

Realising the Right to Healthcare

a Policy Brief
2014

Jan Swasthya Abhiyan



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Introduction

The right to health is a fundamental and universal right of all citizens in India and this right needs to be respected and realized within a definite time frame. This Right to Health needs to be located in the context of access to underlying determinants of health, such as access to secure livelihoods, adequate food and nutrition, housing, and safe water and sanitation. We acknowledge that social inequities also - based on gender, caste, class, religion, ethnicity and other lines – have a profound impact on health status.

Right to comprehensive and good quality health care services is also an important aspect of the right to health. To ensure the fulfillment of this right, the public health system needs to be much better resourced, expanded and made accountable so that it can provide healthcare services that are comprehensive, of good quality, accessible to all, and free at the point of access.

Today across India, people fall ill and die unnecessarily, due to a range of social and economic factors that generate ill-health and disease, as also due to poor access to affordable and effective health care. It is estimated that approximately 1.67 million children under five years of age die each year in India. This is the highest number anywhere in the world. One-third of all malnourished children are estimated to be living in India. The cost of health care has become a leading cause of poverty. Consumer expenditure survey estimates by the National Sample Survey Organisation (NSSO) indicate that every year around 55 million people are pushed to poverty due to expenses on healthcare. Paradoxically, this situation exists in a context of availability of adequate resources, knowledge and skills for genuine change, for betterment and improvement of peoples' health as well as the healthcare system.

In this policy brief Jan Swasthya Abhiyan (JSA) outlines the key features of the current healthcare system, based upon which it makes a set of feasible policy proposals to move towards such a change. It is not possible to provide an exhaustive description and analyses of the health system in a small booklet. We focus on some of the more pressing and critical issues. The issues presented here are inter-related; therefore integrating the information and analysis presented here would help to develop as

well as move towards a vision for transforming the health system in India such that it can genuinely, effectively address the healthcare needs of the people.

The key issues that have been identified are organised in the following six sub-sections:

- Strengthening, Expanding and Re-orienting the Public Health System
- Gender and Health
- Privatisation, Public-Private Partnerships, Insurance
- Regulation of Private Sector and Patients' Rights
- Access to Medicines
- Regulation of Clinical Trials
- Social Determinants of Health

The document ends with a set of demands articulated in order to move towards a people-centric public health care system in the country. These demands are designed to reverse the present -- entirely unacceptable -- situation in the health sector, and to secure conditions of living and health care services that promote health in all its dimensions.

JSA calls upon all political parties to commit themselves to these proposals and to implement them subsequently, when elected to power.

1

Strengthening, Expanding and Reorienting the Public Health System

Why have public health services in India failed to develop as expected? Why have they failed to deliver the health outcomes expected – when so many other nations have been able to achieve better results?

We identify ten important reasons for this poor performance of the public health system:

1. Inadequate Investment
2. Inadequate Public Health Workforce
3. Poor orientation of medical, nursing and technical education
4. High out of pocket expenditure in the public services- mainly on drugs and diagnostics
5. Narrow Range of services available
6. Poor quality of public health services
7. Corruption
8. Over-centralization and bureaucratization- or in other words – failed decentralization
9. Insufficient community participation
10. The negative influence of international aid agencies in health policy and technical assistance and the lack of support to the development of adequate independent national capacity in knowledge management

To address these ten main problems the following steps will need to be taken by those who will be elected to power.

Commitment 1: To Increase Investment in Public Health Systems

Inadequate investment is the single most important reason for poor performance. India's performance in health sector is directly proportional to its health expenditure per capita in a comparison across nations. Any nation doing better for comparable levels of health expenditure has a greater proportion of public health expenditure (See Table A).

India's public health expenditure is only 29% of total health expenditure. Only 17 countries in a list of 196 nations are doing worse. The increased investments in the 11th Plan period brought this up to 6th from the bottom, but in the 12th Plan period it is slipping back again.

The political goal must be to raise public health expenditure to 70% of total health expenditure.

Our current public health expenditure is a paltry Rs.600 per capita, when any reasonable expectation of health care would require us to aspire for

Table A: Public Spending on Health: An International Comparison

	General govt. expenditure on health as % of GDP*		General govt. expenditure on health as % of total expenditure on health (PPP int. \$)		Per capita govt. expenditure on health	
	2000	2010	2000	2010	2000	2010
Bangladesh	1	1.2	38	34	8	8
Brazil	2.9	4.2	40	47	202	483
Chile	3.4	3.8	52	48	320	578
China	1.8	2.7	39	54	42	203
Colombia	5.5	5.5	81	73	314	518
Costa Rica	5	7.4	77	68	360	845
Cuba	6.1	9.7	91	91	341	394
India	1.1	1.2	25	29	16	39
Malaysia	1.7	2.4	52	56	159	356
Nepal	1.3	1.8	25	35	11	22
Pakistan	0.6	0.8	21	38	10	23
South Africa	3.4	3.9	41	44	223	412
Sri Lanka	1.8	1.3	48	45	49	66
Thailand	1.9	2.9	56	75	89	247

Source: WHO, World Health Statistics, 2012

at least Rs. 3000 per capita within this plan period itself. Of this Rs 3000 at least one third or Rs 1000 per capita needs to be provided by the central financing. India's poor investment in health care translates into a failure to create the necessary health infrastructure, or build an adequate public health workforce or provide it with the necessary equipment and supplies. We are just not adding enough beds in public hospitals or enough doctors and nurses to make public services effective.

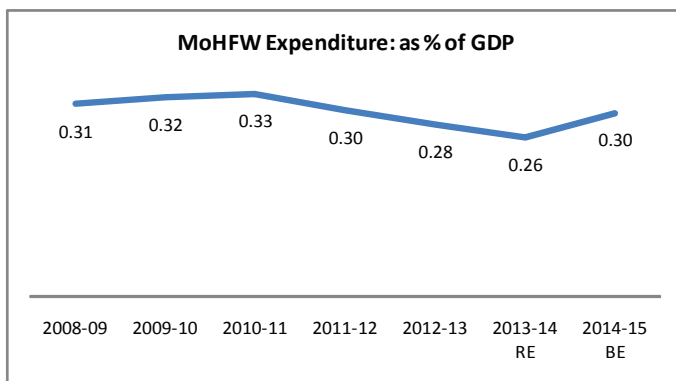
Did not the National Rural Health Mission (NRHM) lead to an increase? It did- but the actual amount released (Rs 68,000 crores) was only one third of what was envisaged and approved as essential for closing the gaps in infrastructure and human resources (Rs 1,75,000 crores). Not surprisingly the achievement level was also only one thirds of the expected level.

Thus for example- currently 8743 Primary Health Center (PHCs) are stated as working around the clock- but the target was 24,000 PHCs!!! There are an estimated 2600 first referral units- but the target was 6000 plus. In 2005, the number of PHCs counted as 24x7 was as low as 1263, and the number of First Referral Units (FRUs) as low- as 940 reflecting how the fiscal crisis and the structural adjustment driven reduction in public health system has almost completely destroyed the system in the previous 15 years.

While it is true that were leakages and inefficiency in use in NRHM funds, the greater truth is that the main failure was that of the government to provide the minimum funds that it, itself had envisaged.

This trend worsened under UPA-2 Government and the 12th Five year plan. The Planning Commission began with proposing a huge increase and calling the 12th Plan as a health plan. But once its plans for handing over much of these increased investment to corporate hands was exposed, it responded by lowering the plan allocation drastically. Further it froze all further increases in the health budget. After three years of the plan, the total funds released have dropped to about 20% of the plan allocation. Thus despite a lot of publicity, people are going to perceive a stagnation or worsening of health access in the last two years and a marked slow-down in the rate of improvement- consequent to the slow-down in investment.

Figure 1: Expenditure and Allocation of Ministry of Health and Family Welfare: as % of GDP



Source: Union Budget, Expenditure Budget Vol. II, various years

Commitment 2: To Ensure an Adequate Public Health Workforce, in numbers, skills and motivation

- a. Reach International and National Standards for number of skilled professionals deployed: The large increases in out-patient and in-patient attendance and institutional delivery owe a lot to one single factor- a substantial increase in human resources. Close to 23,000 doctors, 35,000 nurses and 70,000 ANMs and 10,000 management staff were added on under the NRHM. However as compared to the government’s own standards, the Indian Public Health Standards (IPHS), less than a third of the total number of public health workforce that is required is in place. This persistent gap is mainly reflective of poor investment discussed above.
- b. Regularise all Contractual Staff: Apart from the large gap in personnel, the terms of engagement of these staff are extremely adverse. Almost all of these staff is contractual with no security of tenure and a remuneration packages often less than half of that paid to regular staff that does the same work.
- c. Improve Training and Support: The contractual staff comes in with weak skills. The in-service training schemes either exclude them or is accessed by very few.
- d. Implement Special Packages for Service in difficult areas: We know how to reduce, if not solve the problem of finding skilled

persons to work in rural areas. A mix of measures which includes preference to candidates from under-serviced areas for medical and nursing education, easier access to post graduate seats for those who complete rural service, monetary and non-monetary incentives, fair and transparent transfer policies, and opportunities for skill up-gradation and better support, taken together works best- but due to administrative incompetence, and political indifference, has not been put in place in many states. Compulsory approaches though often projected as the great solution, provoke much resistance and seldom yield results.

- e. **Remove Administrative Incompetence in Workforce Management:** Though few states have shown how well planned and packaged financial and non-financial incentives can ensure that vacancies in rural and remote areas can be filled up, most states have not had the political will required to achieve this- preferring to blame doctors for what is really administrative incompetence. Administrative incompetence and political interference also affect deployment and performance through inappropriate recruitment, posting, training and workforce management policies.
- f. **Strengthen the ASHA programmes with better skills, support and an assured remuneration.** The 9 lakh force of ASHAs has now proven its role as facilitator to access, and community level care provision. The original package of services was only about 15 hours per week, but with increasing work allocation, now exceeding almost 30 hours per week, the government has to recognise her as part of the regular work force, and provide her with the skills and support needed to evolve gradually into a community level nurse. Given India's abysmal nurse to population ratio- even if every ASHA were to become a nurse we would still be short of international norms for number of nurses per population.

Commitment 3: To Re-orient Medical and Technical Education Policies

- a. **Qualify and re-orient plans for expansion:** In recent times there has been a trend to project an unqualified massive expansion in medical, nursing and technical education as the solution to the crisis in human resources in health. This could be misleading. The argument that if

there is an excess of supply, health professionals would be pushed to serve in rural areas is not true. Instead what happens is over-crowding and unhealthy competition in urban areas. However corporate health sector hopes to be able to get professionals at cheaper rates through such expansion.

- b. Ensuring a greater public orientation: For strengthening public health systems, expansion in medical, nursing and technical education is essential but it would be useful for improving public health services only if:
 - i. It is publicly financed and provided. Students, who pay lakhs and crores in capitation fees, cannot be expected to do rural service, or serve the poor.
 - ii. Expansion is in under-serviced areas, and provides preferential admission to students coming from these areas, who would be happy to serve there. This would increase the availability of skilled workers where they are needed most.
 - iii. The syllabus and even professional identity is appropriate to the tasks expected of them. This would ensure that the graduates would be happy and professionally fulfilled to work in such areas.
- c. Conditional Welcome to mid-level providers: The three year mid-level care provider (community health practitioner) and nurse practitioner cadre are good approaches to addressing human resource gaps. But if four essential conditions are not observed it can become a back –door entry for an inadequately qualified doctor who would compete in the over-crowded urban areas- which is the main reason why many in the medical profession oppose this. These conditions include locality based selection and training, conditional licensing to work only in public sector, a syllabus that provides the right skill mix preferably taught in the state language and a strong focus on public health skills- and advancement opportunities as public health, rather than clinical providers.
- d. Address the specialist gaps innovatively: The growing gap in specialists in under-serviced areas needs to be urgently tackled. This can be done by introducing a basic specialist course on the lines of the MD in Family Medicine or General Practice (as seen in Nepal), which

provides the mix of specialist skills required in a secondary hospital at block level and sub-divisional hospital, including emergency surgery and obstetrics and anaesthesia.

