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"SPECIAL ISSUE ON HEALTH CARE"

IC Centre for Governance
NEW DELHI

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The Journal of Governance
IC Centre for Governance
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The IC Centre for Governance has been set up in with the objective of collective thinking and acting on important issues of governance. It believes that public governance is too serious a matter to be left entirely to the state and that the involvement of the Civil Society is not only desirable but also essential. The Centre seeks to strengthen the capacity of Civil Society and government for ensuring good governance.

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EDITORIAL

There are people who see the advantages in our population growth. They often compare our young population with millions joining the work force every year with the situation in China and its aging population and shrinking work force. Demographic dividend is often talked about while talking about the economic growth of India. But the demographic dividend will kick in only if our young population is healthy, well fed and well educated. This really means that we as a nation need to focus on health, education and nutrition of our citizens.

Unfortunately, the states which have the highest growth rate of population have the worst health indicators, malnutrition and most backward as far as education is concerned. These are the states where the young are joining the labour force in thousands every year and their unemployment levels are high. In contrast, States like Tamilnadu and Kerala have already reached the Total Fertility Rate (TFR) of 1.7, well below the replacement rate of 2.1, and have the least number of youth joining their labour force. Yet, they have the best health indicators, higher literacy rates, and comparatively better nutrition levels. Therefore, if demographic dividend has to become a reality, we will need to ensure that the most backward states of the country substantially improve their social development indicators.

Health unfortunately is not a stand- alone subject or sector and many other sectors/ subjects impinge on it and affect the impact of any initiative on the populace. If one looks at it holistically, proper nutrition and food security are as key for good health, as are sanitation and the availability of clean drinking water. Similarly, the essentiality of education to receive and utilize knowledge on public health management cannot be over emphasized, and from where I am sitting and writing this editorial in the pristine environment of the Kumaon hills, the importance of environment management and its impact on health, stands tall. Effective Health Governance therefore, requires close interaction and collaboration with a number of ministries and departments at both Central and State levels, and also with non-governmental

organizations, the private sector, and international organizations such as the WHO, UNICEF, the World Bank etc.

I have tried to cover many facets of health care governance in this Special Issue, but the subject is so vast that it has not been possible to include all the branches of the sector. Apart from the Allopathic System we have the indigenous systems of Ayurveda, Unnani, Siddha and Yoga and Homeopathy which are all recognized systems of medicine. Then the governance of health care involves a lot of regulatory functions also. It includes the regulation of drugs, cosmetics, vaccines, and medical devices. It includes the regulation of blood to ensure safe blood and its derivatives. It includes the regulation of medical education. It also includes the regulation and standardization of food. And then there is the unchartered area of the regulation of stem cell treatment and In Vitro Fertilisation (IVF) which does not exist in our country as yet but does so in several developed countries like the United Kingdom. I have tried to include some articles about these regulatory functions in this Special Issue, but it is nowhere close to full coverage.

I am very happy that such a large number of eminent and knowledgeable experts in this sector, both in the Government and outside, have so readily agreed to write on identified subjects. I am extremely grateful to them for sparing so much time to contribute to this Issue despite their busy schedules. I am also very grateful to the IC Centre for Governance for inviting me to be the Guest Editor for this Special Issue of their journal. I have enjoyed and cherished my three years in the Government of India as Health Secretary and these last few months have made me refocus on this important subject, and also touch base with a number of colleagues in the sector who have contributed enormously to addressing challenges and improving governance of the health sector. But, we are nowhere close to utopia and a lot of work remains to be done to be able to provide a satisfactory level of health coverage to our people, particularly the rural and the poor.

Naresh Dayal

Naresh Dayal

Key Issues in Health Care Governance

The governance of Health Care in India is a complex web of interplay between the Central Government and the State Governments, between government and non-governmental organisations, and between the public sector and the private sector. These players have different capabilities, potential, and may be even motivations, but these can be harnessed to build an effective health care system for the citizens of this country. The challenge is to understand the underlying complexities, the gaps in the existing system, the successes recorded, the potential role of different players, and to identify key priorities. This paper is an attempt in that direction and identifies six key areas to highlight, which need to be understood and addressed in order to achieve the goal of improved health care in the country.

The first key issue is that in our Constitution, Public Health and Sanitation, Hospitals and Dispensaries are listed as State subjects. This means that the primary responsibility for ensuring health care to the citizens is that of the State Government. It also gives the States exclusivity to legislate on these subjects. In case the Central Government wants to initiate legislation in national interest, it requires a resolution supported by at least two thirds of the members in the Rajya Sabha or a resolution from at least two State Houses of Legislature to enable it to introduce such a Bill in Parliament. After the Act is passed by Parliament, it needs to be adopted by each State legislature before it can be given effect to in that State. A recent example is the Clinical Establishments (Registration and Regulation) Act, 2010 that had been enacted by the Central Government after getting State Legislature resolutions from four States – Arunachal Pradesh, Himachal Pradesh, Mizoram, Sikkim and all Union Territories. But, to date, this Act has been adopted by only three States- Uttar Pradesh, Rajasthan and Jharkhand.

This was an important legislation which sought to lay down standards for all categories of clinical establishments, from a single doctor clinic to multi-speciality hospitals, both in the private and the public sector. This means that every time the Central Government wants to make any major country wide change in the public health system, the time required for the enactment and enforcement of law, can be anywhere from five or more years.

Being a State subject also means that all schemes or programmes which are funded by the Central Government have to be implemented through the State health machinery. The standards of governance vary widely among states and therefore, the states which are comparatively well governed have relatively better administered health machinery and vice versa. Over the years, since independence, some states have given more emphasis to health care and they have also managed to attract more Central funds for this sector. But many have neglected it and underfunded the sector, and as a result, their health machinery is weak and their health indicators also fairly dismal.

The National Rural Health Mission (NRHM) has sought to remedy this imbalance through a weighting system which gives more funds to the high focus states which have relatively poor health indicators, mostly the states in the central north Indian belt and the north eastern states. However absorption of this quantum of funds without an efficient health system is a problem. NRHM therefore sought to improve the management of health systems by providing managers, accountants and data managers at every level; by providing skilled human resources on contract and by providing multi-skill training to a wide range of health care providers right from ASHAs, ANMs, nurses to even MBBS doctors in PHCs and CHCs.

The second key issue in health care governance is the persistent public underfunding for health. Ever since India became independent, health has not been a priority for public funding, either in the Centre or in the States. That gave a weak public health system forcing the poor to spend their hard earned money for expensive private health care. Millions of people have fallen below the poverty line because of high out of pocket expenditures on health calamities and this is seen as one of the most important causes of impoverishment in India.

If we examine the comparative figures of public expenditure on health as a percent of GDP, India comes at the bottom and is categorized "Low human development" by the Human Development Report (UNDP). The comparative data of selected countries is given in Table I below.

TABLE – I : Public Expenditure on Health (% of GDP)

Country	**2005**	**2009**	**2010**
India	0.9	1.3	1.2
Malaysia	1.8	2.6	2.4
China	1.8	2.7	2.7
Thailand	2.3	3.1	2.9
Russian Federation	3.2	3.5	3.2
Brazil	3.3	3.8	4.2
South Africa	3.4	4.0	3.9
Norway	7.1	8.2	8.0
United States	6.7	8.4	9.5
United Kingdom	6.8	8.2	8.1

When the UPA–I Government came to power in 2004, its National Common Minimum Programme included the goal to increase public health expenditure to 2 to 3 per cent of the GDP within the next five years. In the right direction, the Government launched the National Rural Health Mission (NRHM) in June 2005 to completely revamp the rural public health care system. It was an ambitious programme in which the Central government had undertaken to spend a total sum of Rs. 1,51,169 crores from 2005-06 to 2011-12. Unfortunately, the rate of expansion of financing did not keep pace with expectations. The budget allocations started flagging from 2007-08 itself and gaps between the promised allocation in the Framework of Implementation of NRHM and the allocated budget became wider and wider as is apparent from the Table II below. If we look at the actual releases, the gap is even wider.

TABLE II - **Financing of NRHM**

(Rs. In Crores)

Year	Central Govt. NRHM Allocation as per Cabinet Approval	Actual Allocation	Actual Releases
2005-06	6500	6731	4434
2006-07	9500	9000	5774
2007-08	12350	10890	8509
2008-09	17290	11930	9625
2009-10	24206	12050	11470
2010-11	33884	13910	12871
2011-12	47439	18172	13878
Total	**151169**	**82683**	**66561**

Under the NRHM, apart from the Central Government's allocation of funds, the State Governments were also committed to increase their budgetary allocations for health. The MOUs signed by all the States with the Central Government under NRHM, included a pledge to increase their expenditures on health by 10 per cent every year. Most states have adhered to their pledge. According to the Report of the Working Group on National Rural Health Mission (NRHM) for the Twelfth Five Year Plan (2012-2017) Para 2.13,"Increase in states own health budget has gone up by more than 10 per cent in most of the States (including EAC states) post NRHM period."

This clearly demonstrates that while the States kept to their commitment of increased health funding, the Central Government failed in its commitment to provide the promised increases in the funding for NRHM. In the initial years, the Central Government expenditure on Health and Family Welfare increased to 2.05 % of total expenditure in 2007-2008 and to 2.09% in 2008-9 but then it declined to 2.00% in 2009-10 , to 1.98% in 2010-11 and further to 1.90% in 2011-12 (Source: Economic Survey 2012-13). The hypothesis is that the funds were diverted to populist schemes like MGNREGA which provides employment to the underemployed rural labour force but does not build any permanent assets and

diverts labour from productive agriculture to unproductive earthwork schemes. The budget for MGNREGA rose from Rs. 11300 crores in 2006-07 to Rs. 30000 crores in 2008-09, to Rs. 39100 crores in 2009-10 and to Rs. 40100 in 2010-11 (Source: MGNREGA Sameeksha 2006-12 website: www.nregs.nic.in). Considering that the expenditure in NRHM was predominantly focused on building new health sub-centres and PHCs and CHCs, etc. and contracting of doctors, nurses and paramedics, this choking of the promised financing of NRHM has had a very adverse effect on the programme. It has also meant that we are nowhere close to achieving the target of reaching 2 to 3 per cent of GDP for public health expenditure which was set by UPA I in 2004.

The third key issue is the role of Public Private Partnerships (PPP) in health care governance. The importance of such partnerships cannot be denied especially in a country where almost 80 per cent of health care is in the private sector. In fact, a large number of PPPs have been fostered under the NRHM. Many of them have been replicated in several states. For instance, the Chiranjeevi Yojana of Gujarat provides for safe deliveries done by private obstetricians in accredited private health facilities. The service providers were paid about Rs.1, 80,000 for 100 deliveries from NRHM. Another famous example which has been replicated in most states is the EMRI model of Andhra Pradesh for emergency health transportation. This scheme was started by the Satyam Foundation and achieved an average reach time for the ambulances of 14 minutes in urban areas and 21 minutes in rural areas. 95 per cent of the funds for the scheme were provided by NRHM and only 5 per cent of the expenses were borne by the NGO, basically for their top management executives. Another good example of successful PPPs is the boat clinics in riverine areas of Assam. These clinics were run by an NGO but paid for by NRHM. There are also examples of 16 PHCs in inaccessible areas of Arunachal Pradesh being run by NGOs – the Karuna Trust, VHAI, Prayas and also similar examples from Orissa and Assam. There are examples of sub-contracting of diagnostic services to private operators in rural areas in West Bengal and Bihar, also under the NRHM.

The lessons learnt from these successful examples of PPPs in the health sector is that such partnerships are very useful in providing skilled manpower in inaccessible areas or to provide specialised expertise which is not available with public health systems. PPPs are also the path to introduce exciting innovations both by the private sector and the NGOs in the public health system. However, the primary responsibility of ensuring a good public health system for its citizens lies with government. The private sector can definitely supplement the gaps in the public health system but cannot substitute the responsibility of the public exchequer to fund public health. The large infrastructure PPPs like in highways, ports, airports etc., are however, premised on financial partnerships with the private sector wherein, the government facilitates, and the private partner provides the major chunk of funding. This private investment, be it a Build-Operate-Transfer or a Build-Own-Operate model, comes backed with sound profit based economics. Unfortunately, the Planning Commission seems to think that PPPs in general can substitute expenditure by government, and a similar partnership can be fostered with the private sector in Health as well.

This takes us to the fourth key issue, which is the absence of an adequate and uniform public health system in urban areas. At least in the rural areas, there is a uniformly structured public health system, starting from a sub-centre through the PHCs and the CHCs to the District Hospitals, all over the country, which has allowed NRHM to build upon it and improve its efficiency. However, in the urban areas, spread over 430 cities with a population of 37.7 crores in 2011, the public health system is by and large, neither uniform nor adequate. These towns/cities are those which have a population of more than 1 lakh each and are not covered by NRHM. The district headquarters are served by a district hospital and bigger cities or state capitals are covered by state hospitals or state medical colleges. Most cities/ towns are therefore served by some basic secondary and tertiary health infrastructure but the infrastructure is missing at the primary level and below. Thanks to the continuing urban migration, this population is expected to further increase to 43.2 crores by 2021.Also

worth noting is that the urban population below poverty line (Tendulkar method) in India was estimated at 7.65 crores in 2011, which puts approximately 30% of the current urban population in the BPL category.

An important initiative to tackle the urban health issues was the launch of the Rashtriya Swasthaya Bima Yojna (RSBY), by the Ministry of Labour and Employment, Government of India, which provides health insurance coverage for Below Poverty Line (BPL) families. It is no doubt an excellent scheme which covers a BPL family up to five members for up to Rs. 30,000 for most diseases that require hospitalization. It even includes maternity benefits and covers both normal and caesarean deliveries. It allows the beneficiaries to go to their chosen empanelled private or public hospitals. However, there are a few problems with the RSBY. It does not cover outpatient treatment (OPD); the treatment costs for non-communicable diseases like cardiac diseases or cancer often go over Rs. 30,000; and lastly, there are increasing numbers of urban low middle class who are not covered in the BPL category but face impoverishment because of health emergencies.

What is therefore required is the introduction of public primary level health facilities roughly similar to PHCs. These Urban Primary Health Centres would basically provide outpatient services and also provide preventive health services such as immunization services. Currently the secondary and tertiary public hospitals are flooded with outpatients. Case in point is the AIIMS which is the apex public tertiary hospital and medical college of the Central Government but is flooded by outpatients. Outreach community services can also be attached to the Urban Primary Health Centres.

The Ministry of Health and Family Welfare has been proposing an Urban Health Mission for a long time but unfortunately the Planning Commission has been opposing it. Its view is that there are adequate private doctors and health facilities in the cities and the urban poor can be covered through health insurance and PPPs. As we have seen, the RSBY does cover the BPL families but not fully. Public primary health centre are required to give outdoor health care and preventive services to the urban poor, including the BPL. Additionally, the secondary and tertiary public hospitals

need to be strengthened to provide health care coverage to the urban poor, including BPL if they exceed the coverage provided by RSBY. The Planning Commission has aimed to address these critical gaps by including the Urban Health Mission inside the NRHM, providing a token outlay for it and combining the Rural and Urban Health Missions into one. This strategy is highly questionable as it will only divert the scarce resources from NRHM and further destroy a good rural health program without adequately addressing the urban health issues at hand. Without doubt, the Government needs to provide adequate funds to strengthen the urban public health infrastructure as an addition to what is provided for NRHM.

The fifth key issue is the need to revamp the Universal Immunization Programme (UIP). India's UIP targets 2.7 crores infants and 3.0 crores pregnant women every year. It needs about 100 million doses of vaccines annually and is the largest immunization programme in the world. Although its coverage has been low earlier, it has improved recently after the launching of the NRHM. The Coverage Evaluation Survey (CES) done by UNICEF assessed it at 61% in 2009. NRHM is also strengthening the service delivery of the UIP by expanding and modernising the cold chain, by inducting alternate vaccine delivery systems and additional/alternate vaccinators and by providing auto-disposable syringes to ensure injection safety. The reporting and monitoring have also improved and the system of monitoring Adverse Events Following Immunization (AEFI) has been completely revamped. The UIP is fully funded by the Central Government. The success of the programme to eradicate Polio has shown how remarkable results can be achieved with sustained hard work and perseverance. When in 2008 most of the foreign donors which had hitherto supported this programme suddenly withdrew their support, it was the then Finance Minister, P. Chidambaram who rescued the campaign by giving the required funds for the continuation of the herculean effort.

However, the UIP needs to introduce new vaccines. The process of taking a decision to introduce new vaccines in the UIP is very cumbersome. A group of experts known as the National Technical Advisory Group on Immunization (NTAGI) was established in 2001. This group meets annually to discuss the technical and policy issues and advise the Ministry about

the introduction of new vaccines. The recommendations are then operationalized by the Ministry. However the lack of availability of domestic burden data often delays the introduction of vaccines which have been introduced in most of the developing countries with help of WHO and UNICEF and the irony is that they are largely sourced from private Indian manufacturers.

The NTAGI had recommended in 2008 to introduce the Pentavalent Vaccine (DPT+Hepatitis B+Hib) in 5 states in the first phase followed by another 5 states in the second phase. There were 85 countries that were using this vaccine. The GAVI Alliance had agreed to supply most of the vaccine required initially. But it has been introduced in 2 states only as yet. The expansion of the programme to other states has been thwarted by some misguided persons who even went to the Supreme Court in a PIL. The NTAGI had also recommended in 2008 the introduction of the Measles – Rubella (MR) vaccine as a second opportunity for immunization against measles, with DPT booster in 18 states which have achieved and sustained 80% or more coverage for measles immunization (MCV1). This has also not been introduced as yet. Further, another recommendation of NTAGI in 2008 was that there was sufficient pneumococcal disease burden in India to warrant introduction of Pneumococcal Conjugate Vaccine in the routine UIP. The NTAGI had finally recommended the introduction of this vaccine in one high mortality state with adequate cold chain space as a pilot study. It was said that the vaccine should cover at least 70% of the stereotypes that cause invasive pneumococcal disease in India. What was available then was a 7-valent vaccine. What is available now in the private market in India is a 13 or 23-valent vaccine which covers more than 75% of the stereotypes in India. However this pilot study has not even started as yet. Another crucial vaccine which is a candidate for introduction in the UIP is the Rotavirus vaccine. This is crucial for saving thousands of deaths of children from diarrhoea diseases. Although the vaccine is being used in most of the developed countries, and is available in the private market in India, we have been so far waiting for the development of an indigenous Rotavirus vaccine. This has been announced recently and it can be hoped that it will be commercialized quickly and introduced in the UIP.

India lags behind most of the world as far as the introduction of new vaccines is concerned. In such a large programme certain adverse effects are bound to happen. As long as we have a robust AEFI system which rigourously follows every AEFI resulting in death and confirms whether it is associated with the vaccine or is due to operational mistakes, it should not scare us from introducing new vaccines. These vaccines are recommended by WHO and are already being used in mass immunization programmes in the majority of developed and developing countries. What is more, they are available in our own market and are being used by the rich. They are even recommended by the Indian Academy of Paediatrics. So we are only denying these vaccines to the poor by not introducing them in the UIP. This is a crucial preventive health programme which should continue to be fully funded by government.

The sixth and last key issue is the paucity of Health Human Resources in the country. There is a big shortage of doctors, especially specialists, nurses and paramedics. There is a big demand, but the supply is lagging far behind. Although the rules have been amended recently to facilitate the setting up of more medical colleges, it is still very difficult to do so. It is a sort of a "chicken and egg" story. You need to have at least a 300 bedded hospital with at least 80% occupancy before you can start admitting students. Also you need to have the full complement of faculty and hostels. There is a dearth of faculty in India. No good teaching faculty would agree to shift to a new medical college which does not have a running hospital. What you get at most places is a "Munnabhai MBBS" type of situation. When the MCI team goes to inspect the facilities, villagers are brought in bus loads to fill the hospital and the faculty is flown in from elsewhere to fill the garb of their faculty. And when a surprise inspection is done, they are all absent!

Despite shortages of practising doctors and teaching faculty, we do not allow non-citizens to practise medicine or teach in our colleges by rule. Our doctors and nurses go abroad and work in developed countries in large numbers but we do not allow doctors who are foreign citizens to work in India. What has happened to reciprocity? Until recently we did not even recognise foreign medical degrees. A large number of our doctors go to get their specialised degrees in

the developed world, but their degrees were not recognised. It is only recently, that degrees from USA, UK, Canada and Australia have been grudgingly allowed to be recognised. This was expected to be a precursor to recognising other foreign degrees from developed countries which have an evolved system of regulation of medical education. But there has been little progress in this. Looking at the gross shortage of teaching doctors we ought to seriously consider allowing foreign faculty and foreign specialised degree holders to meet the demand for faculty, as also doctors.

One obvious solution to the problem is having more medical colleges attached to government hospitals, and this is being done at some places. Most government hospitals have more than 300 beds and they can have medical colleges attached to them. For example, medical colleges were started with the Safdarjung Hospital and the Ram Manohar Lohia Hospital in Delhi by the Central Government. The Ministry of Labour and Employment is also setting up medical colleges attached to their EPF hospitals. This example can be followed by the Railways, the Defence Ministry and the State Governments. Ideally, every district should have a medical college and a nursing college. The practising doctors in these hospitals can be given teaching designations as has been done in Safdarjung Hospital and the RML Hospital. This will make medical education more inexpensive by comparison. Medical students have clearly demonstrated a preference to go to government medical colleges because they cost less compared to private medical colleges. As it is,medical education is prolonged over 6 years for a bachelor degree and another 5 or so years for a specialised degree.The interns and the residents also prefer to do their internship in government medical colleges because they get hands on experience on a variety of patients. Therefore, this is another area where governments, both Central and the State, need to substantially raise their financing. The subject of HR in health is a vast and important subject and I have touched upon it only briefly, as I expect it to be dealt with comprehensively in another paper.

