Chapter 20
Access to Life-Saving Medicines and Healthcare: A Case Study of Aurangabad District of Bihar

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20.1 Introduction

The role of medicines in preventing deaths and reducing incidences of morbidity has been well recognised in modern health systems. There has been significant progress in medical sciences and pharmacology which can support production and delivery of essential medicines to meet the needs of everyone. However, lack of essential medicines for the poor and vulnerable has been a major concern. Lack of access to essential medicines has been recognised as a challenge in India's health and medicine policies consistently during last six decades.

Availability and accessibility of overall healthcare services have been a major concern in India. It is worthwhile to revisit the notion of medical care in this context. Medical care has certain distinct characteristics which do not permit its analysis in the standard framework adopted for other usual commodities (Arrow 1963). An individual's demand for medical services is unexpected and abrupt. It may not be regular. Its predictability is a concern. The value of medical services is recognised in case of health eventualities which affect normal health conditions. Medical service delivery system must address the health concerns satisfactorily and it should pay necessary attention to affordability issue. Financial burden of healthcare and their considerable impact on impoverishment of households is a serious concern in the Indian situation. The overall cost of illness goes much beyond the cost of medical treatment as illness has implications for complete loss or considerable fall in income due to lack of normal functioning of the affected individuals or families. The role of government in addressing healthcare needs

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assumes significance under such circumstances. With some important policies for health sector, there is a stated commitment to address the healthcare needs of population at large. However, it is imperative to study the implications of such policies at the ground level.

It is in this context, a study was undertaken with the broad objective of assessing the availability and accessibility of medicines and healthcare by the poor at the level of PHCs in Aurangabad district of Bihar. This chapter reports the findings of the study.

Aurangabad district has 25,40,073 population as per 2011 Census. It has 11 PHCs and each PHC is assigned to a single block as their jurisdiction area. The study includes all PHCs of the district. The major difference in earlier studies and the present one is that, earlier studies were based on more than one city and even one state, while the present study is based on a district and restricted to PHCs in that district. Accessibility has been measured on three broad parameters—economic and financial condition of the patient, net availability of the medicines and status of healthcare services in all PHCs.

This chapter is structured in the following manner. There are five sections in this chapter including the introductory one. In the second section, an analysis of economic burden of healthcare and pattern of expenditure on medicines is provided. A review of regulations regarding essential medicines and drugs, in general, is given in the next section. The results of the primary study in Aurangabad are presented in the fourth section. Methodology of the study and major findings are outlined in this section. Finally, conclusions are made.

20.2 Economic Burden of Healthcare and Expenditure on Medicine

Epidemiological profile of India is quite bothersome. According to World Health Organisation, more than a quarter (2.8 million) of the world tuberculosis cases is found in India, which is the leading country in the world with maximum number of tuberculosis cases. The country is showing a rising trend in terms of new tuberculosis cases; i.e. 2.2 million in 2014 to 2.8 million in 2015 (Anand 2016). UNAID Report, 2016 revealed that the number of HIV/AIDS in India is 2.1 million in 2015 which places India in third rank across different countries (AVERT 2015). The prevalence of respiratory diseases in India varies between 2.05 and 3.5% of total population (Ghoshal et al. 2016). Child mortality due to diarrhoea is as high as 3 lakh every year, despite reduction in diarrheal deaths in recent years in India. Diarrhoea contributes 13% of under-5 years of age group deaths in India (Lakshminarayanan et al. 2015). The country has reported a considerable number of dengue and chikungunya cases; about 74,454 and 18,639 cases reported respectively in 2013 by National Vector Borne Disease Control Programme. Nearly 167 deaths happened due to dengue in 2013 (Cecilia 2014). There are 2.6 million cases

of Malaria found in South-east Asia, among which India alone contributes 76% of total reported cases (NIMR, n.d.). According to NFHS-III, about 20–40% of maternal deaths are due to anaemia and one in every two women is anaemic in India (Kaur 2014). India's per lakh deaths due to cardiovascular diseases is higher than global average; nearly 235 people die every year globally while in India this rate is 272 per lakh of population (Prabhakaran et al. 2016). National Institute of Cancer Prevention and Research reveals that around 2.5 million cancer cases are reported in India with 7 lakh new cases every year on an average (Nandakumar 2009).

In this context access to medicine and affordable healthcare remains crucial in addressing the burden of disease. In this section, two major themes are discussed on the basis of available secondary information. These are pattern and trend of aggregate expenditure on healthcare and expenditure on medicines in India.

20.2.1 Expenditure on Healthcare in India

India has a wide gap in required health expenditure and what is actually being spent. Private spending dominates overall health expenditure; this is a reflection of inadequate public spending. The aggregate outpatient visits shows declining share of public sector; it declined from 25 to 20% and inpatient treatment have also declined from 60 to 40% during the decade of 1994–1995 to 2004–2005 (Selvaraj et al. 2009).

National Health Account of India illuminates the situation. India's health expenditure has been financed by three major sources; public, private and external sources. The burden of health expenditure is always catastrophic for the general population in India and it is evident from Fig. 20.1. Private expenditure is as high as 78.05% in total health expenditure and it has a share of 3.32% in GDP. Public expenditure remains as low as 19.67% with a meagre share of 0.84% in GDP. Despite the fact that external flow is a very small source of support to aggregate health expenditure but it makes a difference with 2.28% share in total health expenditure and constitutes a 0.10% share in GDP. However with a poor

Fig. 20.1 Health expenditure in India 2004–05. *Source* National Health Accounts India 2004–05
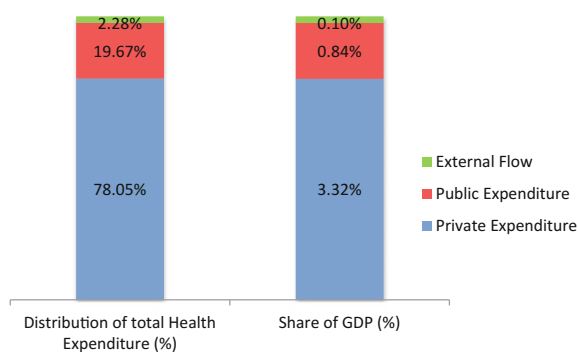
contribution by public sector in health, total health expenditure constitutes 4.25% share in GDP (National Health Accounts: India 2004–05 2004).