Commitment 4: To Reduce out of pocket expenditures at the public hospitals - Focus on free drugs and diagnostics

In practice public hospitals are far from free. This is because of a high level of user fees imposed during the earlier World Bank dictated reforms. The Janani Shishu Suraksha Karyakram (JSSK) programme under NRHM withdrew such fees for care in pregnancy, but left it intact for all other conditions. Even where there are no bed charges or doctors' fees, patients have to pay for diagnostics and for drugs – and this could account for over 70% of all out of pocket expenditure.

The most important measure to improve the social protection rule of public health systems and improve utilization of the public hospital is to make all drugs and diagnostics free. This should not mean only free drugs for a few days, when the patient comes to a facility. As is done for tuberculosis treatment, for any chronic illness the patient should be able to get free drugs all through the year from a provider/place nearest to her home- so that he need not lose a day's wage or spend money on transport just to collect their free drugs and get a routine follow up diagnostic done.

This also means a very good system of drugs and diagnostics procurement and their distribution to the peripheral health facilities. Tamil Nadu and Rajasthan have shown the way on how this can be achieved. But unless it becomes a political commitment to formulate and implement such a system, announcements of free drugs do not by themselves translate into actual benefits for the sick (See section on Medicines for all).

Free ambulance services are also part of the assured package of services. But, shamefully, many states are charging user fees to transport accident victims, and one state government has even tried to earn money through these tenders. Free ambulance services need to be strengthened and expanded on the model of the dial 108 services. It could be linked to local transport arrangements and hospital ambulances for maximal efficiency- but services should be as per needs and cashless.

Commitment 5: To provide an increased package of primary health care services - reject the selective primary health care approach in favour of a comprehensive primary health care approach

One of the most important reasons for underutilization of primary health care facilities is the sheer lack of the full range of required primary care services. Most sub-centers (SCs) and primary health centres (PHCs) provide little beyond immunization services, some ante-natal care and at best care for normal delivery. Most treatment of chronic illness like hypertension and diabetes is referred away, and so is the treatment for most infectious disease, except some of those on the national programmes. Even if all the care for Reproductive and Child Health (RCH) and national disease control programmes were available at these facilities, it would not be serving more than 20% of all health care needs.

This process of substituting comprehensive primary health care by such selective services (selective primary health care) was introduced in the early nineties. In the early years of the NRHM there was a promise of reversing this- but in the last two years, selective health care has re-emerged with a vengeance- with the development of primary health care being increasingly restricted to facilities, which provide delivery services and all the limited financial and human resources made available get absorbed into low priority tasks, while urgent health priorities get neglected. There is scanty or no regard shown to disease prevalence in the community being served when designing the package of services.

What is promised in the Plan and official documents is one thing- but what actually happens is more in line with the priorities of donor agencies- not because they pay for it- but because they influence the thinking of the key implementers.

The net result is that all district hospitals and government medical college hospitals are hugely overcrowded, leading to poor quality of care in these tertiary care centers. Patients have to either face huge costs in addition to the problems of such poor quality or face huge costs in an unregulated private sector.

Commitment 6: To ensure quality of care in all public health facilities

Quality in health care means health care that is effective, safe, rational, and non-exploitative, provided with due dignity and respect to patient

rights, and which aims at patients' comfort and satisfaction. Luxurious appearances should not to be confused with good quality medical care.

Quality norms and standards shall not mean conforming to infrastructure or certain kinds of physical standards, which favor large corporate hospitals, or worse medical tourism, and make it impossible to provide low cost, rational and effective care.

Every public health care facility would be required to provide guaranteed health services appropriate to their level, in assured manner with adequate quality.

Commitment 7: To prevent corruption by exposing and sealing the big fiveleakages

Widespread corruption is well known. What is less well recognized is that the endemic bribe-seeking of corrupt politicians and administrators also has systemic requirements. Potentially therefore one could limit corruption greatly if these channels through which leakages occur(which are a predictable pattern across states) could be publicly exposed and sealed up through administrative reforms.We list these five main channels:

- In procurement of drugs and supplies: The Tamil Nadu Medical Services Corporation (TNMSC) has shown how this can be done, and a legal instrument- the Transparency Act- ensures that no one errant minister or even government can reverse this. Infrastructure development, civil works is another related area of corruption, which is addressed similarly.
- Arbitrariness in appointments to key positions that wield financial power(rent payments in practice). The posting of the chief district medical officer is the most notorious. Where this is done by a due process and transparently, corruption levels are far less.
- Transfers and Postings: Doctors are threatened with transfers unless rent is paid- or those seeking transfers are asked to pay up. This leads to complete lack of accountability on part of the doctors, and provides a perverse justification for their taking bribes from patients. Karnataka has shown how to tackle this and a Transfers Act provides legal support.

- Contracting in Private Players- whether in Public Private Partnerships or NGOs for community level work. This could be eliminated by transparent grant-in-aid committees and partnership oversight mechanisms.
- Private Practice by Government doctors and kick-backs and commissions paid to government doctors by private pharmaceutical, diagnostics and hospital care providers.

These five main leakage channels undermine accountability and efficiency at all levels. They also underlie many problems of lack of management capacity and weak organizational development. They also indirectly encourage the petty corruption at the provider – patient interface, which is what troubles the service user in a most visible way. Petty corruption at the patient –provider interface is not to be ignored either- and here independently managed grievance redressal systems and community monitoring help greatly.

Commitment 8: To decentralize and democratize health care management

Public health systems suffer from over-centralised bureaucratic inefficiencies, which lead to very poor absorption of funds, and their inefficient use. It also means that health care provided is governed by centralized averaged out prescriptions- and is not responsive to local needs or contexts.

The efforts to strengthen district planning in the 11th Plan period did not fructify, because resource allocation could never match the plan, and since the districts were never allowed the powers or the opportunity to develop the institutional capacity required to manage such funds. Fears of leakage were used to justify centralized control, but as has been discussed in the earlier paragraph leakage has other channels, which are not related to district having more powers. Indeed leakages are more in highly bureaucratic environments.

The way forward requires a set of administrative reforms that will allow the space for more participatory and more responsive health care management, where budgets are provided in a minimum number of heads but within a framework that specifies certain essential process requirements like equity in allocation and which makes them accountable for matching increases in services delivered.

Commitment 9: To Ensure adequate Community Participation

The National Health Mission (NHM) has created increased spaces for community participation in the form of public participation in the management of district health societies, hospital development societies, and village health committees. But in most situations the representative is not appropriately chosen, the powers given are inadequate, and there is no effort to build their capacity. Organisations of working people and service user groups are almost completely excluded. Lip service is paid to community monitoring and the roll out of this programme has been limited to less than 5% of the blocks in the nation. This programme needs to be expanded to all blocks.

Commitment 10: To check the negative influence of international aid agencies in health policy and so-called technical assistance and support the development of adequate independent national capacity in knowledge management

External donor agencies bring in less than 1% of total public health expenditure but in the name of technical assistance and policy advocacy they command a disproportionate share of decision-making. Typically their agenda is also present on the national policy statement, but by focusing and amplifying some elements and attenuating and neglecting or even quietly opposing others they change policy.

Broadly their agenda lead to (a) policies that promote privatization and structural reforms that reduce government role in provisioning and increase purchase of health care (active privatization) (b) Limiting government provided health care services and resources to a very narrow and fragmented set of objectives and activities, most of which would not undermine or compete with private provision leaving the way for private sector expansion (passive privatization) (c) promoting public health expenditure on such activities as would lead to the development of international health markets- the purchase of goods and commodities and services from international or national corporates. What flows as capital from developed economies into the Indian health sector and what flows as returns on capital- dwarfs the contribution they make as aid- but their positioning as knowledge managers helps them shape the very thinking about health systems in a way that benefits corporates.

General administrators and other decision makers who have no public health policy experience are particularly gullible, because they have insufficient technical knowledge, and they could succumb to a combination of the perceived authority of the international expert (a hangover of the colonial mindset), along with appropriate inducements that take a wide variety of forms.

External aid comes in one or more of three forms –from multi-lateral institutions like the World Bank, bi-lateral agencies like USAID and DFID, or private corporate agencies like the Bill and Melinda Gates Foundation. Each of them act on different sites in the shaping of Indian health policy- and none of them provide any worthwhile high technology or skills that are not already readily available within the country. For the most part they hire Indian expertise at much higher rates and set them to work on their agenda.

The flip side of this is that Indian institutions, even those which have high credibility and performance languish for both funds and opportunities- and often have to depend on these same donors, undermining their own independent development. Interactions with institutions in similarly placed third world nations is weak or mediated through these same international agencies. Even the funds sanctioned for these purposes remain unspent due to administrative failures. It is easier to assign the work to international agencies than to build national institutions –a task which requires a long term sustained effort.

National pride and the assertion of national sovereignty require that there is a political commitment to phase out such external aid within the next three years and build our own capacity to undertake this work. It is not the knowledge or skills that limit us but the need for administrative reforms required for better knowledge management.

False Reasons and Impractical Solutions

The failures of the public health services (largely due to the above reasons) are being used to give up on strengthening public health services and allowing privatization - through shifting to insurance or by government purchasing health care from private providers. Political parties need to be alert to some of the reasons provided for failure of the public health system by neo-liberal spokespersons and their academic champions. These

are usually excuses to justify passive privatization, the refusal to invest more money in public health services and to make the case for active privatization by transfers in the name of partnerships and insurance.

One common statement made by neo-liberal critics is that public systems are inherently inefficient, because permanent government employees have no motivation to work more, and whether or not they work, they get paid the same. Based on this they suggest that payments to public providers be linked to performance. They also justify user fees stating that people do not value what is provided free.

Public Health care systems are not inefficient. Though they account for only 29% of total health expenditure and employ less than 20% of the medical workforce, they provide about 33 % of all out patient care as provided by a qualified provider, and about 40 to 50 % of all in-patient care, over two thirds of all end of life care in hospitals, and 100% of all preventive and promotive care. In addition they have forensic and regulatory functions. Indeed the efforts to reduce investment are not because it is failing, but because it is in danger of succeeding- cutting into private sector super-profits and prevent monopoly profits.

Performance based payment is impractical and leads to major distortions in what and how health care is provided. Nowhere in the world has it been shown to work. Linkages between service delivery and health outcomes are difficult to measure. However team incentives for good performance on quality of care and overall achievements are probably welcome and some compensation for work beyond the normal call of duty is always appreciated. Those who question neo-liberal theories would point out that health care is essentially a provider – patient relationship based on trust and this is better assured when the patient knows that the provider has no monetary benefits for the advice he provides. But in an atmosphere rife with kick-backs for referrals and diagnostics, legalizing this within the government system would only worsen the situation.

Motivation is a function of leadership and good workforce management. When wars are lost we do not say the soldiers fought badly- we look to the generals. A performance based payment to administrators in charge of ensuring that recruitments, promotions, payments, pensions etc are made on time would be more measurable and have much better motivational outcomes. But typically such measures are only proposed by

the powerful for the most powerless within the systems- for ASHAs and then for ANMs and nurses and then for PHC medical officers.

A political commitment to good governance

Of course the performance of public health services is very sensitive to good governance. But if good governance is not ensured then private sector alternatives like insurance and PPPs will fare even worse. It degenerates into helping a few crony capitalists to loot the government. And if good governance is there- then all these public health systems can be made to function much better.