It is absolutely necessary for the Government to enhance outlays and allocations to build and sustain the public health care infrastructure. Whether it be the revamping of the rural health sub-centres, the PHCs and the CHCs, whether it be the strengthening of the secondary and tertiary urban health

facilities and setting up the primary urban health centres, whether it be the expanding and strengthening of the Universal Immunization Programme, or whether it be the setting up of more medical colleges, it will all need a quantum jump in public expenditure by the Government. It is not to suggest we match the developed economies like Norway and USA which are spending 8 to 9.5 % of their GDP in public health care, but can't we even match Malaysia or Thailand if not Brazil or South Africa? The target set by the UPA–I Government in 2004 to increase the public health expenditure to 2 to 3% of GDP was absolutely correct, and if they had achieved even close to it, by now we may have been touching the level of 4% of GDP rather than being stuck at 1.2%. Whatever populist schemes are sought to be implemented, they should not be at the cost of the health care system for the common man, because even if such schemes manage to pull people above the poverty line, it will take only one health emergency in the family to push them back below it. After more than 65 years of independence, is it too much to expect the Government to try to eliminate one of the biggest causes of pauperism in the country?

Surinder Singh

Regulation of Drugs, Vaccines and Clinical Trials in India – The systemic changes initiated

Introduction

Indian pharmaceutical industry is one of the fastest growing sectors of the Indian economy and has made rapid strides over the years. From being mainly an import oriented industry before independence, the pharmaceutical industry in India has achieved self-sufficiency and gained global recognition as a producer of affordable high quality bulk drugs and formulations. Having proved its mettle in the international market, India is now poised to become destination for Drugs Discovery and Development. Presently, Indian Pharmaceutical Sector is the 3rd largest in the world by volume and 13th in value. The difference between the volume and value of this market is due to the fact that there is strong state-imposed price control, so as to enable wider access to medicine at affordable price. The industry is growing at the rate of 14% per annum and is presently about Rs. 1,26,000 crore out of which exports account for Rs.63,000 crore. Drugs from India are exported to more than 200 countries and vaccines are exported to more than 150 countries. There are about 10,000 drug manufacturing units in the country and about 8 lac sale outlets.

Drugs are one of the most vital component of Public Health Care and they account for substantial part of household expenditure. A staggering 78% of health expenditure in India is out of pocket – one of the highest out of pocket procurement numbers in the world – and 72% of this is spent on drugs. This becomes all the more ominous, if the drugs are not conforming to the prescribed quality standards. Poor quality medicines

may affect health directly and pose a danger to individual patients and to public health. They also have economic and social consequences including direct costs of additional treatment and indirect social costs of lost confidence in the public health system and the government. Increasing public attention and expectations on medicines safety also shape the regulations and warrant a very strong regulatory oversight on this sector.

It is essential to ensure that the drugs available to the public are safe, efficacious and conform to prescribed quality standards. Drugs are in the concurrent list of the constitution and are regulated both by Centre and States Drugs Regulatory Authorities under the Drugs and Cosmetics Act, 1940 and Rules, 1945 [1] as amended from time to time. The Central Government regulates import of drugs, permission to import and manufacture of new drugs in the country, clinical trials, banning of drugs, and laying down rules and regulations under the Drugs and Cosmetics Act and Rules, through Central Drugs Standard Control Organization (CDSCO). The State Governments through their respective Drug Control Authorities regulate manufacture, distribution and sale of drugs, through a system of inspection and licensing.

Schedule Y of Drugs and Cosmetics Rules deals with rules and regulations applicable to the conduct of Clinical trials. The Indian Good Clinical Practices (GCP) [2] and the Indian Council of Medical Research, Ethical Guidelines for Biomedical Research on Human Participants [3] laid down standards and norms for the conduct of Clinical Trials.

Medical devices are also regulated as drugs under the Drugs and Cosmetics Act 1940 and Rules 1945 and presently only those Medical Devices that are notified by Central Government are regulated. These medical devices include Disposable Hypodermic Syringes, Disposable Hypodermic Needles, Disposable Perfusion Set, In vitro Diagnostic Devices for HIV, HBsAg and HCV, Cardiac Stents, Drug Eluting Stents, Catheters, Intra Ocular Lenses, I.V. Cannulas, Bone Cements, Heart Valves, Scalp Vein Set, Orthopaedic Implants and Internal Prosthetic Replacements which have been notified by the Govt. of India from time to time. The last one decade has thrown up number of challenges to the country's drug

regulatory system due to burgeoning growth of Indian Pharma Industry, including Clinical Trials, technological developments and introduction of new therapies. In respect of Clinical Trials, concerns have been raised from time to time about trial designs, the manner in which informed consent is taken with the subjects not fully understanding the implications of participation in Clinical Trials due to illiteracy, language and cultural barriers and issues of compensation in case of injury or death . There have also been concerns expressed in respect of quality of drugs, medical devices, pharmacovigilance and overall capacity of drug regulatory framework in centre and states, to address these issues. The gaps in the Drugs Regulatory System in the country may be attributed to inadequate or weak drug control infrastructure, inadequate drug testing facilities, non-uniformity of enforcement of law and regulation, lack of training to regulatory officials, lack of data base and inadequate IT services.

Systemic Changes Initiated to Strengthen Drugs Regulatory System

Drug Regulation in India is a dynamic process and continuously evolves with the changing times, in order to cover all the areas of pharmaceutical activities so that there is no scope for any regulatory gap, which may have a bearing on the Quality, Safety, Efficacy of the Drugs and protection of health and rights of the subjects participating in the Clinical Trials. Drug Laws provide the basis for drug regulations, regulatory tools such as standards, guidance documents, SOPs and guidelines, equip the regulatory authorities in implementation of the relevant laws in a uniform harmonised manner. Further, to usher transparency in the entire regulatory process these laws are made public to build public confidence.

A series of capacity building initiatives have been taken to strengthen drug regulatory system [4], in tandem with changing national and international regulatory environment with respect to:

1. Amendments to Drugs and Cosmetics Act and Rules
2. Manpower

3. Infrastructure
4. Training
5. Vaccines
6. Clinical trials
7. Other Initiatives

1. Amendments to Drugs and Cosmetics Act and Rules:

A. Drugs

i. The Drugs and Cosmetics Act, 1940 was amended by the Drugs and Cosmetics (Amendment) Act 2008, to provide for more stringent penalties for manufacture and trade of spurious and adulterated drugs. Certain offences have also been made cognizable and non-bailable. It also enabled setting up of special designated courts for speedy disposal of such offences. Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs and Cosmetics (Amendment) Act, 2008 have been prepared for uniform implementation by the State Drugs Controllers.

B. Further, under this amendment, a new provision(Section 26 B) was incorporated to regulate or restrict, manufacture etc of drug in public interest in case of an emergency arising due to epidemic and natural calamities.

ii. Good Laboratories Practices (GLP) were notified under Schedule L-1 w.e.f 1.11.2010.

B. Cosmetics

A system of registration of import of cosmetics has been introduced w.e.f 1.04.2013.

C. Medical Devices

i. In 2005, 10 medical devices have been notified as Drugs under section 3b (iv) of Drugs and CosmeticsAct.

ii. Schedule 'M' in Drugs and Cosmetics Rules which prescribes Good Manufacturing Practices (GMP) to be followed in the manufacturing site to assure consistency in the quality of the product, was amended and made mandatory for new

units w.e.f. from 1st January 2001 and for existing units from 1st July 2005.

D. Clinical Trials

i. Schedule Y in Drugs and Cosmetics Rules which prescribes requirements and guidelines for approval of new drugs and clinical trials was amended w.e.f. 20th January 2005.

ii. In year 2013, three amendments in Drugs and Cosmetics Rules related to clinical trial regulations have been made which are as under:

A. First amendment w.e.f 30.1.2013 specifies procedures to analyse the reports of Serious Adverse Events occurring during clinical trials and procedures for payment of compensation in case of trial related injury or death as per prescribed timelines and other related provisions as under:

(a) As per the Rule in the event of injury of the trial subject, he/she shall be provided free medical management by the sponsor or his representative as long as required.

(b) In the event of injury or death due to following reasons which are considered as clinical trial related injury or death, the Sponsor or his representatives shall provide financial compensation for the injury or death:

i. Adverse effect of investigational product(s)'

ii. Violation of the approved protocol, scientific misconduct or negligence by the sponsor or his representative or the investigator;

iii. Failure of investigational product to provide intended therapeutic effect;

iv. Use of placebo in a placebo-controlled trial;

v. Adverse effects due to concomitant medication excluding standard care, necessitated as part of approved protocol;

vi. For injury to a child in-utero because of the participation of parent in clinical trial;

vii. Any clinical trial procedures involved in the study.

(c) Expansion of responsibilities of Sponsor, Investigator and Ethics Committees to ensure that the report of Serious Adverse Events (SAEs) including deaths are reported, analysed within the prescribed timelines and in case of clinical trial related injury or death compensation are paid as per the prescribed procedures.

(d) Insertion of definition of Serious Adverse Events (SAEs) and detailed procedures for reporting and examination of such events, in Schedule 'Y'.

(e) The check list for study subjects' informed consent documents have been amended to include statements describing that in the event of injury of the trial subject, he/she shall be provided free medical management as long as required and in the event of clinical trial related injury or death, the Sponsor or his representative shall provide financial compensation for the injury or death(f) The Format of Informed Consent Form for clinical trial subjects have been amended to capture the information relating to address, qualification, occupation, annual income of the subject and name and address of his nominee (for the purpose of compensation in case of trial related death). It has also been made mandatory for the investigator to hand over a copy of the patient information sheet and duly filled Informed Consent Form to the subject or his/her attendant.

(g) Insertion of a separate Appendix XII related to compensation in case of injury or death during clinical trials in Schedule 'Y'. The Appendix prescribes the detailed procedures for examination of Serious Adverse Event (SAE) reports including deaths and payment of financial compensation in case of trial related injury or death as per the prescribed timelines.

As per the procedures

I. Investigator shall report all Serious Adverse Events (SAEs) to the DCG (I), Sponsor or his representative and the Ethics Committee within 24 hours of their occurrence.

II. In case of death, an independent Expert Committee constituted by DCG (I) shall examine the case and give recommendations to DCG (I) to determine the cause of death and also to decide the quantum of compensation, in case of clinical trial related death. The Expert Committee, while examining the event may take into consideration, the reports of the Investigator, the Sponsor or his representative and the Ethics Committee. DCG (I) after considering the recommendations of the Expert Committee shall determine the cause of death and decide quantum of compensation to be paid by the sponsor or his representative in case of trial related deaths within three months of receiving the report of SAE of death.

III. In case of Serious Adverse Events (SAEs) other than death, the DCG (I), after considering the reports of the Investigator, the Sponsor and the Ethics Committee, shall determine the cause of injury and also decide the quantum of compensation to be paid by the Sponsor or his representative in case of clinical trial related injury within three months of receiving the report.

B. Second amendment w.e.f 2.2.2013 specifies various conditions for conduct of clinical trials, authority for conducting clinical trial inspections and actions in case of non-compliance as under:

i. Clinical trial shall be conducted in compliance with the approved protocols, requirements of Schedule Y, Good Clinical Practice Guidelines for conduct of clinical trials in India and other applicable regulations;

ii. Approval of the Ethics Committee shall be obtained before initiation for the study;

iii. Clinical trial shall be registered at Clinical Trials Registry of India before enrolling the first patient for the study;

iv. The Sponsor and his representative and clinical trial sites and the Investigator shall allow officers authorized by CDSCO, who may be accompanied by an officer of the State Drug Control Authority concerned, to enter with or without prior notice into their premises and clinical trial sites to inspect, search and seize any record, data, document, books, investigational drugs, etc.

v. In case of non-compliance to the provisions of clinical trials by any Sponsor including the representative, investigators conducting clinical trial and clinical trial sites, DCG (I) can take following actions:

(a) Recommend that study may be rejected or discontinued

(b) Suspend or cancel the clinical trial permission;

(c) Debar the Investigator(s), Sponsor including his representative to conduct any clinical trial in future.

c. Third amendment w.e.f 8.2.2013 specifies requirements and guidelines for registration of Ethics Committee as under:

i. No Ethics Committee Shall review and accord its approval to a clinical trial protocol without prior registration with DCG (I).

ii. An application for registration of Ethics Committee is required to be made to DCG (I) along with detailed information about the committee as per Appendix VIII of Schedule Y which include the Authority under which the committee has been constituted, details of qualification etc of chairman and the members, procedures for replacement or removal of members, maintenance of records, standard operating procedures (SOPs) to be followed by the committee for various activities like policy regarding training of members, prevention of conflict of interest, procedures for vulnerable population etc.

iii. DCG(I) after being satisfied that requirements have been complied with, may grant registration to the Ethics Committee.

iv. The Ethics Committee shall review and accord its approval to a clinical trial and also carry ongoing review of the trial at appropriate intervals, as specified in Schedule Y and the Good Clinical Practice Guidelines for Clinical Trials in India and other applicable regulatory requirements for safeguarding the rights, safety and well-being of the trial subjects.

v. In the case of any serious adverse event occurring to the clinical trial subjects during the clinical trial, the Ethics Committee shall analyse and forward its opinion as per procedures specified under Appendix XII of Schedule Y.

vi. The Ethics Committee shall allow officials authorized by the DCG (I) to inspect their facilities, records, documents etc.

vii. The registration of an Ethics Committee shall be valid for a period of three years from the date of issue. If the Ethics Committee fails to comply with any of the conditions of registration, DCG (I) may suspend or cancel the registration of the Ethics Committee.

Manpower

CDSCO was facing an extreme manpower crunch in early 2008, with only 64 personnel in position against sanctioned posts of 111, while the work load was increasing at an average of 15 to 20%. With the initiatives taken during this period by the Central Government, 216 additional posts in various categories were created in the year 2008-09, raising CDSCO sanctioned strength to 327 which included 169 posts of Drugs Inspectors. Further, to tide over the immediate exigency of the work load, additional 234 contractual staff was sanctioned by the Government to enable CDSCO in discharging its regulatory duties. Many States have also similarly taken initiatives to strengthen their manpower.

Infrastructure

CDSCO Headquarter due to space constraint was shifted in May 2008, from its earlier location in Nirman Bhawan, New Delhi to an independent building christened Food Drugs Administration (FDA) Bhawan , New Delhi. In 2008, CDSCO

had four zonal offices at Mumbai, Ghaziabad, Chennai and Kolkata. In 2010, two of its Sub-Zonal offices located in Hyderabad and Ahmedabad were upgraded to Zonal offices, thus taking the total number of zones to six. Further, four new Sub-Zonal offices were set up at Bangalore, Chandigarh, Jammu and Goa.

Zonal offices at Mumbai and Hyderabad were shifted to new state of art buildings in 2010 and 2011 respectively. These buildings provided adequate space for not only Zonal Offices but also for training centres, conference rooms and Drugs Testing laboratories.

A Pharma Zone for providing dedicated areas for handling, storage and sampling of drugs meant for export / import has been setup at Hyderabad air port. Initiatives have also been taken to set up similar Pharma Zones at Delhi and other ports.

Testing capacities of the existing Central Drugs Testing Laboratories at Kolkata, Mumbai, Chennai and Kasauli and that of Regional Drugs Testing Laboratory Guwahati have been augmented, besides New Drug Testing Laboratories have been set up at Chandigarh and Hyderabad.

Training

Regular training is important for drug regulators to update their knowledge and to enhance their skills on various regulatory activities. CDSCO and NIPER – Chandigarh, under World Bank Assisted capacity building project during the period 2004-2008, jointly organised training programmes for personnel from Central and State regulatory departments, small-scale industry and private laboratories, with an objective of up-gradation of their knowledge/expertise. About two thousand six hundred personnel were trained on Good Manufacturing Practices, Good Laboratory Practices, Drugs Regulation and inforcement, Common Technical Document, Risk Analysis and hands on training on various sophisticated Analytical Instruments during these five years.

In addition, training was also imparted to central and state drug officials in collaboration with various international agencies like WHO, Health Canada, USFDA, in the areas of Vaccines, Clinical Trials and Medical Devices.

Vaccines

WHO in the year 2007 had conducted a National Regulatory Authority (NRA) assessment of CDSCO in respect of Regulatory Control over vaccines manufactured in the country. CDSCO did not meet the WHO assessment criteria and from January 2008 onwards WHO stopped accepting new applications from the Indian Vaccines Manufacturers, who intended to apply for WHO Pre-qualification of their vaccines for global supplies by UN agencies. Ministry of Health and Family Welfare, Government of India in collaboration with WHO and Health Canada, took the initiative beginning from March 2008 for strengthening the Biological Division of CDSCO . A capacity building exercise was undertaken in collaboration with WHO to impart training to CDSCO officials in respect of dossier review , documentation, Quality Management System, Regulatory inspections etc. Common Technical Document (CTD) format for filing the applications by Vaccines manufactures was introduced for the first time. This documentation system for filing application is in accordance with International Conference on Harmonisation (ICH) guidelines and enabled CDSCO to harmonize its documentation procedures with the international Regulatory norms. Further guidelines, guidance documents, Standard Operative Procedures and checklists for all critical functions of dossier review were introduced in the Biological Division of CDSCO.

CDSCO in April, 2009, qualified the WHO follow up NRA assessment in all the critical indicators. This assessment was conducted by 13 WHO Auditors drawn from National Regulatory Agency of USA, France, Belgium, Thailand, Senegal and WHO Headquarters-Geneva. Further, WHO-NRA re-assessment of CDSCO was done in December 2012 by a team of 19 auditors drawn from National Drug Regulatory Agencies of other countries and WHO, HQ, Geneva. CDSCO has once again qualified the WHO audit and has been declared as Functional NRA.

6. Clinical Trials

Clinical trials are required to be carried out in accordance with requirements and guidelines specified in Rule122DA,

122DAA, 122DB, 122E and Schedule Y of Drugs and Cosmetic Rules,1945.The said rules also provide specific application forms and relevant document requirements for seeking permission to conduct Clinical Trials. As per rule 122 DA of Drugs and Cosmetic Rules, 1945, no clinical trial of a new drug can be conducted in the country without permission from the DCGI. Registration of clinical trials [5] in Indian Council of Medical Research (ICMR) Clinical Trial Registry www.ctri.in. [6], has been made mandatory from June 2009, so as to provide all the relevant and necessary information on the web site to make the decision making transparent.

7. Other initiatives to strengthen regulations

- **Guidance Documents** were prepared and uploaded on CDSCO website [7] for information of the stakeholders for various regulatory activities like :
  - New Drugs approval
  - Clinical trials
  - Import registrations,
  - Biological including Vaccines
  - Medical devices
- **12 New Drugs Advisory Committees** in year 2011 were constituted to examine and give their expert advice on the applications for grant of permissions for clinical trials and approval of New Drugs including fixed dose combinations.
- **Overseas Regulatory Inspections** to monitor the quality of bulk drugs and formulations imported into the country were initiated for the first time in May, 2011 by CDSCO. The inspection teams went to China in this regard in May 2011 and February 2012.
- **National List of Essential Medicines (NLEM)** containing 348 drugs was prepared in the year 2011 to promote rational use of medicines in the country. NLEM is used by hospitals, medical institutions as well as Central and State procurement agencies for purchasing drugs for public healthcare system. This is also used by the States for preparing their own List of Essential Medicines and there is also a proposal under consideration for bringing all drugs included in NLEM under price control by

Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, and Government of India.

- Transparency in the functioning of CDSCO has been introduced by regular posting of approvals granted on the CDSCO website www.cdsco.nic.in. from the year 2008. The licences and approval granted are also displayed daily on two LCD screens in FDA Bhavan lobby for information of all stakeholders, including general public. File tracking system has been introduced in CDSCO headquarters as well as in North Zone office of CDSCO in the year 2010-2011. Approval letters in respect of all clinical trials and registrations in respect of import of drugs are posted on the website. Officers of the rank of Deputy Drugs Controller (I), Assistant Drugs Controller (I), Technical Officers and Drugs Inspectors meet industry representatives on respective assigned week days to address their grievances.
- Pharmacovigilance Program of India was launched on 14th July, 2010 to capture Adverse Drugs Reaction (ADR) and Adverse Event Data in Indian population. Indian Pharmacopia Commission, Ghaziabad is the National Coordinating Centre for this programme. Presently 90 ADR monitoring Centres located in Medical Colleges across the country are functional and regularly up-linking the ADR data to WHO collaborating centre in Uppsala, Sweden. More than 43,000 ADRs have already been collected and collated for analysis.
- Haemovigilance Programme to collect and collate data in respect of Adverse Reactions and Adverse events associated with Blood Transfusion and administration of Blood Products was launched on 10th December, 2012 in 90 Medical Colleges under Pharmacovigilance programme of India. National Institute of Biologicals, Noida is the National Coordinating Centre for this Programme. An indigenous haemovigilance software- "HaemoVigil" developed by IT Division of National Institute of Biologicals, Noida is being used for online collection of data from various centres [8].
- Spurious Drugs Survey was conducted in the year 2009 by CDSCO to assess the extent of problem of spurious Drugs in the country. The survey was statistically designed by

the Indian Statistical Institute, Hyderabad. Under the study, 24,136 samples of 62 brands of drugs were drawn from different outlets spread over the country. The survey revealed that the extent of drugs found spurious in the country was 0.046%.

What needs to be done further to Strengthen Drugs Regulatory System

A massive capacity building exercise for strengthening Drug Regulatory System in the country is being under taken in the 12th Five Year Plan (2012-2017) to augment manpower, infrastructure, training, e- Governance , Overseas inspections, Pharmacovigilance etc. both at the level of centre and states. [9] Budgetary allocation of Rs. 1,800 Crore has been made for CDSCO and Rs. 1,200 Crore for states during this plan period to undertake capacity building activities to meet these objectives. Besides this, there is also need to further stream line regulations to address various regulatory gaps in the system.