India holds a very low rank and stands at 184th position in public health spending across 191 countries as revealed by World Health Statistics, 2007 (cited in Rao et al. 2012). In this group of 191 countries, India's per capita health spending is only $29 which is ranked at 164th position. India performs badly in terms of per capita public health spending in comparison to its neighbours—Sri Lanka and China. India's per capita public spending is just about one-third of that of Sri Lanka's spending. China's per capita public spending is higher than India by about 30 per cent (Rao et al. 2012). There is a situation of stagnation in public spending on health in last two decades—during the period 1990–1991 to 2009–2010. A nominal increase in public spending was recorded during this period and the share of health in total GDP increased marginally from 0.9 to 1.2% (Rao et al. 2012; National Health Accounts: India 2004–05 2009).

Financial duress is encountered by about 150 million people in the world in accessing healthcare. Many incur out-of-pocket (OOP) payments for healthcare. Some statistics indicate that around 100 million people are impoverished every year due to OOP payments on health. Expectedly, more than 90% of the mare the habitants of low income countries (Xu et al. 2007). India, Vietnam and Bangladesh top the list of OOP payments for health in whole Asia (van Doorsley et al. 2007). In India, 32–39 million people get impoverished due to high private health expenditure (van Doorsley et al. 2006; Bonu et al. 2007; Garg et al. 2009; Berman et al. 2010).

Low funding in public health system has affected both poor and non-poor adversely. There are various factors which intensify the situation such as very high payments to healthcare results in dissavings, selling of assets and significant borrowings from informal sources such as moneylenders.

Only about one-tenth of India's population is covered under some form of health insurance (Planning Commission 2008). Low insurance coverage coupled with high cost of treatment sought in private sector led to high spending out-of-pocket. Health expenditures have grown rapidly at 14% during the decade 1994–1995 to 2004–2005. The pace of growth of expenditure on inpatient care has been higher (Lal et al. 2005).

Recognising the need for risk pooling for health eventualities, Ministry of Labour and Employment launched Rashtriya Swasthya Beema Yojna (RSBY) in 2007. The initial intervention of the scheme was in 385 districts in 26 states. These districts were having 50% of BPL population. The coverage of BPL families was about 27% in this initial phase (Rao et al. 2012).

State governments also made initiatives in this regard. State government of Andhra Pradesh ran Rajiv Aarogyasri scheme, Vajpayee Aarogyasri was initiated in Karnataka and the Kalaignar scheme implemented in Tamil Nadu to make sure the reach of free healthcare services to poor people. There is evidence of high out-of-pocket expenditure on outpatient treatments. Outpatient low-cost treatments which go for a long period with high frequency of occurrence, costs households to

fall under impoverishment. There are no current health schemes which provide protection from consistent costs of outpatients (Reddy et al. 2011).

20.2.2 Expenditure on Medicine

Over the years, India's drug policies have proven to be dualistic in nature. Generic and branded drugs are produced not only for domestic consumption but also for exports and the country is one of the leading producers of drugs. Therefore, India is also known as 'pharmacy of the global south' (Chaudhuri 2007; Lofgren 2012). It is worth mentioning that life-saving medicines are exported to developing countries and quality drugs are produced for rich and developed countries at affordable prices from India. The appreciable performance of India in the field of medicine production, however, does not reflect in accessibility of millions of Indian households to medicines (Chaudhuri 2007). This is the result of both financial as well as physical—lack of public health facilities. Since past two and a half decades, constraints in medicine accessibility have become worse.

According to National Sample Survey, a significant portion of health expenditure goes to medicines. In the 55th round of National Sample Survey, it has been found that about 77 and 70% of the health expenditure is on medicines in rural and urban households respectively. It is important to note that the share of expenditure on medicines in total health expenditure is higher in case of poorer households (Sengupta et al. 2008).

In Table 20.1, it has been shown that, in 1986–1987, for hospitalisation drugs prescribed for free had a share of 31.2% among three other categories (partly free, on payment and not received). The share of free drugs has fallen sharply in 2004 to

Table 20.1 Trends in access to medicines in India 1986–87 to 2004

	1986–87	1995–96	2004
Inpatient			
Free medicines	31.2	12.29	8.99
Partly free	15.0	13.15	16.38
On payment	40.95	67.75	71.79
Not received	12.85	6.8	2.84
Total (%)	100	100	100
Outpatient			
Free medicines	17.98	7.21	5.34
Partly free	4.36	2.71	3.38
On payment	65.55	79.32	65.27
Not received	12.11	10.76	26.01
Total (%)	100	100	100

Source Planning Commission (2011)

only 9%. For outpatient care share of free drugs has fallen, the margin of fall being 18–5% during 1986–1987 to 2004 (Planning Commission 2011).

It can be observed from Table 20.1 that out-of-pocket (OOP) payments for treatment of ailing population under inpatient care have increased from 41 % to about 72 %t. In case of outpatient care, out-of-pocket expenditure decreased from 80 % to 65% during mid-1990s to 2004. The data in the Table shows that since mid-1990s, when prices of medicines have started rising, there has been a decline in 'on payment' outpatient shares by almost one-fifth. It implies that patients did not receive medicines because of unaffordable prices of medicines.

In Table 20.2, it is clear that the lowest rung of population had higher share of medicine in total health expenditure compared to others. With a miniscule difference between rural and urban expenditure on share of medicine in total health expenditure, the lowest rung of population suffers the most. On the basis of Monthly Per capita Consumption, around 85% of health expenditure is made on medicines in both rural as well as urban areas. Table 20.2 also refers that with the increase in income, share of medicines comes down in total health expenditure. This is evident from the following Table which shows that the top 20% of the population had lower share of medicine (71.59% in rural areas and 62.3% in urban areas) against total health expenditure (Sengupta et al. 2008). National Sample Survey morbidity data strengthen this claim as it shows that expenditure on medicines constitute 81 and 75% share of medicine in total health expenditure in rural and urban areas, respectively (all-India 79%).

Medicine Price Inflation: The price movement of medicines have been steeper than other commodities. Critical and essential medicine prices have shown notable increase during past decades. In a study carried out by Rane (2003) it has been found that among 70 recognised brands that constitute nearly 20% of the pharmaceutical market, 67% were showing price increase, 19% were showing a fall in price whereas 14% had no change in price from 1999 to 2003.

