.6]	113.3]
total out-of-pocket expenditure (constant		36.3 [35.7,	54.3 [53.3,
1999-2000 prices)	25.59 []	37.0]	55.3]
medicines out-of-pocket expenditure	12.8 [12.6,	29.8 [29.3,	73.9 [72.5,
(current prices)	13.0]	30.2]	75.3]
medicines out-of-pocket expenditure 🛛 🦯		26.0 [25.6,	36.1 [35.5,
(constant 1999-2000 prices)	20.86 []	26.4]	36.8]
Share of health to total household			
expenditure (%)			
	4.84 [4.78,	5.78 [5.72,	6.77 [6.70,
share of total out-of-pocket expenditure	4.91]	5.83]	6.84]
share of total medicines out-of-pocket	3.93 [3.87,	4.10 [4.06,	4.49 [4.45,
expenditure	3.98]	4.14]	4.54]
Share of health to non-food household			
expenditure (%)			
	12.37 [12.20,	10.82 [10.72,	11.46 [11.36,
share of oops to non-food expenditure	12.55]	10.91]	11.56]
share of medicines oops to non-food	10.02 [9.88,	7.68 [7.62,	7.60 [7.54,
expenditure	10.17]	7.75]	7.67]

Note: numbers in brackets are 95% confidence interval

The households' financial burden on account of distress in OOP payments leads to i) impoverishment and ii) catastrophe. In Table 2 we present a set of catastrophic thresholds measured as a share of OOP to total household consumption expenditure and non-food expenditure. Estimates are presented for both overall OOP as well as OOPs underlying medicines expenditure of households. Further, we define catastrophic measures at different thresholds.

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Table 2: Percentage of households incurring catastrophic payments with respect to total						
OOP and medicines spending, India, 1993-94, 2004-05 and 2011-12						
Financial Health Equity	1993-94	2004-05	2011-12	Estimated number of		
Measurements				households (2011-12)		
Thresholds using on total						
household expenditure		1	1			
total OOP > 5%	26.9	28.7	35.3			
	[26.6,	[28.5,	[35.0,			
	27.1]	30.0]	35.6]	9,01,07,225		
total OOP > 10%	13.9	14.6	17.9			
	[13.8,	[14.4,	[17.7,			
	14.2]	14.8]	18.2]	4,56,91,766		
total OOP > 25%	3.9 [3.8,	3.5 [3.4,	4.3 [4.2,			
	4.0]	3.6]	4.4]	1,09,76,234		
medicines OOP > 5%	23.3	23.4	27.0			
	[23.0,	[23.2,	[26.7,			
	23.5]	23.6]	27.2]	6,89,20,540		
medicines OOP > 10%	11.5	10.2	11.2			
	[11.3,	[10.2,	[11.0,			
	11.7]	10.4]	11.4]	2,85,89,261		
medicines OOP > 25%	02.9 [2.8,	1.6 [1.5,	1.8 [1.7,			
	2.9]	1.7]	1.9]	45,94,703		
Thresholds using on non-	•	0				
food expenditure						
total OOP > 5%	47.8	46.5	53.5			
	[47.5,	46.2,	[53.2,			
	48.1]	46.8]	53.8]	13,65,64,775		
total OOP > 10%	34.8	31.0	34.9			
	[34.6,	[30.7,	[34.7,			
	35.1]	31.2]	35.2]	8,90,86,180		
total OOP > 25%	16.7	11.4	11.9			
	[16.5,	[11.2,	[11.7,			
	16.9]	11.5]	12.1]	3,03,76,090		
total OOP > 40%	9.7 [9.5 <i>,</i>	4.7 [4.6,	4.9 [4.8 <i>,</i>			
	9.9]	4.9]	5.0]	1,25,07,802		
medicines OOP > 5%	44.7	42.5	46.4			
	[44.4,	[42.2,	[46.1,			
	45.0]	42.8]	46.7]	11,84,41,225		
medicines OOP > 10%	31.2	25.5				
	[31.0,	[25.3,	26.1 25.9,			
	31.5]	25.7]	26.4]	6,66,23,189		
medicines OOP > 25%	13.9					
	[13.7,	7.1 [7.0,	6.3 [6.1,			
	14.1]	7.3]	6.4]	1,60,81,459		
medicines OOP > 40%	7.8 [7.6,	2.2 [2.1,	1.8 [1.7,			
	7.9]	2.3]	1.9]	45,94,703		

Table 2: Percentage of households incurring catastrophic payments with respect to total

At the lowest cut-off level of five percent, over one-third of Indian households incurred OOP payments in 2011-12. This percentage was lower in 1993-94 (27%) and 2004-05 (28%). At the 25% threshold of total household expenditure, over 4% households reported incurring OOP in 2011-12, which again registered increasing trend during the last two decades. This essentially implies approximately 11 million Indian households in 2011-12 incurred OOP payments, which is more than 25% of their total household expenditure. Out of these more than 4.4 million households incurred such payments only on account of purchase of medicines. At a lower threshold of 10% of THE, the number of households facing catastrophe is approximately 46 millions, of which 29 million households incurred catastrophe on account of OOP on medicines. Considering only non-food expenditure of households as the basic living status variable, approximately similar number of households incurred medicine OOP in 2011-12, which is as high as 40% of their non-food expenditure.

Table 3: Impoverishment Inc	licators due to Households' OOP on Medicines, India, 1993-94,
2004-05 and 2011-12	

	1993-94	2004-05	2011-12	Estimate d populatio n (2011- 12)
Using national poverty line*		0		/
Gross Headcount	45.32 [45.03,	37.85 [37.58,	22.17 [21.92,	27,19,03,
	45.61]	38.12]	22.43]	356
Headcount net of total	49.52 [49.22,	42.68 [42.40,	26.65 [26.38,	32,68,48,
OOP	49.81]	42.95]	26.92]	193
Total OOP induced poverty	4.20 [4.07 <i>,</i>	4.83 [4.71,	4.48 [4.35,	5,49,44,8
	4.30]	4.94]	4.60]	37
Headcount net of medicine OOP	48.91 [48.61,	41.54 [41.27,	25.27 [25.00,	30,99,23,
	49.20]	41.82]	25.53]	221
Medicine OOP induced poverty	3.59 [3.47 <i>,</i>	3.69 [3.59 <i>,</i>	3.09 [2.99 <i>,</i>	3,78,97,2
	3.69]	3.80]	3.20]	20
Using international poverty line**				
Gross Headcount	40.96 [40.67 <i>,</i>	33.07 [32.81,	18.37 [18.13,	22,52,98,
	41.24]	33.34]	18.61]	360
Headcount net of total	44.92 [44.63,	37.38 [37.11,	22.41 [22.16,	27,48,46,
OOP	45.21]	37.65]	22.67]	829

Total OOP induced poverty	3.96 [3.85 <i>,</i>	4.31 [4.19 <i>,</i>	4.04 [3.92 <i>,</i>	4,95,48,4
	4.08]	4.42]	4.16]	69
Headcount net of medicine OOP	44.35 [44.06,	36.34 [36.08,	21.37 [21.11,	26,20,91,
	44.64]	36.61]	21.62]	778
Medicine OOP induced poverty	3.39 [3.29,	3.27 [3.17,	2.99 [2.89,	3,66,70,7
	3.50]	3.68]	3.10]	73

Notes: based on Tendulkar Committee methods; ** using USD 1.90 PPP at 2011-12 prices and mixed recall period of household consumption expenditure

Next, we present implications of OOP payments on poverty estimates. To facilitate interpretation, we present 3 basic indicators: i) gross headcount – percentage of population below poverty line, ii) headcount net of OOP – percentage of population below poverty line after netting out OOP from household consumption expenditure and iii) OOP induced poverty which is the difference of the first two reflecting rise in poverty ratio owing to OOP. The last two indicators are presented separately for total OOP and medicine OOP. All these indicators are estimate using Indian official poverty line (Tendulkar Committee method) and international poverty line of US \$ 1.90 PPP.

The difference in mean headcount measure of gross and net poverty ratio, reflects the percentage of population falling below poverty line because of households' OOP on health care. The percentage of headcount of households impoverished due to OOP was 3.97 percent during 1993-94, which increased to 4.30 percent in 2004-05 while in 2011-12 it was at 4.04 percent, as per international poverty line. In terms of Indian state-specific official poverty line, it may be observed that owing to OOP the percentage of households falling below poverty line increased from 4.19 percent in 1993-94 to 4.48 percent in 2011-12. This implies that close to 55 million persons in 2011-12 were pushed into poverty mainly because of OOP payments to healthcare. Out of this approximately 38 million became poor only because OOP payments on purchasing medicines. Using the same measurement, the headcount measure for households OOP on medicines slightly declined from 3.58 percent in 1993-94 to 3.09 percent during 2011-12 using the international poverty line. Two trends stand out clearly from the findings. Impoverishment arising out of households' OOP is rather high and continued to be so during the last two decades. Moreover, the burden of impoverishment arising out of households' OOP on medicines appears to be highest, where three fourth of all health impoverishment is due to medicines spending by households.

OOP expenditure by disease conditions

We also conducted a disaggregated analysis on disease wise expenditure not only with reference to total OOP and medicine OOP but also by type of care - inpatient versus out patient. Most common health condition for seeking outpatient care and inpatient care was

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fever (22.7%) and childbirth (22.3%). In addition, our estimates suggest that cancer had the highest monthly total OOP per capita both for inpatient (INR 5054) and outpatient (INR 5121) care followed by injuries (INR 3045) for outpatient care and cardiac events (INR 2808) for inpatient care.

Since, medicines OOP contribute significantly to catastrophe of households as highlighted above, we mapped disease wise expenditure, frequency of utilization and type of care to generate a holistic scenario to explain how not only hospitalization but outpatient care for majority of the disease also leads to catastrophe and impoverishment (Figure 1). For example, our estimates suggest that per capita medicine OOP for cancer care was significantly higher in outpatient care as compared to the inpatient care. However, as far as total OOP is concerned, it is almost similar and high both for inpatient and outpatient. In contrast, in case of cardio, medicine OOP is similar both for inpatient and outpatient but total OOP is significantly higher for inpatient treatment compared to outpatient treatment. In case of gastro, however, both medicine OOP and total OOP both are higher for outpatient compared to inpatient treatment. Similarly, for mental disorder medicine OOP is higher for outpatient compared to inpatient but total OOP is almost similar both for outpatient and inpatient. In general, average monthly medicine OOP was consistently higher for outpatient care as compared to inpatient cares for majority of disease condition and coupled with higher frequency for outpatient care this is resulting into high incidence of catastrophe. The catastrophic nature of outpatient expenditure is also reflected at the household level.

We plotted outpatient and inpatient total OOP and medicine OOP in relation to households 'usual' consumption expenditure (Figure 2). For a number of households, average monthly outpatient expenditure is not only significantly higher in relation to household's non-medical consumption expenditure but also frequency of such events is higher in outpatient care as compared to inpatient care. The concentration of red (total OOP) and green (medicine OOP) spikes above the consumption expenditure on the right hand side of the graph reflects this scenario succinctly.

Discussion and conclusion

We demonstrated through a well-defined approach of measuring health cost burden on households that medicines OOP payments by households leads to impoverishment and catastrophe. Although evidence exist both in global and Indian literature on catastrophic and impoverishing nature of household's OOP, to the best of our knowledge this research work is the first attempt to capture impoverishing effect of OOP payments on account of medicine OOP in both outpatient and inpatient setting involving disease conditions. We observed that households' OOP is not only high in India but continues to remain so for over two decades. Also, the spending on medicines accounted for the largest share of OOP, accounting for over two-thirds of households' payments on health care. Applying a 10%

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threshold of OOPs on overall consumption expenditure, an estimated 18 percent of Indian households appear to suffer financial catastrophe. In respect to medicines OOP, at similar threshold, an estimated 11 percent of Indian populations are reported to be incurring catastrophe. This essentially implies that an estimated 46 million households faced catastrophic expenditure on healthcare in the year 2011-12, if we consider 10% threshold of household consumption expenditure as catastrophe. Out of this 46 million, 29 million households incurred such expenditure mainly on account of purchasing medicines. Impoverishment of households arising out of households' OOP is high and continues to be so during the last two decades. Measured both by international poverty criteria as well as Indian state-specific official poverty lines, the burden of impoverishment due to households' OOP on medicines appears to be significantly high, where three fourth of all health impoverishment is due to medicines spending. An estimated 55 million population were pushed into poverty because they had to pay for healthcare. Medicines purchasing alone contributed to approximately 38 million of this increase in impoverishment.

Literature suggest that in India, on an average, the government spending on medicines to be around 10 percent, several state governments end up spending even less than five percent of public spending on health care ¹⁸. In addition, except for a couple of Indian states, drug procurement and distribution system is ineffective leading to acute shortages of key essential medicines and chronic stock-outs in public health facilities¹⁹⁻²². This situation has resulted in physical unavailability of medicines. Drawing evidence from large sample surveys for the period from 1986-87 to 2004, it is reported the physical barrier to access to key essential medicines have worsened during this period. Supply of free drugs in government health system in the outpatient care setting, declined sharply from about 18 percent in 1986-87 to five percent in 2004. For the same period, drugs prescribed during hospitalization for free also declined significantly from one-third to about nine percent¹⁸.. As a result, it is pointed out "the number of hospitalization episodes in which an ailing population paid out-of-pocket (OOP), has risen dramatically from about 41 percent to close to 72 percent".

Further, it was observed that from the period spanning mid-1990s to 2004, patients visiting government health facilities did not receive medicines in over one-fourth of outpatient episodes²³. In view of inadequate availability of medicines in government health facilities, households' end up accessing private facilities. Evidence suggests that trend have sharpened in the last couple of decades. For instance, the percentage of population accessing private facilities for inpatient and outpatient treatment has increased significantly between 1986-87 and 2004, households accessing private hospital care increased from around 40 percent to nearly 60 percent in rural India while urban India reported increase from 40 percent to 68 percent²⁴. For similar period, outpatient care visits in private facilities remained high at around 75 percent in 1986-87 in rural India and 73 percent in urban India stepped up to 78 percent and 80 percent respectively for rural and urban India²⁵.

