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THE ABYSMAL STATE OF DRUG COST CONTAINMENT MEASURES IN INDIA: EVIDENCES FROM EXPENDITURE ON CANCER MEDICINE

Sobin George[1], Arun Balachandran[2] and Anushree K N[3]

Abstract

Medicines constitute a significant part of out-of-pocket (OOP) medical expenditure in India. While OOP medical expenditure continues to be high for all diseases in India, cancer treatment needs special attention due to the increasing burden of cancer as compared to other diseases. This paper critically examines the drug pricing policy and drug cost containment measures in India in the light of the spending on and price variations of cancer drugs. The paper used 71st and 75th rounds of NSSO Data on health expenditure for analysing the cost of medicine for in-patient and out-patient cancer care. Data on newly approved cancer drugs and drug prices were obtained from the Central Medicines Standard Control Organisation and the National Pharmaceutical Pricing Authority respectively. Results show that medicines held the highest share in the OOP cancer medical expenditure in private and public sectors and it was more pronounced in the private sector. Further, the increase in spending on cancer medicines was the highest for elderly and children below 14 years for both in-patient and out-patient care. Another significant finding of the paper is the price variation of recently approved anti-cancer medicines across brands, both under and outside price control. These findings confirm the ineffectiveness of price control measures for cancer drugs under the market-based pricing policy in India and the inadequacy of the existing cost containment measures. This calls for the rolling back of cost-based pricing of medicines and adoption of other cost containment measures which include expanding the scope of all forms, types and severities of cancer and anti-cancer medications under health insurance and adoption of a uniform treatment protocol across both private and public sectors.

Keywords: drug pricing, drug cost containment, OOP spending on cancer, drug price variations

Introduction

Medical expenditure is a significant component of out-of-pocket (OOP) health spending in India and research has showed that it has the potential to push households into poverty (Pandey *et al*, 2018). The OOP payments for medicine alone are estimated to have pushed nearly 38 million people to poverty in India in 2011-12 (Selvaraj *et al*, 2018). Pharmaceutical pricing and cost containment are significant measures to increase the affordability of medicine. One of the major reforms in the pricing of medicines in India was the shift from cost-based pricing to market-based pricing (MBP). As per MBP, the ceiling price of a medicine is fixed based on the average prices of its brands that have a minimum of 1% market share. However, studies have already demonstrated that ceiling prices are always closer to the prices of top selling brands and top selling brands are generally highly priced (Selvaraj *et al*, 2012).

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There is also evidence that unlike other commodity markets where consumers have information and can choose the products, the MBP might not lead to competitive pricing due to the nature of the organisation of healthcare industry, procurement policies in low and middle income countries (Danzon *et al*, 2015) and regulatory issues (Phadke *et al*, 2013). We attempt to critically understand the state of India's pharmaceutical cost containment measures by examining the spending on and cost variations of selected drugs for cancer treatment. While OOP medical expenditure continues to be high for all diseases in India, cancer treatment needs special attention, primarily due to the increasing disease burden (Takiar, 2010, Ferlay *et al*, 2015, Dandona *et al*, 2017, Rajpal *et al*, 2018, Fitzmaurice, 2018), higher financial burden of cancer as compared to other diseases (Mohanti *et al*, 2011, Engelgau *et al*, 2012, Mahal *et al*, 2013, Joe, 2014, Rajpal *et al*, 2018), implications for patients from poor economic background (Mallath *et al*, 2014) and the relatively higher cost of anti-cancer medicines (George *et al*, 2018).

Methods

We used the 71st and 75th rounds of NSSO data for analysing the cost of medicine for in-patient and out-patient cancer care. The data on ailments and medical expenditure is self-reported and provided for a reference period of 365 days for in-patient care and 15 days of out-patient care. The survey provides disaggregated data on medical expenditure including doctor's fee, diagnostic tests, bed charges, cost of medicine and other medical as well as non-medical expenditure. The data is also flexible enough to zero in on to disease-specific medical expenditure across social and economic classes. We considered only the spells of in-patient and out-patient cancer care for analysis here. The data on medical expenditure was distributed across monthly per capita expenditure (MPCE) classes, age group, gender, place of residence (rural and urban) and place of service provisioning (public and private sector). We collected data on new anti-cancer medicines approved for marketing in India between 2001 and 2017 from the Central Medicines Standard Control Organisation (CDSCO), Government of India. The web portal of CDSCO provides details of new medicines are approved for marketing in India. These were classified based on indications. We identified 153 new medicines (branded generics and biosimilars) approved for cancer and related treatment in India between 2001 and 2017. The information on prices of medicines was compiled from the website of the National Pharmaceutical Pricing Authority under the Ministry of Chemicals and Fertilisers, Government of India, that provides the prices of generic medicines across various brands.

It is also important to mention certain limitations of the data here. Firstly, data on medical expenditure of NSSO is self reported. Secondly, the sample size of cancer patients is small in the NSSO data and further disaggregation of spending on medicine is not possible. Hence, we have not analysed the medical expenditure data across various Indian states as well as social and religious groups. Thirdly, we have taken only 32 new anti-cancer medicines approved for marketing for the price analysis based on their popularity and availability of authentic data on prices. Finally, some of the new medicines approved for cancer care are not included in the analysis of price variation since only one brand of the medicine was available.

Results

The paper begins by highlighting the increasing cancer burden in India. It then examines the financial burden due to cancer by estimating the total and OOP spending on anti-cancer medicines across socio-economic groups and type of treatment. Further, the paper examines the price variations of the selected newly approved oncology medicines that are approved for marketing in India. Finally, based on the above results, the paper discusses the question of medicine prices in the light of the market-based drug pricing policy in India, regulation of medical practice as well as the options of cost containment of cancer treatment**.**