Planning Commission (2011) analyzed the prices of medicines vis-a-vis other commodities. Figure 20.2 is showing the price index of all commodities and drugs from 1993–1994 to 2003–2004. It is clearly reflected from the figure that inflation

Table 20.2 Pattern of per capita monthly out-of-pocket expenses on medicine and healthcare in 1999–2000

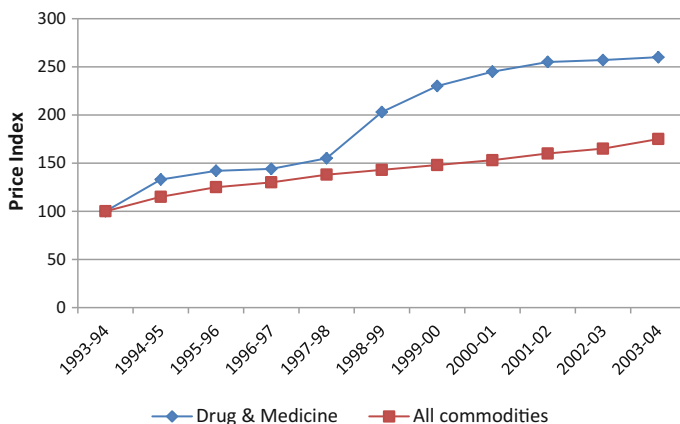|	Region	Quintiles					
		First (Lowest)	Second	Third	Fourth	Fifth	Total
Health exp. (Rs)	Rural	7.72	13.79	19.61	29.98	77.47	29.58
	Urban	11.71	21.66	29.73	47	105.67	43.27
Exp. on medicine (Rs)	Rural	6.68	11.71	16.46	24.44	55.46	22.85
	Urban	9.91	17.79	22.72	34.34	65.9	30.14
Medicine % of health	Rural	86.47	84.89	83.94	81.53	71.59	77.24
	Urban	84.6	80.71	76.44	73.05	62.36	69.66

Source Sengupta et al. (2008)

Fig. 20.2 Trends in pharmaceuticals and all commodity price index. *Source* Planning Commission (2011)

of drugs and medicines is higher than all commodities inflation. There is a sudden increase in rate of inflation of drugs in 1997–1998 to 1998–1999, while all commodities inflation is rising at normal and constant pace (Planning Commission 2011).

Insurance Regulatory and Development Authority (IRDA) conducted a study on medical insurance claims of two periods, 2007–2008 and 2009–2010, to estimate the inflation in medical sector. The insurance claims are subject to the limitations of sum insured, preexisting diseases, etc. Expenditure incurred by the insured reflects the actual amount claimed and hence paid, it is the base of medical cost for comparing the inflation over the years.

Table 20.3 is the base of discussion ahead. The claim severity has increased for 12 diseases. For remaining four diseases (Endocrine, Eye, Infection and Skin), claims are showing negative sign. The maximum claims are made for circulatory diseases, which is 56.99%. Average number of claims made has increased from 199,464 during 2007–2008 to 292,883 during 2009–2010. There is 27.09% increase in the claim severity and the average claim amount has increased from Rs. 98,101 to Rs. 134,550 over a period of 2007–2008 to 2009–2010 (Insurance Regulatory and Development Authority, n.d.).

There are some complications in these calculations. Same disease can be treated with many procedures and the medical cost for these procedures vary significantly based on the technology used, number of days of hospitalisation required and the type of medicines used. The disease-wise claims severity for various diseases are grouped according to the treatment procedure. This data is presented in Table 20.4. The percentage of all the diseases of claim severity is showing the increasing trend over the selected time period. Gall bladder stone has highest increase in claim severity (12.94). Senile cataract has the lowest increase in severities percentages (Insurance Regulatory and Development Authority, n.d.).

Table 20.3 Claim severity analysis of all major diseases

Disease name	2007–08			2009–10			Increase in average claimed amount for 2009–10 in comparison with 2007–08 (%)
	Number of claims	Average claimed amount	Proportion	Number of claims	Average claimed amount	Proportion	
Arthropathies	14,500	1,36,354	10.1	20,330	147,401	7.6	7.49
Blood Diseases	1435	95,992	0.7	1972	107,944	0.54	11.07
Circulatory	35,776	1,53,349	28.04	49,687	356,505	44.95	56.99
Digestive	25,881	75,694	10.01	36,420	79,564	7.35	4.86
Ear	1466	65,841	0.49	2371	68,066	0.41	3.27
Endocrine	5591	1,05,843	3.02	6426	103,402	1.69	−2.36
Eye	6298	60,137	1.94	12,623	57,168	1.83	−5.19
Infections	9759	88,200	4.4	12,969	83,301	2.74	−5.88
Injury	24,508	88,039	11.03	33,400	94,284	7.99	6.62
Neoplasm	21,999	96,287	10.83	31,475	103,566	8.27	7.03
Nervous	4152	1,10,135	2.34	6030	128,055	1.96	13.99
Pregnancy	15,391	56,148	4.42	28,539	57,820	4.19	2.89
Respiratory	8425	85,237	3.67	13,824	92,019	3.23	7.37
Skin	2255	78,747	0.91	3410	78,477	0.68	−0.34
Urology	22,028	72,023	8.11	33,407	77,455	6.57	7.01
Total	199,464	98,101	100	292,883	134,550	100	27.09

Source Insurance Regulatory and Development Authority

Table 20.4 Claim severity with specific diseases

Procedure	Disease name	2007–08			2009–10			Increase in severity for 2009–10 in comparison with 2007–08 (%)
		Number of claims	Claim severity	Proportions (%)	Number of claims	Claim severity	Proportions (%)	
Leiomyoma of uterus	Cancer	1819	66,049	9.54	2609	74,716	7.62	11.6
Senile cataract	Cataract	1667	52,577	8.74	4622	53,266	13.5	1.29
Senile cataract (other)	Cataract	739	53,240	3.88	1196	53,421	3.49	0.34
Acute appendicitis	Appendicitis	1513	60,355	7.94	2749	64,339	8.03	6.19
Inguinal hernia	Hernia	2032	64,417	10.66	3232	67,970	9.44	5.23
Cholelithiasis	Gall bladder stone	2154	63,664	11.3	3529	73,127	10.31	12.94
Calculus of kidney and ureter	Kidney stone	2209	60,701	11.59	4036	64,840	11.79	6.38
Calculus of kidney prostate	Prostate problem	1363	70,381	7.15	2118	75,338	6.19	6.58
Single spontaneous delivery	Pregnancy	1350	53,313	7.08	2025	53,776	5.92	0.86
Single Delivery by caesarean section	Pregnancy	4220	55,709	22.13	8113	56,891	23.7	2.08

Source Insurance Regulatory and Development Authority

Changes in drug policy in recent years have serious impact on drug prices. The implication of changing drug policies can be understood from the fact that 90% of the drugs were price-controlled in the late 1970s, while at the end of the last decade only 10% drugs were price-controlled (Pronab Sen Committee 2005). Pharmaceutical pricing policy has played a major role in the considerable and consistent increase of drug prices over the years (Selvaraj 2007).