Although public sector gained some ground by increasing its share in total outpatient care, private sector continue to dominate both in outpatient and inpatient care in India²³. As an increasing share of households access private health facilities, private retail pharmacies have become a major source of supply of key essential medicines. While availability of medicines may per se not a challenge, affordability appears to act as barrier²⁶. Thus, pricing of medicines and regulation around retail medicine prices becomes critical in improving affordability and consequently reducing medicine induced OOP burden. Although India had a progressive retail price cap policies since 1979, but over the years a policy of deregulation was followed²⁷. In 2013, the Government of India promulgated the Drugs Price Control Order, 2013 (DPCO, 2013) which primarily brought all essential drugs, based on National List of Essential Medicines, 2011, under price cap²⁸. However, the policy has moved from cost based pricing to market-based pricing mechanism. An evaluation of new price regulation has highlighted that, while few of the molecules analyzed (37) had an increase in sales volume attributable to DPCO, majority of the molecules (52) had a negative impact on their sales volume due to DPCO. Overall, the DPCO may have had a negative impact in terms of sales volume of medicines under price control²⁹. Given that the sales volume of price controlled medicines has gone down, households OOP spending may increase on account of high medicine price in unregulated market.

Further, to improve access to health care and to provide financial risk protection to households, the central government and several state governments have been implementing a publicly-funded health insurance programs since 2007, whose primary aim was to provide cashless treatment to economically vulnerable households for hospitalization episodes. Emerging evidence from micro as well as macro level studies point to a trend where such insurance schemes appear to have improved access to hospital care but have been ineffective in preventing catastrophe and impoverishment to households^{4 30} ³¹. These evidence are in line of our findings that hospitalization based treatment constitute only small part of the India's morbidity burden and despite several health insurance schemes majority Indian population continue to incur medicine OOP while seeking outpatient care.

The foregoing clearly points that several policy interventions and program design were conceived and implemented in the recent past to provide financial risk protection to households. However, gross underinvestment in public health system in past had led to inadequate prepayment and risk protection measures²⁴. Several policy interventions and program redesign are required to reverse the trend of high OOP, which leads to catastrophe and impoverishment among significant sections of Indian population. For example, an efficient and a reliable supply chain model existed for over two and half decades in the state of Tamil Nadu, which was replicated in the state of Rajasthan in 2012 have been instrumental in improving access to medicines in the frontline facilities³². Such policies and

programs governing public health facilities are critical, what is even more vital is the price cap intervention in the retail segment. The NHP 2017 also highlighted the need for providing free medicines in public health facilities by stepping up funding and improving drug procurement and distribution mechanisms³³. In addition to DPCO, 2013, the present central government has reduced prices of 200 key essential drugs whose prices were not notified by DPCO earlier²⁸, using a special provision under Para 19 of DPCO to bring more drugs under price ceiling. A recent pronouncement by the government intends to bring legislation for physicians to prescribe drugs only in generic names, holds even greater promise for reducing households' OOP. In summary, government intervention in terms of public provisioning of free medicine has potential to significantly reduce the medicine related OOP as well as total OOP.

Contributorship: AK and SS conceived the idea, designed the analysis, conducted data analysis and wrote the first draft of the paper. AK, SS and HHF conducted the literature review and the interpretation of the results. AS, SS and HHF revised and edited the manuscript to its final stages. All the authors approved the final manuscript version.

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Data sharing: The data used for the analysis is available in public domain.

Ethical approval: Ethical approval for this study was not needed. The study used only anonymised data from secondary sources. Requisite permission to use the data has been obtained from the agency.

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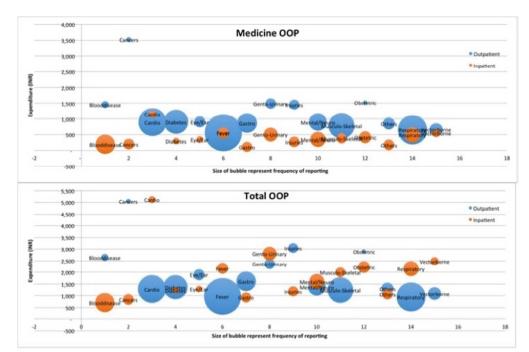
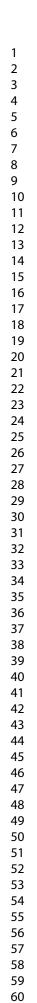


Figure 1: Disease wise average monthly per person medicine OOP and total OOP, 2014

255x178mm (72 x 72 DPI)



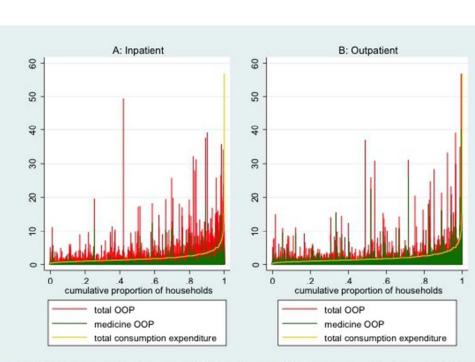


Figure2: Monthly per person total OOP; medicine OOP and consumption expenditure

200x146mm (72 x 72 DPI)

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Supplementary materials

Annexure I: Estimation of out-of-pocket expenditure indicators

a. Out-of-pocket payments

Total out-of-pocket (OOP) payment has been defined as the summation of all kinds of direct expenditure on purchase of medical care including expenditure on family planning devices and transportation costs to access medical care by households either as inpatient or outpatient. According to the NSSO household questionnaire the main item of expenditure considered for inpatient and outpatient are presented in Table A-I.

Table A-I: Main items of expenditure considered for inpatient and outpatient in the NSSO questionnaire

Inpatient	0	Outpatient	
Heads of expenditure	Item code in NSSO questionnaire	Heads of expenditure	Item code in NSSO questionnaire
medicine	410	medicine	420
X-ray, ECG, pathological test, etc.	411	X-ray, ECG, pathological test, etc.	421
doctor's/surgeon's fee	412	doctor's/ surgeon's fee	422
hospital & nursing home charges	413	family planning devices	423
other medical expenses	414	other medical expenses	424
Total inpatient	419=410-414	Total outpatient	429=420-424

The reference period of inpatient and outpatient expenditure in the consumer expenditure surveys are 1 year and 1 month respectively. Based on the information presented in Table A-I, total inpatient expenditure, outpatient expenditure and total OOP expenditure were estimated by converting inpatient expenditure for one month. Accordingly, households with any OOP have been defined as households reporting positive OOP (OOP>0) either as inpatient or outpatient or both.

b. Per person monthly OOP

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Per person monthly OOP is defined as total monthly OOP divided by household size for each household.

c. OOP share

The financial burden of health expenses by households has also been estimated in terms of OOP as a share of total household expenditure and alternatively as a share of total non-food expenditure of households.

 $Sh_{OOP} = T/\exp \qquad (A.1)$

Where, 'T' is total OOP payments and 'exp' is household total (non-food) expenditure by households.

d. Catastrophic payments and headcount

Further, OOP payments are defined as catastrophic when OOP payments as a portion of total household resources are in excess of a certain threshold. A household is said to have incurred catastrophic payments if T/exp>Z, where 'T' and OOP are the same as in equation (A.1) and 'Z' is a certain threshold. The latter is arbitrary and in general, estimates are presented for a range of values for z (5, 10, 15, 25 and 40 per cent).

Accordingly, the headcount ratio of catastrophic payment is calculated as follows:

 $cat_i = \frac{1}{n} \sum 1\left(\frac{T}{exp} > Z_i\right)$ (A.2)

Where, Cat_i is catastrophic headcounts of households with OOP share exceeding a threshold defined as 'i' per cent of total household total (non-food) expenditure, 1(.) is an indicator function, which takes the value 1 if T/exp>Zi is true and 0 otherwise; n is the number of households incurring expenditure on health for various thresholds; Z_1, Z_2, Z_3 are the respective thresholds of the OOP share.

d. Poverty headcount

The usual headcount ratio of poverty is calculated as:

pre $HP = 1/n \Sigma 1$ (xi ≤ PL) (A.3)

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where: 1(.) *is a function, taking the value* 1 *if person belong to a household with consumption expenditure lower the value of poverty line value, x*= *Household total consumption expenditure; PL*= *Poverty Line and n is total population.*

Headcount of poverty after deducting OOP from household consumption expenditure can be defined as:

 $post HP = 1/n \Sigma 1 ((xi-T) \le PL).$ (A.4)

where: T= per capita OOP

The OOP induced poverty headcount finally is estimated as: (*pre HP - post HP*)

Table 1. Average per episode total and medicine out of pocket payments by disease conditions in 2014

	Outpatient 15	5 days reca	dl –				Inpatient 365	days recall				
	Prevalance				estimated i	monthly	Prevalance				estimated r	monthly
Ailment	Freq.	Percent	Total OOP	Drug	Total OOP	Drug	Freq.	Percent	Total OOP	Drug	Total OOP	Drug
Fever	2,71,43,431	22.71	488	280	975	561	74,12,043	12.95	8670	2329	713	191
TB/Filaria/Tetanus	11,08,425	0.93	524	287	1047	573	6,14,933	1.07	14731	4134	1,211	340
STD/HIV/AIDS	1,20,714	0.1	538	268	1076	536	88,935	0.16	6906	1633	568	134
Vectorborne	33,33,651	2.79	549	332	1097	663	22,65,189	3.96	10288	2460	846	202
Cancers	4,52,513	0.38	2527	1763	5054	3526	9,78,764	1.71	62297	14037	5,121	1,154
Blood disease	10,26,129	0.86	1322	731	2643	1463	8,10,752	1.42	15035	3650	1,236	300
Diabetes	1,17,55,081	9.84	683	456	1367	911	8,17,199	1.43 🧹	15746	4224	1,294	347
Other Metabolic	20,50,282	1.72	712	340	1423	679	2,60,707	0.46	15429	3600	1,268	296
Mental/Neuro	61,56,374	5.15	690	451	1380	902	24,87,836	4.35	26428	6685	2,172	549
Eye/Ear	24,67,286	2.06	950	454	1899	908	20,82,420	3.64	11350	1407	933	116
Cardio	1,55,65,223	13.02	645	449	1289	899	37,82,374	6.61	34167	6129	2,808	504
Respiratory	1,69,58,670	14.19	478	328	955	656	21,40,762	3.74	14491	3325	1,191	273
Gastro	77,13,330	6.45	809	434	1617	869	45,40,520	7.93	19587	4260	1,610	350

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.,32,29,065 11.07 21,91,953 1.83 3,64,060 0.3 9,93,646 1.67 28,92,298 2.42 .,46,562 0.12	83118331448671522	391 747 765 730 426 398	1244 2365 2896 3045 1310 1169	782 1494 1529 1460 853 797	19,66,211 28,01,133 22,64,628 46,19,876 12,97,049 1,56,17,000	3.44 4.89 3.96 8.07 2.27 27.29	24379 27085 13050 26242 30196 8508	4677 5094 2189 6000 66666 1729	2,004 2,226 1,073 2,157 2,482 699	384 419 180 493 548 142
8,64,060 0.3 9,93,646 1.67	3 1448 67 1522	765 730	2896 3045	1529 1460	22,64,628 46,19,876	3.96 8.07	13050 26242	2189 6000	1,073 2,157 2,482	180 493 548
9,93,646 1.67	67 1522	730	3045	1460	46,19,876	8.07	26242	6000	2,157 2,482	493 548
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Quantifying the financial burden of households' out-ofpocket payments on medicines in India. A repeated crosssection analysis of National Sample Survey data 1994 to 2014

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9 10	Quantifying the financial burden of households' out-of-pocket payments on medicines in
11	India. A repeated cross-section analysis of National Sample Survey data 1994 to 2014
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Quantifying the financial burden of households' out-of-pocket payments on medicines in India. A repeated cross-section analysis of National Sample Survey data 1994 to 2014

Objective: The objective of this research is to generate new evidence on financial implications of medicines out of pocket (OOP) payments for households. Another objective is to investigate which disease conditions contributed to a significant proportion of households' financial burden.

Setting: All Indian States including Union Territories, 1993-94 to 2014

Design: Repeated cross section household surveys

Data: Secondary data of nationwide Consumer Expenditure Surveys for the years 1993-94, 2004-05 and 2011-12 and one wave of Social Consumption: Health for the year 2014 from National Sample Survey Organisation.

Outcome measure : Out-of-pocket expenditure on healthcare in general and medicines in specific.

Results: Total OOP payments and medicines OOP payments were estimated to be 6.77% [CI: 6.70%, 6.84%] and 4.49% [4.45%, 4.54%] of total consumption expenditure respectively in the year 2011-12 which marked significant increase since 1993-94. These proportions were 11.46% [CI: 11.36%, 11.56%] and 7.60% [CI: 7.54%, 7.67%] of non-food expenditure respectively in the same year. It was observed that total OOP payments and medicines OOP payments were catastrophic for 17.9% [CI: 17.7%, 18.2%] and 11.2% [11.0%, 11.4%] households respectively in 2011-12 at the 10% of total consumption expenditure threshold, implying 29 million households incurred catastrophic out-of-pocket payments in the year 2011-12. Further, medicines out-of-pocket payments pushed 3.09% [CI: 2.99%, 3.20%], implying 38 million, persons into poverty in the year 2011-12. Among the leading cause of diseases that caused significant OOP payments are cancers, injuries, cardiovascular diseases, genito-urinary conditions and mental disorders.

Conclusions: Strengthening government intervention in providing medicines free in public health care facilities has the potential to considerably reduce medicines related spending as well as total OOP payments of households.

Key words: India, out of payment, medicine, catastrophic expenditure, and poverty

Article summary

Strengths and limitations of this study

- 1. The study used multiple points of time and nationally representative data set to highlight the financial burden of households OOP payments on medicines in India;
- 2. The paper links medicines out-of-pocket payments by households with leading disease conditions and identify key disease conditions which cause medicines out-of-pocket payments
- 3. The study has limitations as it uses arbitrary threshold for measuring catastrophic payments
- 4. The ailments, disease conditions and the associated OOP expenditure reported by the households in the survey are self-reports and not clinically diagnosed.