The changes envisaged in the Drugs Act and Rules and the capacity building initiatives in pipeline at the level of centre and states drugs regulatory authorities are as under:

1. Amendments to Drugs and Cosmetics Act and Rules

A. Drugs

- Exports: There is no separate provision in the Act for regulation of Exports. Necessary regulations need to be framed and enacted for Exports, as India has emerged as one of the major supplier of Drugs and vaccines across the globe.
- Good Distribution Practices (GDP) : Regulatory provision needs to be incorporated in the rules to implement GDPs to ensure that the quality of Drugs is maintained during storage and transportation throughout the distribution chain.

B. Clinical Trials

- There should be provision for regulation of clinical trials

in the Act. Presently they are being regulated under Rules.

- To strengthen the regulation of clinical trials further with respect to functioning of the Ethics Committee and informed consent process the following regulations need to be framed and enacted :

(i) To make it mandatory that clinical trials are required to be conducted at sites which have their own Institutional Ethics Committee.

(ii) To make it mandatory for investigators to maintain audio-video recording of informed consent process.

- To bring clarity in the decision making process, policy guidelines and SOPs need to be formulated for approval of new drugs, clinical trials, fixed dose combinations and banning of drugs.

C. Medical Devices

- Medical Devices need to be taken out of definition of drugs and treated as separate category of products in harmonization with the international regulatory norms

Manpower

- Manpower at CDSCO needs to be augmented manifold and the same has been projected in 12th Five Year Plan for strengthening of Drugs Regulation. This increase in manpower at CDSCO is required to cope with challenging task of reviewing the increasingly voluminous data that are submitted for clinical trials, New Drug approvals including Vaccines, imports, Medical devices and Cosmetics .There is a need to create about additional 1200 new posts in various categories for CDSCO, HQ , Zonal Offices and Port offices. 4300 additional personnel are required to man new laboratories, mobile drug testing labs, e-governance and training academy.

2. Infrastructure

- To cope with the regulatory challenges in respect of monitoring the quality of drugs a big capacity building exercise in respect of Infrastructure needs to be taken up

in respect of testing of the drugs, market surveillance, enforcement activities and movement of the Drugs in the International commerce. In the 12th Five Year Plan the following activities for strengthening infrastructure are proposed to be undertaken:

CDSCO Offices

Up gradation of existing CDSCO zonal/sub-zonal and Port offices.

New Buildings to be constructed for housing CDSCO offices at Ahmadabad, Jammu, Bangalore, Indore, Goa , Guwahati, as they are presently in-rented premises.

Drug Testing Laboratories

1. Up gradation of existing 6 Central Drugs Laboratories so as to modernize them and increase their testing capacities.
2. 8 new Central Drugs Testing Laboratories to be set up with a capacity to test around 8,000 samples per annum by each laboratory.
3. 5 new Central Cosmetics Testing labs, 3 new Central Diagnostic kit labs and 5 new Central Medical Devices Testing Laboratories to be set up.
4. Induction of 20 mobile drug testing vans to monitor quality of drugs moving in the market.
5. Creation of Mini labs at all notified Ports (Sea and Air ports) from where drugs are imported /exported.
6. A state of the art Pharma Research Laboratory needs to be set up to not only to have a capacity to carry out analysis of drugs to detect extraneous substances and impurities if any, but also for training laboratory personnel in recent advances in sophisticated analytical techniques.

Training Academy

A National Drugs Regulator Training Academy need to be established to impart continuous training to the drugs regulators from centre and states, so as to keep them updated about the latest developments in National / International drugs regulations and practices. This becomes all the more important

with increased globalisation of the regulatory framework, changing profile of the pharma industry in respect of collaborations in the area of Drug Discovery and Development , New Drugs Delivery Systems, Pharmacovigilance, Haemovigilance and Post Marketing Surveillance

Overseas Country Offices

Globalization and emergence of India as a major drugs and vaccines exporting country, has fundamentally changed the environment for regulating drug products which are moving in international commerce and create unique regulatory challenges for CDSCO for the following reasons:

i. More foreign manufacturing facilities supplying bulk Drugs, Medical Devices, Blood Products, Diagnostics, Anti Cancer drugs to India.

ii. Increasing volume of imported Medicinal Products

iii. Greater complexity in supply chain

iv. Imports coming from countries with less developed regulatory system

v. Drugs manufactured outside India and shipped to other countries with the label "Made in India"

It is, therefore, important that the CDSCO should have India Country Offices, at least one in each continent (Asia, Africa, North America, South America and Europe) so as to be able to address the above mentioned issues promptly and protect the national interest. These country offices could be set up in a phased manner on a need analysis basis. Opening up of the first such office in China is under active consideration of the government, as India imports large quantities of bulk drugs from China and assuring quality of bulk drugs is important, as they have direct bearing on formulations.

3. Strengthening of State Drugs Regulatory Authorities

Presently states have grossly inadequate infrastructure and manpower and this issue for the first time is being addressed in 12th Five Year Plan by keeping a separate budgetary provision of Rs. 1200 Crore. This financial assistance

will be used for strengthening Human Resource, infrastructure in respect of laboratories, office space for HQ and field offices and training needs.

5. Other initiatives to strengthen regulations

- e-Governance System- To increase transparency and build public confidence in the regulatory system all offices of Zonal/Sub-Zonal/Port offices/laboratories of CDSCO and offices of State Drugs Controllers will be interlinked for fast communication by IT enabled services. This exercise will equip CDSCO to create a national data bank of drugs manufacturing units in the country and the bulk drugs / formulations made by them. It will also facilitate, on line filing of applications and grant of approvals, recall of drugs from market and monitoring it, archiving, video conferencing etc.
- Consumer awareness programs to educate and sensitize consumers, medical care providers etc on drug safety alerts, promotion of generic drugs, rational use of drugs etc. needs to be undertaken.
- Pharmacovigilance Program of India and Haemovigilance need to be expanded to cover all the Medical Colleges in the country, Medical institutions, Hospitals , National Health Programmes etc. The Haemovigilance Programme should be linked to International Haemovigilance Network (IHN). There is also a need to have in the country, a Biovigilance program to monitor adverse events associated with organ transplants and cellular therapies and Materiovigilance program to monitor adverse events associated with medical devices so as to ensure safety of patients/ end user. There is also need to build capacity in respect of causality assessment, signal detection and regulatory interventions in these areas.
- CDSCO -WHO collaboration as a part of Institutional Development Plan 2013-2015 for capacity building of the vaccine regulatory system in the areas of:-

➢ e-Governance

➢ Accreditation of Quality Management System

➢ Training in the areas of Marketing Authorization, Licensing, Clinical Trial, GMP Inspection, Pharmacovigilance, AEFI surveillance, supervision of clinical trial

- Implementation of Good Regulation Practices.
- Overseas Inspections

Future Regulatory Challenges

The Drug Regulatory System in the country should keep abreast of the new technological innovations in the healthcare system especially in the areas of Nano-pharmaceuticals, Pharmacogenetics, Biological Medicines and Orphan Medicines. These innovations in the Pharma Sector coupled with its exponential growth, make it imperative that our policy initiatives be directed towards evolving a long term strategic plan, to gear the regulatory system to meet the challenges for next 20-30 Years.

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B K Taimni

Medical Ethics, Negligence and Consumer Protection

"A person who fails to enter the body of the patient with the lamp of knowledge and understanding can never treat diseases. He should first study all the factors, including the environment, which influences a patient's disease, and then practice treatment . It is more important to prevent the occurrence of the disease than to cure it"

Charaka

Medical Ethics

The word 'ethics' is derived from Greek 'ethos', meaning custom or practice, a characteristic manner of acting, or a more-or- less constant style of behaviour in the deliberate actions of people. When we speak of 'ethics', we refer to a set of rules or a body of principles. Every social, religious and professional group has a body of principles or standards of conduct that provides ethic guidance to its members.

Medical profession is one of the oldest professions of the world and is the most humanitarian one. There is no better service than to serve the suffering, wounded and the sick. Inherent in the concept of any profession is a Code of Conduct, containing the basic ethics and underlining the moral values that govern professional practice and is aimed at upholding its dignity. Medical Ethics underpins the values at the heart of the practitioner-client relationship.

The practice of swearing in a member of a guild or profession and taking an oath to do well is very old. Ethics, whether they are classified as general or special, such as legal or medical, are meant to guide us, how to judge the moral rightness and wrongness of their actions. All professional interactions must reflect in a manner of behaviour that supports the principles of Justice and Equality for all human beings as persons, and respect for the dignity of all people.

Medical Ethics, also known as Health-Care Ethics is a system of moral principles that apply 'values' and 'judgments' to the practice of medicine and Nursing. As a scholarly discipline, medical ethics encompasses its practical application in clinical settings as well as work on its history philosophy, theology and sociology.

India has a long history of its contribution towards medicine. The practice of 'Surgery' has been recorded in India around 800 B.C. Shastrakarma (the art of surgery) is one of the eight branches of Ayurveda, which is the ancient Indian System of Medicine. Sushruta, the great Surgeon of India was one of the first to study human anatomy. Ancient Indian scholars like Atreya and Agnivesa have dealt with principles of Ayurveda in 800 BC. Ayurveda consists of two words 'ayur' and ' veda' – 'ayur' meaning ' age or life' and 'Veda' meaning 'knowledge', thus the word 'Ayurveda' means Science of life/ longevity.

Famous Surgeon. They wrote 'Samhitas' in their respective fields of specialization, holding the relationship between Physician and the patient in high esteem; in fact calling it a 'holy-trust'

Hippocratic Oath

Foundation of trust and good faith between the patient and the doctor was very ably brought about by Hippocrates, the early Greek Physician, who later on came to be known as 'Father of Medicine'. He laid down a Code of Conduct on the part of Physicians, which is enshrined in what came to be called "Hippocratic Oath", as he realized that mere knowledge and skill are not enough for a doctor, without a Code of Standards and Ideals. To lay down these standards, he developed a code, incorporating these standards and ideals, which continues to be the basis of swearing of an oath, administered to all doctors, joining the profession, prominent part of which reads:

I solemnly pledge myself to the service of the humanity;

I will practice my profession with conscience and dignity;

The health of my patient will be my first consideration;

I will maintain the utmost respect for human life even under threat;

I will not use my medical knowledge contrary to laws of humanity;

I make these promises solemnly, freely and upon my honour.

While every physician takes the Hippocratic oath to serve as an ethical guide and as a code of conduct, which pledge binds them to uphold certain responsibilities, morals and rules in the science of medicine and practicing the art, in a similar manner nurses also take a pledge or oath upon graduation, often referred to as Florence Nightingale Registered Nurses and Vocational Nurses Pledge. Upholding medical ethics is not only the responsibility of all physicians but also of nurses, medical assistants, and every other member of the medical, nursing and health – care team. When you do your duty, you behave morally and when you behave morally, you follow certain ethics.

In the medieval period, the tradition of Code of Medical Ethics was kept up by Muslim medicine, wherein Ishaqibn Ali al – Ruhawi wrote the first book dedicated to Medical Ethics, titled 'Conduct of Physician', followed by Thomas Percival, a Physician and an author who crafted the first modern Code of Medical Ethics and also coined the word 'Medical Jurisprudence'. In 1847 American Medical Association adopted its first Code of Ethics for the medical professionals.

India joined this league much later. Medical Council of India vide Its Notification came up with Indian Medical Council (Professional Conduct, Etiquette and Ethics Regulations) only in 2002, wherein, besides laying down the norms in several sectors, it stated-

"The Principal objective of medical profession is to render service to humanity with full respect for the dignity of profession and man. Physicians should merit the confidence of the patients entrusted to their care, rendering to each a full measure of service and devotion. Physicians should try continuously to improve medical knowledge and skills and should make available to their patients and colleagues the benefits of their professional attainments. The physician should practice methods of healing founded on scientific basis and should not mix professionally with anyone who violates this principle. The honoured ideals of the medical profession

imply that the responsibilities of the physician extend not only to individuals but also to the society"

The **Declaration of Geneva** was adopted by the General Assembly of the World Medical Association at Geneva in 1948 and amended in 1968, 1984, 1994, 2005 and 2006. It is a declaration of physicians' dedication to the humanitarian goals of medicine, a declaration that was especially important in view of the medical crimes which had just been committed in Nazi Germany. The Declaration of Geneva was intended as a revision of the Oath of Hippocrates to a formulation of that oath's moral truths that could be comprehended and acknowledged in a modern way.

The Declaration of Geneva, as currently amended, reads

AT THE TIME OF BEING ADMITTED AS A MEMBER OF THE MEDICAL PROFESSION:

- I SOLEMNLY PLEDGE to consecrate my life to the service of humanity;
- I WILL GIVE to my teachers the respect and gratitude that is their due;
- I WILL PRACTICE my profession with conscience and dignity;
- THE HEALTH OF MY PATIENT will be my first consideration;
- I WILL RESPECT the secrets that are confided in me, even after the patient has died;
- I WILL MAINTAIN by all the means in my power, the honour and the noble traditions of the medical profession;
- MY COLLEAGUES will be my sisters and brothers;
- I WILL NOT PERMIT considerations of age, disease or disability, creed, ethnic origin, gender, nationality, political affiliation, race, sexual orientation, social standing or any other factor to intervene between my duty and my patient;

- I WILL MAINTAIN the utmost respect for human life;
- I WILL NOT USE my medical knowledge to violate human rights and civil liberties, even under threat;
- I MAKE THESE PROMISES solemnly, freely and upon my honour.

Medical Ethics is and needs to be seen as 'Ethics of Care'. The Principles governing the issue in question could be said to be- Benificence , Non –malificence, Autonomy and Dignity of the profession and the patient.

Medical Negligence

Negligence has been defined severally, but for our purpose, suffice it to say that it has three components:

- a legal duty to exercise 'due care' on the part of party complained of towards the complainant;
- Breach of said duty;
- Consequential damage

On the Other hand, Halsbury's Laws of England defines 'negligence' in following terms;

Negligence- Duties owed to a patient. A person who holds out as ready to give medical advice or treatment impliedly undertakes that he is possessed of skill and knowledge for the purpose. Such person, whether he is a 'registered medical practitioner' or not, who is consulted by a patient, owes him certain duties, namely, a duty of care in deciding whether to undertake the case; a duty of care in deciding what treatment to give; and a duty of care in his administration of that treatment. A breach of any of these duties will support an action of negligence, by the patient.

The test of Medical Negligence, laid down by House of Lords in Bolam's case has been accepted by our Supreme Court, hence the law of the land. In the cited case, Lord Justice McNair, writing the judgment observed

" I must explain what in law we mean by "negligence". In the ordinary case which does not involve any special skill, negligence in law means this: some failure to do some act which a reasonable man in the circumstances would do, or the doing of some act which a reasonable man in the

circumstances would not do; and if that failure or the doing of that act results in injury then there is a cause for action. In an ordinary case it is generally said, that you judge that by the action of a man in the street. He is the ordinary man in the street, but where you get a situation which involves the use of some special skill or competence, than the test as to whether there has been negligence or not is not the test of the man on Clap ham omnibus, because he has not got this man exercising and professing to have that special skill… A man need not possess the highest expert skill at the risk of being found negligent, it is well established law that it is sufficient, if he exercises the ordinary skill of an ordinary man exercising that particular art"

Honourable Supreme Court of India, in the case Laxman Balakrishna Joshi, laid down the contours/ parameters of 'medical. negligence'

"The duties which a doctor owes to his patient are clear .A person who holds himself to give medical advice and treatment impliedly undertakes that he is possessed of skill and knowledge for the purpose. Such a person when consulted by a patient owes him certain duties, viz, a duty of care in deciding what treatment to give or a duty of care in the administration of the treatment. A breach of any of those duties gives a right of action for negligence to the patient. The practitioner must bring to his task a reasonable degree of skill and knowledge and must exercise reasonable degree of care. Neither the very highest, nor a very low degree of care and competence judged in the light of the particular circumstances of each case is, what the law requires.

The skill of medical practitioners differs from doctor to doctor. The very nature of profession is such that there may be more than one course of treatment, which may be advisable for treating a patient. Courts would indeed be slow in attributing negligence on the part of the doctor, if he has performed his duties to the best of his ability and with due care and caution. Medical opinion may differ with regard to the course to be taken by a doctor treating a patient, but as long as a doctor acts in a manner, which is acceptable to the medical profession and the court finds that he has attended on the patient with due care, skill and diligence, and if the patient still does not survive or suffers a permanent ailment, it would be difficult to hold the doctor to be guilty of negligence".

In short, a person who alleges medical –negligence, must prove four elements: -

A duty of care owed by the physician;

The physician violated the applicable standard of care;

The person suffered a compensable injury; and

The injury was caused in fact and caused by the sub-standard conduct on the part of the Doctor

Consumer Protection

Consumer Protection Act 1986 was enacted in India, following a Resolution adopted by U.N. General Assembly in 1985. India was amongst the first few countries to enact such a Statute.

Statement of Object and Reasons

The Consumer Protection Bill 1986 seeks to provide for better protection of the interest of the consumers and for the purpose, to make provision for the establishment of Consumer Councils and other authorities for the settlement of consumer disputes and for matters connected therewith.

It seeks *inter alia*, to promote and protect the rights of the consumer such as-

a. The right to be protected against marketing of goods which are hazardous to life and property;

b. The right to be informed about the quality, quantity, potency, purity, standard and price of goods to protect the consumers against unfair trade practices;

c. the right to be assured, wherever possible, access to an authority of goods at competitive prices;

d. the right to be heard and to be assured that consumers interest will receive the consideration at appropriate forums;

e. the right to seek redressal against unfair trade practice or unscrupulous exploitation of consumers; and

f. Right to consumer education.

The importance and relevance of Consumer Protection Act (CPA) 1986 was very aptly brought about by the Supreme Court of India in the case of Lucknow Development Authority vs. M .K Gupta. Relevant findings/observations are reproduced below:

"To begin with, the preamble of the Act, which can afford useful assistance to ascertain the legislative intention, it was enacted 'to provide for the protection of the interest of the consumers'. Use of the word 'protection' furnishes the key to the minds of the makers of the Act. Various definitions and provisions which elaborately attempt to achieve this objective have to be construed in this light without departing from the settled view that a preamble cannot control otherwise plain meaning of a provision.

In fact the law meets a long felt necessity of protecting the common man from such wrongs for which the remedy under ordinary law for various reasons has become illusory. Various legislations and regulations permitting the State to intervene and protect interest of the consumers have become a haven for unscrupulous ones as the enforcement machinery either does not move or it moves ineffectively, inefficiently and for reasons, which are not necessary to be stated. The importance of the Act lies in promoting welfare of the society by enabling the consumer to participate directly in the market economy.

It attempts to remove the helplessness of consumer which he faces against powerful business, described as 'network of rackets' or a society in which 'producers have secured power' to 'rob the rest' and the might of the public bodies which are degenerating into storehouses of inaction, where papers do not move from one desk to another as a matte of duty and responsibility but for extraneous consideration, leaving he common man helpless, bewildered and shocked. The malady is becoming so rampant, widespread and deep that the society instead of bothering, complaining and fighting against it, is accepting it as part of life.

The enactment in these unbelievable yet harsh realities appear to be a silver lining, which may in course of time succeed in checking the rot. A scrutiny of various definitions such as 'consumer' 'service' 'trader' 'unfair trade practice' indicates that legislature has attempted to widen the reach of the Act. Each one of these definitions are in two parts, the one explanatory and the expandatory. The explanatory or the main part itself uses expressions of wide amplitude indicating clearly its wide sweep, then its ambit is widened to such things which otherwise would have been beyond its natural import".

Section-2. Definitions----- (1)

Medical Services

Whether 'medical services', come within the ambit of Consumer Protection Act or otherwise remained an controversial issue, till it was finally settled by a judgement of the Supreme Court of India in the case of All India Medical Association vs. V.P. Shantha in 1996, wherein the Court held and clarified that the service rendered by a medical practitioner by way of consultation, diagnosis, treatment, both medically and surgically, would fall within the ambit of services rendered under Consumer Protection Act (except where doctor renders the service free of charge to all patients or under a contract of personal service). The services rendered at a Government or Non-government Hospital / Health Center/Nursing/Home, where charges are paid by some who are in a position to pay and persons, who cannot afford to pay, are rendered services free of charge, also fall within the expression of 'service'.

The Supreme Court observed that "Otherwise it would mean that protection of the Act would be available to only those who can afford to pay and such protection would be denied to those who cannot afford to pay, though they are the people who need more protection. It is difficult to conceive that the legislature intended to achieve such a result. We are of the view that in such a situation, the persons belonging to 'poor class' who are provided services free of charge are the beneficiaries of the services, which is hired or availed of by the 'paying class'. It is now a well settled law that hospital authorities rendering services for a consideration are liable to the patient for injury caused to him by the negligence or faults of the doctors, surgeons, nurses and other members of the hospital in the course of work"

" The hospital is also liable for the failures of the doctors and other employees whether their employment is permanent or temporary or casual, paid or honorary, whole or part- time as in the case of visiting surgeons"

In the cited Judgement, the Supreme Court on the basis of detailed discussion, arrived at the following conclusions: -

(1) Service rendered to a patient by a medical practitioner (except where the doctor renders service free of charge to every patient or under a contract of personal service), by way of consultation, diagnosis and treatment, both medicinal and

surgical, would fall within the ambit of 'service' as defined in section 2(o) of the Act.

(2) The fact that the medical practitioner belongs to the medical profession and are subject to the disciplinary control of Medical Council of India and /or State Medical Councils constituted under the Medical Council of India Act would not exclude the services rendered by them, from the ambit of the Act.