20.3 Regulations for Essential Medicines and Drugs

A sizeable proportion of India's population is market-dependent and has to manage increasing health expenditures (particularly cost of medicines) from their own earnings. This makes price regulation of pharmaceutical products necessary (Srinivasan 2001). Steep growth in pharmaceutical industry appears in sharp contrast to high prices of medicines for the majority of Indians. Indian pharmaceutical industry has seen a tremendous growth of 14% since the beginning of 11th five year plan (2007–2012). The rise has been observed mainly from 2007 to 2009–2010; which in value terms implied an increase from Rs. 71,000 crores to more than Rs. 1 lakh crores. India produces 20% of global generics, 9% of the global bulk drugs and about 10% of total global production of medicines. The industry has prestigious ranks in the World—3rd in terms of volume and 14th in terms of value (Planning Commission 2012; National Pharmaceutical Pricing Policy 2012). The industry is highly fragmented; it contains 10,500 units and majority of them are working as unorganised units. Around 300–400 units are identified as organised and medium and small scale enterprises in nature. Of these, top 10 manufacturers have about 36.5% of the market share (Planning Commission 2012).

During the 11th five-year plan, India's pharmaceutical industry experienced a Compound Annual Growth Rate (CAGR) of about 19%, and India holds a position among top 20 pharmaceutical products exporting countries (Planning Commission 2012). Domestic competition, rapid growth of pharmaceuticals exports, contract manufacturing, contract research and development, outsourcing, bio pharmaceuticals, and clinical trials, are the major forces behind the growth of pharmaceutical industry (Dhopatkar 2012). This large-scale production and being a leading exporter of drugs has earned the name for Indian pharmaceutical industry as the 'pharmacy of the global south' (Chaudhuri 2007; Lofgren 2012). But this large production and relatively low prices have not brought the prosperity at home; the Indian health system still confronts the problem of access to essential medicines of good quality for all (Lofgren 2012).

There are regulations on drugs across the countries. Common policy tools applied to control the drug prices are mark-ups, controlled margins to wholesalers and pharmacists, price freezes, reference pricing, ceiling on promotional expenditure, differential value added tax on drugs, etc. (Selvaraj 2007). Apart from price control, there are issues of distribution, quality and patent having repercussions for

affordability of healthcare. These issues are discussed here under two subsections: India's drug policy after independence and other issues.

20.3.1   India's Drug Policy After Independence

Regulations regarding essential medicines are important. WHO (1977) defines essential medicines as those medicines which meet the priority needs of healthcare of the population. Public health relevance, safety, efficacy and cost conditions are the guiding principles for defining the repertoire of essential medicines from time to time. The control regime for drugs in India after independence can be segregated into three phases: Pre-Patent Act Era (up to 1972), Post-Patent Act Era (1972–2005) and Full Trips Compliance (after 2005).

Pre-patent Act Era: Government of India, in 1948 appointed the Tek Chand committee to review the existing patent laws in India to ensure that the system was aligned with the national interest. The committee recommended that there was a need of efficient system to stop the abuse of patent rights and provision of compulsory licensing (Mueller 2007). In 1953, a patents bill based on the committee's report was introduced in Parliament but did not progress further. In 1957, another committee was appointed under Justice Rajagopala Ayyangar. Committee submitted its report in 1959 stating that most Indian patents were held by foreigners and system was being exploited by the foreign patent holders to achieve monopolistic control over the market (Adelman and Baldia 1996). After a long gap, these reports resulted in the formulation of Patent Act, 1970. The law was so constructed that older patent regime was completely disregarded, this was a deliberate step to encourage domestic manufacturing of low-cost generic drugs.

During this period, first statutory control on drugs was introduced in 1962 in the post-independence period in India. The government relented to the demands made by the pharmaceutical industry and agreed to certain changes in drug control policy. Therefore a list of 18 essential drugs was prepared and a tariff commission was setup to analyse the cost structure of these essential medicines. It was asked to suggest reasonable prices for the mentioned drugs. The commission emphasised the need for assessing the prices of drugs on occasions of phenomenal increases in prices. As a result, Drug Price Control Order (DPCO) was introduced by Government of India in 1970. The order provided an in-depth analysis of prices of life-saving drugs and came up with measures to keep the prices of essential enlisted drugs under control to ensure the affordability to consumers while considering required returns to the producers. There were 347 drugs incorporated into the essential medicine list of Drug Price Control Order (WHO 1977).

Drug Price Control Order took the form of Drug Price Control Policy 1979 with Hathi Committee recommendations. The policy came up with notable objectives such as to ensure adequate availability of drugs, to provide drugs at affordable prices, to ensure the quality of drugs and check medicines from being adulterated, to attain self-sufficiency in production and self-reliance in drug technology.

Post-patent Act Era (1972–2005): The Patent Act 1970, implemented in 1972, had indirectly built the base for self-reliant indigenous drug industry. Patents of pharmaceutical products were forbidden, only one production process is allowed to be patented and for the maximum of 7 years. Further, the Foreign Exchange Regulation Act (FERA) curtailed the foreign investments by regulating the companies to keep the foreign equity at 40% or less (Lofgren 2012).

The decade of 70 s has brought the prices of essential drugs to the reach of common people in India (WHO 1977). DPCO 1970 defined drugs under two categories; essential and non-essential. The prices of essential drugs were controlled and the permissible mark-up being not more than 75% of manufacturing costs. Non-essential category drugs were eligible to set mark-up prices up to 150% of manufacturing cost. The Drug Policy 1978 came up with new categorization of drugs. Four different categories were defined with different mark-ups: 40; 55; 100%; and fourth group completely exempted from price control (Selvaraj 2007).

In the 1990s and subsequent period, price control policy went through significant amendments. A reduction in number of drugs under price control was done in phases. In the first amendment in 1987, the list with 347 bulk drugs under purview of drug price control were reduced to 166 and further reduced to 142. Drug Price Control Order (DPCO) of 1995 further weakened the drug price control regime with only 76 drugs under controlled list (Selvaraj 2007).