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Background

Households' in India bear significant financial burden on account of medical treatment, as the current prepayment and risk pooling mechanisms are inadequate. Since both government funding and social health insurance contributions are insufficient to meet health care needs of households, over three-fourth of all health care payments are paid out-of-pocket (OOP) at the point of service delivery while medicines purchase (approximately 63%) account for the single largest component of these payments.¹ Available literature suggests that OOP spending has dominated total OOP payments over the years.² Hence, it can be suggested that expenditure on medicines is major cause of catastrophe at the household level.³

India has the distinction of being pharmacy of the global south - supplies affordable, life saving, quality generic medicines. It ranks 4th in terms of volumes and 13th in terms of value of pharmaceuticals produced globally.⁴ However, according to a WHO report around 68% of the Indian population have limited or no access to essential medicines.⁵ In addition, literature suggests that over last two decades availability of free medicines in public health facilities has declined from 31.2% to 8.9% for inpatient care and from 17.8% to 5.9% for outpatient care.⁶ Another study demonstrated that medicines purchase alone constituted over 70% of overall OOP payments. In addition, the study demonstrated that by removing OOP payments for outpatient care on medicines, the percentage of people falling below poverty because of spending on health reduced to just 0.5% whereas removing OOP payments for inpatient care resulted in a negligible decline in poverty headcount ratio and poverty gap highlighting the role of medicines expenditure in healthcare related impoverishment.⁷

Utilising impoverishment tool to measure affordability, one study assessed the impoverishment effect of medicines purchases by households in 16 low-and-middle income economies.⁸ Comparing four key medicine prices to household income, and using World Bank poverty levels of US\$ 1.25 or US\$ 2 per day, the study concluded that a substantial number of people had to bear financial burden due to unaffordability of medicines. For example, it was pointed out that an originator brand atenolol purchase by individuals would push an additional 22% of population below the US\$ 1.25 per day measurement while even a generic equivalent of atenolol was likely to push about 7% of population below poverty levels in Philippines.⁹ Analyzing economic implications of non-communicable disease in India, a few studies also reported in the past that households incur significant OOP payment burden in certain conditions like cardiovascular diseases (CVD) and cancers. ^{10 11} Using 2004 NSSO data, another study highlighted that hospitalization with CVD resulted in 12% higher odds of incurring catastrophic spending and 37% greater odds of falling into poverty. For cancer, the impact was greatest with the odds of catastrophic expenditures 170% higher than the odds of incurring catastrophic spending when hospital stays are due to a

communicable disease condition.¹² However these studies do not reflect on the relative contribution of medicine in total OOP burden for the diseases they analysed.

Available evidence, both global and Indian, provides insights about the incidence of catastrophic payments and impoverishment impact of rising households OOP payments.^{2 3} ¹³⁻¹⁵ The literature on equity dimensions involving both catastrophe and impoverishment has attempted to address complex methodological and statistical approaches in measurements. However, there is lack of evidence on catastrophe and impoverishment on account of household's medicine OOP expenditure not only from inpatient and outpatient treatment costs perspective but also from the disease specific dimension. Given that medicines contribute to more than 66.6% of out-of-pocket healthcare expenditure, the focus of this research is to explore the consequences of high medicines OOP spending at the household level. Further, we investigated which disease conditions are contributing to high financial burden on households. We attempted to answer - what is the relative burden of medicines OOP payments by households in total OOP payments, catastrophic and poverty headcounts? And which disease conditions cause a relatively higher financial disruption in the living status of households?

Materials and methods

Data

The study utilises secondary data from three waves of nationally representative 'Consumer Expenditure Surveys' (CES): 1993-94, 2004-05 and 2011-12, conducted by the National Sample Survey Organisation (NSSO). In addition, health and morbidity survey (HMS) 2014 of the NSSO was used for disease-wise distribution of OOP payment burden. While the sample size of CES varied between 100,000 to 125,000 thousand households across different rounds, the sample size in HMS 2014 was approximately 72,000 households.

The CES collect socioeconomic and demographic information on households with key focus is on household spending on roughly 350 food and non-food items. Out-of-pocket medical expenses incurred by households are separately recorded for inpatient and outpatient services. The recall periods are one-year and 30-days for inpatient and outpatient expenses respectively. HMS collects detailed information on morbidity pattern, utilisation of health care services and associated expenditure by households. The HMS too separately records expenditure for inpatient and outpatient. However, unlike in CES the recall period for outpatient in HMS is 15 days.

Both CES and HMS are repeated cross-section surveys that are representative at the national and state levels. All districts of a state are included for sampling purposes. Households in CES are sampled evenly in quarterly sub-rounds beginning on 1 July and ending on 30 June of the following year, with equal numbers of households allotted in each quarterly sub-round, to address seasonality. In HMS, survey was completed in two subrounds during January1 to June 30, 2014. All estimates in the present paper are sample weighted.

Outcome indicators

Using CES, we estimated 4 household-level indicators involving financial burden of illness: i) per household member monthly OOP spending on medicines (inflation-adjusted), ii) OOP spending on medicines as a share of total household and non-food spending, and iii) percentage of households reporting catastrophic payments on medicines and iv) percentage of households slipping onto poverty after netting out medicines OOP payments from households' total consumption expenditure. Total OOP spending of households was estimated by adding together expenditure on components of OOP payments. For inpatient OOP payment, we considered institutional spending on medicines, X-ray, ECG, pathological tests etc., doctor's/surgeon's fee, hospital and nursing charges and other medical expenses. For outpatient OOP payment, the components of expenditure are medicines, X-ray, ECG, pathological tests etc., doctor's/surgeon's fee, family planning services and other medical expenses. Expenditure on medicines is directly reported in the data set, both for inpatient and outpatient services (see Table A-I in Annexure). All the analyses report mean OOP spending on two parallel tracks: aggregated (across components of OOP) OOP payments (henceforth referred to as 'total OOP') and OOP payments only on account of medicine purchase (henceforth referred to as medicine/drug OOP).

Catastrophic payment for health care is defined as OOP payments being higher to a predefined threshold of total household consumption expenditure or alternatively household's non-food expenditure. For measuring catastrophic expenditure,²⁹ instead of sticking to a particular threshold, we considered a range of thresholds.²¹⁶⁻¹⁸ We also considered alternative thresholds as OOP spending as a share of household non-food expenditure. For OOP payment induced poverty estimates, we used two different poverty lines: i) Indian official state-specific rural and urban poverty lines¹⁹ and ii) international poverty line based on US \$ 1 per day per person adjusted to US \$ 1.9 purchasing power parity (PPP) per day per person for the year 2011-12²⁰. Yet another important poverty indicator, which particularly estimates magnitude of poverty deepening, is poverty gap. Using both the poverty lines separately, we also estimated mean poverty gaps for the poor. Details of the method used for catastrophic and poverty estimates are presented in Annexure.

In addition, we used NSSO 2014 HMS data for estimating disease level total and medicine OOP spending separately for inpatient and outpatient. Unlike CES, OOP spending in NSSO 2014 has not been recorded as part of the total household consumption expenditure and instead of estimating disease-wise catastrophic headcount, we present distribution of disease conditions based on incidence of occurrence and range of OOP spending separately for outpatient (15 days recall converted for 30 days) and inpatient (365 days recall

converted for 30 days). This helped identifying disease conditions, separately for outpatient and inpatient, which are high frequency occurrence and greater incidence of OOP spending.

Results

First, we present basic financial burden indicators for the years 1993-94, 2004-05 and 2011-12 in Table 1. Over 80% of populations are reportedly spending out-of-pocket while seeking treatment, during 2011-12. The proportion of population reporting any OOP payments have increased sharply from about 60% during 1993-94 to 80% percent in 2011-12. In respect to medicines spending, approximately every OOP spending is associated with expenditure on medicines. There was a significant increase (more than 50%) in household's total consumption expenditure in real terms from INR 517 in 1993-84 to INR 794 in 2011-12. However, during the same period total OOP payments increased by more than 100% from INR 26 in 1993-94 to INR 54 in 2011-12 in real terms. The rise in OOP payments on medicines has been more than 70% during the same period. Consequently, the share of spending on health from households' overall consumption expenditure have registered sharp increase during the past two decades, from a moderate 4.8% during 1993-94 to nearly 7% in 2011-12. If we were to net out food expenditure from total household consumption spending, which are considered a necessity, the share of health spending remained stagnant but as high as 11-12% percent during the period under consideration. It may be observed that in 2011-12 medicines alone contributed up to 67% of the total OOP payments.

Financial burden indicators	1993-94	2004-05	2011-12
Percentage households reporting OOP			
payments	4		
	59.2 [58.9,	64.4 [64.2,	80.5 [80.2,
Total OOP payments (%)	59.5]	64.7]	80.7]
	57.5 [57.3,	63.6 [63.3,	79.0 [78.8,
Medicines OOP payments (%)	57.8]	63.8]	79.3]
Monthly per capita expenditure (INR at			
constant 1999-2000 prices*)			
	517 [515,	619 [616,	794 [790,
Total household consumption expenditure	519]	622]	799]
	25.59 [24.61,	36.3 [35.7,	54.3 [53.3,
Total out-of-pocket expenditure on health	26.25]	37.0]	55.3]
	20.86 [26.0 [25.6,	36.1 [35.5,
Medicine out-of-pocket expenditure	19.50, 21.25]	26.4]	36.8]
Share of health to total household			
expenditure (%)			
Share of total out-of-pocket expenditure to	4.84 [4.78,	5.78 [5.72,	6.77 [6.70
total household expenditure (%)	4.91]	5.83]	6.84]

Table 1: Financial burden indicators	. India.	1993-94	. 2004-05 and 2011-12
	,		

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Share of medicine out-of-pocket expenditure	3.93 [3.87,	4.10 [4.06,	4.49 [4.45,
to total household expenditure (%)	3.98]	4.14]	4.54]
Share of health to non-food household			
expenditure (%)			
Share of total OOP payments to non-food	12.37 [12.20,	10.82 [10.72,	11.46 [11.36,
expenditure (%)	12.55]	10.91]	11.56]
Share of medicines OOP payments to non-	10.02 [9.88,	7.68 [7.62,	7.60 [7.54,
food expenditure (%)	10.17]	7.75]	7.67]

Notes: 1. numbers in brackets are 95% confidence interval; 2. State and rural-urban specific consumer price indices were used to convert current prices values at the constant 1999-2000 prices. 3. The current prices values for monthly per capita total OOP are 15.7, 41.8 and 111.2 and for medicine OOP are 12.8, 29.8 and 73.9 (all in INR) for the years 1993-94, 2004-05 and 2011-12 respectively.

A higher burden of households' OOP payment is often associated with impoverishment and catastrophe. In Table 2, we present a set of catastrophic cut-offs measured as a share of OOP payments to total household consumption expenditure and non-food expenditure. Estimates for both OOP payments as well as OOP payments underlying medicines expenditure by households are presented.

OUP spending and medicines OUP sp	•			
Financial Health Equity	1993-94	2004-05	2011-12	Estimated number
Measurements	(%)	(%)	(%)	of households
		4		(2011-12)
Cut-off for catastrophe using total				
household expenditure				
Total OOP payment > 5%	26.9	28.7	35.3	
	[26.6,	[28.5,	[35.0,	
	27.1]	30.0]	35.6]	9,01,07,225
Total OOP payment > 10%	13.9	14.6	17.9	
	[13.8,	[14.4,	[17.7,	
	14.2]	14.8]	18.2]	4,56,91,766
Total OOP payment > 25%	3.9 [3.8,	3.5 [3.4,	4.3 [4.2,	
	4.0]	3.6]	4.4]	1,09,76,234
Medicines OOP payment > 5%	23.3	23.4	27.0	
	[23.0,	[23.2,	[26.7,	
	23.5]	23.6]	27.2]	6,89,20,540
Medicines OOP payment > 10%	11.5	10.2	11.2	
	[11.3,	[10.2,	[11.0,	
	11.7]	10.4]	11.4]	2,85,89,261

Table 2: Percentage of households incurring catastrophic payments with respect to total
OOP spending and medicines OOP spending, 1993-94, 2004-05 and 2011-12

Medicines OOP payment > 25%	02.9			
	[2.8,	1.6 [1.5,	1.8 [1.7,	
	2.9]	1.7]	1.9]	45,94,703
Cut-off for catastrophe using non-				
food expenditure				
Total OOP payment > 5%	47.8	46.5	53.5	
	[47.5,	46.2,	[53.2,	
	48.1]	46.8]	53.8]	13,65,64,775
Total OOP payment > 10%	34.8	31.0	34.9	
	[34.6,	[30.7,	[34.7,	
	35.1]	31.2]	35.2]	8,90,86,180
Total OOP payment > 25%	16.7	11.4	11.9	
	[16.5,	[11.2,	[11.7,	
	16.9]	11.5]	12.1]	3,03,76,090
Total OOP payment > 40%	9.7 [9.5,	4.7 [4.6,	4.9 [4.8,	
	9.9]	4.9]	5.0]	1,25,07,802
Medicines OOP payment > 5%	44.7	42.5	46.4	
	[44.4,	[42.2,	[46.1,	
	45.0]	42.8]	46.7]	11,84,41,225
Medicines OOP payment > 10%	31.2	25.5	26.1	
	[31.0,	[25.3,	25.9,	
	31.5]	25.7]	26.4]	6,66,23,189
Medicines OOP payment > 25%	13.9			
	[13.7,	7.1 [7.0,	6.3 [6.1,	
	14.1]	7.3]	6.4]	1,60,81,459
Medicines OOP payment > 40%	7.8 [7.6,	2.2 [2.1,	1.8 [1.7,	
	7.9]	2.3]	1.9]	45,94,703

Note: Figures in brackets are 95% confidence interval.

Over one-third of Indian households incurred OOP payments greater to 5% of total household expenditure in 2011-12. This percentage was lower in 1993-94 (27%) and 2004-05 (28%). At the 25% threshold of total household expenditure, over 4% households reported incurring OOP payments in 2011-12. This essentially translates to approximately 11 million Indian households . Out of these, more than 4.4 million households incurred such payments only on account of purchase of medicines. At a lower threshold of 10% of total household expenditure, the number of households facing catastrophe is approximately 46 millions, of which 29 million households incurred catastrophe on account of OOP payments on medicines alone. Considering only non-food expenditure of households as the basic living status variable, approximately similar number of households incurred medicines OOP payments in 2011-12 with OOP payments being as high as 40% of their non-food expenditure.