Burden of cancer in India

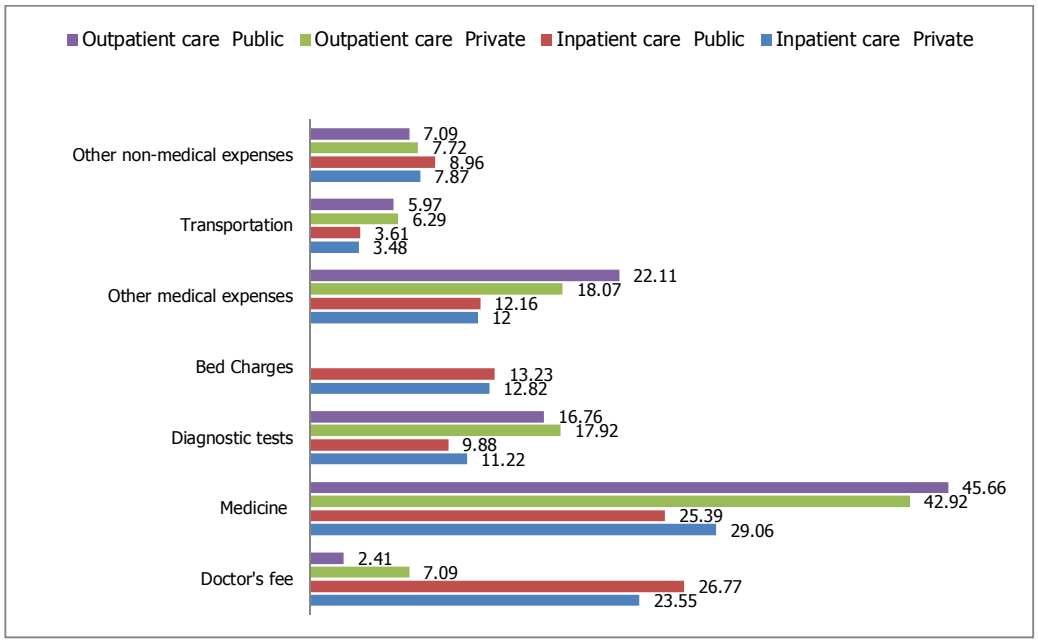
Cancer has been a major cause of morbidity and mortality across the globe. Developing countries like India have also started witnessing the burden from non-communicable diseases, especially cancer. As per the mortality data of the World Health Organisation, cancer accounted for 8.24% of the total deaths in India in 2015 and 13% of deaths within non communicable diseases (NCDs) (see table A1, annexure). Within cancer deaths, mouth and oropharynx cancer was the leading cause of death (12.12%), followed by trachea, bronchus and lung cancer (11%), breast cancer (10%), cervix uteri cancer (9%), stomach cancer (8%), colon and rectum cancer (7%), oesophagus cancer (5.34%) and gallbladder and biliary tract cancer (4.6%). Data also showed that the death was the highest in the age group of 15 to 69 (George *et al*, 2018). Breast cancer accounted for the largest cause of cancer-related deaths among women (nearly 21 per cent) followed by cervix uteri cancer (18 per cent), gall bladder and bilary tract cancer (7 per cent) and colon and rectum cancer (see figure 3.2). Mouth and oropharynx cancer was the largest cause of cancer deaths among men followed by trachea, bronchus and lung cancer, stomach cancer and oesophagus cancer. Tables A2 & A3 (see annexure) provide further information on deaths due to cancer across type and gender.

Spending on cancer medicines

As it is evident from figure 1, medicines constitute the single largest expenditure in the in-patient and out-patient cancer treatment in India. In in-patient care, the percentage share of the cost of medicine within the sector was marginally higher in the private than the public sector while it was the reverse in the out-patient care. However, it must be noted that in absolute terms, the cost was higher for medicines in the private sector. For instance, the in-patient care patients in the private sector spent 38.25% more on medicine than their counterparts in the public sector (table 1). The data further show that in absolute terms, men who were hospitalised in private sector hospitals spent nearly double the amount of their counterparts in public hospitals for cancer medicines. Patients who were hospitalised in private sector hospitals in urban areas and rural areas spent 89% and 40% more respectively for anti-cancer medicines than their counterparts in the public sector. The richest who were hospitalised in the private sector spent 248% more than their counterparts in the public hospitals; the richer group spent 68% more in private than in public and the middle wealth quintile spent nearly 89% more in private than in public sector hospitals for cancer medicine. The cost was more for all age groups in the private sector; however, the 80 plus age group spent nearly 463% more in the private sector than their

counterparts who were hospitalised in the public sector. It should also be noted that patients from the poor and the poorest wealth quintiles, although they availed cancer care services mostly from the public sector, were found to have spent considerably on medicines. Similarly, the out-patient cancer patients in the private sector spent 17.21% more on medicines than the cancer patients in the public sector (table 2).

Figure 1: Percentage Distribution of Medical Expenses Incurred by Cancer Patients in a Year in Public and Private Sector Treatment, 2014



Source: NSSO 71st round on Social Consumption (2014), unit level data

Table 1: Average Hospitalisation Expenses (in Rs.) Incurred Per Hospitalisation Case by Cancer Patients in a Year by Background Characteristics and Public and Private Sector Treatment, 2014

	Public Sector			Private Sector			% difference in medicine expenditure (private and public)
	Medicine Expenditure	% to total	Total Expenditure	Medicine Expenditure	% to total	Total Expenditure	
Gender							
Male	11671.7	35.0	33367.76	23346.11	22.9	102057.2	100
Female	7836.46	24.9	31466.28	11582.65	17.5	66227.95	47.8
Place of residence							
Rural	9064.35	27.4	33092.71	12774.83	17.0	75113.12	40.3
Urban	11115.26	35.4	31442.57	21014.48	24.3	86556.59	89.1
Wealth quintile							
Poorest	15361.33	36.6	41952.71	11451.49	16.1	71124.99	-25.5
Poor	10440.13	43.8	23810.89	4660.91	6.0	77293.11	-55.4
Middle	8410.21	37.3	22531.35	15890.86	21.9	72538.7	88.9
Richer	5925.25	24.6	24124.65	9970.98	16.6	60135.91	68.3
Richest	7546.37	16.8	44889.13	26271.1	26.6	98708.72	248.1
Age-group							
0- 14	9985.57	29.2	34178.22	13049.98	20.1	64923.83	30.7
15-59	11429.33	31.9	35797.99	16465.43	18.6	88686.13	44.1
60-80	8687.22	28.8	30192.12	16411.18	24.2	67923.83	88.9
80+	1421.28	12.3	11522.03	8007.86	24.1	33235.35	463.4

Source: NSSO 71st round on Social Consumption (2014), estimated

Table 2: Medicine and Total Expenses (in Rs.) Incurred by Out-patient Cancer Patients in a Reference Period of 15 days by Background Characteristics and Public and Private Sector