The Drug Price Control Order (DPCO) vested the legal right to fix prices of medicines with the government (Anonymous 2005). In 1975, Hathi committee recommended the complete nationalisation of drug industry (Krishna 2002). But due to intense protests by the pharmaceutical firms, most of the committee's recommendations were not implemented.

Reverse engineering was another fascinating story of this period; domestic companies were free to produce patented drugs but with the process not patented. Indian government had only recognised one production process as patented; domestic companies used another processes or changed the formulation by adding or deducing any smaller molecule. Firms made new processes of medicines production at low cost. Consequently, this has resulted in the beginning affordable medicines (Reddy 2004).

Introduction of TRIPS compliance in the mid-1990s was an important turning point in the politics of pharmaceuticals. The coalition of public health advocates and domestic firms was weakened over product patents as major domestic firms embarked on discovery research activities. The opposition of product patents was slacked from the domestic firms' side; as opportunity of their financial growth is more attractive by opening for their own patenting and the collaboration with MNCs.

At the same time, process of liberalisation was on high, which paved the way for changes in 'Patent Act 1970' possible. The pharmaceutical sector was opened up for Foreign Direct Investments (FDI) and the drug price control policy was weakened (Lofgren 2012). The DPCO has been revised in several years for example in 1979, 1987, 1995 and 2002; the number of drugs under DPCO have fallen sharply from 347 in 1979 to 142 in 1987 and then to just 76 in 1995. The

drug policy of 2002 has further reduced it to 35 only, but due to civil society agitations the 2002 policy was stayed by the Karnataka High Court in 2003 (Selvaraj and Farooqui 2012).

The need of National List of Essential Medicines (NLEM) was recognised in 1996, which paved the way for such listing of medicines. The revised list was released in 2003 by the Ministry of Health. A Task Force was constituted under the chairmanship of Principal Advisor, Planning Commission, Dr. Pronab Sen to consider the issue of price control, options other than price control, and to make recommendations for ensuring availability of life-saving drugs at reasonable prices (National Pharmaceutical Pricing Policy 2011, 2012).

After 2005—Full TRIPS Compliance: In 2005, TRIPS as legislation has been passed in India. It has resulted in re-introduction of the policy similar to prior 'Patent Act 1970'. The patents for pharmaceutical products, foods and chemicals again started taking place. The achievements and benefits from business model of reverse engineering became irrelevant; Indian companies were debarred from reverse engineering practices and they have to get a license to manufacture patented drugs from patent holder (Lofgren 2012).

In National Pharmaceutical Pricing Policy draft, the prices of medicines would be determined by the Market-Based Pricing (MBP) principles and not by the Cost-Based Pricing (CBP) principles which was adopted in the 1994 drug policy (National Pharmaceutical Pricing Policy 2011, 2012).

20.3.2 Other Issues

In India, drug prices were considerably high and regarded as one of the highest in the world (Hathi Committee Report on Drugs and Pharmaceuticals 1975). Access to medicines is significantly determined by drug prices. Private sector takes pivotal role in health service provision and financing in the absence of comprehensive public health insurance systems. The Indian drug companies have developed their capability to indigenously produce both bulk and formulation drugs. India has advantage in drug production costs which translates in lowest drug prices among major drug producing countries at present. However, changes in the 1990s policy have meant that the coverage of drug price control is only applicable to 10% of the market in 1995 (Lofgren 2012).

There are considerable price variations among different variants of the same formulation of drug. It has been experienced that pharmaceutical industry uses the loopholes of lax regulations to set the prices of medicine by complex price setting activities. It is striking that the price variation can be to the tune of 1000% in certain cases of therapeutically similar drugs (Sengupta et al. 2008).

A 40% increase in all drug prices has been reported by Sengupta and others (2008) between 1996 and 2006. Inactivity of drug price control can be realised when prices of drugs in essential medicine list increased by 15%, while the price of controlled drugs rose only by 0.02% for the above mentioned period. It is

worthwhile to note that the prices of drugs neither under price control nor under essential drug list increased by 137%. Liberal policies of 1990s gave sudden rise to drug prices which were never seen in the last 15 years (Sengupta 2008).

There are many instances of companies indulging in unethical practices such as promotion of medicine which are close substitute of price controlled essential medicine; they are often found taking advantage of such loop holes in drug price control regime. GlaxoSmithKline (GSK), a well-known pharmaceutical MNC, sales 'Actifed', a drug prescribed for cold and cough. The ingredient used in this is pseudoephedrine. But, the Company uses Phenylpropanolamine (PPA) in India as the ingredient, which is notable for increased risk of cerebro-vascular accidents and has been banned in several countries. It is due to the fact that pseudoephedrine is under price control in India (Sengupta 2008).

Procurement and Distribution Systems: Reliable and efficient public procurement systems are crucial for drug availability. It necessitates use of funds in a proper and adequate manner. It is also important to take care of the phenomena of drug shortages. There are different kinds of procurement mechanisms adopted in India in different states: pooled or centralised procurement at the state level which is in vogue in Tamil Nadu and Kerala, decentralised procurement as in Chhattisgarh and some combination of the above two as in Bihar. TNMSC of Tamil Nadu is considered as an ideal model. Kerala has adopted this model and other states are planning to adopt this model.

The mix approach of two models has been proven to be an efficient procurement system. This fragmented nature of drugs purchase is non-competitive, therefore value money is less emphasised.

If the essential drug lists are not followed in the drug procurement processes by the states, it may result in an environment where physicians prescribe and use irrational drugs in the public health system. Cost-effectiveness of the drugs also gets compromised in the process. To cite an example, 239 medicines were procured by the state of Bihar during 2008–2009, with only 82 drugs (34.89%) from in EDL list (Selvaraj et al. 2010). Approximately 71% of state's drug budget was used for these drugs. This episode could have been an outcome of decentralised procurement and distribution system of drugs (Selvaraj et al. 2010).

Regulation of Drugs Quality: Health policy should be designed to optimise the use value of medicines. With this view, government agencies monitor and regulate the manufacturing, marketing and distribution of medicines. They must ensure that drugs made available to patients should meet necessary safety, quality and efficacy standards (Lofgren 2012).

Safety, quality and efficacy regulation cannot ensure the access to essential drugs for all and hence, cannot optimise the use value of medicines and also rational or 'quality use' of medicines. Improvement in health outcomes requires measures to ensure the quality use of medicines, including appropriate regulation and monitoring of service providers and prescribers (Srinivasan 2006).