(3) A 'contract of personal service' has to be distinguished from a 'contract for personal services.' In the absence of a relationship of master and servant between the patient and the medical practitioner, the service rendered by a medical practitioner to the patient cannot be regarded as service rendered under a 'contract of personal service'. Such service is service rendered under a 'contract for personal services', and is not covered by exclusionary clause of the definition of 'service' contained in the Act

(4) The expression 'contract of personal service' in Section 2(1)(o) of the Act cannot be confined to contract for employment of domestic servants only and the said expression would include the employment of Medical Officer for the purpose of rendering medical service to the employer. The service rendered by a medical officer to his employer under the contract of employment would be outside the purview of 'service' as defined in Section 2 (1)(o) of the Act.

(5) Service rendered free of charge by a medical officer attached to a hospital//nursing home or a medical officer employed in a hospital/nursing home where such services are rendered free of charge to everybody, would not be 'service' as defined in Section2 (1)(o) of the Act. The payment of a token amount for registration purposes only at the hospital/nursing home would not alter the position.

(6) Service rendered at a Non-Government hospital / Nursing Home where no charge whatsoever is made from any person availing the service and all patients rich or poor) are given free service- is outside the purview of the expression 'service' as defined in section 2(1)(o) of the Act. The payment of token amount for registration purpose only at the Hospital/ Nursing Home would not alter the position.

(7) Service rendered at a non–Government Hospital/ Nursing Home where charges are required to be paid by the

persons availing such services fall within the purview of the expression 'service' as defined in Section 2 (1) (o) of the Act.

(8)Service rendered at a non-Government Hospital/Nursing Home where charges are required to be paid by persons who are in a position to pay and persons who cannot afford to pay are rendered service free of charge would fall within the ambit of the expression 'service' as defined in Section2 (1)(o) of the Act irrespective of the fact that the service is rendered free of charge to persons who are not in a position to pay for such services. Free service, would also be "service" and the recipient a "consumer" under the Act.

(9) Service rendered at a Government Hospital/Health Centre/ dispensary where no charge whatsoever is made from any person availing the services and all patients (rich or poor) are given free service- is outside the purview of the expression 'service' as defined in Section 2(1)(o) of the Act. The payment of token amount for registration purpose only at the Hospital/ nursing home would not alter the position.

(10) Service rendered at a Government Hospital/Health Centre/Dispensary where services are rendered on payment of charges and also rendered free of charge to other persons availing such services would fall within the ambit of the expression 'service' as defined in Section 2(1)(o) of the Act irrespective of the fact that the service is rendered free of charge to persons who do not pay for such service. Free service would also be 'service' and the recipient a 'consumer' under the Act'.

(11) Service rendered by a Medical practitioner or Hospital /Nursing Home cannot be regarded as a service rendered free of charge, if the person availing of the service has taken an insurance policy for Medical care where -under the charges for Consultation, diagnosis and medical treatment are borne by the Insurance Company and such service would fall within the ambit of 'service' as defined in Section 2(1) (o) of the ACT

(12) Similarly, where, as part of conditions of service, the employer bears the expense of medical treatment of an employee and his family members dependent on him, the service rendered to such an employee and his family members by a Medical practitioner or a Hospital/Nursing Home would not be free of charge and would constitute 'service' under Section 2(1)(o) of the Act".

Medical Services under Consumer Protection

By this celebrated judgment Medical profession was brought within the ambit of Consumer Protection Act 1986. All Medical practitioners/Hospitals/Nursing Homes/ Dispensaries were brought within the ambit of 'service' as defined in CPA 1986, except where services were being rendered free of charge to all patients.

The 'Complaint' can be filed by the aggrieved person or his surviving dependents/guardian before a District Consumer Forum/ State or National Consumer Disputes Redressal Commission having the territorial/pecuniary jurisdiction, along with a 'token' fee, depending on the claimed amount. The Pecuniary jurisdiction of each is Rupees 20 Lakh, between Rupees 20 lakh and one crore ,and above rupees one crore, respectively.

If a complaint is decided by a District Forum, any of the aggrieved parties can file an Appeal before the State Commission and a party not satisfied with the Order passed by the State Commission can file a Revision Petition before the National Commission, and finally a 'Special Leave Petition'/ an Appeal, before the Supreme Court of India. .

Procedure followed in dealing with a Complaint is simple. The Complaint (Format for filing a Complaint is given in the bare Act) is filed before an appropriate Forum/Commission, having territorial and pecuniary jurisdiction, which after admission hearing, forward a copy to each of the opposite parties mentioned in the complaint. The opposite parties are than given limited time to file their reply, to which a Rejoinder as well as affidavits, by way of evidence are filed by the Complainant, after which affidavits by way of Evidence are filed by the opposite party(s).

Wherever any cross- examination is required; it is done by filing 'interrogatories' and its Counter by the other parties. Arguments are heard and case is closed for Orders

Party not satisfied/aggrieved, can file an Appeal/ Revision, by way of filing Memorandum of Appeal / Revision, whereupon it is heard for Admission – hearing . Once it is admitted then a copy is given to the Respondent, who can file a reply. Record of the case from the lower Forum is called for, arguments heard and closed for Orders.

Time –limit for filing a Complaint is two years from the 'cause of action', for filing an appeal it is 30 days and for filing a Revision it is 90 days from the passing of the Order by the Lower Forum. In case there is a delay in filing the Complaint/ Appeal/Revision Petition, then an Application can be filed for condonation of delay. Once the delay is condoned then the case is heard and decided on merit.

In conclusion it can safely be said that Medical profession is one of the oldest and noblest professions, which brings succour and relief to the aggrieved people – the patients- taking care of their short/long term problems relating to the 'body' or some of its 'organs'. The relief brought by them and 'care' taken by them of the people in pain / misery/physical suffering has brought their status next to' God's' In these circumstances it only becomes of this profession to be 'ethical, moral and value-based'. Take the patient into confidence and put him at ease. In a study carried out in USA, it was revealed that whenever a susgeon spent 2-3 minutes more than the normal time with the patient to enquire and explain the disease and the options open to deal with the same, it not only instilled a certain confidence in the patient, but also brought down the legal cases against them.

Doctors need to realize that "Sometimes your joy is the source of your smile, but sometimes your smile can be source of other's joy"

A.K. Shiva Kumar

Why don't we deliver on our health promises?

There are good reasons for a large majority of Indians to grumble about the poor state of health affairs in the country. At an individual level, the financial burden of meeting health care expenditures remains among the highest in the world. Private out-of-pocket expenditures in India - 72 per cent – are much higher than in Thailand (25 per cent) and China (46 per cent). Such an unreasonably high level of private health expenditure has been impoverishing many families. Citizens also do not get good value for money despite spending so much out of their pockets. The quality of care that the average citizen gets is poor in both the public and private sectors. Unable to receive decent care in public facilities, the average individual is driven to the private sector that sadly remains dominated either by very high profit-seeking commercial enterprises or by unqualified people (quacks) who dispense dangerous allopathic and other remedies. The plight of the rural resident is much worse than that of others given the extremely poor reach of primary health care in many pockets even today.

At a national level, we have even more reasons to complain. Despite the many new initiatives in health launched over the past decade, India has fallen behind many countries even in South Asia. There was a time when we were next only to Sri Lanka on most health indicators. Today, while India's life expectancy at birth (65.8 years) is still lower than that of Sri Lanka (75 years) and Maldives (77 years), it has fallen behind even Bangladesh and Nepal (69 years) and Bhutan (67 years)[15]. The only country in South Asia with a lower life expectancy at birth is Pakistan (65 years). Particularly disappointing is India's performance compared to that of Bangladesh

particularly in the post-economic reforms era. In 1990, the under-five mortality rate (U5MR) in Bangladesh (139 per 1,000 live births) was some 18 per cent higher than India's U5MR of 114. By 2011, the situation had been reversed. India's U5MR of 61 was 33 per cent higher than in Bangladesh (46). This is despite the per capita income in Bangladesh (US$ 770 in 2011) being barely half of India's (US$ 1410). And over the period 1990-2011, while the GDP per capita in Bangladesh grew at an annual average rate of 3.6 per cent, the corresponding rate for India was much higher at 4.9 per cent.

Many do not realize that the health conditions in India are similar in some respects, and even worse in others, to those prevailing in Sub-Saharan Africa. Whereas India does better on all mortality indicators (only to be expected as a result of the HIV/AIDS impact on life expectancy), the reach of primary health care is quite similar on many counts. Some 71 per cent of children are immunized with DPT3 in Sub-Saharan Africa; the proportion is 72 per cent in India). Similarly, the proportion of institutional births is the same in India and Sub-Saharan Africa (47 per cent). The proportion of mothers attended to by a skilled birth attendant is also similar – 49 per cent in Sub-Saharan Africa and 52 per cent in India. A glaring difference, of course, has to do with child under-nutrition. Whereas close to 43 per cent of children under five are moderately or severely under-nourished in India, the proportion is 21 per cent in Sub-Saharan Africa. And the proportion of babies born of low birth weight – 12 per cent in Sub-Saharan Africa is significantly less than the proportion – 28 per cent in India. This feature alone which captures the inter-generational transfer of under-nutrition from the mother to the child offers the first clue to explaining the high proportion of under-weight children in India.

Analysing under-performance

Why is India consistently under-performing in health? The answers are not difficult to find.The reasons for the under-performance of India's health system have been well known for at least close to three decades. The Sixth Plan (1980-85)

noted: "In spite of several significant achievements, the health care system obtaining in the country suffers from some weaknesses and deficiencies. There has been pre-occupation with the promotion of curative and clinical services through city based hospitals which have by and large catered to certain sections of the urban population. The infra-structure of sub-centres, primary health centres and rural hospitals built up in the rural areas touches only a fraction of the rural population. The concept of health in its totality with preventive and promotive health care services in addition to the curative, is still to be made operational. Doctors and para-medicals arc reluctant to serve in the rural areas. They are generally city oriented and their training is not adequately adapted, to the needs of the rural areas particularly in the field of preventive and promotive"[16] The Seventh Five Year Plan (1985-90) attributed shortfalls in achievements under the family welfare programme to lack of infrastructure facilities, less than optimal use of available resources, and political, social, economic and cultural constraints.[17] The Ninth Five Year Plan (1997-2002) identified a number of problems faced by the health care services including persistent gaps in manpower and infrastructure especially at the primary health care level, suboptimal functioning of the infrastructure, poor referral services, sub optimal inter sectoral coordination, and escalating costs of health care.[18] The Tenth Five Year Plan (2002-2007) reiterated many of the old problems and underscored, in particular, the mismatch between personnel and infrastructure, lack of Continuing Medical Education (CME) programmes for orientation and skill upgradation of the personnel, lack of appropriate functional referral system and the absence of well established linkages between different components of the system as being responsible for the poor functional status of the system.[19]

The Eleventh Five Year Plan (2007-2012) does an even more comprehensive review of the drawbacks of India's public health system. According to the Report: "The conceptualization and planning of all programmes is centralized instead of decentralized using locally relevant strategies. The approach

towards disease control and prevention is fragmented and disease-specific rather than comprehensive. This leads to vertical programmes for each and every disease. These vertical programmes are technology-centric and work in isolation of each other. The provision of infrastructure is based on population norms rather than habitations leading to issues of accessibility, acceptability, and utilization. Inadequate resources also lead to lack of client conveniences and non-availability of essential consumables and non-consumables. The gap between requirement and availability of human resources at various levels of health care is wide and where they are available, the patient–provider interactions are beset with many problems, in addition to waiting time (opportunity cost) for consultation/treatment. The system lacks a real and working process of monitoring, evaluation, and feedback. There is no incentive for those who work well and check on those who do not. Quality assurance at all levels is not adhered to due to lacunae in implementation. This results in semi-used or dysfunctional health infrastructure. There is lack of convergence with other key areas affecting health as the system has been unable to mobilize action in areas of safe water, sanitation, hygiene, and nutrition. Despite constraints of human resources, practitioners of Indian Systems of Medicine (ISM), Registered Medical Practitioners (RMPs), and other locally available human resources have not been adequately mobilized and integrated in the system." It highlights in particular the following:

Box-1

Excerpts from the Chapter on Health

Eleventh Five Year Plan

Drawbacks of the Public Health System

- Centralized planning instead of decentralized planning and using locally relevant strategies
- Institutions based on population norms rather than habitations
- Fragmented disease specific approach rather than comprehensive health care

- Inflexible financing and limited scope for innovations
- Semi-used or dysfunctional health infrastructure
- Inadequate provision of human resources
- No prescribed standards of quality
- Inability of system to mobilize action in areas of safe water, sanitation, hygiene, and nutrition (key determinants of health in the context of our country)—lack of convergence
- Inability to mobilize AYUSH and RMPs and other locally available human resources

Vertical Programmes

Technology-centric

- See the disease as being caused by an agent (parasite/virus/bacteria) and fail to see its social and ecological setting.
- Response is heavily dependent on technology.

Fragmented

- Only one or two of all the factors that go into the disease setting (and that too in isolation) are addressed.

Administration

- The entire planning and packaging is done centrally.
- Only local aspect is the application (under a chain of command).
- Limited role for community participation.

The Result

- An inappropriate package for local needs.
- Local people are indifferent—sometimes even resistant.
- Even the administration cannot in perpetuity keep its attention on the programme alone.

Source: Eleventh Five Year Plan accessible at http://planningcommission.gov.in/plans/planrel/fiveyr/11th/11_v2/11th_vol2.pdf

The Mid-Term Appraisal of the Eleventh Five Year Plan concludes that "…an effective healthcare delivery system can only be achieved if the programmes are administered judiciously and implemented in a transparent and efficient manner. The role of governance is crucial as are technical and social audits. If all available resources are properly utilized and quality governance is provided by the local leadership, we may be able to achieve many of the health targets of the Eleventh Five Year Plan."

The latest Twelfth Five Year Plan (2012-2017)[20] once again repeats what has already been articulated in the past. It draws attention to several weaknesses in India's health system. Availability of health care services from the public and private sectors taken together is quantitatively inadequate. This is starkly evident from the severe shortage of doctors, nurses, and Auxiliary Nurse and Midwifes (ANMs). The overall shortage is exacerbated by a wide geographical variation in availability across the country. Rural areas are especially poorly served. The quality of healthcare services varies considerably in both the public and private sector. Many practitioners in the private sector are actually not qualified doctors. Regulatory standards for public and private hospitals are not adequately defined and, in any case, are ineffectively enforced. Affordabilityof health care is a serious problem for the vast majority of the population, especially in tertiary care. The lack of extensive and adequately funded public health services pushes large numbers of people to incur heavy out of pocket expenditures on services purchased from the private sector. Out of pocket expenditures arise even in public sector hospitals, since lack of medicines means that patients have to buy them. This results in a very high financial burden on families in case of severe illness. A large fraction of the out of pocket expenditure arises from outpatient care and purchase of medicines, which are mostly not covered even by the existing insurance schemes.

Recognizing that India has failed to realize most of the health goals, the Twelfth Five, year plan to a large extent, reiterates the same health goals as were listed for the Eleventh Plan:

- Reduction of Infant Mortality Rate (IMR) to 25 (marginally below the target of 28 set for 2012)
- Reduction of Maternal Mortality Ratio (MMR) to 100 (same as Eleventh Plan)
- Reduction of Total Fertility Rate (TFR) to 2.1
- Prevention, and reduction of under-nutrition in children under 3 years to half of NFHS-3 (2005–06) levels

- Prevention and reduction of anaemia among women aged 15–49 years to 28 per cent
- Raising child sex ratio in the 0–6 year age group from 914 to 950

Why is it that despite repeated in-depth analyses of the under-performance of our health system, India has consistently failed to deliver on its promise of health for all?

Understanding under-performance

Three governance-related factors can help to explain why India's health system has been consistently under-performing.

Vision of universal health coverage*:* The under-performance of India's health care delivery system can be attributed in good measure to the absence until recently of a comprehensive vision of universal health coverage. Separating out India's rural population for preferential treatment under the National Rural Health Mission (NRHM) is a flawed approach. Attempting to correct this by announcing the National Urban Health Mission is not the most appropriate response. We need to think in terms of universal health coverage (UHC). The Twelfth Five Year Plan has called for expanding the reach of health care and working towards the long term objective of establishing a system of Universal Health Coverage in the country. This means that each individual would have assured access to a defined essential range of medicines and treatment at an affordable price, which should be entirely free for a large percentage of the population. This definition paraphrases, to an extent, the definition of UHC contained in the Report of the High Level Expert Group (HLEG) on Universal Health Coverage set up by the Planning Commission. The HLEG defines UHS as: "Ensuring equitable access for all Indian citizens, resident in any part of the country, regardless of income level, social status, gender, caste or religion, to affordable, accountable, appropriate health services of assured quality (promotive, preventive, curative and rehabilitative) as well as public health services addressing the wider determinants of health

delivered to individuals and populations, with the government being the guarantor and enabler, although not necessarily the only provider, of health and related services."[21] Such a definition incorporates the dimensions of universal health assurance: health care, which includes ensuring access to a wide range promotive, preventive, curative, and rehabilitative health services at different levels of care; health coverage, that is inclusive of all sections of the population, and health protection, that promotes and protects health through its social determinants. These services should be delivered at an affordable cost, so that people do not suffer financial hardship in the pursuit of good health. It also underscores the importance of universal entitlement to comprehensive health security and an all encompassing obligation on the part of the State to provide adequate food and nutrition, appropriate medical care, access to safe drinking water, proper sanitation, education, health-related information, and other contributors to good health. According to the HLEG, the following ten principles are imbedded in a system of UHC: India: (i) universality; (ii) equity; (iii) non-exclusion and non-discrimination; (iv) comprehensive care that is rational and of good quality; (v) financial protection; (vi) protection of patients' rights that guarantee appropriateness of care, patient choice, portability and continuity of care; (vii) consolidated and strengthened public health provisioning; (viii) accountability and transparency; (ix) community participation; and (x) putting health in people's hands.

Nearly every country in the world which has achieved anything like universal health coverage has done it through the public assurance of primary healthcare (whether in Europe, Canada, or much of East Asia). The absence of a comprehensive vision of UHC has led to a fragmentation of health care provision. The provision of primary health care has been neglected whereas innovative ways of providing expensive tertiary care have become popular. The Twelfth Plan poses two critical questions:

- How to combine public and private providers effectively for meeting UHC goals in a manner that avoids perverse

incentives, reduces provider induced demand, and that meets the key objectives specified above?

- How to integrate different types and levels of services—public health and clinical; preventive and promotive interventions along with primary, secondary, and tertiary clinical care—so that continum of care is assured?

We have also sought to use the insurance channels to offer financial protection to those living below the poverty line, leaving the rest to fend for themselves. Increasing evidence from across the world shows that adopting a universal approach is critical and that every country should offer the same type of health care and financial protection to every citizen.

Health financing: Deficiencies in the level and patterns of health financing are a second major factor that can explain the persistent gaps in India's health care delivery system - health inequities, inadequate availability, poor reach, unequal access, poor quality and the high cost of health-care services. Many of these shortcomings can be traced to deficiencies in the patterns of health financing. Three features are striking. First, public spending on health in India is abysmally low. At first glance, it would appear that India spends an adequate amount on health care. In 2010, India's total health expenditure as a percentage of the GDP was 3.7% - similar to that of Sri Lanka (3.5%) and Thailand (3.9%).[22] The picture, however, is very different when we examine levels of per capita health expenditure. At PPP international $126 per capita, India's health expenditure was 30 per cent lower than Sri Lanka's and almost 60 per cent lower than Thailand's. The low level of health expenditures is further exacerbated by the low share of public spending which in 2010, was only around 1.2% of GDP – among the lowest in the world. In per capita terms, whereas public expenditure on health was PPP $36 in India, it was PPP$ 80 in Sri Lanka and PPP$ 248 in Thailand. A consequence of this has been the extremely high burden of private out-of-pocket expenditures – close to 72 per cent in India. Two additional features of the private out-of-pocket expenditure are noteworthy. One, almost three-fourths of private out-of-pocket expenditure is incurred on outpatient

treatment, and not on hospital care. Two, costs of medicines account for 72% of the total private out-of-pocket expenditure.

How do we finance UHC for India? To begin with, we need to be realistic and recognize that what India can offer by way of an essential health package is constrained by its economic capacity to pay for service provision. For instance, we should not forget that India's per capita income in 2010 was significantly lower at US$1,340 than that of China (US$4,260), South Africa (US$6,100), Brazil (US$9,390) and the Russian Federation (US$9,910). Even within the constraints set by the relatively low income levels, the financing options before India are quite obvious. First, UHC will have to be primarily tax-funded. Contributory options are unlikely to succeed given that a large segment of the workforce – close to 93 per cent - is in the unorganised sector and vast numbers are below or near the poverty line. Second, services should be provided cashless at the point of delivery and user fees should be abolished. Evidence from across the world has firmly established that, user fees, by and large, tend to be inefficient, inadequate and iniquitous. Third, it is important to ring-fence a significant proportion of public spending to cover the provision of primary health care. The High Level Expert Group has argued for earmarking 70% for the purpose, though the proportion may vary from state to state depending upon the health care needs of the people. Fourth, conventional health insurance schemes (even where the government pays the premium for the poor) should be done away with. There is overwhelming evidence to suggest that quite apart from the problems of oversight to check malpractice, such conventional insurance schemes siphon away large sums for tertiary care, they do not incentivize preventive and promotive care, and they do little to help with cost-containment. Finally, new and flexible mechanisms of transferring financial resources from the Centre to state governments must be introduced so that better performance and health outcomes are rewarded.