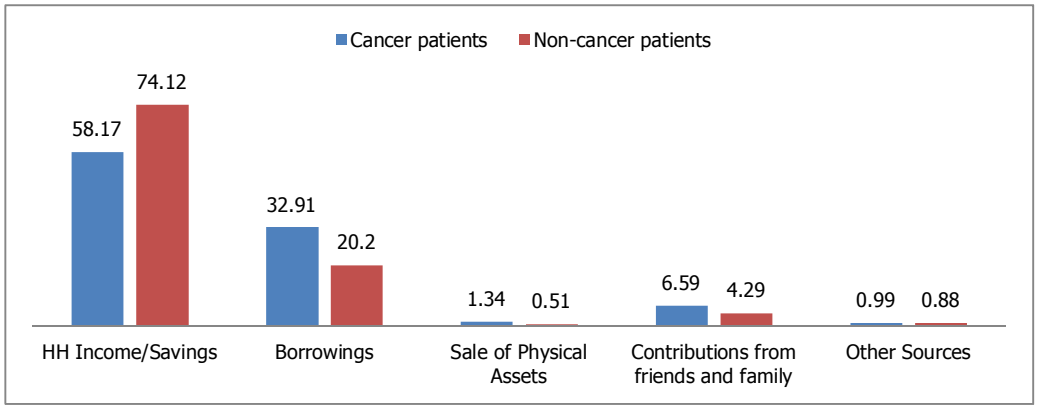
	Public Sector			*Private Sector*			% difference in medicine expenditure (private and public)
	Medicine Expenditure	% to total	Total Expenditure	Medicine Expenditure	% to total	Total Expenditure	
Gender							
Male	136041	73.2	185846	125010	58.6	213285	-8.1
Female	60755	49.8	122067	177801	56.8	312836	192.7
Place of residence							
Rural	92495	55.5	166768	101315	57.9	175005	9.5
Urban	104301	73.9	141145	201496	57.4	351116	93.2
Wealth quintile							
Poorest	20800	70.9	29320	7815	44.3	17635	-62.4
Poor	17305	36.4	47557	16750	77.5	21615	-3.2
Middle	18330	74.6	24572	26615	43.7	60940	45.2
Richer	51530	65.9	78183	64480	53.2	121280	25.1
Richest	88831	69.2	128281	187151	61.4	304651	110.7
Age-group							
0-14	5100	44.4	11480	13800	33.9	40720	170.6
15-59	154830	66.5	232927	215526	60.0	358991	39.2
60-80	35241	57.1	61681	70435	57.2	123060	99.9
80+	1625	89.0	1825	3050	91.0	3350	87.7

Source: NSSO 71st round on Social Consumption (2014), estimated

Out of pocket (OOP) spending on cancer medicine

For most of the households, cancer care not only wore out the household income and savings, but also compelled them to borrow money, sell off physical assets and seek financial assistance from relatives and friends. As is evident from figure 2, nearly 42% of the households had to look for other resources than household income and savings to meet the expenses of cancer care. Importantly, cancer led to more borrowing for patients as compared to diseases other than cancer. It should also be mentioned that the share of households, which sought financial resources other than income and savings for non-cancer diseases was 26%. Further details on source of cancer across age, gender, wealth quintile and place of residence from the latest NSSO round are given in table 3. The data show that financial burden in terms of borrowing, distress sale of assets etc. were found more for the treatment of children and those who were in the age group of 45-59 across age groups; more in rural areas than urban and more in middle, poorest and poor groups than the rich and the richest.

Figure 2: Source of Finance for Cancer Treatment and Non-cancer Treatment (in-patient), India, 2014



Source: NSSO 71st round on Social Consumption (2014), estimated

Table 3: Source of Finance for Cancer Treatment by Socio-economic Characteristics

	Household income/ savings	Borrowings	Sale of physical assets	Contributions from friends and relatives	Other sources	Total
Age						
0-14	66.6	8.1	0.0	25.3	0.0	100.0
15-29	81.1	9.6	5.7	1.2	2.4	100.0
30-44	80.6	13.5	0.8	3.5	1.6	100.0
45-59	67.7	17.2	3.2	10.1	1.8	100.0
60+	81.3	9.2	0.3	3.4	5.7	100.0
Gender						
Male	75.4	13.3	1.2	6.0	4.1	100.0
Female	76.8	12.5	2.3	6.2	2.2	100.0
Wealth Quintile						
Poorest	75.6	19.2	0.2	0.0	5.0	100.0
poor	76.0	10.1	4.6	4.3	5.0	100.0
middle	67.0	18.8	0.6	10.4	3.2	100.0
rich	75.1	13.8	1.6	6.3	3.2	100.0
richest	79.3	10.9	1.1	6.7	1.9	100.0
Place of residence						
Rural	73.2	13.6	2.1	7.8	3.4	100.0
Urban	80.9	11.8	1.1	3.4	2.8	100.0
Total	**76.1**	**12.9**	**1.7**	**6.1**	**3.2**	**100.0**

Source: NSSO 75th rounds (2017), unit level data

Trends in average OOP expenditure on cancer medicines for in-patient and out-patient care by socio economic characteristics are presented in table 4. Needless to mention, expenditure on medicine in in-patient care was notably higher than out-patient care. At an aggregate level, the average expenditure of cancer medicine as part of in-patient care increased by nearly 47 per cent between 2004 and 2017 whereas it increased by nearly 115 per cent for out-patient care. The increase was substantial for elderly patients and children below 14 years for both in-patient and out-patient care. Another striking finding is that medicine expenditure, as part of out-patient care, increased by nearly 778 per cent for the poorest section of the population. While the increase in spending on cancer medicine was more for males in in-patient care, it was more for females when it came to out-patient care. Also, the increase was more for patients in the urban areas in in-patient care whereas it was more for their rural counterparts when it came to out-patient care.

Table 4: Average OOP expenditure on cancer medicine 2004, 2014 and 2017(All India), (Rs.)