In India, universal access to essential medicines and policy for quality use of medicines is at its vestigial stage, it has yet to achieve safety and efficacy

regulations (Planning Commission 2011; Parliamentary Standing Committee on Health and Welfare 2012).

Drugs and Cosmetics Act of 1940 was far from being effective. This necessitated an effective drug regulatory system to control prices, quality and availability of drugs. The Central Drugs Standard Control (CDSCO) was set up to approve and qualify new drugs and clinical trials, defining standards, set control over drug imports, coordinate state drug control authorities. Further, State Drug control authorities were also set up with the express mandate of managing and regulating the manufacturing, sale and distribution of drugs.

Regulatory mechanisms are essential for addressing the case of spurious and substandard drugs in the market. The public consciousness regarding the quality issue—sub-standardisation, inefficacious or unsafe quality of drugs—develops over time. The issue of drugs quality regulation was realised an unfortunate incident when a women in Jodhpur, Rajasthan died due to contaminated drug. While violation of quality norms can be done by any producer, small-scale producers often face allegations of ineffective and standard violations in drug production.

Drugs Patent and its implications: With the affirmation to full TRIPs compliance, a large section of Indian population has been deprived of accessing new medicines. Newly invented drug are now protected under monopoly rights. It is unfortunate as many of these newly invented medicines address important contemporary health concerns, such as, oncology, certain mental conditions and HIV/AIDS. Adoption of such patent regime has its impact on prices of new medicines affecting the access to new life-saving drugs by masses (Planning Commission 2011).

Indian generic drugs have facilitated availability of cheaper drugs to patients across the globe with the large-scale low-cost production of ARVs in 2001. Earlier, the ARV vaccine was monopolised by US due to patents and the price was US $10,439 per annum per patient for AIDS treatment. Indian generic drug industry ensured its availability at only US$350 per annum per patient in 2005 (Menghaney 2009). Now, the cost of the drug is less than US$70 per patient. The irony is that patents prevent the availability of life-saving drugs to the needy and many curable diseases or avoidable deaths cannot be prevented. To cite an example, pegylated interferon alfa-2a, which is used for treatment of Hepatitis C, costs US$390 per 180 mg Pre-Filled Syringe (PFS). This is unaffordable by many middle-class patients (Menghaney 2009).

20.4 Primary Study in Aurangabad

Primary study is discussed under two subsections. The first subsection outlines the methodology adopted for the study. Major findings of the study are presented in the second subsection.

20.4.1 Methodology

Focus Area: Aurangabad is one of the 38 districts of Bihar, situated at the southern part of the state. The major city nearby Aurangabad is Gaya. The district of Aurangabad is administered with two subdivisions namely; Aurangabad and Daudnagar. The district is comprised of 11 blocks namely; Aurangabad, Daudnagar, Rafiganj, Nabinagar, Barun, Haspura, Madanpur, Dev, Obra, Goh and Kutumba (District Health Society, n.d., *b*). The district has been selected as the study area because it is located in rural surroundings and has sufficient reason for a researcher to consider it as a point of study on health at micro-level.

The district has one PHC in each block but population load on each PHC area is excessive. Indian Public Health Standards proposed a PHC with four–six indoor beds for 30,000 rural populations. But in Aurangabad, each PHC is serving a population of approximately 2 lakhs and more. Information provided in District Health Action Plan of 2011–2012 of Aurangabad regarding number of existing PHCs and PHCs required is furnished in Table 20.5.

Collection of Data: Data for this study has been collected in two different phases in 2012—May–June and October–November. The first process was a pilot study. Subsequently, final data collection was done. Two structured interview schedules were prepared to record the responses and information; one for the PHCs and the other for the households.

Block Health Managers were contacted for assessment of services and availability of essential medicines at PHCs. The researcher attained the approval from district Civil Surgeon to get the necessary information from PHCs. All 11 PHCs were covered for assessment of availability of services and medicines.

Table 20.5 Population and number of PHCs in Aurangabad

Block	Population	PHCs/referral at present	PHCs required (after including referral/DH)
Aurangabad	29,006	1	2
Obra	235,222	1	2
Daudnagar	219,785	1	2
Haspura	165,339	1	1
Goh	242,874	1	2
Rafiganj	315,732	1	3
Madanpur	218,147	1	2
Deo	180,895	1	1
Kutumba	240,630	1	2
Nabinagar	320,027	1	3
Barun	212,033	1	2
Total	2,642,689	12	22

Source District Health Society (n.d., *a*)

Table 20.6 Occupational distribution of sample households

Occupation	Persons employed (numbers)	Persons employed (%)
Labour	83	69.2
Vendor/small business/self-employed	9	7.5
Agriculture Labour/share cropper/self cultivator	24	20
Govt./Private employed	4	3.3

Source Field Survey 2012

A total of 86 households were interviewed. Households were selected both at PHC outpatient sections and in villages. Purposively six OPD patients were interviewed from six selected PHCs. The responsible person with patient or patient himself was interviewed in the PHCs. Their responses as immediate users were recorded. Apart from that, 50 households from four villages from different blocks were selected for data collection. All households selected were BPL card holders. There were in total 495 members in these 86 households. Thus, the average household size was 5.76.

Occupational Profile of Respondent Households: There were 120 working members in these 86 households. The worker–population ratio is less than 1:4. The categorization of occupation and corresponding number of employed persons is presented in Table 20.6.

There are four occupation categories mentioned in the table. First category is Labourer, second is Vendor/Small Business holders/Self-Employed, third is Agriculture Labour/Share Cropper/Self Cultivator, fourth is Government/private employee. Data reflects that a large portion of PHC users are labourers by their occupation; about 69.2%. People involved in agricultural activity in various forms constitute 20% and remaining employed are self-employed (7.5%) or government/private employed (3.3%).

20.4.2 Findings

Analysis of Healthcare Services: According to Indian Public Health Standards, PHCs are classified into two types depending on institutional delivery case load and services provided in PHCs. First, 'Type A PHC', has the case load of institutional delivery less than 20 in a month. Second, 'Type B PHC', has the case load of 20 or more institutional deliveries in month. By this criteria all PHC in the district are 'Type B PHCs'.

The number of outdoor patients attended and number of institutional deliveries conducted in the last three months prior to data collection, that is July, August and September, 2012 was analyzed. On an average each PHC has treated 11,168 outdoor patients in a month. If we exclude PHC 1—because it was not fully functional—then each functional PHC has treated 12,085 outdoor patients in a month.