We also observe large variations in the levels of public expenditures across the states and Union territories. It is not surprising to find that health outcomes tend to be better in

states like Tamil Nadu where per capita public expenditure on health is higher than in other states like Bihar. There is a strong case for specific purpose transfer schemes in order to 'equalize' the levels of spending on health by the different states – as a way to offset the general disability of many states to mobilize resources and ensure that everyone gets the same level of health care. Ensuring basic healthcare services to the population, like poverty alleviation or universalising elementary education has nation-wide externalities. There-fore, although implementation of the provision of basic health services has to be done at sub-national (or state) levels, the financing of these services should be predominantly a central responsibility. In other words, the central government should (as in the case of Sarva Shiksha Abhiyan) provide adequate funding for provision of basic primary and secondary healthcare services by ensuring the effective functioning of health sub-centres, primary health centres and community health centres, through specific purpose matching transfers. How can Bihar achieve the same levels of public provisioning of health care as is today available in Tamil Nadu when per capita public spending on health in Bihar is a third of the levels reported by Tamil Nadu? Bihar can hope to catch up with Tamil Nadu only if there is massive infusion of central resources for health. And for this to happen, we need to accept an equalization principle. Given the differential abilities of the states, it is important to ensure that (i) states do not substitute central transfers for their own contribution to health (which is happening now under NRHM); and states continue to assign priority to health even as they receive central funds.

A major factor accounting for the low efficiency of public spending has been the practice of the Central government to develop and enforce uniform national guidelines for financing health across the country. The NRHM has tried to do away with this rigid practice by allowing for flexibility and innovation in the PIPs that are drawn up by state governments. But there is room for further improvements.

Governance deficits: The third major factor that explains under-performance has to do with governance deficits in key areas.

Stewardship deficit: Effective and committed stewardship to making investments in health and universal health coverage a national priority have, for most part of Independent India, been missing. Few national and state leaders in the past had been committed to ensuring Health for All by 2000. Fewer today fully endorse the concept of UHC. Few things capture the indifference to health as the failure to step up public expenditures on health. Despite the frequent commitments by the Prime Minister and the President to step up it up to 2.5 or even 3 per cent of GDP, public spending on health has been hovering around 1.1 per cent of GDP for close to a decade. With a few exceptions like Kerala and Tamil Nadu, leadership gaps are evident in many states, and more so at the district and community levels. Panchayats and local bodies hardly have a say in health decisions, partly the failure to devolve functions and financial powers to these bodies. Though the exercise of drawing up district health plans has started, in many instances, it has been reduced to a mechanical exercise. Seldom do such plans truly reflect the health needs of communities. Another dimension of stewardship has to do with ensuring convergence between health and other Ministries. Seldom do we find joint meetings held between the Ministry of Health and Family Welfare and the Ministry of Women and Child Development that operates the Integrated Child Development Services (ICDS) programme – and addresses issues of under-nutrition. Similarly, there are very few instances of joint programming between the Ministry of Health and Family Welfare and the Ministry of Tribal Affairs or for that matter, with the Ministry of Drinking Water and Sanitation.

Ownership deficit: The second factor adversely affecting governance has to do with ownership. Similarly, decentralization and community participation are frequently invoked in most government strategies and plans. However, this has little significance when several assessments point to

the limited impact and space given to local communities for exercising authority. Health plans are yet to become documents that inform local health service development, programme implementation or community monitoring. The six Common Review Missions of the National Rural Health Mission point out that the involvement of PRIs in the preparation of village plans based on household health data is still an exception. While all states have functioning state and district health societies, regularity of meetings remains an exception rather than the rule and the active participation of non-government sections is still limited. This has to do partly with the increasingly rigid programme component guidelines that cover different aspects of planning. It is also due in part to not using district plans for either budget allocation or programme review. As a result, most health plans, whether drawn up at the village or district level, are not truly owned by anyone. This lack of ownership greatly undermines the efficacy of the health system.

Competency deficit: Quite apart from the overall human resource shortages, there is the additional problem of staff not being adequately competent to undertake many of the health-related management functions. Even the Central government has limited people with the necessary qualifications and expertise to plan, design, monitor and evaluate different interventions. With few exceptions, a professional cadre of public health specialists have not been created by most state governments. The Integrated Disease Surveillance Programme (ISDP) suffers from critical shortages of skilled professionals required for the programme, more so in remote areas. The Common Review Missions have pointed out that although state and district health societies show improved functioning and demonstrate better coordination with Directorates, the capacity of the state programme management units in many states is sub-critical. This has often to do with managing the contractual staff and building capacity. At the community level, progress in improving the functioning of Village Health, Sanitation and Nutrition Committees (VHSNCs) has been slow. The contractual nature of employment under the NRHM is responsible for an

increasing number of problems including lack of proper procedures for renewal of contracts, poor service conditions and increments, high turnover rate, reluctance to depute staff for longer skill-based training and unnecessary and retrogressive hierarchy between the contractual and permanent staff. The lack of sensitive and enlightened workforce management policies for contractual staff is even more apparent when it comes to non-clinical managerial staff including staff of programme management units, data entry and account staff, and staff of government training and technical support institutions. This leads to a revolving door effect, with constant, high attrition and inadequate replacement resulting in poor quality and performance. Most training initiatives rely on ad hoc arrangements with poor institutional linkages and are not sustained.

Knowledge deficit: The fourth factor adversely impacting the health system is knowledge deficit. Systematic data on many aspects of health are simply not available. Government of India in January 2013 released a report titled "A Strategic Approach to Reproductive, Maternal, Child and Adolescent Health (RMNCH+A) in India"[23] rightly reiterates the need to focus on the most vulnerable and underserved sections of the population. It also refers to geographic pockets that have been identified and singled out for concerted action. The intention is to tailor programmes for sections of population that till now have been underserved, including adolescents, the urban poor and tribal communities. However, in the absence of specialized information and knowledge on the health needs, drawing up community-specific or even area-specific strategies becomes difficult. The most recently conducted Sixth Common Review Mission of the NRHM[24] points out that states are slow in building institutional capacity for knowledge management, be it for strengthening State Institutes of Health and Family Welfare, Regional and District training institutions, or the establishment of effective State Health Systems Resource Centers.to various types of shortfalls in knowledge. States remain dependent on ad hoc, time bound externally funded project arrangements for technical support. Partnerships with medical colleges and schools of public health and other

academic and research bodies or with health NGOs are also weak. Whereas management information systems (MIS) have been set up in every state, very little use is made of the MIS to take appropriate and prompt decisions. Similarly, little use is made of disease surveillance data even when they are reliable to inform planning and design of interventions. Similarly, there is no sharing of data on the Rashtriya Swasthya Bima Yojana (RSBY) funded caseloads or disease categories in any state. While Quality Assurance Committees exist, their functioning and value addition is uncertain. There is no "measurement" of quality improvement, except in a few instances. Though the horizontal integration of disease control programmes continues to improve, especially at district and state levels, and amongst peripheral workers and community levels, integration of data management and use remains weak. The use of information and local response to outbreaks and disease reports and use of information for planning is weak in almost all states.

Accountability deficit: Who is accountable for delivering on health care? The exercise of planning for health continues uninterrupted even though health goals and targets are seldom met during any five year plan period. Shouldn't the Ministry of Health and Family Welfare be held accountable if it consistently fails to meet the targets for lowering infant mortality? When pushed, the Central Government tends to conveniently absolve itself of responsibility for health outcomes on the grounds that health is a state subject under the Constitution. On the other hand, state Governments blame rigid central guidelines and norms for not being able to shape their health delivery programmes to meet the needs of the communities. Sometimes, we are told that because health outcomes are influenced by investments in a number of non-health sectors such as education, nutrition, water and sanitation, it is not fair to hold the Ministry of Health and Family Welfare responsible for health outcomes – even improving child survival. The top political leadership as well as the bureaucracy in charge of Departments and Ministries of Health seem reluctant to accept responsibility for health outcomes. In spite of this, it is ironical that every attempt is

made to hold lower level functionaries accountable, be it the Accredited Social Health Activists (ASHAs) or the *anganwadi* workers. Alternatively, if one is to argue that the goal should be to put people's health in people's hands, does this absolve the state of its responsibilities? Surely not. The absence of an accountability mechanism explains much of the under-performance of health systems in India.

Looking ahead

What is the way forward? Several critical and radical steps are required before India can transform its health systems to ensure maximum benefits to its citizens. Embracing the concept of universal health coverage is a necessary requirement. The Centre as well as state governments need to work together to develop a blueprint for the country so that every citizen has an entitlement to good quality essential health care free of cost at the point of service delivery. Such a health system must be almost entirely tax-financed. Needless to say, the several gaps in health care delivery need to be filled up with the allocation of adequate financial resources. As a priority, sufficient resources need to be earmarked for filling the large gaps that still exist in preventive and promotive care. Government of India should rework the principles guiding transfer of financial resources to state governments in order to ensure some reasonable 'equalization' of per capita public spending on health. In addition to giving greater flexibility to state governments, it is equally important for the central government to ensure that state governments put in place the necessary building blocks for UHC. A second requirement would be to induct professionals at plan, administer, monitor and evaluate health interventions that promote UHC. We will need new mechanisms that encourage partnerships and participation of professionals. Strong knowledge generation and management systems will need to be build up so that decision making by competent people is based on reliable knowledge from the field. Finally, and perhaps most critical would be the need to bring in a new culture of public management where accountability to people becomes an imbedded value. A radical transformation of

India's health system is critical for not only advancing health, but sustaining economic growth and progress in the coming years.

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Sujatha Rao

HIV/AIDS Epidemic in India – Issues and Challenges

Introduction

The first case of HIV infection was diagnosed in 1986 in a laboratory of the Madras Medical College in Chennai signaling the entry of HIV into India. India was one of the first countries to come up with a strong response, with a $84 million loan from the World Bank taken in 1993. During the same year, the National AIDS Control Organization (NACO) was instituted to implement the Government's response to HIV/AIDS. This was an innovative approach as NACO, though an integral division of the Ministry, yet enjoyed an autonomy other programmes did not. It was to be headed by an Additional Secretary Level officer, enjoying the delegated powers of the Secretary and reporting to a Board chaired by the Secretary. Providing such an institutional mechanism backed by substantial funding brought focus to the issue.

Number of cases being small, attention during the early years was largely on setting up surveillance mechanisms for gaining a better understanding of the disease causation, transmission and spread. Early data showed the spread of HIV infection due to unsafe sex and an alarming 15% due to contaminated blood. Accordingly, the first phase of the National AIDS Control Programme (NACP 1993-98) went into raising general awareness through nation wide IEC campaigns and improving blood safety. Focus on collection and processing of blood and blood products brought attention to a much neglected but critical area of health care. Analysis showed how the country's blood system was archaic and dependent on professional donors who sold blood in exchange of money. Voluntary blood donors were hardly 10 to 20%.

HIV brought a sense of fear that led to irrational discrimination of those infected and a denial. Dissemination

of information on accessing only safe blood and practicing safe sex were a challenge. While any news of the probability of using contaminated blood in hospitals had the potential to create a scare, as it happened in Mumbai in 1993 disrupting blood collection and processing creating a panic, providing life saving messages related to safe sex and consistent condom use was problematic given the highly conservative attitudes towards matters related to sex and sexual behaviour.

With the gradual expansion of the surveillance centers, it became clear that the route of transmission was from persons practicing high risk behaviour that accounted for over 84% of all infections. Surveillance data based on unlinked anonymous testing of blood, operational research, spot surveys etc. began to increasingly point towards the need to focus on people prone to high risk behaviour viz, sex workers, injecting drug addicts and men practicing same sex. Prevalence levels among such groups were seen to be very high, in places reaching as high as 50% as seen among drug addicts in Nagaland and sex workers in Mumbai.

However, to estimate prevalence levels in the country as a whole, data of infection rates among ordinary pregnant women in the ante natal clinics were used as a proxy to determine the disease prevalence. The logic here was, that high risk behaviour was an exceptional behaviour pattern accounting for less than 0.5% of the population and therefore could not represent the general population.

To arrest the spread of transmission, migrant labour and truck drivers were identified as bridge population groups as they contracted the infection from commercial sex workers , passed it on to other non infected sex workers and took it back into their homes. Likewise, drug addicts were passing on the infection among each other by sharing the same needle to inject drugs. Once infected, the drug addict would pass on the infection to his friends, partners and wives. Thus, over time a gradation of risk groups emerged – core transmitters; bridge populations and the general public. A scientific approach based on epidemiological principles made it clear that priority attention to high risk behaviour needed to be provided with focus on enhancing safe sexual practices through a sustained behaviour change that involved a consistent use of the condom or clean needles as the case may be. This strategy was also partly inspired by the effective 'control' of the epidemic that

Thailand was able to demonstrate by ensuring 100% use of condom by sex workers.

Commercial sex workers, men who have sex with men and drug addicts were marginalized communities and criminalized groups. While the laws relating to sex workers and drug addicts made soliciting sex and selling or consuming banned drugs punishable offences, the same sex behaviour, under Section 377 of IPC made it liable for ten years rigorous imprisonment. Working with such groups, particularly for advocating use of condoms that carried the implicit acceptance of their "illegal" behaviour made the workers 'abettors' and therefore also punishable. Besides being on the wrong side of the law, the groups themselves were difficult to access and work with – their resistance to change, their vulnerabilities, social discrimination, secrecy that shrouded their existence – kept apart from the mainstream, surrounded and watched closely by a whole sub system of goons, traffickers, pimps etc. making access to them a management nightmare.

The NACP II (1999 – 2006) was a significant development, once again reiterating Government's commitment to respond to the emerging crisis of HIV/AIDS. Approved with World Bank and DFID funding for about $250 million, the NACP II had four major components: Targetted Interventions, Promoting access to safe blood; Raising general awareness and expanding access to treatment for sexually transmitted diseases among other bridge populations like truck drivers, migrants and general public; and strengthening programme management.

The key strategic thrust area was the implementation of Targetted Interventions among the high risk behaviour groups. As it became clear that government bodies had no institutional capacity to work among the high risk groups and work with little precedence, NACO turned to NGO's to take up implementation of the intervention. During the 90's, there were hardly any NGOs' with any experience to take up such arduous work. With most field workers from middle class families further compounded the problem as in several instances, their parents objected to working with such criminal groups. Thus, finding willing NGOs' and dedicated workers etc. required motivation, social mobilization and a great deal of nurturing.

Under blood safety, the focus shifted to promoting voluntary blood donation and establishing blood banks and blood component separation units, training personnel, providing equipments and testing kits etc. An innovative approach adopted during this phase was the launch of 'Family Awareness Health Camps' which consisted of organizing for a day a health camp in every village / group of villages focusing exclusively on STD's and other reproductive health problems. This was hugely successful as it addressed a great need of women who, it was evident from the turn out of the camps, suffered substantial morbidity on account of reproductive tract infections and sexually transmitted infections.

NACP II was also the time when programme management shifted to states. All states were required to establish a State AIDS Control Society headed by a Project Director. Funds from NACO went to the SACS that were registered societies. Such an arrangement provided not only flexibility in programme implementation but also enabled a faster absorption of funds.

With focus on prevention strategies, despite international pressure, India did not launch treatment till the latter half of the project period. In 2004, partly also because of the fall of treatment costs from $ 12,000 per patient per year to about $ 300 patient/year, provisioning of ART drugs was taken up in 8 pilot centers, increasing to 24 in 2005 to by end of 2006 covering patients.

The NACP III (2007-12) was clearly a game changer in its sweep and ambition. The plan aimed to mobilize $ 2.5 billion – a ten fold increase from the earlier phase. The strategy was a balanced mix of prevention and treatment. While there was no change in strategy or components to NACP II, the vision was ambitious in the scale and depth of implementation. It was bordered on the principle of universal free access to critical life saving strategies. During this phase the programme saw the structuring of the programme design, standardizing the components and linking them to financing. Thus, for example, the Targetted Intervention was given a structure of a programme manager supported by outreach workers, and peer group workers who were basically from within the community. These persons were trained on how to map and reach out to the target group, counsel them, provide them linkages to services such as condoms, treatment against

STD's, testing facilities etc. The attempt was also to try and empower the target groups into self governed cooperative units so as to make them active participants in the process of change. Such communitization was based on the principle of uniting individuals into groups for countering the violence and injustices faced by them on a daily basis and also access their entitlements. At the National levels, Technical Resource Groups for each target group was constituted under the chairpersonship of the DG NACO in order to give them the sense of inclusiveness. Such a strategy of active participation and empowerment paid rich dividends in bringing in the desired behaviour change. Condom use on a consistent basis, a crucial indicator for reducing disease transmission showed a steady increase as seen in the various behavioural studies carried out by different SACS on an annual basis.

Equal focus was also given to blood safety. Substantial work was done in surveying the status of blood banks from the safety and infection control point of view; training imparted, quality assurance systems put in place, refrigerated vans to transport blood from collection to processing points provided and voluntary blood donation boosted to reach a level of over 80% of total blood collected, making in some states like Tamil Nadu, professional donors history.

Prior to NACP III, STD treatment covered barely 20 to 25% of the total estimated infections. The programme also had lost some amount of focus even though HIV itself was a sexually transmitted disease. New strategies were thus tried out. In all STD treatment clinics located in hospitals, counselors were provided and in all high risk behaviour sites, the target groups were linked to a STD provider of their choice. Treatment protocols were standardized and drugs color coded for ease of administration. NACO and SACS were strengthened with professional help . All these measures increased coverage levels to over 80% and also helped eliminate bacterial STD's, eliminating gonorohoea.

There was also a phenomenal expansion of Integrated Counseling and Testing Centers that enabled increasing the number of persons tested from 6% in 2005 to over 70% by 2012. Mother to Child Transmission was yet another critical intervention but was difficult to implement as the numbers were far too small –finding 0.3% of 27million pregnant women was a logistical challenge.

Provisioning of Ante retroviral treatment to AIDS patients got high priority. India launched pediatric AIDS and also working closely with donors, got the prices further reduced. ART centers expanded to cover over treating more than 4.5 lakh patients. Second line drugs were also provided in accredited facilities. Inventory control and drug tracking measures to ensure no stock outs were closely monitored. What was most helpful was decentralizing the ART centers to Community Health Centers at the block level as Link centers. This improved adherence and reduced drop outs as patients were able to access the facilities with lesser out of pocket expenditures on travel and inconvenience of dislocation. Over 300 Community Care Centers were also established through NGO's for providing treatment for minor opportunistic infections and food and rest for patients coming to the city hospitals for treatment.

Given the approach to base the strategy on evidence and data, the first step was to expand surveillance sites. From about 750, within a year 450 new sites were opened, focusing on high risk sites. For ensuring better quality of information 5 top level institutes such as AIIMS, RIMS, NICED, PGI Chandigarh and NARI were all roped in to train, visit, supervise the collection and also analyze the data. Alongside surveillance data, Integrated Behavioural Studies were also carried out. During the same year of 2006, the Family Health Survey, which is a five yearly survey carried out over1 lakh households brought out its report. In this latest survey HIV was also included. With all this data, an exercise to triangulate it was undertaken in consultation with the 8 top most reputed international Institutions such as UNAIDS, CDC Atlanta, Imperial College London . The result of this exercise was astounding as the prevalence levels halved from the earlier estimate of 5.2 million persons with HIV infections to about 2.7 million.

The district and facility based surveillance data also enabled categorizing high priority districts. Districts in accordance with prevalence levels were graded into 4 categories. Such categorization helped in providing focus, integrating all inputs and better planning and monitoring systems. The A and B districts received disproportionately higher order of funding support and more concentrated attention. By the end of NACP III, this approach helped shift nearly 48 districts out

of the A to B category though giving rise to new ones into the A category.

Increased funding and rapid scaling up could not be done centrally. Decentralization to district level, with district as the planning unit was the natural corollary. District level was accordingly strengthened with additional staff for supervision and financial management. They were also provided intensive training on these aspects. Similar strengthening of SACS and NACO was also undertaken by increasing the skill mix and numbers of staff positions by three times.

NACP III saw the emergence of NACO as the leader of the country's HIV response. It was clear that a weak NACO could not drive the programme and scale up coverage. It was also realized that NACO needed to formulate plans and monitor their implementation based on evidence. In order to ensure a certain amount of quality assurance, standard protocols and processes had to be developed for every intervention – the aim being that a patient in Kerala or Kashmir should get a similar level of treatment. Such standardization helped scaling up with quality. For all this, NACO developed strong management information and financial systems and supervisory structures. Highly experienced people were also recruited to work in NACO, with their salaries being paid for by donors. This was a great help in the effective transmission of skills to NACO staff.

The achievements of NACP III were impressive (See Table), not only in terms of the physical coverage and outreach but the programme impact. End evaluations showed that based on the HIV Estimation studies, there was an overall reduction of 57% in the annual new HIV infections (among adult population) from 2.74 lakhs in 2000 to 1.16 lakhs in 2011, reflecting the impact of various interventions and scaled-up prevention strategies under the National AIDS Control Programme. The adult HIV prevalence decreased from 0.41% in 2001 to 0.27% in 2011. Also, the estimated number of people living with HIV has decreased from 24.1 lakh in 2000 to 20.9 lakhs in 2011. Wider access to ART has resulted in 29% reduction in estimated annual deaths due to AIDS related causes between 2007 and 2011. It is estimated that around 1.5 lakhs lives have been saved due to ART till 2011. (NACO Annual Report, 2012)

The 50% reduction in new infections made India the highest achiever under this most vital indicator. India's strategy that focused heavily on prevention accounting for 70% of the resources was unique as most countries followed a treatment led strategy that helped save lives with access to treatment, but did not help contain new infections making the strategy unsustainable.

The factors responsible for and what distinguished it from other similar programmes lay in the principles of engagement. The HIV/AIDS programme was highly participatory in its real sense. All stakeholders – donors, academia, NGO's, persons suffering from HIV, care providers were all together worked with NACO and SACS in plan formulation, implementation and monitoring. Much of this engagement was also through Technical Resource Groups that were established for internalizing the several suggestions and recommendations on any matter of importance. Most of these were chaired by experts with meetings attended by the DG or senior staff of NACO. The second set of principles were the global 3 ones – one national strategy, one agency responsible and one monitoring system. This '3 ones principle' was faithfully implemented which helped reduce huge amount of duplication of effort and better streamlining of donor efforts with those of NACO without necessarily impinging on their autonomy and independence. And finally the principle of mutual respect, no discrimination and transparency that helped all stakeholders to work as a team, synchronize their respective agendas or priorities with the one single aim of arresting the epidemic.