	In-patient				Out patient			
	2004	**2014**	**2017**	**2004-2017 (%)**	**2004**	**2014**	**2017**	**2004-2017 (%)**
Age								
0-14	5402.4	10546.1	12317.5	128.0	206.3	1070.7	1922.4	831.7
15-29	7257.3	10909.6	9694.2	33.6	771.6	1241.6	1067.7	38.4
30-44	8894.5	11065.0	11272.2	26.7	927.7	697.4	1563.5	68.5
45-59	19434.5	15158.5	15133.3	-22.1	1392.8	5380.8	2033.1	46.0
60+	5373.7	19529.3	18357.5	241.6	1040.4	1566.3	2764.4	165.7
Gender								
Male	8668.9	20312.6	18136.2	109.2	1110.6	3616.2	2317.0	108.6
Female	11346.2	11283.2	12092.5	6.6	973.2	1162.9	2101.4	115.9
Wealth quintile								
Poorest	8238.5	12660.9	10946.9	32.9	469.9	965.9	4124.8	777.7
Poor	10530.8	15438.6	10379.3	-1.4	811.7	9638.8	1188.9	46.5
Middle	7027.4	6791.4	10495.5	49.4	1171.8	1027.9	1752.9	49.6
Rich	9916.6	10017.3	10765.0	8.6	1090.0	1054.6	1817.5	66.7
Richest	12562.3	20560.2	21988.9	75.0	1387.8	2760.2	2653.9	91.2
Place of residence								
Rural	11526.9	10147.4	15159.4	31.5	1025.8	1018.0	2567.1	150.3
Urban	7766.1	22450.4	15032.2	93.6	1054.9	3939.0	1701.6	61.3
Total	**10292.9**	**14615.6**	**15111.3**	**46.8**	**1035.5**	**2232.5**	**2219.7**	**114.4**

Source: NSSO 60th, 71st and 75th rounds, unit level data

Further, we have estimated the average OOP expenditure on cancer medicine across public and private sectors. The average OOP expenditure for cancer medicines for hospitalisation per year was Rs. 15579 with Rs. 7181 for public sector and Rs. 22195 for private sector. We have presented the data of OOP for in-patient and out-patient care across private and public sector in supplementary information (tables 5 & 6). As it is already mentioned, the OOP spending on anti-cancer medicines was more in the private than the public sector in absolute terms. Nevertheless, the cost of anti-cancer medicines as a proportion to the total medical expenditure was high in the public sector as well. For instance, OOP spending on medicines constituted 31% and 61% of the total medical expenditure in in-patient and out-patient care respectively in the public sector. Data further showed that patients from the richest wealth quintile spent the highest for anti-cancer medicines as a proportion to the total medical expenditure of in-patient care in private hospitals. On the other hand, patients from the poor wealth quintile spent the highest for medicines in in-patient cancer care in the public hospitals. In out-patient care, patients who incurred the highest OOP expenditure on cancer medicine in private hospitals belonged to the age group of 80 plus and the poor wealth quintile. Similarly, patients in the age group of 80 plus and who belonged to the middle wealth quintile group spent the highest for cancer medicine in the out-patient care of public hospitals.

Table 5: Average OOP Expenditure (in Rs.) Incurred Per Hospitalisation Case and Medicine to OOP for Cancer Patients in a Year by Background Characteristics and Public and Private Sector Treatment, 2014 (Rs.)

Background characteristics	Private		Public		Difference of OOP medicine between private and public
	OOP total	OOP medicine	OOP total	OOP medicine	
Gender					
Male	84989.86	23346.71	32726.28	11670.19	11676.52
Female	63647.07	11583.77	30495.91	7837.449	3746.318
Place of residence					
Rural	69943.8	12771.74	32580.63	9063.931	3707.807
Urban	74151.44	21014.52	30178.68	11114.81	9899.71
Wealth quintile					
Poorest	51952.06	11450.23	41891.47	15361.6	-3911.37
Poor	77182.29	4661.81	23797.03	10439.76	-5777.95
Middle	70196.83	15892.56	22431.03	8409.393	7483.169
Richer	59881.43	9970.258	22871.56	5926.021	4044.237
Richest	85231	26268.19	42393.88	7546.111	18722.08
Age-group					
one to 14	60904.84	13051.91	34178.22	9986.876	3065.031
15-59	78684.75	16468.72	34497.38	11428.98	5039.736
60-80	62883.6	16412.62	29874.09	8687.385	7725.234
80+	32740.73	8008.383	11500.25	1421.431	6586.952

Source: NSSO 71st round on Social Consumption (2014), estimated

Table 6: Medicine Expenditure as a Percentage of Total Out-of-Pocket Medical Expenses Incurred by Out-patient Cancer Patients in a Reference Period of 15 Days by Background Characteristics and Public and Private Sector (Rs.)

Background characteristics	Private		Public		Difference of OOP medicine between private and public
	OOP total	OOP medicine	OOP total	OOP medicine	
Gender					
Male	125010	73930.91	136041	99595.62	-25664.7
Female	177801	101506.6	60755	30274.22	71232.37
Place of residence					
Rural	101315	58651.25	92495	51297.73	7353.527
Urban	201496	116726.6	104301	77161.88	39564.75
Wealth quintile					
Poorest	7815	3463.608	20800	14755.52	-11291.9
Poor	16750	12982.93	17305	6297.29	6685.636
Middle	26615	11622.77	18330	13676.01	-2053.24
Richer	64480	34284.02	51530	33968.58	315.44
Richest	187151	116220.8	88831	61586.53	54634.24
Age-group					
one to 14	13800	4693.38	5100	2265.93	2427.45
15-59	215526	136277.1	154830	108319.1	27958.02
60-80	70435	42486.39	35241	22945.42	19540.98
80+	3050	2777.33	1625	1446.9	1330.43

Source: NSSO 71st round on Social Consumption (2014), estimated

Price variation of anti-cancer medicines

Medicine affordability assumes significance in the context of the fact that medication is a vital part in the entire process of cancer care. There is already evidence that significant price variations exist for cancer medicines across brands (Lopes, 2013, Kolasani *et al*, 2016). Studies have also shed light on the regulatory failure in the pricing of cancer medicines, which resulted in significant price variations across brands (Howard *et al*, 2015). Our analysis is limited to the selected cancer medicines which have been approved for marketing in India between 2001 and 2017. As per the data obtained from the Central Drug Standard Control Organisation (CDSCO), 153 medicines for the treatment of cancer have been approved for marketing in India during this period. Out of this, we have examined the prices of 32 medicines across their brands in which 24 were under price control and the remaining eight were outside price control. The results are presented in tables 7 and 8.