Institutional deliveries that took place during these 3 months on an average in these PHCs are 250 in a month. After excluding PHC 1, average institutional deliveries in each fully functional PHC are 274 in a month. Hence, PHCs are overburdened with large number of outpatients and large number of institutional deliveries.

Table 20.7 shows availability of Reproductive and Child Health (RCH) services in select PHCs. The list includes 19 services, these services are expected to be there as mentioned in the India Public Health Standards guidelines for PHCs. Female gynaecologist or Lady Health Visitor (LHV) was not available in almost all PHCs. Medical Termination of Pregnancy (MTP) is also not available anywhere except one PHC. Tubectomy and Vasectomy service should be available on priority basis as these are necessary services for successful implementation of family planning. There are few PHCs with fixed days of services for adolescent health and immunisation. Availability of other services is satisfactory.

There have been incidences of outbreak of diseases in most of the PHC areas. The respondents mentioned that in all the PHCs, doctors were available to meet the eventualities of such outbreaks. Adequate care and drugs for chronic illness is

Table 20.7 Availability of reproductive and child health services

RCH services	Available in total number of PHCs	Percent of total ($n = 11$)
Ante-natal clinics	11	100
Normal delivery facility 24 h	11	100
Deliveries monitored through partograph	5	45.5
Tubectomy Services	9	81.8
Vasectomy Services	7	63.6
Female gynaecologist	1	9.1
Examination for gynaecological conditions	6	54.5
Treatment for gynaecological disorders	10	90.9
Fixed day health services for adolescent health	3	27.3
Fixed day health services for family planning	8	72.7
Family planning counselling during MCH services	11	100
Facility for Medical Termination of Pregnancy	1	9.1
Anaemia treatment	11	100
Low birth weight babies managed	9	81.8
Fixed immunisation day	4	36.4
BCG vaccines	11	100
Measles Vaccine	11	100
Treatment for children suffering from pneumonia	9	81.8
Management of children suffering from diarrhoea with dehydration	10	90.9

Source Field Survey 2012

available in eight PHCs. Public display mechanism for complaints and grievances is non-existent in five PHCs.

Medicine Availability: In the context of functioning health systems, essential medicines are expected to be available at all times in certain amount and dosage forms to fulfil the needs of people adequately. At the same time, the systems must facilitate information regarding essential medicines to achieve the goal of efficacy and ensure availability of medicines at reasonable price so that individual and the community can afford (WHO 1977).

Indian Public Health Standards' essential medicines list for PHCs was taken into consideration in this study. There are total of 165 medicines including their different formulations. In Table 20.8 information on availability of medicines is presented. Availability of medicines is distributed in quartile range in order to locate their status of availability. Around 90 medicines are in first quartile of lowest availability; notably among them 52 medicines are not available at all. About 36 medicines are in fourth quartile of maximum availability and remaining 19 and 20 medicines falls in second and third quartile, respectively. Maximum number of medicines prevails in the two extremes of quartile range; mainly in first quartile. More than 50 % of medicines are poorly available and more than half of them are not available. In the other extreme of high availability, it is showing very less number of medicines; only 36 out of 165.

Table 20.9 represents the medicines which are not available in any PHC, and their nature of essentiality. There are 32 names in the first column of medicines; these medicines have various formulations of same molecule, hence there are total 52 medicines with different formulations. The essentiality of medicines varies from vitamins and minerals to cardiovascular, anti-asthmatic medicines. The absence of these medicines has serious implications for public health. The implications include dependence on market, out-of-pocket payments, travelling and travelling cost, unregulated market price and quality of medicines consumed.

A quick review of Table 20.10 shows that almost all the PHCs (except PHC 5) are with less than 40% of essential medicines. The PHC 5 is just above the 40% (40.6%). The average availability of medicine in the whole district at PHC level is only 34.5%.

Treatment, Financing Pattern of Treatment and Perspectives of Users of PHC Services: In this important section, the responses of users are discussed. As mentioned earlier, households were selected purposively to understand the situation of access to essential medicines. As the concern of this study was to record the

Table 20.8 Number of essential medicines available in percent range

Quartile (%)	Number of medicines
<25	90
25–50	19
50–75	20
75–100	36
Total	165

Source Field Survey 2012

Table 20.9 Medicines not available in any PHC and their nature of essentiality

Medicines with various formulations	Nature of essentiality
Acetyl Salicylic Acid 300, 75, 50 mg tab	Cardiovascular—Antianginal medicine
Promethazine 10 mg, 25 mg tab and 500 mg cap	Anti-allergic medicine used in Anaphylaxis
Carbamazepine 200 mg tab and 20 mg syrup	Anticonvulsant/Antiepileptics
Mebendazole 100 mg suspension	Anti-worm
GlyserylTrinitrate 5 mg injection and 0.5 mg sublingual tab	Treatment for Angina and Heart failure
Propranolol 10 mg, 40 mg tab	Antimigraine medicine
Enalapril Maleate 2.5 mg, 5 mg, 10 mg tab and 1.25 mg injection	Cardiovascular—Antihypertensive medicine
Tab. Metoprolol 25, 50, 100 mg tab	Cardiovascular—Antianginal medicine
Hydrochlorthiazide 12.5 mg, 25 mg tab	Cardiovascular—Antihypertensive medicine
Tab. Captopril 25 mg	Antihypertensive and treatment of congestive heart failure
Nalidixic Acid 250 mg, 500 mg tab	Treatment of bacterial infections of the urinary tract
Nitrofurantoin 100 mg tab	Anti-infective—Antibacterial
Griseofulvin 125 mg, 250 mg cap or tab	Anti-infective—Antifungal medicine
Nystatin 500,000 IU tab	Anti-infective—Antifungal medicine
Metronidazole Pessaries 100,000 IU	Treatment for gynaecological disorder
Dipropionate Calamine lotion	Anti-inflammatory and antipruritic medicine
Benzoin Compound tincture	Antiseptic
Formaldehyde IP solution	Disinfectant
Potassium Permanganate crystals for solution	Disinfectant
Aluminium Hydroxide + Magnesium Hydroxide suspension and tab	Gastrointestinal—Antacid and antiulcer medicine
Domeridone 1 mg/ml syrup	Gastrointestinal—Antiemetics
Hyoscine Butyl Bromide 10 mg tab	Gastrointestinal—Antispasmodic medicine
Bisacodyl tab/suppository 5 mg	Gastrointestinal—Laxative
Isphagula Granules	Gastrointestinal—Laxative
Sulphacetamide Sodium 10%, 20%, 30% eye drops	Opthalmological Preparations—Anti-infective agent
Tetracycline Hydrochloride eye 1% ointment	Opthalmological Preparations—Local Anaesthetics
Prednisolone Sodium Phosphate 1% eye drops	Opthalmological Preparations—Anti-inflammatory agent
Beclomethasone Dipropionate 50 mg, 250 mg/dose inhalation	Anti-asthmatic medicine
Salbutamol Sulphate 2 mg/5 ml syrup	Anti-asthmatic medicine
Dextromethorphan 30 mg tab	Antitussive
Ascorbic Acid 100 mg, 500 mg tab	Vitamin and Mineral
Clofazimine 100 mg tab	Anti-leprosy medicine