Issues and Challenges

As India's NACP enters its Fourth Phase, it still has issues to settle and challenges to face. While the struggle is not over, there is every danger of getting complacent and reducing the guard. The epidemic is still in our midst and while eradication can never be possible, its effective containment on a sustainable basis will continue to be an ongoing struggle. Some of the issues and challenges that NACO will need to address in the future years are as under :

1. With new cohorts of sexually active persons coming in, the need to continue on information and education campaigns will be there. Sexual Education at school and college levels will have to be integrated as routine activity by

educational institutions.

2. The nature of sex trade is dramatically changing in keeping with the rapid technological changes. Instead of the traditional brothels that made accessing sex workers easier as brothels had a hierarchy and outreach was guaranteed, the new styles of work are far more hidden and difficult to track. Networks now operate on cell phones, out of hotels and lodges and are highly mobile. The class composition of sex workers is also undergoing change – in addition to the illiterate and desperately poor sex workers, there are educated women indulging in sex work for increasing their incomes. Understanding the nature of the trade and accessing these 'invisible' people is a great challene calling for different strategies than the older one that was based on out reach workers and peer educators working in a physically fixed population group.
3. Similar is the challenge with MSM strategies as more are likely to come out now with the Section 377 struck down by the Delhi High Court. The Traditional golden triangle between India, Mynamar and Afghanistan is now giving way to large tracts of drug abuse in the Punjab belt, creating new pockets of HIV infection due to unsafe injections being used by drug addicts. For NACO the emergence of highly vulnerable new pockets implies creating capacity and implementing strategies the way it did in the high focus districts. Tracking the shift of the HIV infections among people and geographical areas is the single most important issue.
4. The ART programme will need to be continued with the same vigour and speed so as to achieve universal coverage. NACO will also have to gear itself up to scaling up access to second line drugs which will not only be more expensive but more demanding in terms of qualified personnel, diagnostic tests and a system that is able to ensure minimum drip rates an high adherence levels by close monitoring of drugs availability and patient response.
5. During NACP III, donors played a very critical role in providing technical capacity not available with NACO. With the withdrawal of donor support for NACP IV, barring World Bank, NACO will need to ensure building on gains, nurturing the talents and skills created in the NACP III

and utilize them creatively in the emerging areas.

6. Funding support needs to be ensured in a reliable and predictable fashion.

Conclusion

HIV is an infection that is here to stay as it is a very behavioural disease and difficult to eradicate and eliminate altogether. HIV infections therefore need to be contained, kept within limits and under constant vigil. The socio – economic shifts have a profound impact on the HIV infection – the more destabilisng the economic model is in terms of increasing migration or inducing poverty will have their toll. Inability to control illegal drug trades, making their availability easier will impact on the extent of injecting drug addicts and HIV injection. Strict governance, close supervision and tight control on quality assurance would be essential of keep the blood system functioning well and also hospitals HIV infection free.

In the ultimate analysis, India's success in effectively reducing the transmission of the infection was on account of NACO leadership and political support provided to NACO by the Government. Technical strategies are known most of the time and money can also be provided. But what really translates these into desired outcomes is the instruments of governance and role of leadership. In such large programmes that involve a non homogenous set of people, leadership is not an individual but a set of individuals cutting across the spectrum of interventions – leadership of programme officers, NGO's , donors, sex workers, doctors, academic institutions etc. working at different levels. Unless all this is synchronized success cannot be achieved or sustained. The experience of India's battle with HIV AIDS is of great value in terms of management of people and varied activities.

ANNEXURE I

Achievements under National AIDS Control Programme

(End Phase I, II and III)

S.No.	Indicator	Achievement		
		End NACP I	End NACP II	End NACP III
1	No. Of TIs established	199	721	1821
2	Coverage of HRGs (%)			
	FSW		55	80
	MSM		06	64
	IDU		53	80
3	STI clinics set up(cumulative)	494	974	1112
4	STD Coverage	NA	17.98	91.25
5	No. of ICTCs set up	109	4027	12897
6	No. of people diagnosed as HIV Positive	10583 (in 1998-99)	202485 (in 2006-07)	245830 (in 2011-12)
7	No. of Blood Units collected (in lakh per year)	NA	46.5	81.8
8	Percentage of Blood collected through VBD	26	58.9	83.1
	Number of ART centres	NIL	107	355
	Number of PLHIV on ART	NIL	65907	516412
9	No. of HSS sites set up	180	1130	1359
10	Modes of HIV Transmission (%)			
	Sexual transmission	74.15	85.8	89.7
	Blood and blood Products	7.05	2.0	1.0
	IDUs	7.3	2.2	1.7
	Mother to Child	NIL	3.8	5.0
	Others	10.92	6.2	2.7
10	Awareness levels (%)	76.1%	84.6	>90
11	Consistent Condom Use	51.9	61.7	74.0
12	Funds allocated (in crore) only budget	267.88	2064.65	7717.18
13	Expenditure incurred(%)	274.26	1965.92 (95.2)	6237.48(80.8)

Deepak Gupta and L S Chauhan

National TB Control Programme

Introduction

This article is an attempt to tell the story of tuberculosis and its control in India, and in particular, the success of the Revised National TB Control programme. The essential elements of good governance are policy formulation in public and national interest with a bias towards the marginalised or poor; transparency, credibility and accountability; and proper and timely implementation. Since this Journal deals with governance issues, we seek to highlight these as the story unfolds both in relation to policy and, perhaps more importantly, as is the case in India of many programmes, in implementation.

Tuberculosis (TB) continues to be the primary infectious killer disease in the developing world. In 2001, WHO estimated that 1.86 billion people globally were affected by TB and nearly 2 million died of this disease annually. TB continues to be the commonest opportunistic infection amongst the HIV affected. In 2000, India accounted for 33% of the global TB burden. Currently, India has an estimated incidence of 2.2 million cases which is approximately 25% of the estimated global TB incidence of 8.8 million. Therefore, for India, successful TB control is very important.

TB can be of many types but it is important to note that it primarily affects the lungs (pulmonary TB). The infection gets transmitted when the patient coughs, sneezes and breathes. The only way to control and reduce incidence of TB in the long run is to control the transmission of infection.

Historical Background

The journey of TB control in India started in the 1930's with the establishment of Sanatoria which attempted to control infection through isolation of patients. The TB Association of India was established in 1939 which set up the first TB clinic in Delhi. After independence, a special TB Division was set up in the Ministry of Health. The mass BCG campaign started in 1951 was the first nationwide campaign started for TB control. In 1956 the TB Research Centre was set up in Chennai and in 1959 the National TB Institute was set up in Bangalore.

The discovery of specific and potent drugs against TB, and the efficacy of domiciliary treatment, made it possible to start a comprehensive National TB Control Programme (NTP) in the sixties, though it took almost two decades to cover the entire country. Treatment was given for 12-18 months. In the eighties, with the availability of Rifampicin, a new and more potent drug, the treatment duration was reduced to 6 months. In course of time, half the country was covered by this short course chemotherapy. (SCC)

However, despite the NTP being in existence since 1962, little change was seen in the epidemiological situation of TB in the country for almost 3 subsequent decades. In 1990, with the beginning of the global HIV epidemic, TB incidence everywhere began to rise which led WHO to declare it as a global emergency. Thereafter,in 1992, Government of India undertook a comprehensive evaluation of the NTP. It was found that though the NTP was technically sound, it suffered from managerial weaknesses, inadequate funding, over reliance on X-ray for diagnosis and frequent interruptions in drug supply resulting in unacceptably low rates of treatment completion. This was critical as incomplete treatment leads to poor cure rates, high risk of recurrence (relapse) and amplification of drug resistance. The presence of an unregulated private sector and free availability of drugs in the open market compounded the problem. Most of the aforesaid issues were attributable to poor governance, both within and outside the Government. With a large and growing population, a high

burden of TB and somewhat ineffectual policies of control, India not unsurprisingly was identified and branded as one of the world's biggest TB problem areas.

Revised National TB Control Programme (RNTCP)

These deficiencies were intended to be rectified in the revised programme by arranging adequate funds with assistance from international agencies; changing the diagnosis from x-ray to sputum microscopy; ensuring patients take treatment under direct observation; improved supervision through decentralised additional staff with provision for mobility for them and the district officer; establishing decentralised diagnostic and treatment facilities to facilitate access to patients; uninterrupted supply of drugs in patient wise boxes ensuring complete course of treatment and robust system of recording and reporting. All this was designed to ensure that most people contracting the disease are actually detected, that both detection was done and treatment initiated early to prevent transmission and treatment completion is facilitated. The focus was on sputum positive patients who spread infection. Ambitious targets of 70% detection rate and 85% cure rate amongst those detected were set. There were many important technical changes, but above all it was about political and administrative commitment, which was clearly lacking in the earlier decades. Adequacy of funding and proper management became the key. This programme was started as a pilot in 1993 and scaled up with World Bank assistance in 1996.

This was a paradigm shift which would result in the success of the programme as is quite evident years later. Following elements of the programme ensured this:

- World Bank assistance initially, and support from the newly formed Global Fund later, ensured adequate funds. Adequacy of funds has been, and will remain, a critical factor and now with international assistance declining, domestic funds are also being increased.
- Microscopy labs were set up at health facilities including primary, secondary and tertiary health centres to

provide free, quality assured, accessible and convenient TB services to the community. Treatment centres were decentralised even further and made more accessible through engagement of community DOT providers.

- The daily drug regimen was changed to intermittent so that drugs were administered on alternate days. The efficacy remained the same but this significantly reduced incidence of adverse reactions. Moreover, because of the well - known tendency of patients not taking their drugs, now drugs had to be given in the presence of, and by, a provider to ensure that they were actually taken. This is called Direct Observation Treatment (DOT)
- There was a strong emphasis on supervision and monitoring. A separate "RNTCP Supervision and Monitoring Strategy" was formulated as a tool for an objective review of the programme at all levels - from the peripheral health institutions to district, state and national levels. It also listed out detailed protocols for supervisory visits and reviews. Two additional staff were contracted at local levels and provided with transport facility (motorcycle) to supervise diagnostic and treatment services. District TB Officers became District Programme Managers and were also provided vehicles, through hiring, for mobility. These were small but crucial inputs.
- Drug supply was ensured with a robust monitoring system. A great innovation was the patient wise box which ensured that drugs for the complete treatment for every patient were ensured right from the beginning of the treatment. The patient also got this confidence apart from getting the message that he has to take all the drugs in the box for getting cured. Quality assurance of drugs was guaranteed through a variety of measures.
- A huge programme of training of all staff from top to bottom was implemented. Strong management programmes were also included. The idea was that the medical persons in charge also became programme managers and did not treat TB only as a clinical issue to be treated but as a public health problem to be managed. Strict financial control was exercised.

- There was a very robust system of recording all information; its collection; reporting; review; checking. It allowed in quick time to have information from bottom up. It also helped the monitoring process considerably.

The design and implementation, therefore, took every possible step to prevent the normal inadequacies and weaknesses of our governance system which have been the perpetual bane of our systems, including that of the health sector. No wonder RNTCP succeeded.

However, one must admit that the help provided by WHO through its network of consultants at the national level (with the central TB Division) and in the states and districts played a crucial role in facilitating the scale up of the programme and ensuring supervision and monitoring. In fact , so crucial was this support to the success of RNTCP that one of the continuing governance challenges would be how to internalise such support in future, not only for TB but for other programmes too. This kind of support also facilitated small pox eradication in the seventies and polio eradication recently. Such support could have also assisted in elimination of leprosy, filaria and kalaazar and considerable reduction in incidence of malaria in the high endemic areas. Sufficiency of resources, both human and financial and ensuring optimal utilisation is a crucial factor. Unfortunately, these aspects keep getting neglected, again and again.

It is now time to see what progress the programme actually made and then revisit and analyse the governance challenges. Many years have gone by since the programme started and one can see results in a broader perspective.

Expansion of RNTCP

Let us briefly discuss expansion issues.

Coverage of the country

The Revised National TB Control Programme incorporating the DOTS Strategy started with World Bank support in 1995. It had limited objectives and had only proposed a total coverage

of about 271 million people and there was uncertainty of continued funding. The project also had not started well and was perilously poised in 1998. The country would then have had three kinds of TB control programmes (two earlier, NTP and SCC, and the new one, RNTCP) running simultaneously in different parts, clearly unhealthy and unacceptable. Also, if a new, better and more effective programme had become available, how could its coverage be restricted and large areas denied the benefits? But the question was will we be able to cover the entire country quickly given that this required a paradigm shift and enormous administrative challenges in a somewhat dysfunctional health system, while ensuring that the desired cure rate of detected patients would be obtained which demanded strict quality control and monitoring of the spread in new areas.

There was the enormity of the challenge but also the enormity of the opportunity. The Prime Minister had called the immense burden of morbidity and mortality caused by TB unacceptable. But this burden was also faced disproportionately by the poor. Social economists have explained the causal relationship between health costs and poverty and the vicious circle of poor health and poverty. Therefore, we saw the programme also through the lens of poverty alleviation. All told then, the benefits were so great and the needs so immense, that we decided to take the plunge to cover the entire country by RNTCP by 2005. Few believed that this would be possible, thinking that the Joint Secretary was either incorrigibly optimistic or foolhardy, and the then National TB Programme Manager disagreed vehemently. But the then Health Secretary, Javed Choudhury, and Additional Secretary, JV Prasada Rao, agreed that we must be bold. We couldn't cover the entire country by 2005 as planned with some pockets of difficult areas of Bihar and UP left out but we succeeded largely making India's RNTCP the biggest and fastest expansion ever of DOTS.

Coverage of Sectors

Expansion was of two kinds. The first was the geographical one where we spread the programme to all areas of the country. But this did not mean that all the patients of TB would come to the public health system from the district downwards. In order to deepen the coverage, therefore, it was essential to expand in depth by bringing in the other stakeholders within the fold of the RNTCP. This included the public and private Medical Colleges; hundreds of NGO hospitals (at one time 50% of the case detection in Varanasi was from NGO hospitals!); the health structure of the line Ministries - Defence; Railways; ESIC; para - military and police forces; the large number of corporate health facilities, particularly of the public sector like Coal India; SAIL. The Tea Gardens became an important sector; and of course, thousands of private practitioners who were often the first point of contact and probably the weakest link in the chain of TB control.

Medical Colleges

Being tertiary care medical centres, large number of patients seek care from the medical colleges leading to a substantial proportion of patients with TB being managed there across the country. In addition, the role of medical college faculty in TB control as key opinion leaders and role models for practicing physicians and as teachers imparting knowledge, skills and shaping the attitude of medical students cannot be underestimated. Thus, from the TB control point of view, medical colleges, in both the government and private sectors,were recognized to occupy a key position with a unique potential for involvement in the implementation of RNTCP. It was essential that they advocated and practiced DOTS strategy to demonstrate and convince that this provided the best opportunity for cure of TB patients. In addition, medical colleges have the diagnostic facilities for extra-pulmonary TB (EPTB), human immunodeficiency virus (HIV)-TB co-infection, multidrug-resistant TB and extensively drug resistant TB (M/XDR-TB). Recognizing this potential, the RNTCP, for the first time in the world, conceived and implemented the unique experiment of involving the academicians who

constitute the faculty in the public health programme for TB control. A mechanism of National, Zonal and State Level Task Forces was conceived making the faculty responsible for their involvement and participation in DOTS strategy. This perhaps not only made them more responsive, but also led to a much wider coverage and acceptance. Contribution of medical colleges in RNTCP has been published in the February 2013 issue of Indian Journal of Medical Research as Special Report on page No. 283-294.Overall, at national level, medical colleges have contributed to 25 per cent of TB suspects referred for diagnosis; 23 per cent of 'new smear-positives' diagnosed; 7 per cent of DOT provision within medical college; and 86 per cent treatment success rate among new smear-positive patients.

Private Sector

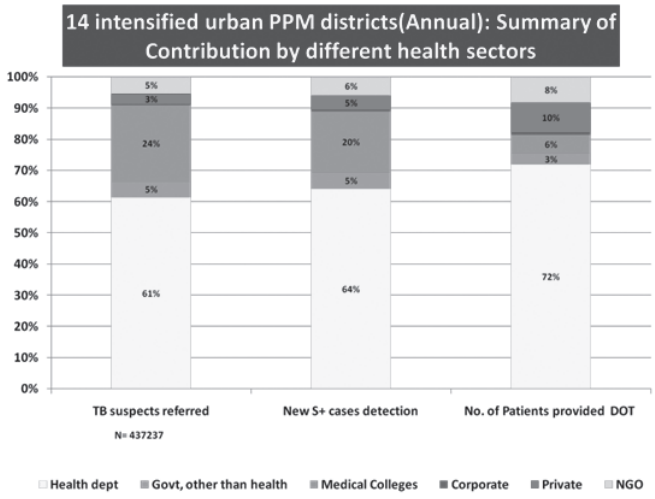
With the Global Fund grant support in 2010, community engagement activities were initiated in 374 districts where the RNTCP performance was sub-optimal. Activities under project Axshya included bringing all the non-governmental organisation working for TB Control under a single umbrella of Partnership for TB Care and control, and through a network of Non-Government Organisations, undertake communication and social mobilisation activities at the community level, and advocate with various stakeholders at the district level, state level and national levels to enhance the TB control efforts.

Efforts to engage the private sector have revolved around outreach, directly via public-private mix (PPM) schemes and through intermediary groups such as the Indian Medical Association (IMA). The IMA, with a Global Fund grant, had initiated large-scale sensitization of qualified private providers in 16 states. As of December 2011, 46,923 providers were sensitized, and 3,396 DOT centres have been established in the private sector. Nevertheless, problems related to this sector persist.

Contribution of Sectors

Unfortunately, in general, there has been little involvement of the entire health infrastructure with national

disease control programmes. The DOTS strategy and the design of the RNTCP presented a unique opportunity for a large scale collaborative effort for implementation. It was also a necessity. All sectors needed to contribute to have the necessary epidemiological impact and the DOTS strategy needed to become the norm and the standard across the board. We vigorously followed this agenda in reaching out to all. We faced difficulties and doubts but many responded enthusiastically. And India perhaps became the most vibrant partnership story of TB control. All kinds of people became community volunteers to give DOTS treatment. The book



referred to lists some remarkable contributions. The following diagram shows the relative contribution of the different sectors to the suspects examination, new smear positive case detection and the number of patients provided DOT from the various sectors in the 14 intensified urban Public-Private Mix districts in 2004-5.

The most difficult sector continued to be the private practitioners whose contribution (despite their vastness) to the TB suspects referred was 3% of the total, 5% to the new smear positive cases detected and 10% patients provided DOT.

There are many wonderful examples. Some of these have been explained in the referred book, but one example is worth

special mention. Falah-e-am was a small NGO dispensary in a very crowded muslim colony near Meerut. This was upgraded as a Microscopy cum DOTS treatment Centre. This was made possible by the enthusiastic efforts of the DTO supported by the Chief Medical Officer and the Collector as well as by the local community. This centre then treated hundreds of patients including many sputum positive ones. Imagine the benefit it provided. Imagine also what if this centre had not been opened.It showed the potential and the scale of impact which was possible. It became one of the quoted success stories in global workshops! Not far away is a market which has many medical shops. We went to many shops and they generally claimed to have a roaring sale of TB drugs, though impacted somewhat after our programme.

Thrust areas

From the socio economic point of view, we tried to give special attention to three areas. First, to the extent possible, poorer areas/populations were identified and services strengthened. Second, urban slums became a special focus and we involved municipal corporations and NGOs working in these areas along with community drug providers. Third, tribal areas and pockets were given special attention. In tribal/hilly areas, the norms for setting up facilities were relaxed. This special attention actually gave huge dividends, though challenges remained immense. It has often been said that TB is a poor man's disease – in fact this is true for all communicable diseases. Therefore, the more poor people could be brought into our network, the greater would be the anti-poverty as well as epidemiological impact and lesser the damage the private sector could do. We often felt that it was the richer class by choice which did not become part of the RNTCP, and we often also heard of the huge costs charged by the private hospitals for the corporate rich.

Impact of the programme

As per a study undertaken and published by Mark Goodchild et al "A cost-benefit analysis of scaling up tuberculosis control in India "Int J Tuberc Lung Dis 2011 Mar; 15(3):358-62", the

scale-up of TB control in India has resulted in total health benefit of 29.2 million disability-adjusted life years (DALYs), including 1.3 million deaths averted. The study used the country level programme and epidemiological data from 1997-2006. In 2006, the burden of TB measured in terms of DALYs lost would have been 1.8 times higher in the absence of the programme. The total gain in economic well-being from TB control is estimated at US$88.1 billion over the 1997-2006 (a 10-year period). The study concluded that the scale-up of TB control has been a very cost-effective strategy for improving the health status of India's population, while the return on investment has been exceptional from a societal perspective.

As per the WHO estimates in the Global TB report of 2009-10, the prevalence of Tuberculosis in the year 1990 was 586 per 100,000 population and the mortality due to TB was 42 per 100,000 population. In comparison, by the year 2007, the prevalence of TB in India was estimated by WHO to be 283 per 100,000 population (a 51.8% reduction), and the mortality due to TB is 28 per 100,000 population (a 33% reduction).

The annual risk of TB infection is a measure of the risk of uninfected children getting infected every year. The risk was about 1.5 a decade back. This risk has been reduced considerably. The reduction in annual risk of TB infection between 1997 and 2007 is one of the key indications that the newer infection rates are coming down.