That is why we look for a political leadership that can provide good governance, as expressed by its willingness to make the above ten political commitments required for strengthening public health systems.

2

Gender and Health

A gendered perspective on health takes into account the diversity of identity and vulnerability in the context of health, recognizes the right to express sexual preference, and is mindful of the unique but also shared experiences, needs and aspirations across genders (including heterosexual, homosexual, lesbian, gay, bisexual, queer, transgendered, transsexual and asexual persons).

Importantly gender is intersectional with other identities and experiences, including class, caste, ethnicity, marital status, disability, which can either enhance or harm health. An equitable health system is one that recognizes and caters to these intersectionalities – being fair to varying needs. Needs can vary drastically: a study in Kerala found that, 88% more SC/ST women and 73% more OBC women than forward caste women were likely to report poor health.

A gendered perspective on health incorporates the biomedical, the socio-cultural as well as the lived experience of everyday lives. Women's health is predicated on access to other indivisible rights, like the right to water, food, shelter, education, social security, and freedom from discrimination; rights which are not typically considered in our highly bio-medicalised health encounters. Over 620 million Indians defecate in the open, and one in ten of these lives in an urban area. When a patient is sick, s/he is not asked about hygiene and food habits or where she lives, much less what she does for a living, each of which can explain so much of his/her morbidity. While some efforts to act on the social determinants of health have been attempted, as in the Janani Shishu Suraksha Karyakram (JSSK), these are ad hoc, fragmented, and exceptions to a system that typically ignores the social determinants of women's health.

The burdens faced by women and girls become apparent in a life-cycle approach. The National Family Health Surveys (NFHS 3) have shown that while boys are more likely than girls to die in the first month of birth, child mortality rates for girls are 61 per cent greater than those of boys after this first month, all the way up through age four. Among 15-19 year olds in the country, complications during pregnancy are the leading cause

of death. As many as two out of three adolescent girls living in India's backward districts have experienced sexual violence.

In a country where at worst nine out of ten and at best one in two pregnant women is anemic and malnourished, it is only in the Fourth National Family Health Survey that anaemia is even being monitored.

Maternal mortality continues to be an unjustifiably significant problem in India, in spite of the issue garnering a lot of attention and being the focus of policy and programme by the Government of India and international bodies. Maternal Death Reviews, though mandated since 2010, have not been institutionalised in many districts across various states, and are not being carried out in several communities, especially in rural areas. Social autopsies of maternal deaths show that maternal deaths are highest amongst young women and primis – girls continue to be married off before the legal age of marriage and their malnourished, anaemic state is a contributory factor. Many women also continue to die around child birth because health facilities in many parts of the country are not equipped to provide Emergency Obstetric Care, the quality of antenatal care provided is inadequate, and safe abortion services in the public sector are inaccessible for the majority of women. Quality contraceptive services as an integral part of Maternal Health Care are also inadequate and the target approach continues to be the norm.

Another area of concern is the Government of India's single minded policy focus on Institutional Deliveries. Such a focus prevails at a time when the institutions are not geared to handle the load of all childbirths, and when several areas exist in the country with serious access problems.

The burden of communicable, non-communicable diseases and mental distress is also gendered. Sexually transmitted diseases amongst women are asymptomatic and remain undiagnosed, and when diagnosed can have drastic social consequences for them. Heart attack and stroke are more lethal for women, and depression twice as common. Women over the age of 60 years have greater disability and co-morbidity than men of the same age-group, due to myriad factors: biological vulnerability, delays in or lack of health-seeking, mismatched care provision (as women are under-represented in research, particularly related to non-communicable diseases). We do know, however that women are twice as likely to suffer from common mental disorders as men.

It bears mentioning that we do not even know the burden of diseases – communicable or not – faced by transgender and other sexual minorities, nor do we have any idea of their mental health condition. A large proportion of India's sizeable transgender population has for years endured stigma, discrimination and derision from the health system, only to be given some attention, limited only to HIV services in most cases.

Women and girls lack access, furthermore to essential drugs, diagnostics and supplies, including contraception, iron folic acid, blood, and sanitary pads. Many drugs, like Co-trimoxazole for bacterial infections, tamoxifen for post-breast cancer cases, and hormonal supplements needed by trans-persons are overpriced and should be made accessible and affordable. Policies around unbanked direct blood transfusion need to be re-examined - over 30 % maternal deaths are due to haemorrhage and unavailability of blood in emergencies.

Across genders, people with disabilities face greater co-morbidity; for example, individuals with Down's Syndrome have a 30% greater risk of hypothyroidism. Women and girls with disabilities are highly prone to depression which can often go undiagnosed by a health system that is both phobic and hostile towards differential ability. Particularly problematic is the continued use of non-therapeutic chemical or surgical sterilization, hysterectomies and abortions of women and girls with disabilities.

The female body as a research subject is another vexing challenge. The mushrooming phenomenon of Phase II and III clinical trials in India, accompanied by attenuated regulatory environment has resulted in gross violations of research ethics, including problematic recruitment protocols, inadequate consent procedures, and shockingly poor compensation for adverse events to clinical trial participants. There are many motivations for clinical trial participation, not least related to the perception that trial participation amounts to free treatment, is trustworthy, and assures greater priority to the health needs of research subjects (something that may not occur). Information asymmetry and breaches of doctor-patient trust and confidentiality are also major concerns for trial participant across genders (See section on Clinical Trials later).

Privatization has also adversely affected the health of women, leading to a commodification of health care and spike in expensive medical procedures including hysterectomies and Caesarian sections. In part, this

increase is associated with state-sponsored insurance schemes: doctors peddle these procedures aggressively and women, failed by the larger health system, see this as a way of avoiding future morbidity. Over the past few years, India has seen a sharp growth in commercial surrogacy and the use of Assisted Reproductive Technologies (ARTs). In the year 2008, the surrogacy business is reported to be worth \$ 445 million in India. ARTs including commercial surrogacy has drawn much attention and raised several ethical and legal concerns. There is an urgent need to regulate the private sector, especially in domains where the damages to the health of women and vulnerable genders is extreme.

Gender-based violence has been found to be extremely high, with as many as 40.3% of women reporting at least one instance of physical abuse. There seems to be an epidemic of sexual violence against women in the recent years. The high figures maybe partly attributed to increased reporting. Mental and physical consequences of violence against women need to be addressed by the health sector. Smaller studies suggest that the violence is even more pervasive for sexual minorities. Similarly, gender based violence is a crucial factor that has major health implications in accessing antenatal care, in some cases leading to the death of the woman.

The situation is exacerbated by the state's regressive demographic goals and coercive population policies that have dictated health policies and programmes for women especially in terms of financing, resource allocation, and conditionalities affecting health schemes. There is enough evidence to suggest that attention to ante natal and post natal care has suffered because of the priority accorded to the family planning programme in the country.

Even with the extensive focus on family planning, across genders, India is still lacking programmes focused on body literacy and health and sexuality education for young people. An understanding of masculinities, of health promotion and wellness, of productive, respectful and resilient relationships between humans and their environment is sorely lacking and not given adequate priority even in the health sector.

Women play a prominent role in the health workforce, formally as nurses, doctors, and allied health professionals and informally as health workers, and care-givers. Their conditions of work – with poor safety, transportation, housing, sanitation, hygiene, and inadequate social

security - often render them vulnerable to violence and ill-health. Further, even the health sector does not recognize the reproductive roles and responsibilities for parents and care-givers across genders! Promotion policies disadvantage women who take breaks to bear and rear children, and assume that men will not play an active role in the same. Much in the same fashion, National Health Accounts do not include unpaid, home-based care often performed by women that heavily subsidise the work and health of other family members.

Recommendations

1. Provide comprehensive, accessible, quality health services, drugs and diagnostics for people of all genders – including women, girls, men, boys, and trans-persons- commensurate with their health needs which includes but is not limited to pregnancy care.
2. Ensure that essential drugs, diagnostics and supplies, including contraception, iron folic acid, blood, and sanitary pads are available at all times.
3. Abolish all coercive laws, policies and practices that violate the reproductive, sexual and democratic rights of women; and regulate use of invasive reproductive technologies.
4. Recognise gender based violence as a public health issue in order to (a) ensure access to comprehensive health care (physical as well as psychosocial), screening, documentation, referrals, as well as coordinated, ethical medico-legal processes for survivors; (b) organize inter-sectoral campaigns on violence prevention involving broad-based community participation.
5. Guarantee comprehensive, quality, accessible, adolescent-friendly health promotive, preventive, curative and rehabilitative services, including for the reproductive and sexual health needs of all genders.
6. Assure women of gender-specific health entitlements (maternity leave, abortion leave, sterilization leave, crèches, toilets) in public and private employment.
7. Assure comprehensive maternal health services – including contraceptives and safe abortions – along a continuum of quality care.

8. Register all deaths and initiate audits of all maternal deaths.
9. Ensure safety, transparency and accountability in all clinical trials, and guarantee that the post-trial benefits of research are made available to women even from marginalized groups. Ensure disclosure of funding and of potential conflict-of-interest in all clinical trials, medical research and publications.
10. Make mandatory the inclusion of women's organizations and women's health advocates on ethics committees, from national to local and institutional level.
11. Regulate use of assisted reproductive technologies including commercial surrogacy, and genetic engineering.
12. Include the topics of 'Violence against women' and 'sexuality and gender' as part of medical and paramedical curricula to equip medical professionals to deal sensitively with survivors of violence, including domestic violence. Train forensic experts on the social aspects of sexual assault and rape, collection and retention of proof in cases of individual or mass sexual violence.
13. Repeal Section 377 of the Indian Penal Code, and other laws, policies and practices that discriminate on the basis of sexuality.
14. Address malnutrition and anaemia in girls and women through coordinated policy actions across sectors.
15. Recognise work performed by women and trans-persons and correspondingly address the health burdens to which they become vulnerable as a result, including unpaid home-based work and care-giving
16. Build health system capacity to recognize, measure and monitor gender concerns, making data routinely and publicly available

Privatisation, Public-Private Partnerships and Insurance

It is well-established that Government policies in the health sector have always been favourable for the growth of the private sector, in various direct and indirect ways. There has been direct support in form of customs duty exemption/reduced duties on imported equipment, concessional loans, land at subsidized rates for construction of hospitals, etc. Indirect support has been by accommodating private interests in the government healthcare sector for purchase of drugs, supplies and equipment, and allowing private practice by government hospital doctors.

In addition, there has been a process of passive privatization as a consequence of overall neglect of public services including public health services and allocation of abysmally low finances for health, leading to stagnation, and quantitatively and qualitatively inadequate services, compelling people to seek care from private providers.

Health Systems Strengthening and UHC - the Trojan Horse for privatization

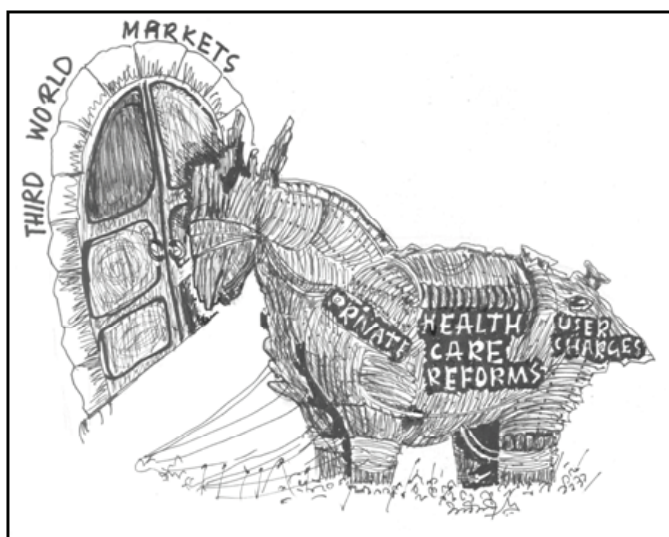
Instead of improving the weak public facilities by adopting a range of measures such as: infusing funds, inducting personnel, improving infrastructure, supplies, and management, introducing accountability mechanisms, etc., the neo-liberal ideology has propagated the idea that public health services are inherently inefficient and hence there is need for reforms and restructuring. A further assertion is that privatization and markets are the panacea to the problems of the public sector, such as poor quality of services, unresponsiveness and unaccountability to patients, poor management, in general, overall technical inefficiency. A further unstated assumption is that the market/private sector does not have these or other kinds of problems.