Out of 24 formulations, which are under price control, ceiling prices were available only for 14 since the remaining ten were brought under price control very recently (in February 2019). Data shows that the prices of nearly 40% of the branded generics out of 241 brands of 14 formulations examined here have their prices higher than the ceiling price fixed by the National Pharmaceutical Pricing Authority (NPPA) in India (see table A4). The highest number of branded generics, which were more than the ceiling price were found for L-*asparaginase* powder for injection (5000 ku), which is used for treating acute *lymphoblastlc leukaemia*, followed by of the brands of *gemcitabine* powder for injection (1 gm), a medicine used for different types of cancer treatment, *cytarabine* 1000 mg injection, used for treating *leukaemia*, *capecitabine* 500 mg and *bortezomib*, powder for injection 2mg. The increase from ceiling price for these medicines ranged from 2% (*temozolomide* 250 mg) to 589% (*bicalutamide* tablet 50 mg). Price variations between the highest and lowest priced brands for the same formulation ranged from 8% (*decitabine* 50mg) to 1701% (*pemetrexed* 500mg injection) for the cancer medicines, which are under price control presented in table 6. It should also be noted that *temozolomide* 250 mg (capsule) and *bicalutamide* tablet 50 mg have only one brand and *letrozole* 2.5mg tablet have only two brands above the ceiling price.

Some of the expensive medicines such as *trabectedin* (1 mg) injection (price ranges from Rs. 28600 to Rs. 121485.7) used for treating *Leiomyosarcoma* are outside price control (see table A5). Further, we have found that among the anti-cancer medicines outside price control, nearly 44% of 55 brands (of 8 formulations) examined here priced their medicines above the average unit price. The price variations of medicines which are outside price control are also notably high. For instance, price variation is as high as 4170% across brands for *sorafenib* (200 mg) tablet. Similarly, the variation for *abiraterone* (250 mg) tablet, which is also outside price control, across brands, is 1760%.

Discussion

Our results with regard to the financial burden of anti-cancer medicines and their price variations across brands inform us of the policy imperatives of the effectiveness of price control of cancer medicines under the existing Market Based Pricing (MBP), problems with the insurance-based financial risk protection of cancer care and the need for standardisation of medicine prescription in India. These are discussed in the following sections.

The failure of price ceiling of cancer medicines

Our results indicated that the market based pricing of anti-cancer medicines has reduced neither the prices of anti-cancer medicines nor the vast variation of prices across brands. It is true that the development of branded generics and biosimilars has contributed immensely to the treatment of cancer in India (Renner *et al*, 2013, Chopra and Lopes, 2017). It is also true that positive measures have been taken recently to include more cancer medicines under price control. For instance, as per the official statement of NPPA, Government of India, nearly 72 formulations with the addition of 42 non-scheduled cancer medicines and 355 brands are under price control as of August 2019. NPPA has also imposed a cap of 30% on profit margin for the newly included 42 formulator medicines. However, our analysis shows that the price ceiling did not have the potential to improve the affordability of cancer medicines because of MBP. For instance, as it is clear from table 4, ceiling prices have not reduced the price variations across brands and the prices of several brands are far above the ceiling prices. Further, we have found that most of the newly approved anti-cancer medicines are manufactured by a single brand. For instance, the newly approved brands for marketing in India such as *nilotinib* capsules, 150 mg, *pazopanib* (as hydrochloride) film coated tablets, 200 mg, *sunitinib* (12.5 mg) capsules, *temsirolimus* (25 mg) injection, *crizotinib* hard gelatin capsules 200mg/250mg, *degarelix* (120 mg) injection, *lapatanib* tablet 250mg , *axitinib* (5 mg) tablet *ruxolitinib* (15 mg) tablet, *pazopanib* (400 mg) tablet, *triptorelin* (22.5 mg) injection, *crizotinib* (250 mg) capsule, to list a few, have only one brand available. MBP has no effect on prices in such cases. Furthermore, even after the attempts of the state to regulate prices of medicines with the introduction of the list of essential medicines and price ceiling, several newly approved medicines continue to be outside the price control (see table 7). Finally, most of the newly approved anti-cancer medicines are very expensive (see tables 6 and 7) and MBP, based on the present method of calculation, cannot bring down this since it takes the average of the prices of available brands. The escalating cost of medicine in healthcare and the price variations of branded generics thus clearly points to the inability of MBP to improve the affordability of anti-cancer medicines.

There is a growing literature on Value Based Pricing (VBP) of originator medicines (those are under patent protection), which is often projected as an alternative to cost-based and market-based pricing for reducing the cost of care (Jayadev and Stiglitz, 2008, Dang *et al*, 2016, Basu and Sullivan, 2017, Kaltenboeck and Bach, 2018). The essence of VBP in pharmaceuticals is sharing of risk between the manufacturer of the medicines and the payee, who mostly is an insurance company or state in countries where there is universal health protection or state negotiation on prices is in place. In VBP, both the parties also agree to "link payment of medicines to the health outcomes achieved" (Neumann *et al*, 2011). While VBP appears to be a robust policy initiative to check the prices and prescription of specialised medicines, the success of this model has hitherto been limited to a few cases even in the evolved markets. A study from UK (Neumann *et al*, 2011), for instance, based on a few case studies of risk sharing conducted in the UK, noted that although risk sharing can be advantageous for both the parties in its conceptual understanding, the success rate is very low. Similarly, studies from the US found that in some cases, VBP resulted in improved outcomes and the payers and the patients benefited out of the agreements (Stanley *et al*, 2012). However, there were concerns raised from

manufacturers and they wanted these agreements restricted mostly to highly-priced and competitive medicines.

Is it possible to adopt VBP in India as an alternative to MBP to increase the affordability of cancer care? While VBP has been successful in increasing the affordability of highly priced anti-cancer medicines in the developed world, several structural, systemic and behavioural impediments could come its way in India. The main barrier is the scope of VBP, which is limited only to originator medicines that are under patent protection. Other significant barriers are the limited role of the state in price fixation and the poor financial risk protection in cancer care in India. State and insurance firms are significant players in negotiating the price of the medicines under VBP model. Under VBP, medical and non-medical risks of medicines are shared between companies and patients/or payers (insurance companies) on behalf of the patients. The model also suggests that the doctor should "choose the right medicine for the right patient at the right time" (KPMG, 2016) and the patients should be clear about the right medicines for them. While MBP can be successful in highly evolved care settings which have a deliberative or informative model of doctor-patient interaction and decision making (wherein information asymmetry pertaining to the medicines, its effectiveness and value among the manufacturer, practitioner and the patient is less), it could fail and lead to further escalation of costs in Indian care settings where doctor-patient interactions are predominantly paternalistic in nature. We view that cost-based pricing may be a better option to increase the affordability of medicines in general and anti-cancer medicines in particular in India when it comes to branded generics and biosimilars. VBP may be a better option for highly priced originator anti-cancer medicines, which are under patent protection, provided that the state plays an active role in price negotiation along with health insurance providers.