	Survey I	**Survey II**	**Change*/year (1997-2007)**
All children	**1.4%** **(1.3-1.5)**	**1.1%** **(1.0-1.2)**	**-3.6%** **(-4.7 - -2.2).**
BCG-	**1.5%** **(1.4-1.6)**	**1.1%** **(0.9-1.3)**	**-3.5%** **(-5.6 - -1.4)**

This clearly indicated that the programme had impacted the TB epidemiology to a large extent and if the intensity of implementation continues, there would be substantial gains to be made. We are also on track to achieve the MDG so far as TB is concerned.

Governance challenges and management issues

There are lessons in this.

To begin with, leadership matters and it makes the crucial difference. A dedicated team is also necessary. When the problems are so many, big ambition is also required to deal with them. We must take some risks, so long as they are not unacceptably high, although by its very nature, bureaucracy is risk averse. Sufficient wherewithal needs to be provided and an intense and honest effort has to be made on implementation, including in crucial areas, micro management. All these are generic issues and problems of Indian governance. We have plenty to catch up. To our mind there was no room for hesitancy or complacency. In the book referred to, the strategy has been explained in detail along with the challenges and the steps taken to ensure that expansion took place without dilution of quality. It's like a case study which shows that things can actually be done. In the case of RNTCP, soon WHO began to call it the inspirational success story from India.

General Management Practices

The story of this programme tells us something about general management practices which appear so routine and mundane but probably in the end make the crucial difference. So it may be useful to repeat these from the referred book where these have been noted. First, is the concept of doing things on time. Delay does not seem to trouble or worry people and work getting done in the normal course is perfectly acceptable – so we won't chase people or files or performance. We chased constantly. Second, in states and districts, decisions kept getting not taken, even small ones. They just led to more delay. So we reminded and reminded, and tried to help develop the decision making culture. This is also a generic problem. Third, and enmeshed in both, is lack of problem solving. We must not only plan but anticipate and be on the lookout all the time for possible problems, present and emerging, and their solutions, which we did by keeping our antennae alert. Fourth, all this meant that one must also pursue relentlessly. Often the frustrations caused by the almost continuous roadblocks and delays tend to just make you give up. This we cannot afford to

do and we must keep on with dogged determination. Fifth, all this leads to the overwhelming importance of monitoring and supervision, an aspect that is being increasingly neglected in the administrative ethos of today. At senior levels this gets lesser attention even as the capacity to deliver declines at lower levels. So monitoring must become a ritual – a daily list, the weekly check list, a fortnightly review, crisp monthly reports, regular field visits and reviews, inspections – the e-mail and mobile being handy instruments now. How often were we talking to people at different levels in states and districts! This approach along with frequent state/district visits increased our credibility and showed our commitment. Some of it had to rub off. And we spoke from the heart, and perhaps somewhere sometimes we managed to touch other's hearts too. I think this greatly helped us.

Nature of Reviews

The nature of review is also important. This is a hugely neglected area and mostly done in a routine way. In the ministry we together reviewed every issue fortnightly and followed up. Dr Chauhan at his level was reviewing virtually daily. We followed up all issues which came up in various reviews. We insisted on tours and field visits. We both visited a large number of districts and tried to solve problems and give directions on the spot. It is surprising to note how things crop up at the local level. Others also toured though we felt it was not enough. But this improved performance and helped local officials too. The tour reports were insisted upon and became necessary tools to follow up. Not everyone of course followed these instructions and the performance showed. The nature of the review also was important as it sought to trace actual problems and ways to solve and improve. This is an important issue. The State TB Officer in Rajasthan and the then Health Commissioner in Gujarat, Amarjeet Singh, currently JS in HRD, did the best reviews and results followed. We also changed the review pattern of a district by reviewing not only global performance but also of each of its sub units, which the design of the programme permitted. Glaring differences within the district then came up which

showed local problems not being attended to. We later started reviewing the performance of each big hospital as also urban slums or tribal areas etc. We have been urging the Ministry of Health Deptt. of Women and Child Development to similarly start reviewing the problems of the worst 100 or 200 blocks in matters related to staff; safe deliveries; nourishment; immunisation etc. The Cabinet Secretariat has started a programme of Ministries formulating annual Result Frameworks Documents. Hopefully, this year reflects the start of this process. One could also think of this when we look at the worst affected Naxal districts.

Financial Management

Good financial management is a key to success for centrally sponsored schemes. It starts from quick release of funds from the Centre, and from States downwards in turn. This remained a constant monitoring item and action point for us starting from within the Ministry itself. Transfer of these funds through State and District Societies made this task easier. It is now proposed to transfer funds through state budgets. One can foresee that this process is now going to experience considerable hardships. Proper budgeting is also important so that funds are available at all times under all sub heads. Finally, accounts must be kept up dated and utilisation certificates received routinely. We can tell you that all this is not an easy process and often the programme suffers on account of problems faced here. Therefore, it must demand personal attention.

Adequacy of finance is also important. TB got that money. It also got human resources with help from the WHO. Now that international funding is declining there must be assurance of commensurate increase in domestic funding. This will be crucial. Any shortage will impact the programme adversely. If WHO support lessens then the human resource will also become a challenge. This must be addressed. Often critical gaps remain.

Political and Administrative Commitment

It was clear that, in a sense, we had political commitment,

because the necessary approvals were given to the projects and adequate funds got allocated. But there was nothing much beyond that. In a way this was generally absent, which is unfortunate. The larger question is when will health become part of the political agenda? Communicable diseases probably will not, except in an episodic manner, which will get like attention too. As far as TB was concerned, nobody ever asked us what we were doing and only in a few states did we see any real interest at ministerial level. Of course nobody bothered us also. This had the advantage of creating a lot of free space where committed officers can deliver. Many programmes could fall under such a category. We cannot and should not blame the politicians for everything. There are areas where the bureaucracy has to take a lead and deliver. However, the problem was that there was also not so much commitment at the administrative levels in the states. It was a rare Health Secretary who took great interest, but when he or she did, it made an immediate impact! The same went for the Directors of Health Services, perhaps even more so, and their influence was also marginal. Often we felt that both of us were performing their functions in different states. This was equally applicable to other disease control programmes too. There is no other explanation for leprosy and kalaazar and filaria not being eliminated from traditionally endemic districts and blocks by now, because the tools are all there.

Multi Drug Resistant TB

New challenges are emerging and the biggest is that of Multi-drug Resistant TB (MDR-TB). This is defined as resistance to at least isoniazid and rifampicin (two of the most potent first line anti-TB drugs), with or without resistance to other first-line drugs. Many people go to private practitioners who misdiagnose TB and recommend anti-TB drugs to people, who, worried about this dreaded disease, simply go and buy expensive anti-TB drugs from the market. These drugs ease the problem and make the patient feel better. As the treatment in private sector is not supervised, the patient once relieved of symptoms, stops this costly treatment and again goes to the doctor once symptoms re-emerge. This

leads to irregular and incomplete treatment which is the most important factor for the development of MDR-TB. MDR TB requires relatively costly laboratory diagnosis and treatment for at least two-years with drugs that are expensive, toxic, and not particularly potent.MDR TB patients respond poorly to standard anti-TB treatment with first-line drugs. A case of MDR TB is about 100 times more expensive to manage than a case of drug-sensitive TB. This is, therefore, emerging as a major problem and also stumbling block in the control of TB. Therefore, two things are critical – first, stop irregular treatment in the private sector and second, detect all MDR patients and ensure that they are put onto treatment as soon as they are detected.

State representative community based drug resistance surveys carried out in the states of Gujarat and Maharashtra and Andhra Pradesh estimate the prevalence of Multidrug resistant TB (MDR-TB) to be ~3% among new TB cases and 12-17% among previously-treated TB cases. These surveys have been used by WHO in the Global TB Report 2011, which estimated among the 1.5 million RNTCP-notified cases of pulmonary TB in India in 2010, approximately 66,000 cases of MDR TB could be diagnosed. Currently we are diagnosing about 10000 only!

The strategy under RNTCP for prevention and control of MDR-TB includes prevention of development of MDR-TB by providing high quality DOTS services, promoting rational use of anti-TB drugs and implementing infection control measures. The programme is also in the process of establishing quality laboratory for rapid diagnosis of MDR-TB and effectively treating these patients with second line drugs which will help in preventing further transmission of MDR-TB.However, it is essential that MDR-TB management activities should not be at the cost of quality basic DOTS services which are essential to treat large number of drug sensitive TB case and prevent development of MDR-TB.

Dealing with the private sector, therefore, has become a very important issue. Once in a workshop in Patna, a private practitioner said TB was his bread and butter. Dealing with

such practitioners, and also some specialists who feel they know better, remains TB's biggest challenge. People must be referred to the nearest centre rather than be misdiagnosed and treatment started only after proper diagnosis and, once started, its completion ensured. TB is now a notifiable disease. The jury is out on what will actually happen. But this actually touches upon another issue not generally discussed – good governance in the sense of accountability and responsibility is required equally outside the government, in private institutions and individuals.

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Polio Eradication in India
The successes and lessons learnt

Introduction

India reported its last case of polio in January 2011. The World Health Organization (WHO) removed India from the list of polio endemic countries in February 2012. With completion of three years without detection of indigenous poliovirus, by early 2014 the South East Asia Region of WHO that has India and 10 other countries as its member states is expected to be certified as having eradicated polio. The WHO regions of the Americas, Europe, and Western Pacific are the other regions that have already been certified as polio free. Polio is still endemic in the Eastern Mediterranean and African regions of WHO, since poliovirus transmission is yet to be interrupted in Afghanistan, Pakistan and Nigeria.

Many public health experts, policy makers and international groups were convinced that polio could never be eradicated in India. The main reasons cited included the socio-economic diversity of India, a population size of more than a billion, often settled in densely populated areas with poor sanitation and hygiene. It seemed an impossible task to dislodge a virus that has a fecal-oral transmission route and which was deeply entrenched in its ecologic niche for thousands of years. Other concerns included the depth and durability of the commitment and ability of the Union Government to coordinate, support and align the state governments and Union Territories for a unified national program that required an all of society and government mobilization to be successful.

The story of polio eradication in India is an epic tale of perseverance, resilience, innovation and enduring partnerships. The instruments of success involved political commitment at key administrative nodes of the government, at Union, state and district levels, and this commitment

was motivated, focused and bound by high quality data from poliovirus surveillance and program performance monitoring. This combination of the strong political and administrative commitment and high quality credible data led to inescapable accountability for program performance, most crucially at the implementation level. In the entire dynamic, the central role of the coordination between the medical officers of the National Polio Surveillance Project (NPSP) of WHO, India and District Magistrates, who constantly drove the administrative machinery towards high quality implementation of vaccination campaigns, cannot be over-emphasized. Although variable at times and in certain places, the leadership provided by Chief Medical Officers/Civil Surgeons in some of the most challenging districts was strong and often heroic.The vision and inspiration that engendered political support and civil society engagement for polio eradication was led by Rotarians and their leaders in India.

In areas with most reluctance and often strident refusal to accept vaccine, an unprecedented massive network of community mobilizers was set up by UNICEF in polio endemic areas of western Uttar Pradesh. This unique social mobilization network complimented by advocacy of Rotarians with religious leaders and the well-designed 'Underserved Strategy' jointly implemented by WHO and UNICEF was instrumental in overcoming community concerns about the program and the polio vaccine.

Background

India was the largest endemic reservoir of polio in the world and as such faced a huge public health, social and economic burden for centuries. Independent estimates by the Indian Academy of Paediatrics and the WHO indicate that 200,000 to 300,000 cases of paralytic polio occurred each year in India before the introduction of the oral polio vaccine (OPV) in India's national childhood immunization program in the nineteen seventies. Following the introduction of OPV, the incidence of polio declined substantially, and yet this epidemic prone disease affected 50,000 to 100,000 children each year until India launched its polio eradication program in 1995.

Given its size and importance in trade and travel, India remained an important source for international spread of poliovirus. These 'importations' of poliovirus often resulted in

large and prolonged outbreaks in countries as far as Angola. During years preceding cessation of polio transmission in India, multiple importations of poliovirus from India into Angola were detected which led to the spread of virus from Angola to adjoining Democratic Republic of Congo and the Republic of Congo, causing explosive and lethal outbreaks in these countries. As late as 2010, a large outbreak of polio occurred in Tajikistan that paralyzed more than 450 persons and which was caused by spread of poliovirus from India.

Beginning and Early Years of Polio Eradication in India

India launched its polio eradication program in 1995 when for the first time a mass polio vaccination campaign was conducted in the State of Delhi. Subsequently a series of mass vaccination campaigns of increasing size were conducted across the country. The intense social and administrative mobilization for these initial campaigns created public awareness and demand for the program, particularly in urban areas, as well as a sense of a national movement to get rid of a disease through collective action. Soon the scope of these vaccination campaigns expanded and became nationwide. These National Immunization Days came to be known as NIDs or the Pulse Polio Program. During the NIDs, all children in India were targeted for vaccination with OPV during a 3 day period.

In late 1999 and early 2000, India took a bold decision to conduct a series of four NIDs followed by two large sub-national immunization days (SNIDs) targeting high polio burden states over a six month period. This intense monthly nationwide series of immunization campaigns led to major strides toward reduction of polio in India. By the year 2002, all states of India, except Uttar Pradesh and Bihar, had interrupted the transmission of their indigenous poliovirus strains. All poliovirus strains detected in India during and after 2002, either originated in Uttar Pradesh or in Bihar. Poliovirus from these states periodically spread to other states of India causing sporadic outbreaks of polio and the two states continued to infect each other. It became evident that interruption of poliovirus transmission in Uttar Pradesh and Bihar was central to the success of polio eradication in India and that the interruption of transmission should be

synchronous to prevent cross-state infections.

In late 1999, India stopped the transmission of one of the three types of naturally occurring (wild) poliovirus. In fact the last case of wild type 2 poliovirus in the world was detected in Aligarh that year.

National Polio Surveillance Project

In late 1997, the National Polio Surveillance Project (NPSP) was initiated as a collaborative project between the Government of India and the WHO. The main purpose of NPSP was to help implement surveillance for cases of acute flaccid paralysis (AFP) including timely collection and transport of fecal specimens from such cases to allow laboratory detection of poliovirus, if polio were the cause of the paralytic case (there are several other non-polio causes of flaccid paralysis). With the Enterovirus Research Center (ERC) in Mumbai serving as the apex institution, facilities in several additional institutions across India were selected and inducted as WHO-accredited poliovirus testing laboratories. As a global specialized laboratory, the ERC also acquired the capacity to conduct genetic sequence analysis of poliovirus strains that permitted deep understanding of chains of poliovirus transmission and pathways of spread within and outside India.

The laboratory supported acute flaccid paralysis surveillance is a fundamental global strategy to detect the location and extent of poliovirus transmission, identify affected and at risk populations, assess effectiveness of vaccination efforts and track overall progress of the program. Effective poliovirus surveillance also guides concentration of resources and efforts in high-risk areas and population sub-groups. With strong coordination between NPSP, state governments, and the Indian Poliovirus Laboratory Network, effective surveillance for AFP with laboratory confirmation of polio cases through identification of specific poliovirus strains began in 1998 and continued to grow in strength, reliability and high level of sensitivity to detect cases.

In setting up the collaboration with WHO to constitute National Polio Surveillance Project and then empower the Project to coordinate poliovirus surveillance and manage the surveillance data, an important policy decision was made by the Government of India that demonstrated important

foresight. In order to make the massive financial and administrative commitments for polio eradication with due diligence, the Government had to be absolutely certain about the independence and veracity of the polio data as well as the credibility and reliability of the information that would be used by the policy makers, administrators and the public at large.

Key Challenges to Polio Eradication in India

The main challenges to polio eradication in India can be categorized as political, social, operational and technical. Moreover, there was a complex interplay between these factors that made these challenges exceedingly difficult to address.

Political Challenges

Both national and international political commitments were essential to fully engage administrative support and harness domestic and external financial resources. The political commitment was also necessary to rally public support for the eradication effort. Considerable advocacy and negotiations by WHO, UNICEF, other international organizations and champions within the Government of India were necessary for the government to seriously consider and ultimately commit to polio eradication. The Indian Rotarians played a crucial role in persuading their government and political leaders to take on the massive task of polio eradication. Although the Union Government committed to polio eradication while recognizing its obligation as a signatory to the World Health Assembly resolution in 1988 that committed all member states of WHO to polio eradication, skepticism remained within parts of the Union Ministry of Health and some state governments about the feasibility of polio eradication and the priority the program was being given.

Sustaining government commitment proved to be more challenging than obtaining the initial commitment. During the long and hard fought years of polio eradication there were many setbacks and periods of despair. Polio is epidemic prone, thus two to three years of progress were periodically followed by large out breaks in Bihar or Uttar Pradesh that spread to other states. Increasingly it became evident that the scope and frequency of polio campaigns will need to be substantially increased in high risk areas putting escalating

demands on the national budget, administrative mobilization and management of complex vaccine procurement and supply processes. While progress towards polio eradication ebbed and flowed, stagnating routine childhood immunization coverage in the high risk states raised concerns about excessive focus on a single vaccine-preventable disease. Outbreaks often became flashpoints for a blame game between states and the central government, one alleging poor quality of vaccine as the cause, while the other pointing to gaps in the quality of vaccination campaigns. Recommendations and decisions on frequency and size of campaigns became subjects of negotiations and occasionally controversial between the states and Union government.

Over the course of the eradication program there were strong and visionary leaders within the Union and state governments, who maintained national commitment and kept a firm and steady grip on the rudder in choppy waters. The national commitment was publicly reaffirmed when the President and the Prime Minister launched annual national polio campaigns, as did Chief Ministers in many states. Regardless of party affiliation, the Union Ministers of Health and Family Welfare consistently maintained a strong position and support for completing polio eradication. While such high level commitment was essential, the crucial leadership that maintained momentum and navigated the program through treacherous waters was exercised by some key Union Secretaries of Health and Family Welfare, some Additional and Joint Secretaries, and a few Chief Secretaries and Principal Health Secretaries in high risk states.

The bold policy decisions and sound management practices undertaken by these government leaders included the decision around 2006-2007 to fund the polio campaigns entirely through the domestic budget with annual allocations in excess of INR 1.2 billion. Until then, a substantial proportion of vaccine and operational costs of polio vaccination campaigns was financed through external donor funding. Serious attention was given to the assessments and recommendations of the independent India Expert Advisory Group (IEAG) that met at least twice each year and helped define the strategic roadmap for the program. Monthly meetings of the Operations Group were chaired by the Union Secretary of Health and Family Welfare, in which progress, challenges and immediate implementation

plans were reviewed together with partners and state government representatives. Important decisions were made right then during the meeting. The high quality of polio surveillance and immunization monitoring data facilitated evidence-based timely decision making. Similarly, Principal Health Secretaries in states, sometimes under leadership of the Chief Secretaries, conducted video-conferences with District Magistrates and District Chief Medical Officers, in high risk districts, to review the performance of the last vaccination campaign and preparations for the next round.

The ultimate winning combination at the implementation level was the resourcefulness of the District Magistrates and Chief Medical Officers, guided by the high quality of credible surveillance and program monitoring data generated by NPSP, and the water tight accountability enabled by the timely and reliable information. At the heart of this winning combination was the relentless pursuit of the missed child with an incredible refusal to give up in the face of challenges and a 'can do' attitude that led to constant innovations and tactical adjustments. A program culture developed that demanded continuous commitment to improve performance and coverage of children during each vaccination round.

Social Challenges

By 2001, reluctance and refusal to vaccinate children was increasing among underserved populations, particularly Muslim communities in parts of western Uttar Pradesh. This 'resistance' to the program continued to increase and became strident in some places. The height of this challenge peaked between 2002 and 2004. There were several determinants of this program rejection that ranged from unfounded concerns about the polio vaccine, mistrust of a government service that was being delivered at the doorstep in a setting where essential health and civic services were often totally absent or extremely inadequate, the service providers were not from the communities, and the vaccinators could not answer fundamental questions about the rationale for repeated vaccination rounds and multiple doses of the vaccine. The situation was further aggravated by lack of engagement of relevant political, religious, academic, medical and civil society leaders that were trusted by these communities.

The initial program response focused on community

empowerment. Vaccinators and their supervisors were selected and trained from within the local communities. Inclusion of a third vaccination team member who had to be a female from the local neighborhood was made mandatory. Vaccinators were trained in inter-personal communications skills to be able to answer questions asked by families.

A number of additional steps were taken by the program, particularly the polio eradication partnership to address the resistance to the program. Leadership and faculty of Aligarh Muslim University, Jamia Millia and Hamdard University were mobilized who played a significant role in community engagement. Rotary convened the Ulema Conclave that included prominent Muslim religious scholars who expressed strong support to the program and helped clear misinformation about the vaccine and its constituents. UNICEF and WHO launched the 'Underserved Strategy' that required systematic engagement of religious and community leaders, doctors, local mosques and influential persons, particularly in areas with high rates of program rejection.

In areas with persistent poliovirus transmission and most concentrated and clustered resistance to the program an extensive social mobilization network was deployed by UNICEF and the CORE group of NGOs. More than 5000 community mobilizers were recruited from within the communities and were trained to interact and build trust with families, register newborns and children in their neighbor hood and provide basic guidance on accessing vaccination and health services.

Gradually community trust and engagement with the program were built up through a combination of interventions outlined above. This led to increases in vaccination coverage among underserved communities and overtime eliminated disparities in levels of coverage between different communities.