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Table 3: Impoverishmen India, 1993-94, 2004-05		households' tot	al OOP and me	dicine spending ,
				Estimated
				population
	1993-94	2004-05	2011-12	(2011-12)
I. Using national				
poverty				
line*				
1. Headcount ratio				
indicators				
(%)	4			
Gross Headcount	45.32 [45.03,	37.85 [37.58,	22.17 [21.92,	
	45.61]	38.12]	22.43]	27,19,03,356
Headcount net of total	49.52 [49.22,	42.68 [42.40,	26.65 [26.38,	
OOP	49.81]	42.95]	26.92]	32,68,48,193
Total OOP payment		4.83 [4.71,	4.48 [4.35,	
induced poverty	4.20 [4.07, 4.30]	4.94]	4.60]	5,49,44,837
Headcount net of		6		
medicine OOP	48.91 [48.61,	41.54 [41.27,	25.27 [25.00,	
payment	49.20]	41.82]	25.53]	30,99,23,221
Medicine OOP				
payment induced		3.69 [3.59,	3.09 [2.99,	
poverty	3.59 [3.47, 3.69]	3.80]	3.20]	3,78,97,220
2. Poverty gap				
indicators			Ο.	
(INR current				
prices)				
		103.4 [102.7,	154.2 [152.3,	
Gross poverty gap#	63.3 [62.9, 63.8]	104.2]	156.0]	
Gap net of total OOP		115.8 [115.1,	182.8 [181.0,	
payment ##	69.7 [69.3, 70.1]	116.5]	184.7]	
Total OOP payment		12.4 [12.2,	28.6 [28.0,	
induced gap##	6.4 [6.3, 6.5]	12.6]	29.2]	
Gap net of medicine		113.7 [113.0,	176.7 [174.9,	
OOP payment ###	68.9 [68.5, 69.3]	114.4]	178.5]	
Medicine OOP				
payment induced		10.3 [10.1,	22.5 [22.0,	
gap###	5.6 [5.5, 5.7]	10.4]	23.0]	

Table 3: India, 1

poverty				
line**				
1. Headcount ratio				
indicators				
(%)				
Gross Headcount	40.96 [40.67,	33.07 [32.81,	18.37 [18.13,	
	41.24]	33.34]	18.61]	22,52,98,360
Headcount net of total	44.92 [44.63,	37.38 [37.11,	22.41 [22.16,	
OOP payment	45.21]	37.65]	22.67]	27,48,46,829
Total OOP payment	3.97 [3.85,	4.31 [4.19,	4.04 [3.92,	
induced poverty	4.08]	4.42]	4.16]	4,95,48,469
Headcount net of	4			
medicine OOP	44.35 [44.06,	36.34 [36.08,	21.37 [21.11,	
payment	44.64]	36.61]	21.62]	26,20,91,778
Medicine OOP				
payment induced	3.39 [3.29,	3.27 [3.17,	2.99 [2.89,	
poverty	3.50]	3.68]	3.10]	3,66,70,773
2. Poverty gap				
indicators				
(INR current				
prices)		6.		
		96.1 [95.3,	150.7 [148.8,	
Gross poverty gap#	59.3 [58.9, 59.7]	96.8]	152.7]	
Gap net of total OOP	65.4 [64.9,	107.5 [106.8,	177.0 [175.1,	
payment ##	65.8]	108.3]	179.1]	
Total OOP payment		11.5 [11.2,	26.3 [25.7,	
induced gap##	6.1 [6.0, 6.2)	11.7]	27.0]	
Gap net of medicine		105.8 [105.0,	172.0 [170.0,	
OOP payment ###	64.6 [64.2, 65.1]	106.5]	174.0]	
Medicine OOP				
payment induced			21.3 [20.7,	
gap###	5.3 [5.2, 5.4]	9.7 [9.5, 9.9]	21.8]	

Notes: based on Tendulkar Committee methods; ** using USD 1.90 PPP at 2011-12 prices and mixed recall period of household consumption expenditure; # only for poor; ## only for poor net of total OOP; ### only for poor net of medicine OOP

Next, we present implications of total and medicine OOP payments on poverty estimates (Table 3). To facilitate interpretation, we present 3 basic headcount ratio indicators: i) gross headcount – percentage of population below poverty line, ii) net of OOP headcount – percentage of population below poverty line after netting out OOP payments from

household consumption expenditure and iii) OOP payments induced poverty which is the difference of the first two reflecting rise in poverty ratio owing to OOP payments. The last two indicators are presented separately for total OOP payments and medicine OOP payments. Table 3 also provides estimates on poverty gap representing extent of poverty deepening in terms of monetary value. All these indicators are estimated using Indian official poverty line (Tendulkar Committee method) and international poverty line of US \$ 1.90 PPP.

The difference in mean headcount measure of gross and net poverty ratios reflects the percentage of population falling below poverty line because of households' OOP payments on health care. The headcount ratio of households impoverished due to OOP payments was 3.97% during 1993-94, which inched up to 4.30% in 2004-05 while in 2011-12 it was at 4.04%, as per international poverty line. In terms of Indian state-specific official poverty lines, percentage of households falling below poverty line increased from 4.19% in 1993-94 to 4.48% in 2011-12. This translates to 55 million persons in 2011-12. Out of this, approximately 38 million became poor only because they had to purchase medicines through OOP payments. Using the same measurement, the headcount measure for households OOP payments on medicines appear to have marginally declined from 3.58% in 1993-94 to 3.09% during 2011-12 using the international poverty line. As far as poverty gap is concerned, based on the Indian official poverty line, total OOP payments and OOP payments on medicines resulted in poverty deepening among poor by INR 29 and INR 23 respectively in 2011-12. Further poverty deepening because of total and medicines OOP payments sharply increased in 2012 compared to that in the years 2004-05 and 1993-94.

OOP expenditure by disease conditions

We also conducted a disaggregated analysis on disease wise expenditure not only with reference to total OOP payments and medicines OOP payments but also by type of care - inpatient care versus outpatient care. The survey results suggested that most common health condition for seeking outpatient care was fever (22.7%) and for inpatient care was childbirth (27.3%). In addition, our estimates suggest that households incurred highest monthly per capita OOP spending both for inpatient and outpatient care on account of cancer treatment (INR 5,054 and INR 5,121 respectively) followed by injuries for outpatient care (INR 3,045) and cardiovascular events for inpatient care (INR 2,808).

We also mapped disease-wise expenditure, frequency of healthcare utilization and type of care to demonstrate that not only hospitalization but also outpatient care can lead to catastrophe and impoverishment of households (Figure 1). For example, our estimates suggest that monthly per capita medicines OOP payments for cancer care were significantly higher in outpatient care as compared to the inpatient care. However, as far as total OOP spending for cancer treatment is concerned, it is almost similar across inpatient and outpatient but significantly higher compared to that for other disease conditions. In

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contrast, in respect to cardiovascular conditions, medicines OOP payments were similar for both inpatient and outpatient treatment but total OOP payments were significantly higher for inpatient treatment as against outpatient treatment. In treatments involving gastroenterology conditions, however, both medicines OOP payments and total OOP payments were higher for outpatient compared to inpatient treatment. Similarly, for mental disorders, medicines OOP payments were higher for outpatient care compared to inpatient but total OOP payments were almost similar both for outpatient and inpatient treatment. Therefore, it is noted that the average monthly medicines OOP payments were consistently higher for outpatient care as compared to inpatient care among key disease conditions. A relatively higher frequency of outpatient treatment visits compared to inpatient treatment coupled with a significantly larger medicines OOP payments may yield a higher incidence of catastrophe. A detailed estimate of prevalence and OOP payments by disease conditions cross-classified by inpatient and outpatient care are presented in Table A-II in Annexure.

Further, we plotted outpatient and inpatient OOP payments and medicines related OOP payments with respect to households 'usual' consumption expenditure. In Figure 2, households are ranked from the poorest to the richest on the X-axis based on their mean monthly per person consumption expenditure and on the Y-axis mean monthly per person OOP expenditure (total and medicine) are measured separately for outpatient and inpatient. It is observed that for a number of households, average monthly outpatient expenditure is not only significantly higher in relation to household's non-medical consumption expenditure but the frequency of such events is also higher in outpatient care as compared to inpatient care. In Figure 2, the concentration of red (total OOP payment) and green (medicine OOP payment) spikes above the consumption expenditure on the right hand side of the graph which reflects that even among richer households total OOP and medicine OOP payments are significantly higher than total non-medical consumption expenditure of households. Moreover, concentration of medicine OOP payments above households' non-medical consumption expenditure is more prominent in case of outpatient compare to the inpatient episodes.

Discussion and conclusion

Using standard methods of measuring catastrophe and impoverishment, ^{17 18} this paper demonstrates the financial burden of households' OOP payments on medicines in India, spanning two decades from 1993-94 to 2011-12. To our knowledge, this is a first attempt to link medicines' OOP spending to key diseases conditions. Two trends stand out clearly from our findings. First, the households' impoverishment on account of OOP expenditure is rather high and continued to be so during the last two decades. The impoverishment burden is largely driven by households spending on medicines, which accounted for over three-fourth of all medical impoverishment in India. Second, as far the catastrophe measurement is concerned, applying a 10% threshold of OOP payment on overall

consumption expenditure, an estimated 18% percent of Indian households appear to suffer financial catastrophe. Medicines' OOP expenditure alone contributed to an estimated 11% of financial catastrophe. In absolute numbers, this translates to a scenario where an estimated 46 million households appear to face catastrophic expenditure on account of OOP payments while 29 million households faced such hardship because they had to pay for medicines from their pockets.

Recent evidence from the National Health Accounts for India points out that during 2013-14, an estimated INR 1,331 per capita was spent on medicines, while households alone contributed INR 1,200 per capita, accounting for 90% of all medicines expenditure in the country.¹ On the other hand, past evidence about government expenditure on medicines in India, underscores that, on an average government spent about 10% percent of health expenditure on medicines. However, the national average masks significant underspending on medicines by several state governments, with many reportedly spending less than five percent of their health budgets.⁶ Besides poor allocation of resources, except for a couple of Indian states, drug procurement and supply chain system is inefficient and ineffective leading to acute shortages of key essential medicines and chronic stock-outs in public health facilities.²¹⁻²⁴ This situation has resulted in physical unavailability of medicines. Drawing evidence from large sample surveys for the period from 1986-87 to 2004, it is reported the physical barrier to access to key essential medicines worsened during this period.¹⁵ Supply of free drugs in government health system in the outpatient care setting, declined sharply from about 18% in 1986-87 to 5% in 2004. For the same period, drugs prescribed during hospitalization for free also declined significantly from one-third to about 9%.⁶ As a result, it is pointed out the number of hospitalization episodes in which an ailing population paid outof-pocket (OOP) payment, has risen dramatically from about 41% to close to 72%.⁶ Further, it was observed that from the period spanning mid-1990s to 2004, patients visiting government health facilities did not receive medicines in over one-fourth of outpatient episodes. Affordability of medicines is an important access indicator, because it translates into poor access or no access for people who have low purchasing power.³ The consumer behaviour theory also predicts that raising the price (via high OOP expenditure on medicines or high copayment) for a service in the public health sector will move more consumers into the private sector, depending on the elasticity of substitution and transaction costs in the public sector.²⁵

In view of inadequate availability of medicines in government health facilities, households end up accessing private facilities where they end up incurring significant OOP payment, in the absence of any financial risk protection. Past evidence suggests that the trend has sharpened in the last couple of decades. For instance, the percentage of population accessing private facilities for inpatient and outpatient treatment has accelerated significantly between 1986-87 and 2004. It may be observed that households accessing private hospital for inpatient care increased from around 40% to nearly 60% in rural India

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while urban India reported a rise from 40% to 68%.²⁶ During the same period, outpatient care visits in private facilities remained high at around 75% in 1986-87 in rural India and 73% in urban India stepped up to 78% and 80% respectively for rural and urban India.³

The other critical evidence emerging from this paper focuses on disease specific medicines expenditure. The results demonstrate a pattern where households' medicine spending is concentrated on low frequency, high-value spending and high frequency, high-value spending. By disease-wise classification, expenditure on treatment of cancers, CVDs and injuries, both for outpatient and inpatient care dominate the spending pattern. Available literature confirms such an expenditure pattern, wherein the share of non-communicable diseases (cardiovascular disease, diabetes, cancer, mental illness, injuries and others) in OOP health expenses has increased from 31.6% in 1995-96 to 47.3% in 2004.¹² The literature further indicates high odds of catastrophic hospitalization expenditures for certain NCDs. For example, the odds for catastrophic expenditure in cancer are nearly 170% greater, for cardiovascular diseases (CVD) and injuries nearly 22% greater than the odds due to infectious diseases. Other studies on cardiovascular diseases highlighted that CVD affected households had more outpatient visits and inpatient stays, spent extra money per hospitalization ¹¹ and have high probability of incurring catastrophic expenditure.²⁷ Another Indian study on socio-economic inequalities in financing of diabetes and cardiovascular disease reported that out-of-pocket payments for hospital treatment claimed a large share of annual household expenditures; 30% for CVD and 17% for diabetes.²⁸ In respect to injuries (both road traffic and non-road traffic), high incidence of catastrophic expenditure was 30%, and was significantly higher among those belonging to the lowest income quartile and with an inpatient stay greater than 7 days.²⁹

Although public facilities have slightly stepped up their share in outpatient care in recent years, private sector continue to dominate both in outpatient and inpatient care in India.³⁰ As an increasing share of households' access private health facilities, private retail pharmacies have become a major source of supply of key essential medicines. While availability of medicines may per se is not a challenge in the private health care setting, affordability appears to act as critical barrier.³¹ Thus, pricing of medicines and regulation around retail medicine prices becomes a key factor in improving affordability and thereby leading to a reduction in medicines related OOP payment burden. Although India had a progressive retail price cap policies since 1979, but over the years a policy of deregulation was followed.³² In 2013, the Government of India promulgated the Drugs Price Control Order (DPCO), 2013 (DPCO, 2013) which primarily brought all essential drugs, based on National List of Essential Medicines, 2011, under price control.³³ An evaluation of new price regulation has highlighted that, while few of the medicines (37) had an increase in sales volume attributable to DPCO, majority of the medicines (52) had a negative impact on their sales volume due to DPCO. Overall, the DPCO may have had a negative impact in terms of sales volume of medicines under price control.³⁴ Given that the sales volume of pricecapped medicines has declined, households OOP spending may continue to increase since over 80% of retail pharmacy market is not price-capped.