Inadequacy of insurance based cancer risk protection

It is also important to bring attention to a few issues associated with the available financial risk protection for cancer care while discussing OOP spending on anti-cancer medicines. One of the major limitations of the available health insurance policies in India is the exclusion of out-patient care (Pramesh *et al*, 2014). It affects a cancer patient's medicine affordability since nearly 60% of the OOP spending in out-patient cancer care was for medicines (see table 4). Another issue pertains to the risk coverage of cancer. It must be highlighted that the insurance regulations in India do not mandate the insurance firms to cover cancers of all types, severities and stages. For instance, the guidelines of the Insurance Regulatory and Development Authority of India (IRDAI) on the standardisation in health insurance exclude all thyroid cancers, chronic lymphocytic leukaemia less than RAI stage 3, non-invasive papillary cancer of the bladder, all tumours in the presence of HIV infection and several pre-cancer conditions like all tumours described as *carcinoma in situ, benign, pre-malignant, borderline malignant, low malignant potential, neoplasm of unknown behaviour*, or *non-invasive carcinoma in situ of breasts, cervical dysplasia CIN-1, CIN -2* and *CIN-3* (IRDAI, 2019) from insurance coverage. Certain anti-cancer medicines are also excluded by the private insurers in India. For instance, some of the health insurance policies that we have examined clearly stated that certain "oral chemotherapy, immuno therapy and

biologicals, except when administered as an in-patient, when clinically indicated and hospitalisation warranted" are excluded[4].

Issues of practitioner-centred approach, prescription practices and affordability

Although affordability predominantly is an economic question, qualitative attributes like informed choices and shared decision-making are also equally important determinants. Studies conducted in developed countries showed that patients had several unmet needs and they tended to be non-active participants in cancer treatment plans, which have significant implications for affordability (Khan *et al*, 2012, Cancer care, 2017, Wang *et al*, 2018). For instance, a study by Cancer care (2017) also found that new cancer patients often are not in a position to discuss the treatment plans due to the sudden shock and lack of knowledge about treatment options and its possible benefits and side effects. They also found that patients often were not aware that they can ask questions on cancer treatment plans. Significant price variations of anti-cancer medicines across brands can have implications for affordability in practitioner-centred medical care settings in countries like India where practitioners are allowed to prescribe brands of medicines instead of their corresponding generics. Certain prevailing conditions in India such as lower regulation medical practice (Porter and Grills, 2015, Bhaskarabhatla and Chatterjee, 2017) and the non-standardisation of prescription practices of doctors (Bandameedi *et al*, 2016) may further add to the problem.

Studies, including the present one, have not accounted for the systemic and behavioural determinants such as choice of treatment, doctor-patient interaction, patients' economic and non-economic priorities and more importantly the shared decision making while estimating health affordability in general and medicine affordability in particular in India due to various reasons. One of the major reasons of this omission is the overpowering effect of OOP in countries like India due to the issues associated with regulatory failures (Bonu *et al*, 2009, Narula, 2015), poor health protection (Devadasan *et al*, 2007, Selvaraj and Karan, 2012), income of patients, competition and state's procurement policy of medicines (Danzon *et al*, 2015), which always necessitate economic determinants of affordability to be at the core of analysis. Another important reason is that discourses of patient-centred care and shared decision making have not yet received sufficient attention in academic and policy circles in India. Rather, the existing paternalistic nature of doctor-patient interaction makes the care practitioner centred, which could also lead to another set of affordability issues due to physician induced demand[5] (McGuire, 2000). Studies already reported instances like irrational use of diagnostic and treatment interventions that lead to escalation of medical expenditure are common in several countries (Johnson, 2014).

Nevertheless, evidences also showed that shared and informed decision making, deliberative doctor-patient interactions, patient-centred communication and accounting patient's concerns on cost in

[4] For details, see Star Group Health Insurance SHAHLGP19028V011819, retrieved from https://www.starhealth.in/sites/default/files/policy-clauses/Star-Group-Health-Insurance.pdf

[5] McGuire (2000) defines physician-induced demand as the demand that "exists when the physician influences a patient's demand for care against the physician's interpretation of the best interests of the patient".

cancer care reduced medical overuse and expenditure (Stewart, 2001, Levit *et al*, 2013, Sabbatini *et al*, 2014, Wintemute, 2016). We suggest that there is a need to expand the analysis of health affordability by including more sociologically relevant categories of medical interactions and the agency of the patient/relatives to have informed and shared decision of treatment on cost and value in India, especially for diseases like cancer for which OOP expenditure is one of the highest.

Concluding Remarks

Our results showed that price control measures in India under market-based pricing are not effective to increase the affordability of anti-cancer medicines. The economic burden of anti-cancer medicines calls for effective pharmaceutical cost containment measures in India. The paper notes that rolling back of cost-based pricing for medicines and options like value-based pricing for originator drugs with the involvement of the state in price negotiation could reduce the prices of anti-cancer medicines. Also, available private and public health insurance policies do not cover cancer care sufficiently and there is a need to expand the scope of these policies by including all forms, types and severities of cancer and anti-cancer medications. This has significance, especially in the wake of the announcement of the ambitious national health protection scheme in India, which aims to cover 500 million poor people. Further, the paper suggests that standardisation of cancer care with a uniform treatment protocol across private and public sector including prescription of generic medicines is an important measure to contain the cost of medicines. It is also important to expand the conceptual boundary of affordability by including non-economic indicators such as the doctor-patient relationship, prescription practices and shared decision-making that enable patients and their families to choose medicines and treatment options based on their economic priorities and values.