Since the 1990s health policy and planning in the country have explicitly promoted privatization in the guise of reforms, with the National Health Policy of 2002 welcoming private sector participation in all spheres of

health activities. There has been active privatisation through mechanisms such as handing over of public health facilities to private parties or outsourcing various public health services to the private sector in the name of public-private partnership (PPPs) arrangements, medical tourism, offering tax holiday for setting up hospitals in class II cities/towns and directly providing public funds to the private sector through insurance mechanisms.

The Trojan Horse of Privatisation

Increasing Corporate presence



A more serious development, not totally unrelated to the liberalization-privatization regime of the early 1990s, has been the steady corporatization of medical care and increasing investments by private companies as against government investment in health services. Increasingly over the past decade, the provision of health services has become increasingly commercialized, and is being projected as a revenue / profit generating activity. Healthcare is now viewed by industry and policy makers as a big business opportunity and an engine of growth, and there is strong advocacy and promotion by the industry of the idea that “Health care infrastructure should not just be viewed as a social good but also as a viable economic venture with productivity”. Healthcare in India was

reported to be one of the largest service sectors, constituting 5% of GDP and offering employment to around 4 million people. According to Investment Commission of India, the sector has witnessed a phenomenal expansion in the last 4 years growing at over 12% per annum. PPPs are being viewed by the industry as having potential to create 'an enormous market with a reliable, multi-year revenue stream for private investors'. The corporate sector and other big private hospital chains are now expanding beyond the metro cities to semi-urban and rural areas, to smaller cities and towns; some of the corporates are receiving loans for this expansion from agencies such as the International Finance Corporation of the World Bank group.

As a result of all these there is now a huge and diverse private sector in healthcare, ranging from individual medical practitioners, to small nursing homes and hospitals, to large corporate and specialty hospitals and diagnostic centres. Many of these private hospitals and diagnostic centers are also becoming centers for post-graduate education in certain specialties.

The accommodation of the private sector in healthcare provision with use of public funds is now being legitimized in the name of health systems strengthening and universal health coverage (UHC). The Twelfth plan for health (2012-17) has come up with a 'new strategy' as part of a longer term reform of the system over the next decade. According to its proposals the health system will continue to have a mix of public and private service providers, and the two would need to coordinate for delivery of a continuum of care. It proposes that various options of financing and organization should be explored by states, including a combination of public and private facility networks. The current health budget and initiatives by the Planning Commission and other actors indicate that the strategies for 'managed care', and large scale privatization and corporatization of public health still remain on the cards.

Performance/Experience of Private Sector in utilizing public funds and implementing government programmes

While there is a lot of study and criticism of failures of the government healthcare facilities, there is no corresponding examination of the private facilities. There is continuing dearth of systematic information on the spread, composition, infrastructure, efficiency and effectiveness of the

private sector hospitals, services provided and their quality, employment conditions, costs, and status of adherence to rational, ethical practices. There are no rigorous evaluations yet on the terms and conditions, and functioning of PPPs in healthcare sector. There is rarely, if any, comparable demand for accountability and transparency from private hospitals and diagnostic facilities as there is from the public sector.

Anecdotal reports are on the increase pointing to a host of problems across private hospitals in India – fleecing of patients for money, lack of facilities, lack of proper trained staff, poor employment conditions, payment of commissions for referrals, performing un-indicated procedures, prevalence of several irrational and unethical practices (such as sex selective abortions, unnecessary hysterectomies or cataracts or surgeries, not releasing a relative's body till dues are cleared, and so on). In 2000 the Health and Family Welfare Department of the Government of National Capital Territory (NCT) of Delhi constituted a 10-member High Level Committee, to review the existing free treatment facilities extended by the charitable and other private hospitals that had been allotted land on concessional terms/rates by the government. This Qureshi Committee Report clearly documents the greed, corruption and mismanagement of private and corporate hospitals in Delhi, their indifference and resistance to any monitoring and regulation, and the role of the government in condoning and conniving with these activities and attitude. This report observed that 'some who have been allotted government land had not bothered to even reply to the questionnaire in a spirit of open defiance'. Thus, available reports point to blatant misuse of concessions granted to the corporate sector so far. Similar observations have been reported of the 'uncharitable nature' of the charitable trust hospitals in Mumbai.

Available studies on PPPs and on insurance mechanisms point to a range of problems regarding access and quality of services, and raise doubts over the claims to bring in equity and reduce out-of-pocket expenses.

PPPs

There are no rigorous evaluations yet on the terms and conditions, and functioning of PPPs in healthcare sector, such as outsourcing of diagnostic services in Delhi, W Bengal, and Bihar. The experience of outsourcing of diagnostics in Bihar indicates that it has led to decreased access to

services and even denial of services for the poor, increased out of pocket expenditure and decline in the quality of services. The 6th Common review Mission of NRHM in Bihar (2012) states that: “laboratory services are delivered through PPP model which is not functioning properly. At most of the places below district hospital level, the agency outsourced to has set up only collection centres. This leads to prolonged turn-around time and reporting time. The contracted agencies were to provide those diagnostic tests that were not conducted at the respective public facilities. However, the contracted agencies were conducting those same tests that were being performed by the in-house lab. This had led to under-utilization and even dysfunction of in-house labs, leaving the government lab technicians without their professional work and to their sub-optimal use.

A recent evaluation of the Chiranjeevi programme of Gujarat, the much-acclaimed PPP on maternal care services found that the scheme was “not associated with changes in the probability of institutional delivery (including delivery at private institutions), maternal morbidity or delivery-related household expenditure”. They also found little or no association between the programme and out-of-pocket costs of deliveries. They deduced that this could be arising from private hospitals charging the patients some money, whereas delivery should have been free under this programme. It is also observed that private sector contracting in urban areas for maternal health services bypasses government health services rather than strengthening them.

Insurance schemes

There has been an increase in the number of publicly-financed insurance schemes floated by central and state governments, with the stated aim of protecting the poor and the informal sector workers from catastrophic expenditures on health. The Yeshasvini Health Insurance Scheme in Karnataka in 2003 and the Rajiv Aarogyasri Scheme in Andhra Pradesh in 2007 are the precursors to the Rashtriya Swasthya BimaYojana (RSBY) launched by the Ministry of Labour, Government of India in 2007. The health insurance coverage of about 75 million people in 2007 (roughly about 16 million family beneficiaries), increased to an estimated 302 million people in 2010, covering roughly one-fourth of the population. However, in terms of benefit package, all the publicly funded schemes provided only limited secondary and tertiary level hospitalisation cover,

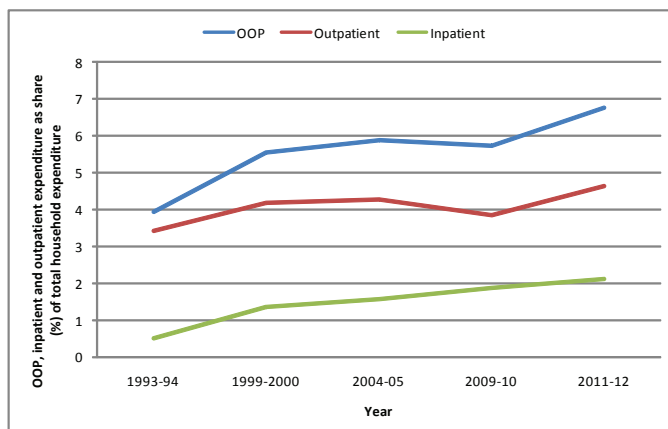
with the exception of the Employees' State Insurance Scheme (ESIS) and Central Government Health Services (CGHS).

These insurance schemes have not been very effective in providing equitable, rational, and free health services. In most states more private than public hospitals have been empanelled for providing services under the insurance scheme. These private facilities are concentrated mainly in the mainstream areas and cities, while lesser number of private hospitals is available and therefore empanelled in rural, tribal and remote areas. Beneficiaries were often found to be concentrated in the easier to reach villages and left out in the hard to reach villages or hamlets.

Furthermore, it has been found that these insurance schemes focus on specific treatment procedures rather than on treatment of illnesses, and therefore conditions treatable at primary level end up being admitted (for example, for uncomplicated anemia or diabetes mellitus) or transferred to secondary/tertiary levels. This also resulted in public funds being shifted from primary level care to secondary and tertiary level care, or to private providers. The focus on funding procedures was encouraging irrational practices. Many unnecessary procedures like hysterectomies (removal of uterus) had been performed by the private sector hospitals in order to benefit from the insurance money; thousands of such instances have been documented in Bihar, Chhattisgarh and Andhra Pradesh. There is no real choice for the beneficiaries in terms of which hospital they can go to; as it is the hospitals that were dictating what conditions and which patients they wanted to treat, as per their potential for profits. This was also leading to higher out of pocket expenditure. There was no service guarantee at the facilities, neither by the level (primary/secondary/tertiary) nor by the speciality (surgery, gynecology, eye and so on). While private hospitals were 'cherry picking' the most profitable conditions/procedures, public hospitals were unable to compete. However, in the more remote areas with a very small private sector, the public facilities were getting an increased patient load.

These insurance schemes were to protect people from high medical expenses. However, per capita expenditure of households on healthcare is reported to have increased significantly during the last five years of the NSSO survey period. This rise appeared to be largely due to hospitalization expenditure, while outpatient and drugs expenditure remained almost stable during the period.

Figure 2: Out-of-pocket expenditure on health increasingly eating up people's spending



Source: Unit Records, various rounds of NSSO, Consumer Expenditure Survey, Selvarajet. al. (forthcoming)

There is evidence from several states that such insurance schemes were not successful also due to rising costs over a period of time. There is continuous demand from the private sector to increase the ceiling of packages, which is not surprising, given that their main motive was to maximize profits. Very recently, in mid-March, the union health ministry suspended empanelment of several hospitals, including corporates such as Fortis Group, Escorts, Narayana Hrudayalaya and Moolchand Hospital, Delhi. These hospitals denied credit facilities to eligible CGHS beneficiaries due to delay in settlement of hospital bills, as also reasons such as lower package rates. Reports from Chhattisgarh and Andhra Pradesh have shown that RSBY and Arogyashri respectively were not in the pink of health as demands from private sector had increased and some hospitals had even stopped providing services. Thus, private hospitals under the insurance schemes are seen to hold the government to ransom by denying medical care to needy patients, completely belying promises of prompt, efficient, effective, and cashless care.

Clearly, commercial and profit motives have become major forces guiding healthcare provision, leading to unnecessary procedures, wastage of

resources and no improvement in health outcomes. The corporates, directly or indirectly, through their associations and multi-lateral and bilateral financing agencies, and other interested parties, are involved in the formulation of national priorities and in influencing health care provisioning and financing. The corporate sector is also devising means and mechanisms to edge out the not-for-profit providers and the smaller for-profit facilities, such as by standards-setting and accreditation. Their goal clearly is that of profiting from ill-health, rather than working towards actual improvement of health of all people.

The need of the hour is to keep alive and strengthen the ‘social logic’ in the health sector and to push back ‘profit logic’. There is need to utilize private resources to serve public benefit rather than continue with the present situation where public resources are being utilized to serve private benefits. Jan Swasthya Abhiyan opposes this trend of public resources serving private benefit and the increasing corporatization of healthcare services in the guise of increasing capacity and efficiency.