In order to improve access to health care and to provide financial risk protection to households, the central government and several state governments have been implementing a publicly funded health insurance programs since 2007, whose primary aim was to provide cashless treatment to economically vulnerable households for hospitalization episodes. Emerging evidence from micro as well as macro level studies point to a trend where such insurance schemes appear to have improved access to hospital care but have been ineffective in preventing financial catastrophe and impoverishment to households.^{2 35 36} These bodies of evidence are in line with our findings that hospitalization based treatment cost constitute only one-third of India's morbidity burden. Despite implementation of several health insurance schemes, a majority of Indian population continues to incur a relatively significant medicines OOP payment while seeking outpatient care. It would be pertinent to highlight that the frequency of hospitalization is considerably smaller than outpatient visits in general, especially for non-communicable diseases (NCDs), which are chronic in nature that require multiple consultations and long-term or life-long medication support. Such medical conditions result in catastrophic expenditure for households even in the absence of hospitalization episodes. Moreover, since a relatively larger proportion of population seeks outpatient care in private facilities, which is often multiple times expensive than public health facilities, we observe a disproportionately higher burden of medicines related OOP payment for outpatient care.

The evidence presented in this paper, however, suffers from a few limitations. The first set of challenge relates to co-morbidities and associated expenditure. In respect to inpatient cases, since NSSO data captures disease expenditure separately for various disease conditions, the issue of co-morbid conditions did not play major role. However, for outpatient cases, we had to adopt apportioning technique to handle co-morbid conditions. The second set of challenge pertains to the potential recall bias for disease specific expenditures, which cannot be ruled out especially for hospitalization treatment since the recall period is a longer time span of 365 days.

The foregoing underlines several policy interventions and program design that were conceived and implemented in the recent past to provide financial risk protection to households. However, gross underinvestment in the public health system in past had led to inadequate prepayment and risk pooling measures.²⁶ Several policy interventions and program redesign are required to reverse the trend of high OOP expenditure for healthcare in India. An efficient and a reliable medicines supply chain model existed for over two and half decades in the state of Tamil Nadu, which was replicated in the state of Rajasthan in 2012 have been instrumental in improving access to medicines in the frontline facilities in these two states.³⁷ Such policies and programs governing public health facilities are critical.

2 3	The National Health Policy 2017 also highlighted the need
4	public health facilities by stepping up funding and improvi
5	
6	chain mechanisms. ³⁸ A recent pronouncement by the gove
7	legislation for physicians to prescribe drugs only in generic
8	promise for reducing households' OOP payments on medi
9	financial risk protection. To sum up, both national and sta
10	required for providing free medicines in public health facil
11 12	
12	mechanism of price capping of key essential medicines in
14	
15	Contributorship: AK and SS conceived the idea, designed t
16	analysis and wrote the first draft of the paper. AK, SS and
17	review and the interpretation of the results. AS, SS and HH
18	manuscript to its final stages. All the authors approved the
19 20	manuscript to its final stages. All the authors approved the
20	<u> </u>
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31	to publish, or preparation of the manuscript.
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33	Data sharing: The data used for the analysis is available in
34	c ,
35	Ethical approval: Ethical approval for this study was not ne
36 37	
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39	obtained from the agency.
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for providing free medicines in ing drug procurement and supply ernment intends to bring c names, holds even greater icines and ultimately providing te governments' intervention is lities along with expanding the the private market.

the analysis, conducted data HHF conducted the literature HF revised and edited the e final manuscript version.

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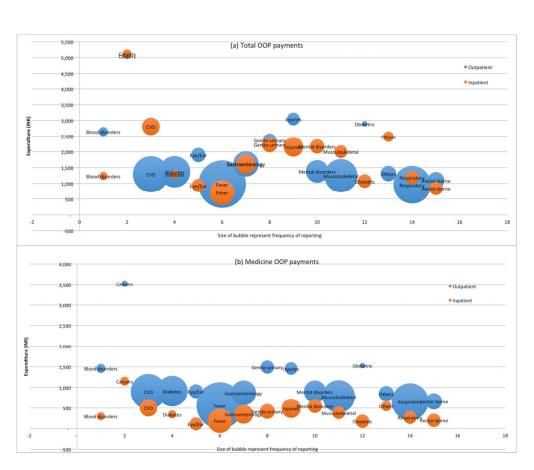
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Fie	uve legend
-	gure legend: gure 1: Frequency and monthly per person (a) total OOP and (b) medicine OOP spend
	select disease conditions, 2014
	gure 2: Monthly per person total OOP payment, medicine OOP payment and consum
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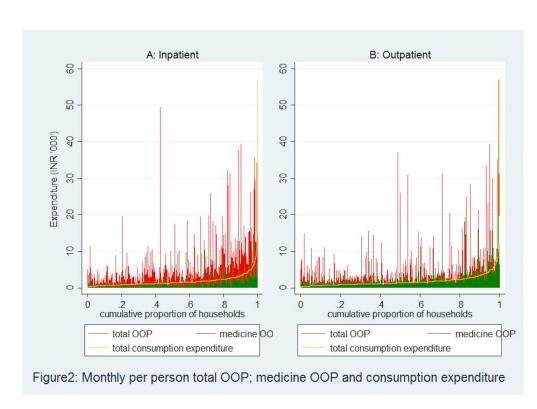
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Frequency and monthly per person (a) total OOP and (b) medicine OOP spending on select disease conditions, 2014

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Monthly per person total OOP payment, medicine OOP payment and consumption expenditure

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Annexure

36/bmjopen-2017-01802 Estimation of out-of-pocket expenditure indicators and related indicators

a. Out-of-pocket payments

Total out-of-pocket (OOP) payment has been defined as the summation of all kinds of direct expenditure on purchase of medical care including expenditure on family planning devices and transportation costs to access medical care by households either as inpatient or outpatient. According to the NSSO household questionnaire the main item of expendifure considered for inpatient and outpatient are presented in Table A-I.

Table A-I: Main items of expenditure considered for inpatient and outpatient in the NSSO question haire

Inpatier	nt	Outpatient ਰੂੱ			
Heads of expenditure	Item code in NSSO questionnaire	Heads of expenditure	Item code in NSSO question aire		
medicine	410	medicine	420 g		
X-ray, ECG, pathological test, etc.	411	X-ray, ECG, pathological test, etc.	421 <u>h</u>		
doctor's/surgeon's fee	412	doctor's/ surgeon's fee	422 g		
hospital & nursing home charges	413	family planning devices	423 May ω		
other medical expenses	414	other medical expenses	424 202		
Total inpatient	419=410-414	Total outpatient	429=420- 4 24		

The reference period of inpatient and outpatient expenditure in the consumer expenditure surveys are 1 year and 1 month respectively. Based on the information presented in Table A-I, total inpatient expenditure, outpatient expenditure and total OOP expenditure were estimated by converting inpatient expenditure for one month. Accordingly, households with any OOP have been defined as households reporting positive OOP (OOP>0) either as inpatient or outpatient or both. ed by copyright

b. Per person monthly OOP and OOP share

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Per person monthly OOP is defined as total monthly OOP divided by household size for each household.

The financial burden of health expenses by households has also been estimated in terms of OCP as a share of total household expenditure and alternatively as a share of total non-food expenditure of households.. May 2018

 $Sh_{OOP} = T/\exp$ (A.1)

Where, 'T' is total OOP payments and 'exp' is household total (non-food) expenditure by households.

c. Catastrophic payments and headcount

Further, OOP payments are defined as catastrophic when OOP payments as a portion of total household resources are in excess of a certain threshold. A household is said to have incurred catastrophic payments if T/exp>Z, wher \hat{s} 'T' and OOP are the same as in equation (A.1) and 'Z' is a certain threshold. The latter is arbitrary and in general, estimates are presented for a range of values for z (5, 10, 15, 25 and 40 per cent). mjopen.bmj.com/

Accordingly, the headcount ratio of catastrophic payment is calculated as follows:

$$cat_i = \frac{1}{n} \sum 1\left(\frac{T}{exp} > Z_i\right)$$
(A.2)

Where, Cati is catastrophic headcounts of households with OOP share exceeding a threshold defined as 'i' per cent of total household total (non-food) expenditure, 1(.) is an indicator function, which takes the value 1 if T/exp>Zi is true and 0 otherwise; n is the number of households incurring expenditure on health for various thresholds; Z_1, Z_2, Z_3 are the respective thresholds of the OGP share.

d. Poverty headcount

The usual headcount ratio of poverty is calculated as:

Gross HP = $1/n \Sigma 1$ (xi ≤ PL)(A.3)

where: 1(.) is a function, taking the value 1 if person belong to a household with consumption expenditure lower the value of poverty line value, x= Household total consumption expenditure; PL= Poverty Line and n is total population.

Headcount of poverty after deducting OOP from household consumption expenditure can be defined as:

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Net $HP = 1/n \Sigma 1$ ((xi-T) $\leq PL$). (A.4)

where: T= *per capita OOP*

The OOP induced poverty headcount finally is estimated as: (Gross HP - Net HP).

e. Poverty gap

 Poverty gap is defined as difference between values of poverty lines and household consumption expenditure for the poor as defined in the sub-section d above. Using the household level data poverty gap for the poor is estimated as follows:

Gross poverty gap = $1/n \Sigma 1$ (xi- PL) | if i=poor(A.5)

In equation A.5 'xi-PL' is the difference between household expenditure per person and poverty line. For al positive values of this difference mean gap is estimated. Finally, poverty gap net of OOP payments is estimated as follows: :p://bmjopen

Net poverty gap = $1/n \Sigma 1$ ((xi-T)- PL) | if i=poor after netting OOP (A.6)

Table A-II. Prevalence and average per episode total and medicine out of pocket payments by disease conditions in 2014

	Outpatient 15	Inpatient 365	Į. Į									
	Prevalence	-	Per epis	sode	estimate		Prevalence	7/	ÅPer epis	ode	estimate	
					monthly	7			20		monthly	7
Ailment	Number of	%	Total	Dr	Total	Dru	Number of	%	ਔTotal	Dru	Total	Dru
	episodes		OOP	ug	OOP	g	episodes		SOOP	g	OOP	g
									ues			
Fever	2,71,43,431	22.71	488	280	975	561	74,12,043	12.95	8670	2329	713	191
TB/Filaria/Tetan	11,08,425	0.93	524	287	1047	573	6,14,933	1.07	6 14731	4134	1,211	340
us									ctec			
STD/HIV/AIDS	1,20,714	0.1	538	268	1076	536	88,935	0.16	26906	1633	568	134
Vector-borne	33,33,651	2.79	549	332	1097	663	22,65,189	3.96	§10288	2460	846	202

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Cancers	4,52,513	0.38	2527	176 3	5054	352 6	9,78,764	1.71	62297	1403 7	5,121	1
Blood disease	10,26,129	0.86	1322	731	2643	146 3	8,10,752	1.42	115035 May	3650	1,236	,
Diabetes	1,17,55,081	9.84	683	456	1367	911	8,17,199	1.43	815746	4224	1,294	,
Other Metabolic	20,50,282	1.72	712	340	1423	679	2,60,707	0.46	°°15429	3600	1,268	1
Mental disorders	61,56,374	5.15	690	451	1380	902	24,87,836	4.35	§26428	6685	2,172	Ĺ
Eye/Ear	24,67,286	2.06	950	454	1899	908	20,82,420	3.64	a11350	1407	933	
Cardiovascular diseases	1,55,65,223	13.02	645	449	1289	899	37,82,374	6.61	634167	6129	2,808	ļ
Respiratory diseases	1,69,58,670	14.19	478	328	955	656	21,40,762	3.74	14491	3325	1,191	,
Gastroenterlogy	77,13,330	6.45	809	434	1617	869	45,40,520	7.93	19587	4260	1,610	
Skin	28,34,892	2.37	522	370	1043	740	3,80,346	0.66	8 12123	3514	996	
Musculo-Skeletal	1,32,29,065	11.07	622	391	1244	782	19,66,211	3.44	24379	4677	2,004	3
Genito-Urinary	21,91,953	1.83	1183	747	2365	149 4	28,01,133	4.89	27085	5094	2,226	4
Obstetric	3,64,060	0.3	1448	765	2896	152 9	22,64,628	3.96	g13050	2189	1,073	-
Injuries	19,93,646	1.67	1522	730	3045	146 0	46,19,876	8.07	້ຜ26242 ເວັ	6000	2,157	4
Others	28,92,298	2.42	655	426	1310	853	12,97,049	2.27	<u>6</u> 30196	6666	2,482	Ľ
Childbirth	1,46,562	0.12	585	398	1169	797	1,56,17,000	27.29	Š 8508	1729	699	

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Quantifying the financial burden of households' out-ofpocket payments on medicines in India. A repeated crosssection analysis of National Sample Survey data 1994 to 2014

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Quantifying the financial burden of households' out-of-pocket payments on medicines in India. A repeated cross-section analysis of National Sample Survey data 1994 to 2014

Objective: The objective of this research is to generate new evidence on financial implications of medicines out of pocket (OOP) payments for households. Another objective is to investigate which disease conditions contributed to a significant proportion of households' financial burden.

Setting: All Indian States including Union Territories, 1993-94 to 2014

Design: Repeated cross section household surveys

Data: Secondary data of nationwide Consumer Expenditure Surveys for the years 1993-94, 2004-05 and 2011-12 and one wave of Social Consumption: Health for the year 2014 from National Sample Survey Organisation.

Outcome measures: Out-of-pocket expenditure on healthcare in general and medicines in specific.

Results: Total OOP payments and medicines OOP payments were estimated to be 6.77% [CI: 6.70%, 6.84%] and 4.49% [4.45%, 4.54%] of total consumption expenditure respectively in the year 2011-12 which marked significant increase since 1993-94. These proportions were 11.46% [CI: 11.36%, 11.56%] and 7.60% [CI: 7.54%, 7.67%] of non-food expenditure respectively in the same year. It was observed that total OOP payments and medicines OOP payments were catastrophic for 17.9% [CI: 17.7%, 18.2%] and 11.2% [11.0%, 11.4%] households respectively in 2011-12 at the 10% of total consumption expenditure threshold, implying 29 million households incurred catastrophic out-of-pocket payments in the year 2011-12. Further, medicines out-of-pocket payments pushed 3.09% [CI: 2.99%, 3.20%], implying 38 million, persons into poverty in the year 2011-12. Among the leading cause of diseases that caused significant OOP payments are cancers, injuries, cardiovascular diseases, genito-urinary conditions and mental disorders.

Conclusions: Purchase of medicines constitute the single largest component of the total OOP payments by households. Hence, strengthening government intervention in providing medicines free in public health care facilities has the potential not only to considerably reduce medicines related spending and total OOP payments of households but also reduction in OOP induced poverty.