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Annexure

Table A1: Deaths Due to Non-communicable Diseases, Persons ('000)

Cause of death	2015	per cent	2010	per cent	2005	per cent	2000	per cent
Malignant neoplasms	773.3	13.29	682.9	13.06	601.6	12.93	524.4	12.39
Other neoplasms	14.3	0.25	11.8	0.23	9.0	0.19	6.9	0.16
Diabetes mellitus	298.2	5.13	232.6	4.45	172.8	3.71	129.0	3.05
Endocrine, blood, immune disorders	26.2	0.45	36.6	0.70	52.1	1.12	57.6	1.36
Mental and substance use disorders	27.4	0.47	23.1	0.44	20.4	0.44	17.4	0.41
Neurological conditions	189.9	3.26	168.3	3.22	153.5	3.30	132.4	3.13
Cardiovascular diseases	2474.5	42.54	2247.3	42.98	1958.0	42.07	1730.3	40.88
Respiratory diseases	1038.6	17.86	936.2	17.90	895.9	19.25	919.8	21.73
Digestive diseases	502.9	8.65	460.5	8.81	400.0	8.60	356.1	8.41
Genitourinary diseases	294.6	5.06	260.9	4.99	224.8	4.83	190.5	4.50
Skin diseases	11.2	0.19	11.1	0.21	11.0	0.24	9.7	0.23
Musculoskeletal diseases	46.4	0.80	35.3	0.68	27.4	0.59	20.7	0.49
Congenital anomalies	116.1	2.00	119.0	2.28	127.1	2.73	134.9	3.19
Oral conditions	0.5	0.01	0.4	0.01	0.3	0.01	0.3	0.01
Sudden infant death syndrome	2.4	0.04	2.8	0.05	3.2	0.07	3.0	0.07
Total NCDs	5816.5	100	5228.9	100	4653.8	100	4233.0	100

Source: WHO health repository, compiled

Table A2: Deaths Due to Malignant Neoplasm, Persons ('000)

Malignant neoplasms	**2015**	**%**	**2010**	**%**	**2005**	**%**	**2000**	%
Mouth and oropharynx cancers	94.4	12.21	83.1	12.18	70.4	11.70	57.6	10.98
Oesophagus cancer	41.3	5.34	36.8	5.39	32.2	5.35	28.5	5.43
Stomach cancer	61.4	7.94	56.9	8.34	53.1	8.83	50.7	9.67
Colon and rectum cancers	53.4	6.91	45	6.60	37.2	6.18	29.7	5.66
Liver cancer	28.6	3.70	25.9	3.80	22.8	3.79	18.8	3.59
Pancreas cancer	15.7	2.03	13	1.91	11.4	1.89	10	1.91
Trachea, bronchus, lung cancers	84.9	10.98	70.3	10.30	58.2	9.67	49	9.34
Melanoma and other skin cancers	4.4	0.57	3.5	0.51	2.9	0.48	2.6	0.50
Breast cancer	76.4	9.88	66.2	9.70	57.4	9.54	49.9	9.52
Cervix uteri cancer	68.9	8.91	67.7	9.92	68.9	11.45	64	12.20
Corpus uteri cancer	5	0.65	4.6	0.67	4.6	0.76	4.2	0.80
Ovary cancer	21.7	2.81	18.4	2.70	16	2.66	13.6	2.59
Prostate cancer	13.6	1.76	11.2	1.64	9.2	1.53	7.6	1.45
Testicular cancer	1.5	0.19	1.4	0.21	1.4	0.23	1.6	0.31
Kidney cancer	6.7	0.87	5.4	0.79	4.5	0.75	3.9	0.74
Bladder cancer	10.5	1.36	8.7	1.28	7.6	1.26	6.5	1.24
Brain and nervous system cancers	16.3	2.11	14	2.05	12.3	2.04	10.6	2.02
Gallbladder and biliary tract cancer	35.6	4.60	33.5	4.91	30.7	5.10	26.5	5.05
Larynx cancer	19.1	2.47	16.3	2.39	14.6	2.43	13.5	2.57
Thyroid cancer	3.5	0.45	3.1	0.45	3	0.50	3	0.57
Mesothelioma	0.4	0.05	0.4	0.06	0.4	0.07	0.5	0.10
Lymphomas, multiple myeloma	29.3	3.79	25.3	3.71	22.4	3.72	20.4	3.89
Leukaemia	27.8	3.59	24.9	3.65	22.2	3.69	20.9	3.99
Other malignant neoplasms	53.3	6.89	47.4	6.95	38.3	6.37	31.1	5.93
Total Cancer death	773.3	100	682.9	100	601.6	100	524.4	100

Source: WHO health repository, compiled

Table A3: Percentage Distribution of Deaths Due to Malignant Neoplasm Across Male and Female

	2015		2010		2005		2000	
	Male	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**
Mouth and oropharynx cancers	17.6	6.4	17.7	6.5	17.1	6.6	16.0	6.4
Oesophagus cancer	6.8	3.7	6.8	4.0	6.7	4.1	6.8	4.2
Stomach cancer	10.6	5.0	11.2	5.4	12.3	5.6	13.7	6.0
Colon and rectum cancers	7.7	6.1	7.4	5.8	7.0	5.4	6.4	5.0
Liver cancer	4.5	2.8	4.6	2.9	4.7	2.9	4.5	2.8
Pancreas cancer	2.0	2.1	1.9	1.9	1.9	1.9	2.0	1.8
Trachea, bronchus, lung cancers	15.7	5.9	15.0	5.5	14.7	5.0	14.5	4.6
Melanoma and other skin cancers	0.8	0.3	0.7	0.3	0.7	0.3	0.7	0.3
Breast cancer	0.0	20.6	0.0	19.6	0.0	18.6	0.0	18.2
Cervix uteri cancer	0.0	18.6	0.0	20.1	0.0	22.3	0.0	23.3
Corpus uteri cancer	0.0	1.3	0.0	1.4	0.0	1.5	0.0	1.5
Ovary cancer	0.0	5.8	0.0	5.4	0.0	5.2	0.0	4.9
Prostate cancer	3.4	0.0	3.2	0.0	3.2	0.0	3.1	0.0
Testicular cancer	0.4	0.0	0.4	0.0	0.5	0.0	0.6	0.0
Kidney cancer	1.2	0.6	1.0	0.5	1.0	0.5	1.0	0.5
Bladder cancer	2.1	0.6	2.0	0.5	2.1	0.5	2.0	0.5
Brain and nervous system cancers	2.6	1.6	2.6	1.5	2.7	1.4	2.7	1.4
Gallbladder and biliary tract cancer	2.3	7.1	2.5	7.4	2.7	7.4	2.7	7.2
Larynx cancer	4.3	0.5	4.2	0.5	4.4	0.5	4.7	0.6
Thyroid cancer	0.3	0.7	0.3	0.7	0.3	0.7	0.3	0.8
Mesothelioma	0.1	0.0	0.1	0.0	0.1	0.0	0.2	0.0
Lymphomas, multiple myeloma	4.8	2.7	4.8	2.6	5.0	2.6	5.1	2.7
Leukaemia	4.2	3.0	4.4	2.9	4.5	2.9	4.9	3.1
Other malignant neoplasms	9.0	4.6	9.2	4.6	8.6	4.3	8.0	4.0
Total	**100.0**	**100.0**	**100.0**	**100.0**	**100.0**	**100.0**	**100.0**	**100.0**