A strong public sector can function as an effective check on the vast unregulated the private sector, where the private sector must function in a more responsible, rational manner or become progressively irrelevant. However, such major expansion and strengthening of the public sector health services would take some time. For such strengthening in the near future resources presently available in the private sector, such as specialist doctors have to be reclaimed and the influence of the private sector have to be rolled back. Hence there is need to draw up appropriate mechanisms for interaction with the private providers, for PPPs, with the idea of strengthening the public health system, where the contracted private providers work towards public health goals and not merely for their profits and income.

Our demands

1. Stop the ongoing active and passive privatization of health care services. Necessary measures should be taken to stop active privatization in the form of transfer of public resources or assets to private entities that provide services on a commercial basis. Measures should be taken to stop passive privatization by increasing, strengthening and improving public health services and expanding range of services available in public facilities. Public facilities should provide comprehensive health

- care services, and not be limited to only reproductive health care, immunization and treatment for a few diseases.
2. Lay down clear terms and conditions for interaction with the private providers through PPPs and other mechanisms. In this there needs to be clear distinction between the commercial and corporate sector on one hand, and the not-for-profit and voluntary sector on the other. The objective of such interaction should be to strengthening and achieving public health goals. There should be appropriate and prompt payment with dignity for private partners, so that ethical, rational, low cost providers are favoured.
 3. Institute effective mechanism for regulations for the vast private sector, which should not be limited to legal regulation. There needs to be differential treatment of public and private hospitals given their different roles and functions; one can explore the option of a separate act for the public health system. Furthermore, there should be different set of standards for different categories of clinical establishments (especially for not-for-profit hospitals and small healthcare providers in rural and tribal areas).
 4. The national Clinical Establishment Act should have provisions for: observance of patient's rights in all clinical establishments; regulation of the rates of various services; elimination of kickbacks for prescriptions, diagnostics and referrals; and establishment of government supervised independent grievance redressal mechanisms for patients.
 5. Absorb, over a period, existing publicly funded health insurance schemes (RSBY and different state health insurance schemes) into an expanded public health system publicly financed through general taxation. All entitlements available under these schemes would be made available through the public health system, suitably expanded and adequately resourced. This should include a comprehensive system for health care protection of unorganized and organized sector workers (providing primary, secondary and tertiary health care), linked with expansion and rejuvenation of the ESIS.

4

Private Sector Regulation and Rights of Patients

Why should private health care providers be regulated?

India has one of the most privatized healthcare sectors in the world. Almost 80% of out-patient care and 60% of in-patient care is accessed in private hospitals. The private health care sector has increased especially rapidly during the last twenty years. Despite its rapid growth and large size, this private medical sector in India suffers from a wide range of serious problems. It is widely acknowledged that these problems arise due to the profit motive, linked with the total lack of regulation of the private providers. Overall, this has led to huge urban-rural divide, massive wastage, prevalence of excessive and/or irrational medication, exploitation of patients by overcharging and unnecessary interventions, major variations in quality and largely substandard care, and violation of patients' rights. These problems of private provisioning are worsened by the presence of an exploitative pharmaceutical industry, which manufactures and sells irrational drugs, expensive brands, and overpriced medicines. Furthermore, during the last twenty years there has been proliferation of private medical colleges and of an unregulated medical equipment industry. Thus, barring few centres of excellence, private medical care in India is sub-standard, exploitative and needlessly expensive.

The rapidly growing number and influence of corporate hospitals and diagnostic centres have added to the problems outlined above. This influence of the corporate entities is extending beyond big cities. The genuine Trust hospitals of the 1970s and 1980s, which by and large offered rational ethical care and provided some solace to poor patients, are getting replaced to a substantial extent by a newer variety that are registered as Trust hospitals, but in practice behave more like commercial and even corporate hospitals.

In such a scenario, if patients are to get a fair deal and satisfactory healthcare at reasonable cost, these private providers have to be socially regulated. Additionally, now through various insurance schemes the

government has started paying the charges of private hospitals on behalf of the citizens. Since progressively larger amount of public funds are being spent in this manner, it is necessary that the quality and price of private health care be regulated.

What should be the overall framework of regulation?

Regulation of private health care should consist of both, self-regulation by doctors themselves, as well as external regulation by an external regulatory structure that is participatory and backed up with legal mandate. So far there has been complete failure on both counts. Prior to the enactment of the Clinical Establishments Act in 2010, there was no law for nearly sixty years since Independence regulating private clinical establishments, except in a handful of states. The state laws that exist are largely unimplemented and hence practically useless.

All doctors, whether allopathic or from other indigenous systems, are currently supposed to be self-regulated by their respective statutory Councils. But it is widely known that these Councils have not been able to curb the irrational, unethical, exploitative practices widely prevalent in the private sector. Secondly, the current structure and procedure for patients for seeking grievance-redressal is not fair for the patients and carries no credibility in the eyes of the lay people. Associations of doctors such as the Indian Medical Association (IMA) work to protect the interests of doctors. It is neither their mandate nor is it their objective to regulate the content of medical practice and the charges levied by their members. The Medical Council of India (MCI) is the statutory body which is supposed to curb unethical conduct of allopathic doctors. But it is widely known to be a corrupt body; and has been quite ineffective in performing its statutory duty. Similarly, the Councils for practitioners of Ayurveda and Homeopathy are also ineffective.

However, over the last ten years there have been some welcome changes in some respects. The MCI code of ethics, Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, has laid down more stringent norms to curb unethical practices. But there has not been much impact at the ground level.

Moreover, the MCI code of ethics does not apply to hospitals, a lacuna misused by hospitals. For example, one comes across advertisements by

hospitals, despite prohibition of such practices by the MCI code. Secondly, MCI has now made Continuing Medical Education (CME) a pre-condition for renewal of registration of doctors. However, there are many problems with this compulsory CME, due to which it cannot achieve its objectives.

This situation has to change radically. Effective mechanisms are needed for both internal and external regulation of health care providers. The regulatory structure and the mechanism for its implementation should be democratic, transparent, just and have space for participation of multiple stakeholders. It should take into account the special vulnerability of patients vis-à-vis the medical establishment, and hence should certainly protect patients' human rights.

Mechanisms for Regulation

Any regulatory mechanism has to be of two types - enabling and binding.

Enabling regulatory mechanisms

These may consist of:

- Appropriate orientation of medical students in medical colleges and paramedic schools specifically about rational, ethical practice and patients' rights, and about political economy of health care.
- Continuing Medical Education of doctors and other health care providers. Unlike the current situation, it should be relevant, appropriate, standardized, user-friendly and should also be available online.
- Mandatory ethical guidelines for promotion and marketing by pharmaceutical and other health care related industries. Experience shows that in absence of such mandatory guidelines, the pharmaceutical industry tends to indulge in unethical promotion and marketing of medicines.

Binding regulatory mechanisms

These may consist of indigenous, local minimum standards for

- a. Infrastructure and human-power
- b. Standard Treatment Guidelines to be evolved by State and National level boards with involvement of professional organizations.

- c. Observance of Standard Charter of Patient's Rights
- d. System of regular audit of prescriptions and inpatient records, death audit and other peer-review processes.
- e. Clear norms for payment and quality/rational care

An External regulatory structure supported by a legal mandate as outlined below is needed to ensure adherence to these binding norms.

Clinical Establishment Act 2010: will it make any real difference?

The Central Government enacted the Clinical Establishment Act (CEA) in 2010. It was a response to the long-standing demand from various quarters for regulation of private health care providers.

The Clinical Establishment Act 2010 has some positive features:

- i. All kinds of clinical establishments in private as well as in the public sector providing any clinical service (outpatient clinics and hospitals from allopathic and non-allopathic disciplines, laboratories, diagnostic centres) have been covered in this Act.
- ii. All hospitals and clinics will have to maintain some minimum standards and adopt Standard Treatment Guidelines. This would help protect patients from irrational, exploitative treatment and from sub-standard facilities.
- iii. Charges by hospitals will have to be within the range fixed by the government, after consultations with all stakeholders, including doctors' representatives. This will prevent levy of exorbitant charges by some doctors.
- iv. Clinical establishments will have to display charges for some of the standard procedures like consultation, room charges, and so on. This will equip patients with some information regarding medical expenses, to be able to decide upon the affordability of each hospital.
- v. There is provision for representatives of private providers, civil society, women's organizations in the State and National Councils.

Notwithstanding these features, the CEA suffers from many serious gaps and problems. We mention here a few which are crucial from the point of view of patients.

- 1. There is no separate, autonomous structure and budget for implementation of the Act. At present the number of doctors in

private health services is five to six times the number of doctors in the government service. Yet, the CEA entrusts the stupendous task of their regulation to the already over-burdened Directorate of Health Services without providing any additional staff or budget. The CEA would thus remain largely on paper.

2. The multi-stakeholder National and State Councils are meant to guide and steer the implementation of CEA and these councils have some representation of doctors and civil society organizations. However at the district level there is no such multi-stakeholder body, leaving more scope for misuse of powers by officials and of corruption. There is no space at all for civil society representatives at the district level.
3. The Act is silent on the crucial issue of Patients' Human Rights and there is no grievance redressal mechanism for patients in case of major denial or violation of rights in a private hospital (for instance: a hospital not admitting or discharging a HIV positive person, or a hospital not giving x-ray or sonography films to the concerned patients, and so on).

What are the modifications needed in CEA 2010?

The following modifications are needed from the point of view of the patients

A. Clearly delineated structures for effective implementation

There should be a separate, autonomous Clinical Establishment Regulatory Authority, which should be an additional wing of the Health Department. This Authority would be on par with the Directorate of Health Services. The huge regulatory work can be performed satisfactorily only if such additional machinery is set up with designated mandate, staff and budget; and is headed by a person at the level of Director of Health Services, Director of NRHM, Commissioner, Employees State Insurance Scheme (ESIS).

B. Autonomous Appellate Bodies at state and district levels

The multi-stakeholder State Appellate Body should be a smaller, autonomous sub-committee consisting of some ex-officio members of the State Council, to be headed by a retired judge of the High Court. At the district level, this should be a compact, multi-stakeholder District Appellate

Body, headed by a retired judge of a district court. It would be separate from the Local Regulatory Authority entrusted with the task of day to day implementation and which would be headed by an experienced Public Health official not below the level of Assistant District Health Officer. He/she would be autonomous from the District Health Officer.

C. 'Charter of Patient's Rights' And Grievance Redressal should be part of the Minimum Process-Standards in CEA-2010

The basic objective of any clinical establishment has to be to serve the citizens/patients. The very process of opening up one's body and mind to the doctor, so necessary for proper diagnosis and treatment, inevitably places doctors in a position of power over the patient. Medical ethics demands that doctors should use this 'medical power' for patient's benefit. That is why medicine is regarded as a 'noble profession' and this is one of the key reasons for the adoption by doctors of the Hippocratic oath and of medical ethics in general. To effectively ensure the protection of patient's interests, there is the need to incorporate a Charter of Patient's Rights in the legally empowered regulation of Clinical Establishments.

This Charter of Patient's Rights shall include but would not be limited to, right of patients / attendants to the following -

- adequate relevant information about the nature of illness, proposed investigations and care, expected costs of treatment, possible complications.
- right to reasonable quality of care based on Standard Treatment Guidelines.
- access to case papers, patient records, investigation reports and detailed bill.
- informed consent prior to potentially hazardous tests/treatment (e.g. surgery, chemotherapy).
- second opinion from any clinician of patients choice.
- confidentiality, human dignity and privacy.
- presence of a female in case of physical examination of a female patient by a male practitioner.
- non-discrimination on the basis of HIV status.