Source Field Survey 2012

Table 20.10   Availability of all essential medicines PHC-wise

	Number of available medicines	Percent of total prescribed medicines[*]
PHC 1	23	13.9
PHC 2	60	36.4
PHC 3	52	31.5
PHC 4	65	39.4
PHC 5	67	40.6
PHC 6	58	35.2
PHC 7	63	38.2
PHC 8	50	30.3
PHC 9	64	38.8
PHC 10	62	37.6
PHC 11	63	38.2
Mean	57	34.5

Note [*]Percent out of 165 medicines in essential category at the time of survey
Source Field Survey 2012

situation of poor families, therefore, purposively only BPL families were selected in the PHCs and the villages.

A total of 86 households were interviewed, while total number of individuals in those households was 495. Individuals identified as patients were cumulatively 171 (34.5%). Table 20.11 is showing treatment order of households. There are three orders in the list representing the number of persons under treatment, number of persons treated in the last 6 months of data collection and number of persons who did not seek treatment or discontinued treatment. All the orders include both minor as well as major nature of illness.

The data is showing that among identified 171 patients, 105 were under treatment. In the last 6 months, 37 patients were treated; there are 29 patients who either did not get any treatment or those who discontinued their treatment. The reasons for not seeking or discontinuation of treatment were many. Lack of money for treatment or loss of livelihood and assets due to treatment, prolonged period of treatment, etc. were the most common reasons. It is important to note that perceptions such as, treatment not available in PHC or lack of faith in public health system widely exists. People still believe that public hospitals (PHCs) do not provide quality treatment. They believe that corruption in public health centres causes extraction of money from patients.

Some respondents said that they have no time for treatment. In other words, they do not want to wait in queue for a minor treatment wasting their whole day. Either they could afford to let those illnesses as they are or managed to visit any private medical outlet and buy a tablet for Rs. 1 or 2. In case of emergency treatment, they choose to go to a private hospital in nearby place instead of going to a PHC or District Hospital.

Most patients visited PHCs for treatment of minor illnesses such as fever, cough, cold, various types of body pain and others (see Table 20.12). This is followed by

Table 20.11 Access to treatment (including all the family members) (*n* = 171)

Treatment	Patients (in number)	Patients (in %)
Ongoing treatment	105	61.4
Treated in last six months	37	21.6
No treatment/treatment discontinued	29	17.0

Source Field Survey 2012

Table 20.12 Nature of illness/treatment (*n* = 171)

Nature of illness	Patients	Percentage
Child birth/Reproductive health problem	37	21.6
Heart/Diabetics/Respiratory/BP Patients	20	11.7
Apendice/Jaundice/Piles	9	5.3
Tuberculosis	4	2.3
Injury/Accident	7	4.1
Disability treatment	18	10.5
Leprosy	3	1.7
Mental illness/Epilepsy	8	4.7
Minor illness/Fever/Cough/Cold	65	38.0

Source Field Survey 2012

Table 20.13 Financing of treatment (*n* 83; No response: 3)

	Number of households	Households (in %)
Money borrowed on interest	58	69.8
Borrowed without interest	5	6.0
Self-financed	83	100
RSBY smart card	0	0.0
Health insurance	13	15.6

Source Field Survey 2012

child births/reproductive health problem and illnesses related to heart/diabetics/respiratory/blood pressure problem. Data in percentage signifies the share of minor illness in the next column.

Table 20.13 is showing the financing pattern of treatment by the households in terms of five major sources. The first source of financing of treatment is self-finance, so it is represented as 100% by all responded households.

After self-financing, if expenses of health are not met then households borrow money mainly on interest; about 70% households are in debt. Only 6% of households borrowed money which is interest-free. About 15.6% households have health insurance coverage. There are 12.8% of households having RSBY Smart Card but none of them have used this card for treatment. This was due lack

awareness. When enquired about the use of this card, most of them thought of it as another kind of identity proof just like voter ID card.

20.5   Conclusions

Low level of drugs availability has many implications. First, it may lead to a serious loss of patient's life, if necessary medicines are not available at the time of need. This kind of experiences may change the belief of general people towards public health system. This assumed situation is not very far away from the reality. In case of emergency, people rarely think of going to public hospital; instead they rush directly to any private hospital. The importance of life for them is such that for obvious reasons, they are ready to spend more than their income and whole savings. Second, there may be some private medical supplier nearby PHC and is patronised by patients in the hospital in need of essential medicines that are not available in the PHC. Again this is also not an assumption, there are number of private medical outlets around all the PHCs of Aurangabad, flourishing on the missing contents of the PHCs. Patients have no option other than purchasing the medicines from these private outlets with no financial support such as reimbursement from health centre. Third, the qualities of medicines are always compromised by the private retailers to achieve greater margins on prices of medicines. In other words, there is no quality check of the drugs provided by petty sellers near PHCs. They are most unregulated and settled around the PHCs on temporary basis because whenever drug administrator (Drug Inspector) gets tough on them they disappear from the sight. Fourth, many treatments are of prolonged nature and regular dependency on private medicines can push the households into severe poverty and make them liable for large debts. This statement is again based on field experiences, which is showing that 17% of identified patients either have no treatment or treatment discontinued due to lack of money. The relationship between households and public health services needs to be improved by addressing the issues such as low awareness about public health programmes and schemes, developing a more user-friendly environment in the PHCs, improving the availability of essential drugs and services, ensuring that no private costs are incurred on health inside the PHC as well as outside the PHC by ensuring proper coverage of state-provided insurance.

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