Key words: India, out of payment, medicine, catastrophic expenditure, and poverty

Strengths and limitations of this study

- 1. The study used multiple points of time and nationally representative data set to highlight the financial burden of households OOP payments on medicines in India;
- 2. The paper links medicines out-of-pocket payments by households with leading disease conditions and identify key disease conditions which cause medicines out-of-pocket payments
- 3. The study has limitations as it uses arbitrary threshold for measuring catastrophic payments
- 4. The ailments, disease conditions and the associated OOP expenditure reported by the households in the survey are self-reports and not clinically diagnosed.

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Background

Households' in India bear significant financial burden on account of medical treatment, as the current prepayment and risk pooling mechanisms are inadequate. Since both government funding and social health insurance contributions are insufficient to meet health care needs of households, over three-fourth of all health care payments are paid out-of-pocket (OOP) at the point of service delivery while medicines purchase (approximately 63%) account for the single largest component of these payments.¹ Available literature suggests that OOP spending has dominated total OOP payments over the years.² Hence, it can be suggested that expenditure on medicines is major cause of catastrophe at the household level.³

India has the distinction of being pharmacy of the global south - supplies affordable, life saving, quality generic medicines. It ranks 4th in terms of volumes and 13th in terms of value of pharmaceuticals produced globally.⁴ However, according to a WHO report around 68% of the Indian population have limited or no access to essential medicines.⁵ In addition, literature suggests that over last two decades availability of free medicines in public health facilities has declined from 31.2% to 8.9 % for inpatient care and from 17.8% to 5.9% for outpatient care.⁶ Another study demonstrated that medicines purchase alone constituted over 70% of overall OOP payments. In addition, the study demonstrated that by removing OOP payments for outpatient care on medicines, the percentage of people falling below poverty because of spending on health reduced to just 0.5 % whereas removing OOP payments for inpatient care resulted in a negligible decline in poverty headcount ratio and poverty gap highlighting the role of medicines expenditure in healthcare related impoverishment.⁷

Utilising impoverishment tool to measure affordability, one study assessed the impoverishment effect of medicines purchases by households in 16 low-and-middle income economies.⁸ Comparing four key medicine prices to household income, and using World Bank poverty levels of US\$ 1.25 or US\$ 2 per day, the study concluded that a substantial number of people had to bear financial burden due to unaffordability of medicines. For example, it was pointed out that an originator brand atenolol purchase by individuals would push an additional 22% of population below the US\$ 1.25 per day measurement while even a generic equivalent of atenolol was likely to push about 7% of population below poverty levels in Philippines.⁹ Analyzing economic implications of non-communicable disease in India, a few studies also reported in the past that households incur significant OOP payment burden in certain conditions like cardiovascular diseases (CVD) and cancers. ^{10 11} Using 2004 NSSO data, another study highlighted that hospitalization with CVD resulted in 12% higher odds of incurring catastrophic spending and 37% greater odds of falling into poverty compared to those hospitalized with communicable conditions. For cancer, the impact was greatest with the odds of catastrophic expenditures 170% higher than the odds of incurring catastrophic spending when hospital stays are due to a communicable disease condition.¹²

However these studies do not reflect on the relative contribution of medicine in total OOP burden for the diseases they analysed.

Available evidence, both global and Indian, provides insights about the incidence of catastrophic payments and impoverishment impact of rising households OOP payments.^{2 3} ¹³⁻¹⁵ The literature on equity dimensions involving both catastrophe and impoverishment has attempted to address complex methodological and statistical approaches in measurements. However, there is lack of evidence on catastrophe and impoverishment on account of household's medicine OOP expenditure not only from inpatient and outpatient treatment costs perspective but also from the disease specific dimension. Given that medicines contribute to more than 66.6% of out-of-pocket healthcare expenditure, the focus of this research is to explore the consequences of high medicines OOP spending at the household level. Further, we investigated which disease conditions are contributing to high financial burden on households. We attempted to answer - what is the relative burden of medicines OOP payments by households in total OOP payments, catastrophic and poverty headcounts? And which disease conditions cause a relatively higher financial disruption in the living status of households?

Materials and methods

Data

The study utilises secondary data from three waves of nationally representative 'Consumer Expenditure Surveys' (CES): 1993-94, 2004-05 and 2011-12, conducted by the National Sample Survey Organisation (NSSO). In addition, health and morbidity survey (HMS) 2014 of the NSSO was used for disease-wise distribution of OOP payment burden. While the sample size of CES varied between 100,000 to 125,000 thousand households across different rounds, the sample size in HMS 2014 was approximately 72,000 households.

The CES collect socioeconomic and demographic information on households with key focus is on household spending on roughly 350 food and non-food items. Out-of-pocket medical expenses incurred by households are separately recorded for inpatient and outpatient services. The recall periods are one-year and 30-days for inpatient and outpatient expenses respectively. HMS collects detailed information on morbidity pattern, utilisation of health care services and associated expenditure by households. The HMS too separately records expenditure for inpatient and outpatient. However, unlike in CES the recall period for outpatient in HMS is 15 days.

Both CES and HMS are repeated cross-section surveys that are representative at the national and state levels. All districts of a state are included for sampling purposes. Households in CES are sampled evenly in quarterly sub-rounds beginning on 1 July and ending on 30 June of the following year, with equal numbers of households allotted in each quarterly sub-round, to address seasonality. In HMS, survey was completed in two sub-

rounds during January1 to June 30, 2014. All estimates in the present paper are sample weighted.

Outcome indicators

Using CES, we estimated 4 household-level indicators involving financial burden of illness: i) per household member monthly OOP spending on medicines (inflation-adjusted), ii) OOP spending on medicines as a share of total household and non-food spending, and iii) percentage of households reporting catastrophic payments on medicines and iv) percentage of households slipping onto poverty after netting out medicines OOP payments from households' total consumption expenditure. Total OOP spending of households was estimated by adding together expenditure on components of OOP payments. For inpatient OOP payment, we considered institutional spending on medicines, X-ray, ECG, pathological tests etc., doctor's/surgeon's fee, hospital and nursing charges and other medical expenses. For outpatient OOP payment, the components of expenditure are medicines, X-ray, ECG, pathological tests etc., doctor's/surgeon's fee, family planning services and other medical expenses. Expenditure on medicines is directly reported in the data set, both for inpatient and outpatient services (see Table A-I in Annexure). All the analyses report mean OOP spending on two parallel tracks: aggregated (across components of OOP) OOP payments (henceforth referred to as 'total OOP') and OOP payments only on account of medicine purchase (henceforth referred to as medicine/drug OOP).

Catastrophic payment for health care is defined as OOP payments being higher to a predefined threshold of total household consumption expenditure or alternatively household's non-food expenditure. For measuring catastrophic expenditure,²⁹ instead of sticking to a particular threshold, we considered a range of thresholds.²¹⁶⁻¹⁸ We also considered alternative thresholds as OOP spending as a share of household non-food expenditure. For OOP payment induced poverty estimates, we used two different poverty lines: i) Indian official state-specific rural and urban poverty lines¹⁹ and ii) international poverty line based on US \$ 1 per day per person adjusted to US \$ 1.9 purchasing power parity (PPP) per day per person for the year 2011-12²⁰. Yet another important poverty indicator, which particularly estimates magnitude of poverty deepening, is poverty gap. Using both the poverty lines separately, we also estimated mean poverty gaps for the poor. Details of the method used for catastrophic and poverty estimates are presented in Annexure.

In addition, we used NSSO 2014 HMS data for estimating disease level total and medicine OOP spending separately for inpatient and outpatient. Unlike CES, OOP spending in HMS 2014 has not been recorded as part of the total household consumption expenditure and instead of estimating disease-wise catastrophic headcount, we present distribution of disease conditions based on incidence of occurrence and range of OOP spending separately for outpatient (15 days recall converted for 30 days) and inpatient (365 days recall

converted for 30 days). This helped identifying disease conditions, separately for outpatient and inpatient, which are high frequency occurrence and greater incidence of OOP spending.

Results

First, we present basic financial burden indicators for the years 1993-94, 2004-05 and 2011-12 in Table 1. Over 80% of populations are reportedly spending out-of-pocket while seeking treatment, during 2011-12. The proportion of population reporting any OOP payments have increased sharply from about 60% during 1993-94 to 80% percent in 2011-12. In respect to medicines spending, approximately every OOP spending is associated with expenditure on medicines. There was a significant increase (more than 50%) in household's total consumption expenditure in real terms from INR 517 in 1993-84 to INR 794 in 2011-12. However, during the same period total OOP payments increased by more than 100% from INR 26 in 1993-94 to INR 54 in 2011-12 in real terms. The rise in OOP payments on medicines has been more than 70% during the same period. Consequently, the share of spending on health from households' overall consumption expenditure have registered sharp increase during the past two decades, from a moderate 4.8% during 1993-94 to nearly 7% in 2011-12. If we were to net out food expenditure from total household consumption spending, which are considered a necessity, the share of health spending remained stagnant but as high as 11-12% percent during the period under consideration. It may be observed that in 2011-12 medicines alone contributed up to 67% of the total OOP payments.

Financial burden indicators	1993-94	2004-05	2011-12
Percentage households reporting OOP			
payments	4		
	59.2 [58.9,	64.4 [64.2,	80.5 [80.2,
Any out-of-pocket payments (%)	59.5]	64.7]	80.7]
	57.5 [57.3,	63.6 [63.3,	79.0 [78.8,
Medicines out-of-pocket payments (%)	57.8]	63.8]	79.3]
Monthly per capita expenditure (INR at			
constant 1999-2000 prices*)			
	517 [515,	619 [616,	794 [790,
Household consumption expenditure	519]	622]	799]
	25.59 [24.61,	36.3 [35.7,	54.3 [53.3,
Out-of-pocket expenditure on health	26.25]	37.0]	55.3]
	20.86 [26.0 [25.6,	36.1 [35.5,
Medicine out-of-pocket expenditure	19.50, 21.25]	26.4]	36.8]
Share of health to total household			
expenditure (%)			
Share of total out-of-pocket expenditure to	4.84 [4.78,	5.78 [5.72,	6.77 [6.70,
total household expenditure (%)	4.91]	5.83]	6.84]

Table 1: Financial burden indicators	. India, 1993-94	1. 2004-05 and 2011-12
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Share of medicine out-of-pocket expenditure	3.93 [3.87,	4.10 [4.06,	4.49 [4.45,
to total household expenditure (%)	3.98]	4.14]	4.54]
Share of health to non-food household			
expenditure (%)			
Share of total OOP payments to non-food	12.37 [12.20,	10.82 [10.72,	11.46 [11.36,
expenditure (%)	12.55]	10.91]	11.56]
Share of medicines OOP payments to non-	10.02 [9.88,	7.68 [7.62,	7.60 [7.54,
food expenditure (%)	10.17]	7.75]	7.67]

Notes: 1. numbers in brackets are 95% confidence interval; 2. State and rural-urban specific consumer price indices were used to convert current prices values at the constant 1999-2000 prices. 3. The current prices values for monthly per capita total OOP are 15.7, 41.8 and 111.2 and for medicine OOP are 12.8, 29.8 and 73.9 (all in INR) for the years 1993-94, 2004-05 and 2011-12 respectively.

A higher burden of households' OOP payment is often associated with impoverishment and catastrophe. In Table 2, we present a set of catastrophic cut-offs measured as a share of OOP payments to total household consumption expenditure and non-food expenditure. Estimates for both total OOP payments as well as medicine OOP payments by households are presented.

OUP spending and medicines OUP spending, 1993-94, 2004-05 and 2011-12							
Financial Health Equity	1993-94	2004-05	2011-12	Estimated number			
Measurements	(%)	(%)	(%)	of households			
		4		(2011-12)			
Cut-off for catastrophe using total							
household expenditure							
Total OOP payment > 5%	26.9	28.7	35.3				
	[26.6,	[28.5,	[35.0,				
	27.1]	30.0]	35.6]	9,01,07,225			
Total OOP payment > 10%	13.9	14.6	17.9				
	[13.8,	[14.4,	[17.7,				
	14.2]	14.8]	18.2]	4,56,91,766			
Total OOP payment > 25%	3.9 [3.8,	3.5 [3.4,	4.3 [4.2,				
	4.0]	3.6]	4.4]	1,09,76,234			
Medicines OOP payment > 5%	23.3	23.4	27.0				
	[23.0,	[23.2,	[26.7,				
	23.5]	23.6]	27.2]	6,89,20,540			
Medicines OOP payment > 10%	11.5	10.2	11.2				
	[11.3,	[10.2,	[11.0,				
	11.7]	10.4]	11.4]	2,85,89,261			

Table 2: Percentage of households incurring catastrophic payments with respect to total
OOP spending and medicines OOP spending, 1993-94, 2004-05 and 2011-12

Medicines OOP payment > 25%	02.9			
	[2.8,	1.6 [1.5,	1.8 [1.7,	
	2.9]	1.7]	1.9]	45,94,703
Cut-off for catastrophe using non-				
food expenditure				
Total OOP payment > 5%	47.8	46.5	53.5	
	[47.5,	46.2,	[53.2 <i>,</i>	
	48.1]	46.8]	53.8]	13,65,64,775
Total OOP payment > 10%	34.8	31.0	34.9	
	[34.6,	[30.7,	[34.7,	
	35.1]	31.2]	35.2]	8,90,86,180
Total OOP payment > 25%	16.7	11.4	11.9	
	[16.5,	[11.2,	[11.7,	
	16.9]	11.5]	12.1]	3,03,76,090
Total OOP payment > 40%	9.7 [9.5,	4.7 [4.6,	4.9 [4.8,	
	9.9]	4.9]	5.0]	1,25,07,802
Medicines OOP payment > 5%	44.7	42.5	46.4	
	[44.4,	[42.2,	[46.1,	
	45.0]	42.8]	46.7]	11,84,41,225
Medicines OOP payment > 10%	31.2	25.5	26.1	
	[31.0,	[25.3,	25.9,	
	31.5]	25.7]	26.4]	6,66,23,189
Medicines OOP payment > 25%	13.9			
	[13.7,	7.1 [7.0,	6.3 [6.1,	
	14.1]	7.3]	6.4]	1,60,81,459
Medicines OOP payment > 40%	7.8 [7.6,	2.2 [2.1,	1.8 [1.7,	
	7.9]	2.3]	1.9]	45,94,703

Note: Figures in brackets are 95% confidence interval.