- choosing the pharmacy or diagnostic centre/laboratory from which to avail services.
- choosing alternative treatment if option is available.
- seeking redressal in case of grievance.
- discharge summary, or in case of death, death summary.
- claiming body of deceased patient by the concerned relative without preconditions.
- compliance by clinical establishment with ICMR ethics guidelines in case of clinical research.

D. District and State Commission for patients

A Charter of Patient's Right will be of practical value only if there is a mechanism at district and state level in the form of District and State Commission to receive complaints from patients in this regard. The Consumer Protection Act provides financial compensation in certain instances. But if a hospital refuses to give reports of laboratory investigations or refuses to treat HIV positive patients or if the consent-form to be signed by the patient before undergoing surgery is unfair to the patients, a mechanism is needed for patient to seek corrective action.

There will have to be provision for Redressal of patients' complaints and problems. Relevant provisions from other countries can be adapted to suit Indian conditions. Some countries in the European Union have specific provisions for step wise process for settling such grievances.

5

Medicines for All?

Access to essential medicines is a major determinant of health outcomes and an integral, and often crucial, component of health care. It has been estimated by different sources that 50% to 80% of the Indian population is not able to access all the medicines that they need. The World Medicine Report of the World Health Organization finds that India is the country with largest number of people (649 million) without having access to essential medicines. Further, evidence suggests that over two-third of out-of-pocket expenses on health care are accounted for by expenditure on medicines (See Table B). Given that India today is the third largest producer of drugs (by volume) in the world and exports medicines to over 200 countries, this is clearly an unacceptable situation.

Several reports of Parliamentary Committees, the report of the High Level Expert Group (HLEG) and a number of observations and orders by different courts in India have recommended a range of necessary corrective measures. These include recommendations to make available medicines free of cost in all public health facilities, to effectively control the prices of all essential medicines, to ban all irrational and hazardous formulations, and to strictly regulate the conduct of clinical trials in the country. The Government, however, has responded by instituting policies and programmes which are designed to promote rampant profiteering and unethical practices by the pharmaceutical industry.

Betrayal regarding Free Medicines Scheme

In India over 80% of medicines are directly procured from retail chemists, thus forcing people to pay exorbitant prices charged by pharmaceutical companies. The most important reason for this situation is the non-availability of medicines in public health facilities in most parts of the country. In 2012, Prime Minister Manmohan Singh (in his Independence Day speech) announced a “free medicines” scheme, under which all essential medicines would be available at no cost in all public facilities. While initially proposed as a scheme that would be financed by the central government, the responsibility has now been passed on to state

governments. Insignificant progress has taken place in most parts of the country. 'Free medicines for all' programs in public facilities have been operational in some states for a long time, most notably through the Tamil Nadu Medical Services Corporation (TNMSC) and more recently in Kerala and Rajasthan. TNMSC, for example, procures only essential medicines in generic names, directly from manufacturers. This practice reduces wastage of resources on procurement of costly branded drugs and on irrational formulations.

JSA demands that these positive experiences be replicated in other states. In addition to improving access to medicines, they have helped develop transparent norms for drug procurement and distribution for public sector facilities. JSA also demands that the central government allocate a minimum of Rs.5,000-6,000 crores every year, which it had earlier proposed, to make this scheme operational in all parts of the country. The lack of political consensus in supporting free availability of medicines in government facilities is a matter of grave concern. This is exemplified by some recent developments in Rajasthan, where the free medicine scheme in operation is now being neglected as the newly elected BJP government sees this as a 'Congress scheme'!

Table B: Expenditure on Medicines as major component of out of pocket expenditure on health						
Quintiles	OOP Expenditure (INR)		Drug Expenditure (INR)		Drug as a share of OOP (%)	
	2004-05	2011-12	2004-05	2011-12	2004-05	2011-12
Poorest	12.2	40.2	9.6	28.5	73.3	72.0
2nd Poorest	22.4	64.3	17.0	44.5	69.5	69.9
Middle	32.8	91.9	24.4	62.9	68.9	69.0
2nd Richest	51.9	130.3	37.4	87.5	70.4	67.6
Richest	112.9	292.8	75.7	123.5	70.5	63.6
All	41.8	111.2	29.8	73.9	70.3	66.4

Source: National Sample Survey Organisation (NSSO), Consumer Expenditure Survey 2004-05 and 2011-12

Even with the rolling out of a comprehensive free medicines scheme in government facilities, in the short and perhaps even medium term, it is to be expected that a large number of people will continue to access health care from private facilities. Such patients will continue to be forced to purchase medicines directly from retail outlets. In addition to effective price control on medicines (discussed later) it is necessary that the government takes steps to set up generic drug outlets in all parts of the country, that sell drugs of assured quality at low cost. The Government's earlier Jan Aushadi scheme of opening such outlets was never pursued with any degree of seriousness – only around 100 outlets were actually opened all over the country. The experience from Chittorgarh district in Rajasthan, where the District Administration and the Health Department played a proactive role in setting up 'generic drug stores', needs to be noted. In the brief period that the initiative was operational, there was clear evidence that retail chemists charging high prices for branded drugs were finding it difficult to compete. A nationwide initiative to open generic drug stores in every municipal ward and gram panchayat needs to be accompanied by legislative and administrative measures to promote prescribing of drugs by their generic names.

Irrational Medicines

In India, an average family spends Rs.3,000 annually to buy medicines and on diagnostic investigations. It has been estimated that at least 50% of this expenditure is incurred on irrational or unnecessary drugs and diagnostic tests. This adds up to a colossal waste of Rs.30,000 - 40,000 crores every year, and amounts to an average unnecessary drain of Rs.1,500 per year for every family.

There are an estimated 60,000 to 1,00,000 brands of various drugs available in the Indian market while the essential drug list in India contains just 348 drugs. A majority of products in the market are either hazardous, or irrational or useless. The pharmaceutical companies and the government regulatory bodies – prominently the Central Drug Standards Control Organisation (CDSCO) is clearly to blame. Several reports have provided evidence of a corrupt nexus that exists between drug control authorities, drug companies and a few leading doctors.

The 59th Report of the Parliamentary Standing Committee of Health and Family Welfare, for example, has extensively documented this nexus.

The report documents clear evidence of doctors providing ‘expert’ opinion of a dubious nature in collusion with drug companies to allow the introduction of new drugs in the market. In January, 2013 the Union Health Ministry issued a directive ordering cancellation of licenses to manufacture drug formulations falling under purview of ‘New Drugs’, including fixed dose combinations (FDCs) as defined under Rule 122 (E) of the Drugs & Cosmetics Rules. As many as 1,105 combination drugs were covered by this order. It later transpired that the CDSCO had only provided verbal directives to state drug controllers, and as a result these drugs were never withdrawn from the market!

The collusion between a section of doctors and their associations, the drug control authorities and the industry needs to be probed and remedial measures need to be instituted. An absence of a functioning system for continuing medical education, combined with rampant unethical promotion of medicines, contributes to the situation of extreme anarchy in the medicines market. The Medical Council of India (MCI), tasked with the regulation of ethical practices in the medical profession, is itself plagued with corruption and inefficiency. The MCI was superseded by the Central Government in 2010, after the arrest of the MCI President, Ketan Parekh, on very serious charges of corruption. Yet, in 2013, after the MCI was again reconstituted, Ketan Parekh and many of his group of pliant and corrupt members are poised to make a comeback into the MCI. The JSA demands that a statutory code for ethical promotion of medicines be enforced and the MCI be revamped completely.

Medicine Pricing Policy

Since 1970, the government has attempted to regulate the prices of some drugs through successive Drug Price Control Orders (DPCOs). However, the number of drugs covered has come down from 342 in 1979 to 74 in the latest DPCO of 1995. After a Public Interest Litigation was filed by the All India Drug Action Network (AIDAN) and others in 2003, highlighting that high drug prices were a major cause for catastrophic medical expenses in the country, the Supreme Court issued a directive to expeditiously put in place a mechanism to control essential drug prices to affordable levels.

In response to the Supreme Court directive, the government has now introduced price control on 348 drugs listed as essential. Ceiling prices

of 371 formulations --based on the Essential Drug List (EDL) -- have been notified by the National Pharmaceutical Pricing Authority (NPPA). However, there will only be a marginal effect on the prices of essential drugs, because the new DPCO fixes ceiling prices based on an average of existing prices in the market (a departure from the earlier practice of fixing based on manufacturing cost). This methodology would largely reflect the price of the brand leaders, serving to legitimize the rampant overpricing of drugs today. Further, the new DPCO, only covers the exact dosage forms specified in the EDL, thus allowing a large number of formulations of essential drugs (including almost all their combination products) to stay outside price control. This (the new formula for price fixation) is nothing but a parting gift by the UPA government to the pharmaceutical companies. The JSA demands that all essential medicines be placed under price control and ceiling prices be fixed based on manufacturing costs of these medicines.

In a blatant distortion of truth the National Pharmaceutical Pricing Authority (NPPA) claims that price reduction will be to the tune of 40%. In fact, the new DPCO will affect less than 20% of the entire drug market (approximately Rs.11,200 crores against the total market of approximately Rs.75,000 crores). Within this 20% of the market that is now under price control, the average price reduction will be around 11%. This will have an effect of reducing drug prices of the entire market by less than 2%. This is a far cry from the spirit of the Supreme Court directive, which had ordered institution of measures that would lead to significant decrease in prices of drugs.

Vaccine Manufacture

Through a well-planned conspiracy, designed to benefit private vaccine manufacturers, three Public Sector Units engaged in vaccine manufacture were closed down in 2008. Subsequently a Parliamentary Committee observed that closure of these units was “ill-advised” and not based on “sound reasoning”. The committee further recommended that they should be reopened and this should be accompanied by infusion of adequate finances for their modernization. However, the Government has continued to starve these vaccine manufacturing units of necessary resources and these remain far removed from the earlier situation of being the leaders of vaccine production in the country. This has provided

an opportunity to private vaccine manufacturers to increase their market share enormously and this has also led to a steep increase in the prices of vaccines.

Work on a new vaccine manufacturing complex has been initiated in Chengalpattu, being established by HLL Life Care, a public sector company, at an estimated cost of Rs. 594 crores and the project is likely to be completed by 2014. HLL has also been entrusted with the task of revival of two other PSUs. The government has sanctioned Rs. 64.72 crore and Rs. 149.16 crore respectively for upgrading the BCG Vaccine Laboratory (BCGVL) in Guindy and the Pasteur Institute of India in Coonoor but work has not progressed beyond the stage of planning. The JSA demands that immediate steps be taken to revive vaccine manufacture in the public sector at a scale that is able to meet the requirements of the national immunization programme.

Multinational Companies poised to take over the Indian Drug Industry

The Government's policy of allowing 100% foreign direct investment (FDI) in pharmaceutical industry has become an instrument that promotes the acquisition of Indian companies and has led to a cumulative inflow of FDI to the tune of Rs. 45,516 crores in the last 12 years. This policy continues to be promoted in spite of a Parliamentary Committee recommendation for a ban on FDI in the pharmaceutical sector unless accompanied by infusion of new technology. Several Indian companies have been acquired in the past 6 years and a number of such acquisitions are on the anvil (See Table C). During the UPA regime multinational companies (MNCs) have increased their share of the Indian market from 24% to 30%. MNCs have not invested in increasing manufacturing capacity, but are engaged in increasing their market share through the capture of domestic companies. Another extremely disturbing trend in the drug industry is that de-industrialisation has increased at a frightening pace and many companies are dependent on imported bulk drugs. A continuation of these trends would take us to the pre-1970s situation when MNCs dominated the Indian market, charged exorbitant prices, were not involved in any domestic manufacturing and had made India entirely dependent on imports.