Source: WHO health repository, compiled

Table A4: Price Variation of Selected Cancer Drugs Approved for Marketing Between 2001 and 2017, India (under price control)

Drug name	Indication	NPPA ceiling price per unit (INR)	No of brands selling above ceiling	Highest price across brands (INR)	% difference of highest from ceiling price	Lowest price across brands (INR)	% variation between highest and lowest
Bortezomib, powder for injection 2mg	Multiple myeloma (antineoplastics)	11544	9 (16)	13115	13.6	2625	399.6
Capecitabine 500 mg	Breast, colon and rectal cancer	118.62	15 (24)	182	53.4	70.6	157.8
Docetaxel, powder for injection 80 gms	Breast cancer, non-small cell lung cancer, prostate cancer, stomach cancer, and head/neck cancer	10682	8 (17)	11566.2	8.3	1290	796.6
Doxorubicin injection 50 mg/ml	Ovarian cancer, breast cancer, hodgkin's disease, multiple myeloma	763.31	8 (16)	1250	63.8	307.2	306.9
Gefitinib tablet 250 mg	Lung cancer	402	3 (27)	426	6.0	98	334.7
Gemcitabine powder for injection 1 gm	Metastatic bladder cancer, metastatic bladder cancer, non-small cell lung cancer, metastatic epithelial ovarian carcinoma, metastatic breast cancer	4979.45	18 (25)	6825	37.1	2375	187.4
Imatinib tablet 400 mg	Leukaemia, systemic mastocytosis, dermatofibrosarcoma protuberans, gastrointestinal stromal tumor	200	9 (16)	367.5	83.8	74	396.6
Cytarabine 1000 mg injection	Various types of leukaemia	1006	5 (7)	1925	91.4	947	103.3
Temozolomide 250 mg (capsule)	Forms of brain tumours	4399	1 (4)	4485	2.0	4050	10.7
L-asparaginase powder for injection 5000 ku	Acute lymphoblastic leukaemia	972.6	8 (9)	1510	55.3	970	55.7
Paclitaxel injection 100 mg	Breast and ovarian cancer	209.47	9 (21)	311	48.5	32	871.9
Bicalutamide tablet 50 mg	Metastatic carcinoma of the prostate	64.3	1 (15)	442.7	588.5	27	1539.6
Letrozole 2.5mg tablet (femara)	Breast cancer in postmenopausal women	38.27	2 (44)	136	255.4	2.5	5340.0
Exemestane 25 mg	Breast cancer	Na*	Na	325	Na	32	914.1
Erlotinib 150 g	Non-small cell lung cancer, pancreatic cancer	Na*	Na	4030	Na	230	1652
Lenalidomide (25 mg) capsule	Multiple myeloma, myelodysplastic syndromes, mantle cell lymphoma	Na*	Na	740	Na	577	28
Decitabine (50 mg) injection	Chronic myelomonocytic leukaemia	Na*	Na	8000	Na	7428	7.8
Fulvestrant (250 mg) injection	Breast cancer in postmenopausal	Na*	Na	21428	Na	8440	154

	women						
Bendamustine (100 mg) injection	Chronic lymphocytic leukaemia, a type of non-hodgkins lymphoma	Na*	Na	11000	Na	3095	255
Cabazitaxel (60 mg) injection	Metastatic castration-resistant prostate cancer	Na*	Na	99999	Na	19947	401
Everolimus (5 mg) tablet	Breast cancer in postmenopausal women	Na*	Na	6015	Na	1250	381
Pemetrexed (500 mg) injection	Lung cancer	Na*	Na	81026	Na	4500	1701
Regorafenib (40 mg) tablet	Colon and rectum cancer	Na*	Na	2118	Na	1230	72
Enzalutamid E (40 mg) capsule	Castration-resistant prostate cancer	Na*	Na	2997	Na	982	205

* Recently included under price control and ceiling prices were not available

Sources: CDSCO and NPPA, compiled

Table A5: Price variation of selected cancer drugs approved for marketing between 2001 and 2017, India (outside price control)

Drug name	Indication	Average per unit price (INR)	No of brands selling above average price	Highest price across brands (INR)	lowest price across brands (INR)	% deviation between highest and lowest
Anastrazole 1 mg	Breast cancer	51.4	4 (8)	59.6	47.7	25
Fasnorm 250 mg Injection	Breast cancer	4146	4 (8)	5115	3573	43
Aprepitant (125 mg) capsule	Supportive drugs for cancer patients to prevent nausea and vomiting	1323	3 (9)	1586	1090	46
Sorafenib (200 mg) tablet	Liver cancer, thyroid cancer, advanced renal cell carcinoma	855	1 (3)	2434	57	4170
Trabectedin (1 mg) injection	Leiomyosarcoma	75043	2 (3)	121485.7	28600	325
Fosaprepitant (150 mg) injection	Supportive drugs for cancer patients to prevent nausea and vomiting	2216	3 (7)	2571	1400	84
Abiraterone (250 mg) tablet	Metastatic high-risk castration-sensitive prostate cancer	697	6 (15)	2790	150	1760
Palonosetron (0.5 mg) tablet	Supportive drugs for cancer patients to prevent nausea and vomiting	15.7	1 (2)	21	10.4	102

Sources: CDSCO and NPPA, compiled

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