Over one-third of Indian households incurred OOP payments greater to 5% of total household expenditure in 2011-12. This percentage was lower in 1993-94 (27%) and 2004-05 (28%). At the 25% threshold of total household expenditure, over 4% households reported incurring OOP payments in 2011-12. This essentially translates to approximately 11 million Indian households. Out of these, more than 4.4 million households incurred such payments only on account of purchase of medicines. At a lower threshold of 10% of total household expenditure, the number of households facing catastrophe is approximately 46 millions, of which 29 million households incurred catastrophe on account of OOP payments on medicines alone. Considering only non-food expenditure of households as the basic living status variable, approximately similar number of households incurred medicines OOP payments in 2011-12 with OOP payments being as high as 40% of their non-food expenditure.

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Table 3: Impoverishmen	It Indicators due to	households' to	tal OOP and me	dicine spending,
India, 1993-94, 2004-05	and 2011-12			
				Estimated
				population in
				millions, (2011-
	1993-94	2004-05	2011-12	12)
I. Using national				
poverty				
line*				
1. Headcount ratio				
indicators				
(%)	45.32 [45.03,	37.85 [37.58,	22.17 [21.92,	
Gross Headcount	45.32 [45.03,	37.85 [37.58, 38.12]	22.17 [21.92, 22.43]	272
Headcount net of total	49.52 [49.22,	42.68 [42.40,	26.65 [26.38,	212
OOP	49.32 [49.22,	42.08 [42.40,	20.03 [20.38, 26.92]	327
Total OOP payment	+3.01]	4.83 [4.71,	4.48 [4.35,	521
induced poverty	4.20 [4.07, 4.30]	4.03 [4.71,	4.48 [4.33,	55
Headcount net of	4.20 [4.07, 4.30]	4.94]	4.00]	55
medicine OOP	48.91 [48.61,	41.54 [41.27,	25.27 [25.00,	
payment	49.20]	41.82]	25.27 [25.00,	310
Medicine OOP	+5.20]	41.02]	23.33]	510
payment induced		3.69 [3.59,	3.09 [2.99,	
poverty	3.59 [3.47, 3.69]	3.80]	3.20]	38
2. Poverty gap		5.66]	0.20]	
indicators				
(INR current				
prices)				
1/		103.4 [102.7,	154.2 [152.3,	
Gross poverty gap#	63.3 [62.9, 63.8]	104.2]	156.0]	
Gap net of total OOP	· · · ·	115.8 [115.1,	182.8 [181.0,	
payment ##	69.7 [69.3, 70.1]	116.5]	184.7]	
Total OOP payment		12.4 [12.2,	28.6 [28.0,	
induced gap##	6.4 [6.3, 6.5]	12.6]	29.2]	
Gap net of medicine		113.7 [113.0,	176.7 [174.9,	
OOP payment ###	68.9 [68.5, 69.3]	114.4]	178.5]	
Medicine OOP		10.3 [10.1,	22.5 [22.0,	
payment induced	5.6 [5.5 <i>,</i> 5.7]	10.4]	23.0]	

Table 3: Impo India, 1993-9

gap### II. Using international				
poverty				
line**				
1. Headcount ratio				
indicators				
(%)				
Cross Haadsourt	40.96 [40.67,	33.07 [32.81,	18.37 [18.13,	
Gross Headcount	41.24]	33.34]	18.61]	225
Headcount net of total	44.92 [44.63,	37.38 [37.11,	22.41 [22.16,	
OOP payment	45.21]	37.65]	22.67]	275
Total OOP payment	3.97 [3.85,	4.31 [4.19,	4.04 [3.92,	
induced poverty	4.08]	4.42]	4.16]	50
Headcount net of				
medicine OOP	44.35 [44.06,	36.34 [36.08,	21.37 [21.11,	
payment	44.64]	36.61]	21.62]	262
Medicine OOP	ý			
payment induced	3.39 [3.29,	3.27 [3.17,	2.99 [2.89 <i>,</i>	
poverty	3.50]	3.68]	3.10]	37
2. Poverty gap		· C		
indicators				
(INR current		4.		
prices)				
		96.1 [95.3,	150.7 [148.8,	
Gross poverty gap#	59.3 [58.9 <i>,</i> 59.7]	96.8]	152.7]	
Gap net of total OOP	65.4 [64.9,	107.5 [106.8,	177.0 [175.1,	
payment ##	65.8]	108.3]	179.1]	
Total OOP payment		11.5 [11.2,	26.3 [25.7,	
induced gap##	6.1 [6.0, 6.2)	11.7]	27.0]	
Gap net of medicine		105.8 [105.0,	172.0 [170.0,	
OOP payment ###	64.6 [64.2, 65.1]	106.5]	174.0]	
Medicine OOP				
payment induced			21.3 [20.7,	
gap###	5.3 [5.2, 5.4]	9.7 [9.5, 9.9]	21.8]	

Notes: based on Tendulkar Committee methods (poverty lines range between INR 695 in Odisha and INR 1018 in Kerala in rural and INR 861 in Odisha and INR 1169 in Haryana in urban areas among the major states); ** using USD 1.90 PPP at 2011-12 prices and mixed recall period of household consumption expenditure (INR equivalent to USD 1.90 PPP are 771.21 in rural and 945.41 in urban areas); # only for poor; ## only for poor net of total OOP; ### only for poor net of medicine OOP

Next, we present implications of total and medicine OOP payments on poverty estimates (Table 3). To facilitate interpretation, we present 3 basic headcount ratio indicators: i) gross headcount – percentage of population below poverty line, ii) net of OOP headcount – percentage of population below poverty line after netting out OOP payments from household consumption expenditure and iii) OOP payments induced poverty which is the difference of the first two reflecting rise in poverty ratio owing to OOP payments. The last two indicators are presented separately for total OOP payments and medicine OOP payments. Table 3 also provides estimates on poverty gap representing extent of poverty deepening in terms of monetary value. All these indicators are estimated using Indian official poverty line (Tendulkar Committee method) and international poverty line of US \$ 1.90 PPP.

The difference in mean headcount measure of gross and net poverty ratios reflects the percentage of population falling below poverty line because of households' OOP payments on health care. The headcount ratio of households impoverished due to OOP payments was 3.97% during 1993-94, which inched up to 4.30% in 2004-05 while in 2011-12 it was at 4.04%, as per international poverty line. In terms of Indian state-specific official poverty lines, percentage of households falling below poverty line increased from 4.19% in 1993-94 to 4.48% in 2011-12. This translates to 55 million persons in 2011-12. Out of this, approximately 38 million became poor only because they had to purchase medicines through OOP payments. Using the same measurement, the headcount measure for households OOP payments on medicines appear to have marginally declined from 3.58% in 1993-94 to 3.09% during 2011-12 using the international poverty line. As far as poverty gap is concerned, based on the Indian official poverty line, total OOP payments and OOP payments on medicines resulted in poverty deepening among poor by INR 29 and INR 23 respectively in 2011-12. Further poverty deepening because of total and medicines OOP payments sharply increased in 2012 compared to that in the years 2004-05 and 1993-94.

OOP expenditure by disease conditions

We also conducted a disaggregated analysis on disease wise expenditure not only with reference to total OOP payments and medicines OOP payments but also by type of care - inpatient care versus outpatient care. The survey results suggested that most common health condition for seeking outpatient care was fever (22.7%) and for inpatient care was childbirth (27.3%). In addition, our estimates suggest that households incurred highest monthly per capita OOP spending both for inpatient and outpatient care on account of cancer treatment (INR 5,054 and INR 5,121 respectively) followed by injuries for outpatient care (INR 3,045) and cardiovascular events for inpatient care (INR 2,808).

We also mapped disease-wise expenditure, frequency of healthcare utilization and type of care to demonstrate that not only hospitalization but also outpatient care can lead to catastrophe and impoverishment of households (Figure 1). For example, our estimates

suggest that monthly per capita medicines OOP payments for cancer care were significantly higher in outpatient care as compared to the inpatient care. However, as far as total OOP spending for cancer treatment is concerned, it is almost similar across inpatient and outpatient but significantly higher compared to that for other disease conditions. In contrast, in respect to cardiovascular conditions, medicines OOP payments were similar for both inpatient and outpatient treatment but total OOP payments were significantly higher for inpatient treatment as against outpatient treatment. In treatments involving gastroenterology conditions, however, both medicines OOP payments and total OOP payments were higher for outpatient compared to inpatient treatment. Similarly, for mental disorders, medicines OOP payments were higher for outpatient care compared to inpatient but total OOP payments were almost similar both for outpatient and inpatient treatment. Therefore, it is noted that the average monthly medicines OOP payments were consistently higher for outpatient care as compared to inpatient care among key disease conditions. A relatively higher frequency of outpatient treatment visits compared to inpatient treatment coupled with a significantly larger medicines OOP payment may yield a higher incidence of catastrophe. A detailed estimate of prevalence and OOP payments by disease conditions cross-classified by inpatient and outpatient care are presented in Table A-II in Annexure.

Further, we plotted outpatient and inpatient OOP payments and medicines related OOP payments with respect to households 'usual' consumption expenditure. In Figure 2, households are ranked from the poorest to the richest on the X-axis based on their mean monthly per person consumption expenditure and on the Y-axis mean monthly per person OOP expenditure (total and medicine) are measured separately for outpatient and inpatient. It is observed that for a number of households, average monthly outpatient expenditure is not only significantly higher in relation to household's non-medical consumption expenditure but the frequency of such events is also higher in outpatient care as compared to inpatient care. In Figure 2, the concentration of red (total OOP payment) and green (medicine OOP payment) spikes above the consumption expenditure on the right hand side of the graph which reflects that even among richer households total OOP and medicine OOP payments are significantly higher than total non-medical consumption expenditure of households. Moreover, concentration of medicine OOP payments above households' non-medical consumption expenditure is more prominent in case of outpatient compare to the inpatient episodes.

Discussion and conclusion

Using standard methods of measuring catastrophe and impoverishment, ^{17 18} this paper demonstrates the financial burden of households' OOP payments on medicines in India, spanning two decades from 1993-94 to 2011-12. To our knowledge, this is a first attempt to link medicines' OOP spending to key diseases conditions. Two trends stand out clearly from our findings. First, the households' impoverishment on account of OOP expenditure is

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rather high and continued to be so during the last two decades. The impoverishment burden is largely driven by households spending on medicines, which accounted for over three-fourth of all medical impoverishment in India. One of the reasons could be compared to OOP payments on medicines, hospitalization/bed charges in India are comparatively low, and often subsidized in the public sector. Second, as far the catastrophe measurement is concerned, applying a 10% threshold of OOP payment on overall consumption expenditure, an estimated 18% percent of Indian households appear to suffer financial catastrophe. Medicines' OOP expenditure alone contributed to an estimated 11% of financial catastrophe. In absolute numbers, this translates to a scenario where an estimated 46 million households appear to face catastrophic expenditure on account of OOP payments while 29 million households faced such hardship because they had to pay for medicines from their pockets.

Recent evidence from the National Health Accounts for India points out that during 2013-14, an estimated INR 1,331 per capita was spent on medicines, while households alone contributed INR 1,200 per capita, accounting for 90% of all medicines expenditure in the country.¹ On the other hand, past evidence about government expenditure on medicines in India, underscores that, on an average government spent about 10% percent of health expenditure on medicines. However, the national average masks significant underspending on medicines by several state governments, with many reportedly spending less than five percent of their health budgets.⁶ Besides poor allocation of resources, except for a couple of Indian states, drug procurement and supply chain system is inefficient and ineffective leading to acute shortages of key essential medicines and chronic stock-outs in public health facilities.²¹⁻²⁴ This situation has resulted in physical unavailability of medicines. Drawing evidence from large sample surveys for the period from 1986-87 to 2004, it is reported the physical barrier to access to key essential medicines worsened during this period.¹⁵ Supply of free drugs in government health system in the outpatient care setting, declined sharply from about 18% in 1986-87 to 5% in 2004. For the same period, drugs prescribed during hospitalization for free also declined significantly from one-third to about 9%.⁶ As a result, it is pointed out the number of hospitalization episodes in which an ailing population paid outof-pocket (OOP) payment, has risen dramatically from about 41% to close to 72%.⁶ Further. it was observed that from the period spanning mid-1990s to 2004, patients visiting government health facilities did not receive medicines in over one-fourth of outpatient episodes. Affordability of medicines is an important access indicator, because it translates into poor access or no access for people who have low purchasing power.³ The consumer behaviour theory also predicts that raising the price (via high OOP expenditure on medicines or high copayment) for a service in the public health sector will move more consumers into the private sector, depending on the elasticity of substitution and transaction costs in the public sector.²⁵

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In view of inadequate availability of medicines in government health facilities, households end up accessing private facilities where they end up incurring significant OOP payment, in the absence of any financial risk protection. Past evidence suggests that the trend has sharpened in the last couple of decades. For instance, the percentage of population accessing private facilities for inpatient and outpatient treatment has accelerated significantly between 1986-87 and 2004. It may be observed that households accessing private hospital for inpatient care increased from around 40% to nearly 60% in rural India while urban India reported a rise from 40% to 68%.²⁶ During the same period, outpatient care visits in private facilities remained high at around 75% in 1986-87 in rural India and 73% in urban India stepped up to 78% and 80% respectively for rural and urban India.³

The other critical evidence emerging from this paper focuses on disease specific medicines expenditure. The results demonstrate a pattern where households' medicine spending is concentrated on low frequency, high-value spending and high frequency, high-value spending. By disease-wise classification, expenditure on treatment of cancers, CVDs and injuries, both for outpatient and inpatient care dominate the spending pattern. Available literature confirms such an expenditure pattern, wherein the share of non-communicable diseases (cardiovascular disease, diabetes, cancer, mental illness, injuries and others) in OOP health expenses has increased from 31.6% in 1995-96 to 47.3% in 2004.¹² The literature further indicates high odds of catastrophic hospitalization expenditures for certain NCDs. For example, the odds for catastrophic expenditure in cancer are nearly 170% greater, for cardiovascular diseases (CVD) and injuries nearly 22% greater than the odds due to infectious diseases. Other studies on cardiovascular diseases highlighted that CVD affected households had more outpatient visits and inpatient stays, spent extra money per hospitalization ¹¹ and have high probability of incurring catastrophic expenditure compared to those using inpatient facilities for communicable conditions.²⁷ Another Indian study on socio-economic inequalities in financing of diabetes and cardiovascular disease reported that out-of-pocket payments for hospital treatment claimed a large share of annual household expenditures; 30% for CVD and 17% for diabetes.²⁸ In respect to injuries (both road traffic and non-road traffic), high incidence of catastrophic expenditure was 30%, and was significantly higher among those belonging to the lowest income quartile and with an inpatient stay greater than 7 days.²⁹

Although public facilities have slightly stepped up their share in outpatient care in recent years, private sector continue to dominate both in outpatient and inpatient care in India.³⁰ As an increasing share of households' access private health facilities, private retail pharmacies have become a major source of supply of key essential medicines. While availability of medicines may per se is not a challenge in the private health care setting, affordability appears to act as critical barrier.³¹ Thus, pricing of medicines and regulation around retail medicine prices becomes a key factor in improving affordability and thereby leading to a reduction in medicines related OOP payment burden. Although India had a

progressive retail price cap policies since 1979, but over the years a policy of deregulation was followed.³² In 2013, the Government of India promulgated the Drugs Price Control Order (DPCO), 2013 (DPCO, 2013) which primarily brought all essential drugs, based on National List of Essential Medicines, 2011, under price control.³³ An evaluation of new price regulation has highlighted that, while few of the medicines (37) had an increase in sales volume attributable to DPCO, majority of the medicines (52) had a negative impact on their sales volume due to DPCO. Overall, the DPCO may have had a negative impact in terms of sales volume of medicines under price control.³⁴ Given that the sales volume of price-capped medicines has declined, households OOP spending may continue to increase since over 80% of retail pharmacy market is not price-capped.