Table C: Acquisitions by MNCs and other Deals between MNCS and Indian Companies			
MNC	Indian Company	Deal Entered Into	Date
Daiichi Sankyo	Ranbaxy	Acquired	June 2008
Pfizer	Aurobindo	Contract Manufacturing	March 2009
Fresenius	Dabur	Acquired	April 2009
Pfizer	Claris Life Sciences	Contract Manufacturing	May 2009
GSK	Dr Reddy's	Partnership	June 2009
Mylan Labs	Biocon	Contract Manufacturing & Developing	June 2009
MNC	INDIAN	THE DEAL	FROM
Mylan Labs	Famy Care	15% stake	August 2009
SanofiPasteur	ShanthaBiotechnics	Controlling stake	August 2009
Hospira	Orchid Chemicals	Buyout of injectable antibiotics	Dec 2009
Pfizer	Strides	Collaboration	Jan 2010 & \ May 2010
Abbott	Nicholas Piramal	Takeover of healthcare business	May 2010
Litha Healthcare	NatcoPharma	Marketing of products	Sept 2011

Patents and Access to Medicines

The change in the Indian Patent Act in 2005 took away a valuable tool available with Indian companies. The health safeguards in the 2005 amendments to India's patent are being used to an extent to ensure continued access to new drugs. There have been several positive judgments pronounced recently that have made use of the health safeguards. These include the issuing of the first compulsory license (i.e. a license to an Indian company to produce a patented drug manufactured by a foreign company) for an anti-cancer drug (Sorafenib), reversal of the first drug patent since 2005 that had been issued for a drug for Hepatitis-C (peg-interferon), and the upholding of the refusal of patent for an anti-cancer drug (Gleevec) to Novartis.

In spite of these victories many new drugs are now being granted patents and are way out of the reach of almost all Indians (see Table D). Multinational corporations continue to try to challenge the positive parts of the Indian law. The JSA demands that the Government establish an institutional mechanism to monitor the impact of patented medicine on access to medicine and recommend suitable measures to ensure access.

Table D: Prices of some Patented Medicines			
Drug	Company	Treatment	Cost/month
Pegalyted interferon alfa 2-b	Merck	Hepatitis C	Rs.60,000
Raltegravir	Merck	HIV resistant to first line drugs	Rs.10,000
Dasatanib	BMS	Leukemia	Rs.160,000
Sunitinib	Pfizer	Renal cell Carcinoma, GI Stromal Tumour	Rs.1,75,000
Sorafenib*	Bayer	Hepatocellular Carcinoma	Rs.2,80,000

* Price of Sorafenib has now come down drastically after a compulsory license was issued in 2013.

Demands

- Medicines, vaccines and medical devices procured through a public system should be provided in free of cost in all government facilities.
- A nationwide initiative to open generic drug stores needs to be accompanied by legislative and administrative measures to promote prescribing of drugs by their generic names.
- All medicines should be covered by price control and the ceiling price must be based on production cost. The National List of Essential Medicines should be expanded and revised to include treatment for cancers and other diseases that are not adequately reflected in the present EDL.
- A National Pharmaceutical Authority, involving inter-ministerial co-ordination, should be formed to oversee public health issues in the context of medicines access and the production, regulation and research on medicines and vaccines.

- Production and sale of all irrational medicines should be banned immediately.
- No FDI should be permitted in pharmaceuticals unless accompanied by infusion of new technology.
- Public Sector Units to be expanded for production of essential medicines and vaccines.
- All public sector research institutes should be provided with adequate resources.

In addition to the specific demands listed in each of the sections above, JSA demands the following measures to ensure the right to health and healthcare for all:

1. Act on the Social Determinants of Health: This would include promotion of food security by universalisation and expansion of the Public Distribution System (to also provide local cereals, pulses and oil); a national policy on Child Health and nutrition and universalisation of Integrated Child Development Services (ICDS) with expansion of staff and services to effectively cover under-3 children; ensure universal availability of safe water in each village and habitation; and universal access to safe hygienic toilets in all habitations.
2. Address the Gender dimensions of Health through the various measures listed in the section above.
3. Immediately reverse Caste Based Discrimination: Take immediate and effective steps to entirely reverse all forms of caste based discrimination, which is one of the most important social determinants of ill health. Steps should be taken for an immediate ban on manual scavenging. In the health care sector, special measures should be instituted to promote priority access to discriminated sections of society.
4. Enact a Right to Health Act which assures universal access to good quality and comprehensive health care for the entire range of primary, secondary and tertiary services, and that makes denial or non-availability for reasons of access, affordability or quality a justiciable offence.
5. Eliminate the role of multi-lateral and bilateral financing agencies from all areas of technical assistance or health policy formulation. Eliminate the influence of agencies such as the World Bank, USAID and Gates

Foundation, as well as consultancy organizations such as Deloitte and McKinsey – in formulation of national priorities and approaches to health care provisioning and financing. Build international collaboration for generation and sharing of knowledge resources, especially with other developing countries. Exert pressure at the governmental level to free WHO, UNICEF and other UN agencies from dependence on corporate financing and influence. Critically examine the offer of advice and expertise from such agencies till such time as they continue to be influenced by corporations and private foundations.

6. Increase Public Expenditure on Health to 3.6% of GDP annually. All public health expenditure to be tax financed. Public health spending to be increased to 5% of GDP in medium term.
7. Training of Health workforce: Increase public investment in education and training of the entire range of health personnel. Ensure that government run colleges to train a range of health workers, nurses and doctors are located in areas where they are needed most. Training to be reoriented to impart skills that address the health needs of local communities. The trend of commercialization of higher education in medical and allied health sciences to be reversed, along with stringent mechanisms for regulation of existing private institutions in a transparent manner. The functioning of the Medical Council of India and the Nursing Council of India to be thoroughly scrutinized and revamped to weed out rampant corrupt and unethical practices in these institutions.
8. Build National and State level capacity for Health research and development: The government would invest at least 5% of its public health budget on health research including health systems research. The government, for the purpose of promoting health systems research and research for domestic priorities, would develop institutions and strengthen existing institutions that are financed through public funds.
9. Ensure access to treatment and care of persons with mental illness (PWMI) through integration of the revised District Mental Health Program with the National Health Mission. The rights of PWMI need to be protected by adoption of the Mental Health Act and action on the draft mental health policy.

6

Regulation of Clinical Trials and Ethics in Biomedical Research

In 2005, the Government of India made the patent regime of the country fully compliant with the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement of 1994, and thereafter changed its rules to promote clinical trials in India. The provision of phase lag in Schedule Y (1988) of the Drugs and Cosmetic Act was removed in the amendments of 2005. Along with this weakening of regulatory oversight, both the government and the industry promoted India as an attractive destination for clinical trials. It was projected by the industry that value of the clinical trial industry in India would reach US \$ 1 billion by 2016.

However, over the past few years, the issues of unethical trials and objectionable functioning of the Central Drugs Standards Control Organisation (CDSCO) have come to the fore. Two government committees have examined the conduct of clinical trials in the country: the 59th Parliamentary Standing Committee Report on the functioning of the Central Drugs Standard Control Organisation (May 2012) and the 72nd Parliamentary Standing Committee Report on the alleged irregularities in the conduct of studies using the Human Papilloma Virus (HPV) vaccine (August 2013). The former report begins by stating that the drug regulatory system in the country, including regulation of clinical trials, “suffers from several deficiencies and shortcomings, some systemic and several man-made”. There were also reports from the civil society on the issue of clinical trials. Together, these reports pointed to various serious problems in the conduct and regulation of clinical trials in India.

Responding to these, in 2013 the Supreme Court imposed a stay on clinical trials in country. At the same time there were amendments in the regulatory provisions on clinical trials, regarding informed consent, constitution of ethics committees and compensation. The industry is now claiming that these developments have slowed down the growth of industry. Though overall numbers of new applications for trials has declined over some duration, the claim that the industry has slowed

down and will continue to do so needs closer inspection. Firstly, the projections for the industry were too ambitious. The industry was not growing as per forecasts even prior to the recent regulatory changes. The overall decline in clinical trials in India should also be viewed in the context of the state of the world economy. Finally, almost all the clinical trials suspended after 2013 have been approved after a three-tier review. Thus, the 'industry slowdown' argument is an industry ploy to further weaken regulations. Exploiting opportunities for profits rather than transparency appears to be the driving force for this industry. Despite the strengthening of regulations, a lot of ground remains to be covered to ensure ethical conduct of trials and adequate protection of the clinical trial participants.

Key Issues and Gaps in the conduct and regulation of Clinical trials

1. Regulation of Contract Research Organizations (CROs): CROs are developing the infra-structure for clinical trials by making inroads into small towns, identifying trial sites in small private hospitals and preparing databases of potential subjects for clinical trials. There is no regulatory oversight on these organizations.
2. Targeting of Marginalized Populations: Trials are being conducted on vulnerable and marginalized populations. The unequal social context in which such trials are being conducted is enabling easy access of drug companies to such populations, indicating how conditions of inequality are facilitating a global proliferation of drug trials. There is an urgent need to safeguard the vulnerable populations from such clinical trials, which may not have any specific benefits for them.
3. Accountability of Ethics Committees: Even though Ethics Committees are getting registered, a mechanism for accreditation of these committees needs to be put in place. Most of the committee members are untrained and may not be competent to assess ethical and scientific issues related to clinical trials. There is also no clarity about the extent of their responsibility and their accountability. The current law in no way addresses the issue of the conflicts of interest amongst members of ethics committees. It should be ensured that the committees are qualified, and accountable and responsible for safeguarding the rights of the clinical trial participants.

4. Reporting, assessment of Adverse Events, their management in clinical trials: Reporting of adverse events is dismally low in post licensure studies and post marketing surveillance. Though it is expected that new guidelines may improve the reporting, it needs to be closely monitored for implementation. It should be ensured that the CDSCO monitor the conduct of clinical trials at the trial sites and permit trials only at those sites that are equipped to handle Serious Adverse Events (SAEs).
5. Issues of Transparency- Intellectual Property Rights and Data Exclusivity: Clinical trial data exclusivity sought by foreign companies can delay the introduction of generics and increase the cost of medicines. It is important to ensure that clinical trial related information and applications, protocols, informed consent forms, information about the sites of clinical trials, ethics review decisions, Adverse Events and follow-up actions, and both positive and negative outcomes are available in the public domain. No data exclusivity should be granted for clinical trial data.
6. There is no systematic regulation of trials under alternative systems of medicine such as Ayurveda and Homeopathy.

Demands

- In the regulatory framework specific provisions have to be made to protect the rights of trial participants, particularly those that are from marginalized and vulnerable sections. Issues of consent, ethical review, monitoring of adverse events etc. need to be specifically spelt out and detailed in any such law.
- The accountability and liability of multiple stakeholders, particularly ethics committees, principal investigators, sponsors and CROs need to be clearly laid down. Conflicts of interest of persons involved must be declared prior to beginning the trial.
- A charter of rights of clinical trial participants to be developed and made justiciable.
- Further clarity is required with regard to the reporting of adverse events, and their management and compensation. Fair compensation norms for trial participants who suffer from adverse events need to be expeditiously developed and implemented.

- Bio-equivalence and bio-availability (BA/BE) studies of all forms (for export of drugs) must be listed in the clinical trial registry of India. which is not stipulated under current rules.
- Mechanisms should be put in place to check the risky practice of participation in multiple trials; and to make it the responsibility of sponsors to ensure that vulnerable people are not exposed to multiple trials at the same time.
- Recently a formula has been devised to calculate compensation for the adverse event of deaths in the clinical trials. This formula does not cover other serious adverse events. Clear guidelines stipulating compensation for all adverse events during clinical trials need to be issued.
- There is also need to provide grievance redressal mechanism for appeal if there is disagreement regarding the compensation provided.

Public Services and Social Determinants of health

Healthcare system in India is in a pretty bad shape, owing to flawed public health policies implemented especially over last couple of decades after liberalisation of economy. This fact is compounded by even poor record of ensuring proper food security, drinking water availability, sanitation facilities, education, employment opportunities, and social security to all sections of the society. This has direct bearing on poor health outcomes for the population.

Child malnutrition

India is one of the highest ranking countries in the world for the number of children suffering from malnutrition. The prevalence of underweight children in India is among the highest in the world, and is nearly double that of Sub-Saharan Africa with dire consequences for mobility, mortality and productivity. Its matter of national shame and human rights violation.

The 2011 Global Hunger Index (GHI) Report ranked India 15th, amongst leading countries with hunger situation. It also places India amongst the three countries where the GHI between 1996 and 2011 went up from 22.9 to 23.7, while 78 out of the 81 developing countries studied, including Pakistan, Nepal, Bangladesh, Vietnam, Kenya, Nigeria, Myanmar, Uganda, Zimbabwe and Malawi, succeeded in improving hunger condition.

According to NFHS-3, in India - 48% children below 5 years age are stunted while 43% children are underweight. Stunting and underweight in India are 20 times as high as would be expected in a healthy, well-nourished population. Poor nutrition contributes to 54% of deaths of children below 5 years age. Compared with their better-fed peers, nutrition-deficient individuals are more likely to have infectious diseases such as pneumonia, tuberculosis, measles, diarrhea and malaria which lead to a higher mortality rate. In addition, nutrition-deficient individuals are less productive at work. Low productivity not only gives them low pay that traps them in a vicious circle of under-nutrition.

Nutritional problems in adults - 55% of women, 59% pregnant women and 24% men are suffering from anaemia. 36% females and 34% males in the age category of 15-49 years were found to be too thin, indicating malnourishment in adults too.

Nutrition and Food Security - Malnutrition itself is the result of several other determinants that have extended and extenuating lifetime impact on the health and wellbeing of women and their children. Even states with higher per capita income - Gujarat, Maharashtra, Andhra Pradesh and Karnataka – have high levels of food insecurity. Nutrition is a social determinant of health and is influenced by numerous other social determinants. Programme like ICDS and mid-day meal programmes for supplementary nutrition alone will not provide complete or lasting solutions.

As per one study, the concentration of nutrition-related morbidity follows a reverse age gradient, rendering the youngest up-to 3 years age most vulnerable for malnutrition (HLEG Report, 2011). But, ICDS programme concentrates on supplementary nutrition for age group 4 to 6 years. There is a need to focus adequately on nutrition of children up to age of 3 years. NFHS-3 report says that 72% of enumeration areas are covered by an anganwadi centers (AWC). Although ICDS coverage is fairly high, only 33% of children under age 6 years received any service from an AWC in the last one year while only 26% children got supplementary nutrition. Children of migrant families, those living on the streets, remote tribal villages etc. are minimally covered by the service. Thus, ICDS programme is marred by poor out-reach, exclusion and poor delivery.

Food Security Act - Amid this dismal situation, the Government of India has recently passed the Food Security Act 2013 to provide monthly 5 Kgs food grain to 67% population across India. Food Security Act is a welcome step for its increased coverage in terms of reaching out to almost double the number of families and near universal maternal entitlement. However, provisions for adequate food grain, pulses and oil etc. have not been included in the act. Current entitlement is much lower than the 35 Kgs per household recommended by the Supreme Court. It is a matter of concern that the conditions like cash transfers, mandatory ADHAR card and provision of GM foods are part of the Act. While the direct entry for contractors has been discouraged, commercial interests have

not been fully removed. Further, “force Majeure” relating to withdrawal of right in the time of natural calamities when people need food more than ever, continues in the statute book. Similarly, the section 18 of the Act allows for back door entry for direct benefit transfers as an alternative to the Public Distribution. This seems to be part of the larger trend, where the government is slowly abdicating its responsibility to provide basic services to its citizens. Cash does not guarantee food security to debt ridden poor families. The fixed cash transfer offers no protection from inflation and price fluctuations in the food market. Women, who control the kitchen, but not the cash, will be disempowered.

Sanitation - It is estimated by UNICEF that on an average, only 31 per cent of India’s population use improved sanitation. This proportion drops to meagre 21 per cent in rural India (2008). In comparison to countries such as Bangladesh and Brazil, where only seven per cent of the population defecates in the open, India has 638 million people defecating in the open; over 50 per cent of the population.

Water - It is estimated by UNICEF that 88 per cent of our population has access to drinking water from improved sources in 2008, as compared to 68 per cent in 1990. However, only a quarter the total population in India has drinking water on their premise. A study of urban poor communities in Mumbai found that water-related illnesses accounted for almost a third of all morbidity in the last year among adults, and almost two-thirds of all morbidity among children. Over last two decades, there are multiple attempts to privatize water sources and thus limiting right to access to drinking water.

Employment Guarantee and nature of employment - The Guarantee under MGNREGA is only for 100 days i.e. for less than 28% of the year. Interestingly, this 100 day guarantee is not per person, but per family. Assuming three able-bodied adult persons per family, employment is guaranteed to a person for only 9% of the year under MGNREGA! Further, under pressure from the large farmer lobby, fearing lower supply of cheap labour, EGS works are not started during the agricultural season. Additionally, MGNREGA discriminates against the urban unemployed, who have not been guaranteed any work at all. Besides that, there is lot of corruption and bureaucratism in the implementing this scheme, thus severely limiting its affectivity.

Globalisation and the concomitant casualisation of labour have resulted in the growth of informal economies that account for 93% of the Indian workforce. Migrant workers are among the poorest and most exploited, often performing unskilled and hazardous work. They face significant disease burdens including musculoskeletal injuries, chronic obstructive lung diseases, toxic chemical exposure and poisoning and noise-induced hearing loss (HLEG Report, 2011).

Education - The fact that people who are better educated have lower morbidity rates from the most common acute and chronic diseases is due in part to the fact that education level and educational achievement play a role in determining what sort of job or career one has, which in turn directly correlates with one's financial or socioeconomic status. India has the largest number of people in any country in the world without access to education. While close to 90 per cent children in the 6-11 age groups are formally enrolled in primary schools, nearly 40 per cent drop out at the primary stage. The enrolment ratios of Scheduled Caste (SC), Scheduled Tribe (ST) and Muslim children (especially girls) still remain far lower than the national average. Malnutrition, hunger and poor health remain core problems, which comprehensively affect attendance and performance in classes. The added burden of home chores and child labour influence a large number of children, especially girls, to drop out of school.

Demands

Education, health care, food security, domestic water and sanitation, employment security – these are all people's basic rights. Provision of these services and forms of social security is the undeniable responsibility of the state.

1. Free health care, education, water for domestic use and highly subsidised food security must be made available to all without any official demands to fulfill certain preconditions or present various kinds of 'cards'.
2. Currently taxation levels in developed countries are in the range of 25 to 50% of GDP, while in India this is only about 17% of GDP. Further the state is heavily subsidizing the corporate sector in various forms, and if such subsidies to the corporate sector are withdrawn,

this would make available substantial additional funds for the social sector. For example in 2012 – 13, tax waivers of 1,13,000 crores have been given to the corporate sector and rich sections of the population. Similarly, natural resources are being handed over to private companies at extremely discounted rates, for example during approval of contracts for exploiting coal resources to large companies, due to massive under-pricing there has been an estimated loss of 1.86 lakh crores to the public exchequer which would amount to about 2% of the GDP! Similarly today massively discounted sale of shares of public sector companies is being carried out by the government, leading to loss of public resources.

3. Ensure Universalization of Food Security benefits, PDS and ICDS- Though the central government has agreed to support for 4.7 crore (76.32%) people in rural areas of and 2.3 crore (45.34%) in urban areas, we demand that state governments should put in their own resources to universalize the PDS. The experience of targeting over the past few decades has shown that lakhs of genuine persons have been excluded from receiving benefits. Universalize ICDS with expansion of staff and services to effectively cover under-3 children.
4. No to Cash transfers in PDS and other food programmes; strengthen the present PDS and other systems. Make procurement and distribution local and decentralized. Include locally produced coarse grain like Jawari, bajara, Nachani etc. in PDS. Provide pulses and oil through PDS considering rampant malnutrition in the country.
5. Stop contractization and privatisation of mid-day meal, packed Take Home Ration, ICDS and PDS.
6. Take home ration in Anganwadi Centers should be produced in a decentralized manner keeping in mind local tastes and preferences.
7. Ensure universal availability of safe drinking water in each village and habitation; and universal access to safe hygienic toilets in all habitations. Remove the discrimination in the supply of water between rich and poor. Take immediate action against local goons and water mafias selling water illegally. Equitable norms must be adopted for water provision in urban and rural areas.

8. Provision of good quality education to all is a powerful means of reducing social inequities. Ensure free education for all upto 12th standards. Open more public schools, strengthen them and improve quality of education. Stop privatisation of schools.
9. Public systems providing social services must be internally democratised, with involvement of social sector employees in the decision making process linked with their capacity building. Decision making which is currently over-centralised and often prone to influence by the corporate and private sector, must be made more decentralised, transparent and accountable.
10. Ensure convergence across all social services at local level with integrated community based monitoring over them.

DEMANDS

1. Act on the Social Determinants of Health: This would include promotion of food security by universalisation and expansion of the Public Distribution System (to also provide local cereals, pulses and oil); a national policy on Child Health and nutrition and universalisation of ICDS with expansion of staff and services to effectively cover under-3 children; ensure universal availability of safe water in each village and habitation; and universal access to safe hygienic toilets in all habitations.
2. Immediately reverse Caste Based Discrimination: Take immediate and effective steps to entirely reverse all forms of caste based discrimination, which is one of the most important social determinants of ill health. Immediate ban on manual scavenging. In the health care sector, special measures to promote priority access to discriminated sections of society.
3. Enact a Right to Health Act which assures universal access to good quality and comprehensive health care for all the entire range of primary, secondary and tertiary services, and that makes denial or non-availability for reasons of access, affordability or quality a justiciable offence.
4. Absorb, over a period, existing publicly funded health insurance schemes (RSBY and different state health insurance schemes) into an expanded public health system publicly financed through general taxation. All entitlements available under these schemes would be made available through the public health system, suitably expanded and adequately resourced. This should include a comprehensive system for health care protection of unorganized and organized sector workers (providing primary, secondary and tertiary health care), linked with expansion and rejuvenation of the ESI.
5. Eliminate the role of multi-lateral and bilateral financing agencies from all areas of technical assistance or health policy formulation. Eliminate the influence of agencies -- such as the World Bank, USAID and Gates Foundation, as well as consultancy organizations such as Deloitte and McKinsey – in formulation of national priorities and approaches to health care provisioning and financing. Build international collaboration for generation and sharing of knowledge resources, especially with

other developing countries. Exert pressure at the governmental level to free WHO, UNICEF and other UN agencies from dependence on corporate financing and influence. Critically examine the offer of advice and expertise from such agencies till such time as they continue to be influenced by corporations and private foundations.

6. Build National and State level capacity for Health research and development: The government would invest at least 5% of its public health budget on health research including health systems research. The government, for the purpose of promoting health systems research and research for domestic priorities, would develop institutions and strengthen existing institutions that are financed through public funds.
7. Ensure access to treatment and care of persons with mental illness (PWMI) through integration of the revised District Mental Health Program with the National Health Mission. The rights of PWMI need to be protected by adoption of the Mental Health Act and action on the draft mental health policy.

The Jan Swasthya Abhiyan is the Indian circle of the People's Health Movement, a worldwide movement to establish health and equitable development as top priorities through comprehensive primary health care and action on the social determinants of health and consists of over 20 networks and 1000 organisations as well as a large number of individuals.

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