In order to improve access to health care and to provide financial risk protection to households, the central government and several state governments have been implementing a publicly funded health insurance programs since 2007, whose primary aim was to provide cashless treatment to economically vulnerable households for hospitalization episodes. Emerging evidence from micro as well as macro level studies point to a trend where such insurance schemes appear to have improved access to hospital care but have been ineffective in preventing financial catastrophe and impoverishment to households.^{2 35 36} These bodies of evidence are in line with our findings that hospitalization based treatment cost constitute only one-third of India's morbidity burden. Despite implementation of several health insurance schemes, a majority of Indian population continues to incur a relatively significant medicines OOP payment while seeking outpatient care. It would be pertinent to highlight that the frequency of hospitalization is considerably smaller than outpatient visits in general, especially for non-communicable diseases (NCDs), which are chronic in nature that require multiple consultations and long-term or life-long medication support. Such medical conditions result in catastrophic expenditure for households even in the absence of hospitalization episodes. Moreover, since a relatively larger proportion of population seeks outpatient care in private facilities, which is often multiple times expensive than public health facilities, we observe a disproportionately higher burden of medicines related OOP payment for outpatient care.

The evidence presented in this paper, however, suffers from a few limitations. The first set of challenge relates to co-morbidities and associated expenditure. In respect to inpatient cases, since NSSO data captures disease expenditure separately for various disease conditions, the issue of co-morbid conditions did not play major role. However, for outpatient cases, we had to adopt apportioning technique to handle co-morbid conditions. The second set of challenge pertains to the potential recall bias for disease specific expenditures, which cannot be ruled out especially for hospitalization treatment since the recall period is a longer time span of 365 days. Lastly, although there are significant state level and rural-urban differentials in the estimates presented in this paper, we focused on

the All India average and believe that the state level and rural-urban analyses could be a potential research for the future.

The foregoing underlines several policy interventions and program design that were conceived and implemented in the recent past to provide financial risk protection to households. However, gross underinvestment in the public health system in past had led to inadequate prepayment and risk pooling measures.²⁶ Several policy interventions and program redesign are required to reverse the trend of high OOP expenditure for healthcare in India. An efficient and a reliable medicines supply chain model existed for over two and half decades in the state of Tamil Nadu, which was replicated in the state of Rajasthan in 2012 have been instrumental in improving access to medicines in the frontline facilities in these two states.³⁷ Such policies and programs governing public health facilities are critical. The National Health Policy 2017 also highlighted the need for providing free medicines in public health facilities by stepping up funding and improving drug procurement and supply chain mechanisms.³⁸ A recent pronouncement by the government intends to bring legislation for physicians to prescribe drugs only in generic names, also holds promise for reducing households' OOP payments on medicines and ultimately providing financial risk protection. To sum up, both national and state governments' intervention is required for providing free medicines in public health facilities along with expanding the mechanism of price capping of key essential medicines in the private market.

Contributorship: AK and SS conceived the idea, designed the analysis, conducted data analysis and wrote the first draft of the paper. AK, SS and HHF conducted the literature review and the interpretation of the results. AS, SS and HHF revised and edited the manuscript to its final stages. All the authors approved the final manuscript version.

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Data sharing: The data used for the analysis is available in public domain.

Ethical approval: Ethical approval for this study was not needed. The study used only anonymised data from secondary sources. Requisite permission to use the data has been obtained from the agency.

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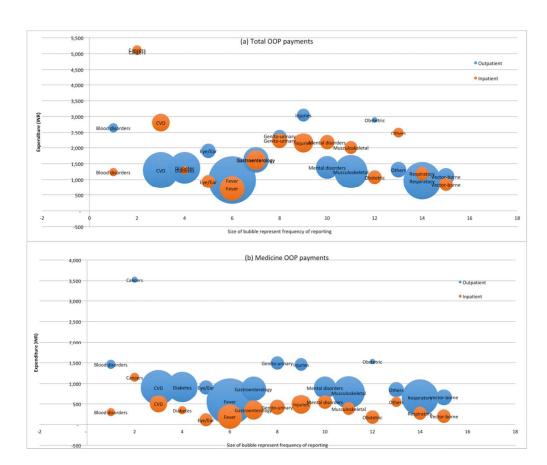
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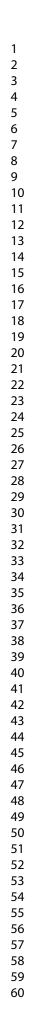
Figure 1: Frequency and monthly per person (a) total OOP and (b) medicine OOP spending on select disease conditions, 2014

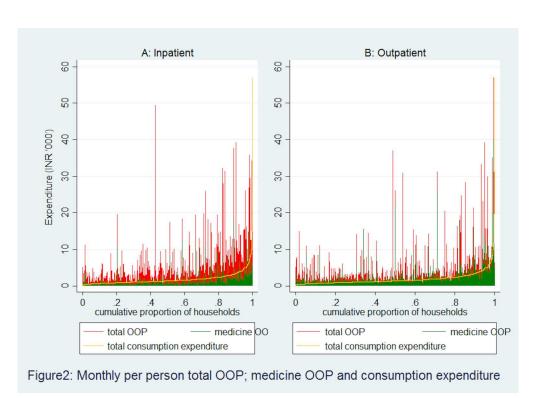
Figure 2: Monthly per person total OOP payment, medicine OOP payment and consumption for peer terien only expenditure



Frequency and monthly per person (a) total OOP and (b) medicine OOP spending on select disease conditions, 2014

228x190mm (300 x 300 DPI)





Monthly per person total OOP payment, medicine OOP payment and consumption expenditure

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Annexure

36/bmjopen-2017-01802 Estimation of out-of-pocket expenditure indicators and related indicators

a. Out-of-pocket payments

Total out-of-pocket (OOP) payment has been defined as the summation of all kinds of direct expenditure on purchase of medical care including expenditure on family planning devices and transportation costs to access medical care by households either as inpatient or outpatient. According to the NSSO household questionnaire the main item of expendifure considered for inpatient and outpatient are presented in Table A-I.

Table A-I: Main items of expenditure considered for inpatient and outpatient in the NSSO question haire

Inpatier	nt	Outpatie	ent fro
Heads of expenditure	Item code in NSSO questionnaire	Heads of expenditure	Item code in NSSO question aire
medicine	410	medicine	420
X-ray, ECG, pathological test, etc.	411	X-ray, ECG, pathological test, etc.	421 <u>bn</u> i. 60
doctor's/surgeon's fee	412	doctor's/ surgeon's fee	422 [₹]
hospital & nursing home charges	413	family planning devices	423 May ω
other medical expenses	414	other medical expenses	424 NO
Total inpatient	419=410-414	Total outpatient	429=420- 4 24

The reference period of inpatient and outpatient expenditure in the consumer expenditure surveys are 1 year and 1 month respectively. Based on the information presented in Table A-I, total inpatient expenditure, outpatient expenditure and total OOP expenditure were estimated by converting inpatient expenditure for one month. Accordingly, households with any OOP have been defined as households reporting positive OOP (OOP>0) either as inpatient or outpatient or both. d by copyright

b. Per person monthly OOP and OOP share

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Per person monthly OOP is defined as total monthly OOP divided by household size for each household.

The financial burden of health expenses by households has also been estimated in terms of OCP as a share of total household expenditure and alternatively as a share of total non-food expenditure of households.. May 2018

 $Sh_{OOP} = T / \exp$ (A.1)

Where, 'T' is total OOP payments and 'exp' is household total (non-food) expenditure by households.

c. Catastrophic payments and headcount

Further, OOP payments are defined as catastrophic when OOP payments as a portion of total household resources are in excess of a certain threshold. A household is said to have incurred catastrophic payments if T/exp>Z, wher \hat{s} 'T' and OOP are the same as in equation (A.1) and 'Z' is a certain threshold. The latter is arbitrary and in general, estimates are presented for a range of values for z (5, 10, 15, 25 and 40 per cent). mjopen.bmj.com/

Accordingly, the headcount ratio of catastrophic payment is calculated as follows:

$$cat_i = \frac{1}{n} \sum 1\left(\frac{T}{exp} > Z_i\right)$$
(A.2)

Where, Cati is catastrophic headcounts of households with OOP share exceeding a threshold defined as 'i' per cent of total household total (non-food) expenditure, 1(.) is an indicator function, which takes the value 1 if T/exp>Zi is true and 0 otherwise; n is the number of households incurring expenditure on health for various thresholds; Z_1, Z_2, Z_3 are the respective thresholds of the OGP share.

d. Poverty headcount

 The usual headcount ratio of poverty is calculated as:

Gross HP = $1/n \Sigma 1$ (xi ≤ PL)(A.3)

where: 1(.) is a function, taking the value 1 if person belong to a household with consumption expenditure lower the value of poverty line value, x= Household total consumption expenditure; PL= Poverty Line and n is total population.

Headcount of poverty after deducting OOP from household consumption expenditure can be defined as:

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Net $HP = 1/n \Sigma 1$ ((xi-T) $\leq PL$). (A.4)

where: T= *per capita OOP*

The OOP induced poverty headcount finally is estimated as: (Gross HP - Net HP).

e. Poverty gap

Poverty gap is defined as difference between values of poverty lines and household consumption expenditure for the poor as defined in the sub-section d above. Using the household level data poverty gap for the poor is estimated as follows:

Gross poverty gap = $1/n \Sigma 1$ (xi- PL) | if i=poor(A.5)

In equation A.5 'xi-PL' is the difference between household expenditure per person and poverty line. For al positive values of this difference mean gap is estimated. Finally, poverty gap net of OOP payments is estimated as follows: :p://bmjopen

Net poverty gap = $1/n \Sigma 1$ ((xi-T)- PL) | if i=poor after netting OOP (A.6)

Table A-II. Prevalence and average per episode total and medicine out of pocket payments by disease conditions in 2014

	Outpatient 15	Inpatient 365 days recat										
	Prevalence	Per episode		estimated monthly				∑Per epis 8	ے Per episode		ed y	
Ailment	Number of episodes	%	Total OOP	Dr ug	Total OOP	Dru g	Number of episodes		Grotal COOP	Dru g	Total OOP	Dru g
Fever	2,71,43,431	22.71	488	280	975	561	74,12,043	12.95	<u>ة</u> 18670	2329	713	191
TB/Filaria/Tetan us	11,08,425	0.93	524	287	1047	573	6,14,933	1.07	0 14731	4134	1,211	340
STD/HIV/AIDS	1,20,714	0.1	538	268	1076	536	88,935	0.16	2 6906	1633	568	134
Vector-borne	33,33,651	2.79	549	332	1097	663	22,65,189	3.96	§10288	2460	846	202

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Cancers	4,52,513	0.38	2527	176 3	5054	352 6	9,78,764	1.71	0 62297	1403 7	5,121	1,15 4
Blood disease	10,26,129	0.86	1322	731	2643	146 3	8,10,752	1.42	15035	3650	1,236	300
Diabetes	1,17,55,081	9.84	683	456	1367	911	8,17,199	1.43	815746	4224	1,294	347
Other Metabolic	20,50,282	1.72	712	340	1423	679	2,60,707	0.46	<u>۳</u> 15429	3600	1,268	296
Mental disorders	61,56,374	5.15	690	451	1380	902	24,87,836	4.35	§26428	6685	2,172	549
Eye/Ear	24,67,286	2.06	950	454	1899	908	20,82,420	3.64	<u></u> 11350	1407	933	116
Cardiovascular diseases	1,55,65,223	13.02	645	449	1289	899	37,82,374	6.61	634167	6129	2,808	504
Respiratory diseases	1,69,58,670	14.19	478	328	955	656	21,40,762	3.74	14491	3325	1,191	273
Gastroenterlogy	77,13,330	6.45	809	434	1617	869	45,40,520	7.93	19587	4260	1,610	350
Skin	28,34,892	2.37	522	370	1043	740	3,80,346	0.66	1 2123	3514	996	289
Musculo-Skeletal	1,32,29,065	11.07	622	391	1244	782	19,66,211	3.44	24379	4677	2,004	384
Genito-Urinary	21,91,953	1.83	1183	747	2365	149 4	28,01,133	4.89	27085	5094	2,226	419
Obstetric	3,64,060	0.3	1448	765	2896	152 9	22,64,628	3.96	g13050 ន្ត	2189	1,073	180
Injuries	19,93,646	1.67	1522	730	3045	146 0	46,19,876	8.07	یے 26242 ک	6000	2,157	493
Others	28,92,298	2.42	655	426	1310	853	12,97,049	2.27	<u>6</u> 30196	6666	2,482	548
Childbirth	1,46,562	0.12	585	398	1169	797	1,56,17,000	27.29	\$8508	1729	699	142

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