Operational Challenges

The socio-economic, cultural and geographic diversity plus the sheer number of children in India posed a daunting challenge to the program goal to reach every child every time. A nationwide campaign in India vaccinated around 172 million children with the help of 2.3 million vaccinators. The risk factors for polio transmission were so prevalent that it was

imperative to achieve very high vaccination coverage during polio campaigns. A major policy and strategic shift in vaccine delivery was made around the year 2000 when in many states of India decision was made to conduct vaccination campaigns house-to-house, not just through fixed vaccination posts. In the high risk states of Bihar and Uttar Pradesh, this meant multiple visits to more than 58 million houses to vaccinate around 60 million children during repeated vaccination rounds each year.

A number of operational tactics and strategies were developed and refined to ensure high vaccination coverage. Close field monitoring and analyses provided a clear understanding of the reasons why children were missed during campaigns. This understanding led to specific tactics to reach high risk sub-population groups. A special 'Newborn Strategy' was implemented in Uttar Pradesh and Bihar, in which each vaccination team used a standard 'Newborn Booklet' to register newborns and track their vaccination during each subsequent round. The 'Transit Strategy' was developed to vaccinate children who were out of their homes, in busy markets or were in transit during travel. During an NID, approximately 8 million children were vaccinated at train and bus stations, in moving trains and in markets and busy intersections.

The Kosi River area in Bihar was the most difficult terrain to conduct vaccination campaigns. The flooding, multiple rivulets and the lack of roads made access to children in remote areas of the Kosi River districts a formidable challenge. The area suffered neglect, lack of proper planning and minimal supervision, as it usually took 6-8 hours to reach many villages from district capitals and large towns. Young children kept in farming field huts called 'Basas' were especially more likely to be missed. The area provided refuge to the last remaining strain of wild poliovirus type 1 in India from where it spread to other parts of the country. A major logistical and human resource deployment operation was developed as part of the 'Kosi River Strategy' to ensure planning, implementation and monitoring of high quality vaccination campaigns in the area. Special grid planning was undertaken instead of administrative boundaries, night shelters and temporary satellite offices were established to enable field presence and supervision by staff. The State Government offered special

incentives to medical officers who served in the area. NPSP concentrated its medical officers and Field Volunteers in high risk areas of Kosi districts.

During the final stages of the eradication program, migrants, especially those from Bihar, Uttar Pradesh and West Bengal, played an important role in survival and spread of poliovirus across India and occasionally into Nepal. The children among the migrant sub-populations were at much higher risk of being missed during vaccination campaigns. They were also more likely to be exposed to poliovirus and spread it further due to their mobility. Between 2007 and 2011, 40% of poliovirus type 1 cases outside Bihar and Uttar Pradesh were among migrants. After establishing a programmatically relevant definition of various categories of migrants, a detailed and painstaking census and mapping exercise was undertaken by NPSP medical officers in collaboration with state and district authorities. Specially mapped micro plans with dedicated mobile and outreach vaccination teams were created to reach nomads, migrants in large construction sites, brick kilns, and in peri-urban slums. Extra resources were deployed by authorities and NPSP to intensify monitoring of vaccination among migrant communities. By 2011, 162,000 migrant sites had been mapped in high risk states and more than 4.2 million children among migrants were vaccinated during vaccination campaigns. Surveillance for cases of AFP among migrants was also intensified.

Technical Challenges

Large population size and density, and a high birth rate in settings of poor sanitation and hygiene, and a hot tropical climate are primary risk factors for efficient fecal oral transmission of poliovirus. These demographic, social and environmental factors converged in parts of Bihar and western Uttar Pradesh and facilitated highly efficient and intense poliovirus transmission. The program was in a race with the poliovirus in which around 700,000 babies born each month in Bihar and Uttar Pradesh needed to be reached with vaccine multiple times before the wild poliovirus got to them. This was one of the reasons why vaccination campaign rounds had to be conducted much more frequently in these states – sometimes up to 10 rounds a year in certain high risk districts.

The same conditions with attendant high rates of diarrhoea and other intestinal infections adversely affect the efficacy of the oral polio vaccine (OPV) which is a live attenuated virus vaccine that is administered orally and must replicate in the gut to induce immunity. By 2004, it became evident that the trivalent OPV (tOPV) was much less efficacious in Uttar Pradesh and Bihar than in other parts of India. Despite repeated vaccination rounds using tOPV, poliovirus transmission persisted in the two states. Moreover, it was known that the type 2 polio component of the tOPV interfered with the immunogenicity of the vaccine against the remaining wild poliovirus types 1 and 3.

As a major technical innovation, monovalent type 1 (mOPV1) and monovalent type 3 (mOPV3) vaccines were introduced in the program in 2005. Important policy decisions were made in India based on advice of the IEAG and the global Advisory Committee on Polio Eradication. The program in India decided to sequentially eradicate poliovirus, giving primacy to eradication of type 1 polio which is more virulent, spreads more widely and causes outbreaks more frequently than the type 3 virus. The mOPV1 was, therefore used preferentially more often than mOPV3 or tOPV. To its credit, the Government of India maintained this policy, even during outbreaks of polio caused by type 3 polio, recognizing that it was much more important to curtail type 1 poliovirus in order to achieve the goal of polio eradication faster with fewest cases of polio.

The dichotomy of preferential vaccination against type 1 versus type 3 polio with intermittent outbreaks of types 1 and 3 polio was addressed by the introduction of bivalent (types 1 and 3) vaccine (bOPV) in 2010. The bOPV was evaluated in a clinical trial conducted in India which demonstrated its superiority to tOPV in inducing immunity to types 1 and 3 polio and led to the licensure of bOPV and its availability for use in India and globally.

One of the major strengths of the India program was the capacity it developed for very important research studies and field trials that were conducted with increasing frequency beginning in 2007. These studies addressed crucial questions and knowledge gaps related to serum and gut immunity to polio among children of different age groups in the most high risk populations of Bihar and Uttar Pradesh; immunogenicity

of different polio vaccines in India and particularly in the most polio affected areas; and dynamics of poliovirus transmission in such areas. These unique field-based studies conducted with high scientific rigor were possible mainly because of the network of NPSP Surveillance Medical Officers, Field Volunteers, presence of community mobilizers, and the close partnership with the Enterovirus Research Center in Mumbai and the support of district and state governments.

The program in India was able to overcome the unprecedented scale of technical and epidemiological challenges through detailed analyses of poliovirus surveillance data and appropriately designed and conducted field studies and clinical trials, which together guided important technical innovations in the program, most notably deployment of more effective oral polio vaccines and more strategically designed regimens for their use. The new vaccines and the regimens which guided their use were most suited to the local conditions and epidemiology of poliovirus in India.

The Overarching Success Factors

The overarching factors that underpinned the success of India's polio eradication program relate to how the essential elements of a global eradication program were brought together in India and how the program overcame the extraordinary challenges that it was confronted with. In summary, strong political commitment at each level of the government backed up by national financing of the program and support of the civil society were fundamental for the program to be launched and sustained through incredible difficulties. The enduring partnership between the Government of India and the spearheading partners of the Global Polio Eradication Initiative (WHO, UNICEF, US Centers for Disease Control, and Rotary International) was central to the effectiveness and ultimate success of the program.

From a public health perspective the program in India faced two broad challenges at an unprecedented scale – 'Failure to vaccinate' and 'Vaccine failure'. In other words, the imperative to reach and vaccinate every child in India; and the necessity to use vaccines that were effective in conditions that represent an extraordinary confluence of risk factors for poliovirus to thrive and spread and which jeopardize effectiveness of OPV. The challenge to vaccinate was met with unshakable

resolve to reach every child and entailed development of innovative operational tactics and strategies based on high quality data and effective social mobilization. The high quality implementation of these strategies was assured by the engagement and support of District Magistrates who mobilized all sectors of administration and who had access to credible monitoring data that provided the currency to enforce performance accountability. The problem of vaccine failure was overcome through deep analyses of epidemiological data, clinical trials and field research which ultimately resulted in deployment of more efficacious vaccines and regimens for their strategic use.

Lessons and Legacy of Polio Eradication in India

Important lessons have been learned during the many years it took India to reach the goal of polio eradication. These lessons would be important for other large national and international public health programs and include:

- Perseverance, resilience and flexibility to overcome obstacles and a willingness to adapt to evolving challenges. Consistency of commitment and clarity of vision in government despite changes in leadership;
- No short cuts. Painstaking planning, execution, monitoring and performance accountability;
- Program should mobilize and empower communities;
- Preparedness to be surprised with ability to rapidly mount a high quality response;
- Disease surveillance is essential for evidence based implementation. Generation and use of high quality credible data to monitor progress, guide strategic planning and program actions;
- Tactical and scientific innovations with capacity to conduct research even in advanced stages of the program;

The legacy of polio eradication in India is extraordinarily rich. The program has developed the experience and tools for reaching the most underserved and hard to reach sub-populations. For example, the large number of migrant and mobile populations have been characterized, mapped and can now be consistently reached. There is a blue print for how to build a very robust and highly sensitive laboratory

supported disease surveillance system. Surveillance for measles and rubella outbreaks has already been set up building on poliovirus surveillance. More than a 100 million children under ten years of age have been vaccinated in states with high measles mortality using the micro-planning and management and accountability structures of the polio eradication program. Childhood routine immunization programs are being strengthened and improved in states and districts with the most unvaccinated children in India using the human resources, knowledge and best practices applied for polio eradication. Capacity has been built on the ground for micro-planning, mapping, monitoring, data analysis and supervision. Excellent models of community engagement and social mobilization have been developed and implemented effectively.

A model private-public-UN partnership for polio eradication has been sustained through the years. Highly effective program management and accountability processes have been established. A culture of evidence based decision making and accountability has been created at the implementation level.

India's leadership role in global polio eradication has been well recognized and the program has shared its experience, best practices, and lessons learned with Pakistan and Nigeria through visits of high level delegations to observe the program in India and deployment of NPSP surveillance medical officers to northern Nigeria to share their experiences.

Remaining Risks

Until global polio eradication has been certified, India remains at risk of resurgence of polio. Endemic polio transmission is continuing in Afghanistan, Pakistan and Nigeria and outbreaks of polio caused by international spread of poliovirus to Somalia and Kenya have been recently reported and wild poliovirus has been detected in sewage samples collected in Egypt and Israel. India must maintain the ability to promptly detect and rapidly respond to any poliovirus. This necessitates that India stay at high alert, maintain sensitive surveillance for poliovirus and keep the immunity of children against polio at very high levels through routine immunization and mass vaccination campaigns. Moreover, the well-developed national and state emergency

preparedness and response plans must be kept up-to-date. Complacency is a major risk.

Although a very rare event in populations with suboptimal immunity, India is at risk of emergence and circulation of vaccine derived poliovirus (cVDPV). Among the three types of attenuated viruses in the tOPV, the type 2 is the one most likely to emerge as cVDPV, whereas wild poliovirus type 2 was eradicated globally in 1999. The Global Polio Eradication and Endgame Strategic Plan 2013-2018 was launched during the World Health Assembly in May 2013 and includes as one of its objectives improvement in routine immunization coverage, complete withdrawal of type 2 OPV with a switch from tOPV to bOPV for routine immunization The strategy inlcudes introduction of at least one dose of the injectable Inactivated Polio Vaccine (IPV) during the transition phase to mitigate the risks associated with the change in vaccines. This is an important strategy for a double benefit, first to improve protection against the remaining types 1 and 3 wild polioviruses with the use of bOPV, and second, to reduce the risk of cVDPV. The global strategic plan has incorporated experiences and insights from India's polio eradication program and many of the strategies are based on findings of research studies conducted in the country. India should continue to play its leadership role in global polio eradication by protecting itself from importation and spread of polio and by finalizing its implementation plans for the 'Polio Endgame'.

Sailesh Mohan and K. Srinath Reddy

Tackling Non-Communicable Diseases in India

Introduction

Notwithstanding the significant improvements in India's health status since independence, the country faces new challenges of a very different kind and magnitude now. While communicable diseases and maternal and child health issues continue to be important priorities, the growing threat posed by the rising burden of chronic non-communicable diseases (NCDs) such as cardiovascular disease (CVD), diabetes, cancer and chronic obstructive pulmonary disease(COPD) is presenting newer challenges for the health system, societal development and progress.

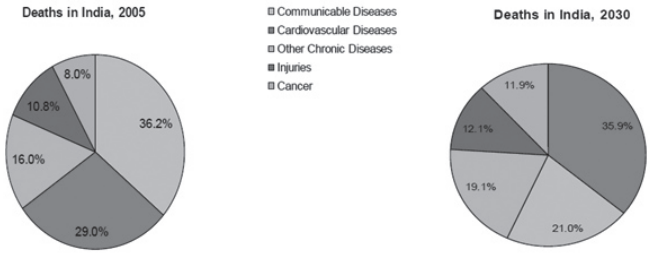
In this paper we examine the principal reasons for the rise of NCDs, review the current and projected burden in terms of risk factors and disease, the responses to date and highlight key public health actions that can contribute to stemming the increase.

Why are NCDs rising in India?

Over the past few decades, India has witnessed significant changes in economic development, nutritional status, life expectancy, fertility and mortality rates. Decreases in mortality due to communicable diseases have been accompanied by a gradual and parallel increase in NCDs. Diverse and rapid demographic (characterised by population ageing), epidemiological (shift from communicable to non-communicable diseases) and nutritional (increased calorie intake and reduced activity levels) transitions have shifted

the disease profile with NCDs currently accounting for 53% of the total mortality and 44% of disability adjusted life years (DALYs) lost. Projections indicate a further increase to 67% of total mortality by 2030. CVD is the major contributor to the present burden, contributing to 52% of NCD associated mortality and 29% of total mortality (Figure 1).

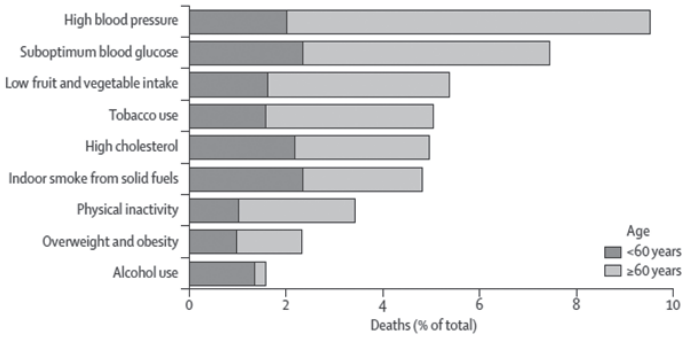
Figure 1: Changing disease profile in India



Risk Factors

Major NCDs have common risk factors (tobacco use, unhealthy diet, physical inactivity, alcohol use) and they are largely amenable to prevention. As current risk factor burden is indicative of future disease burden, information on these risks is vital for designing appropriate interventions, monitoring and evaluating them. Leading NCD risk factors are shown in Figure 2 and their contribution to the disease burden summarized below.

Figure 2: Mortality (%) attributable to leading chronic disease risk factors in India



Tobacco use

Tobacco use is a leading cause of premature, NCD-associated death and disability. It is used in multiple ways (bidis, cigarettes and smokeless forms) with India being the second largest producer, the third largest global consumer and home to nearly 275 million tobacco users. Disconcertingly, usage is increasing among youth, women and among the poor. Over one million deaths are attributable to tobacco use, with the majority occurring the in poor and among adults in the economically productive age group of 30-69 years. However, it not only has calamitous health consequences but also has huge economic implications, with the cost of treating three major tobacco-related NCDs (cancer, heart disease and COPD) being substantially more than the revenue accrued to the public exchequer from tobacco trade.

Diet, physical inactivity and alcohol use

Although substantive change in the per capita calorie consumption has not occurred over past few decades in India, notable increases in edible oil and fat intake have been reported in both rural and urban areas. Consumption of oil had increased from 18 grams per person daily in 1990-1992 to 27 grams per person daily in 2003-2005, while fat consumption increased from 41 grams to 52 grams per person daily during the same period. Further, aggregate consumption data also points to an increasing trend in edible oil consumption, which has risen from 9.7 million tonnes in 2000-2001 to 14.3 million tonnes in 2007-2008, with a large proportion of unhealthy oils high in saturated and trans-fats which are linked to NCDs.

The consumption of fruits and vegetables, which are protective against NCDs, is inadequate, particularly so among the poor. Similarly, physical activity which is another protective factor has been reported to be less than recommended levels, with 29% of the population being insufficiently active. Widespread urbanization, mechanization of work and sedentary lifestyles are contributing to this.

Dietary salt consumption, a strong determinant of hypertension and associated CVD, is also very high with the

average intake ranging between 9-12 grams/day. This exceeds the World Health organization (WHO) recommended intake of 5 grams/day as well as the National Institute of Nutrition's recommended intake of 6 grams/day.

Alcohol consumption, which has both adverse health and social implications is, increasing and accounts for not only a significant proportion of neuropsychiatric disorders but also fatal road traffic accidents and suicides. It is also a risk factor for hypertension, obesity and some cancers. Its usage is higher among the poor and less educated but is also increasing among youth.

Cardiovascular disease

There are currently about 30 million coronary heart disease (CHD) patients, with 14 million residing in rural and 16 million in urban areas. The prevalence of CHD in those aged ≥ 20 years ranges from 6.6% - 12.7% in urban and 2.1% - 4.3% in rural India. Over the past four decades, CHD prevalence has increased almost fourfold in rural areas and six fold in urban areas. The prevalence of paralytic stroke, most common due to uncontrolled hypertension, is between 334 - 424 per 1,000,00 population in urban areas and between 244 - 262 per 1,000,00 population in rural areas.

Diabetes

Type-2 diabetes mellitus has been rising rapidly, with the country often labeled as the 'diabetes capital' of the world. Currently there are about 61 million people with diabetes, with projected increase to 101 million by 2030. Furthermore, diabetes is an important risk factor for CVD and CVD is the most common cause of death and disability in persons with diabetes. Diabetes currently accounts for almost a million deaths annually.

Hypertension

Hypertension is responsible for nearly 10% of all deaths in India currently with 20-40% adults in urban areas and 12-17% in rural areas having it. The number of hypertensive Indians will nearly double from 118 million in 2000 to 213 million by

2025. In addition, nearly 40% adults have pre-hypertension, a precursor condition which converts to hypertension if left unaddressed.

Despite the availability of proven and effective prevention and treatment strategies for hypertension and diabetes, their detection and control rates are abysmally low. There is a huge gap between detection and adequate treatment: less than half of those who have hypertension or diabetes are actually detected, less than half of those detected receive appropriate treatment and less than half of those receiving treatment have their blood pressure or blood sugar treated to recommended targets ("The rule of halves"). Lack of awareness and absence of treatments are particularly problematic in rural areas. Besides poor control rates, of concern is the fact that once hypertension-related CVD occurs, the use of proven, inexpensive evidence-based secondary prevention therapies is also very low in primary and secondary care, leading to a large and escalating burden of avoidable and premature mortality. A recent global study indicated that upto 80% individuals were not on proven and effective life saving drug treatment after a stroke or heart attack in countries like India. This results in avoidable complications, increased healthcare costs, premature disability and death.

Chronic obstructive pulmonary disease

It is more common among men as the major underlying cause is tobacco smoking but is also increasing among women due to the adverse impact of indoor air population as a result of solid fuels used for cooking. The number of COPD patients is estimated to increase, from 1,30,00,000 in 1996 to 2,22,00,000 by 2016, with many likely to require hospitalization with attendant financial implications for individuals and the healthcare system.

Cancer

About 800000 new cases of cancer and 550000 deaths occur each year. The most common cancers in men are those of the oral cavity, esophagus and lung while in women the main sites are the cervix, breast and ovaries (apart from

tobacco-related cancers). Diagnosis and treatment are often delayed, with more than 75% of cancer patients presenting and seeking care when already in advanced stages of the disease, thereby reducing the likelihood of positive treatment outcomes. Tobacco use is one of the leading risk factors, while alcohol use contributes to a substantial proportion of head, neck and stomach cancers.

Injuries

Against the backdrop of increased urbanization, population growth and accelerated economic progress, motorization has increased prodigiously in India. This has been compounded by the inadequacy of public transport systems, leading to high rates of road traffic accidents and associated injuries. Currently, about 2.8 million people are hospitalised due to road traffic accidents, a figure projected to increase to 3.6 million hospitalisations by 2015. States with higher motorisation rates have greater numbers of related injuries and deaths. Agriculture related occupational injuries are also common, mostly among rural men belonging to the lower income groups.

Mental health disorders

Mental health disorders are emerging as a significant public health problem in India. Conditions such as schizophrenia, mood disorders (depression and bipolar disorders) and mental retardation account for 8.5% of the total burden of diseases. It is estimated that nearly 7% of the adult population suffer from a serious mental disorder, with no considerable rural urban difference but with a higher burden observed in women. The working age group of 25-44 years is more vulnerable. Mental health disorders not only are independent risk factors for other NCDs such as CVD and diabetes but can also result from them, as a sequel of long term suffering.

Economic burden

NCDs and their associated risk factors are accountable for large costs not only to individuals but also to the country's economy. Most people spend out-of-pocket to meet NCD

related healthcare costs, with medicines accounting for up to 45% of the expenditure. Estimates indicate that in 2004 the annual income loss among working adults due to NCDs was Rs. 251 billion and that due to hypertension alone amounted to Rs. 43 billion. In 2010, the annual median direct cost per diabetic individual was reported to be US$525, and the annual total cost of diabetes care in India was estimated to be US $32 billion. During 2005-2015, the projected income loss due to CVD and diabetes alone is likely to be more than $237 billion. In addition, there is also significant income loss to families impacted by NCDs, not just on account of disease but also due to care giving. NCDs also lead to distress financing and huge amounts of catastrophic expenditure, pushing people irrevocably below poverty. A 36 country study by WHO found that in most countries, including India, a month's treatment with just one anti-hypertensive medication costs 1.8 day's wages which becomes even more unaffordable if multiple drugs are necessary for attaining treatment targets and if more than one family member has hypertension.

Special facets of NCDs in India

Of note, unlike in developed countries, most NCDs, particularly CVD, diabetes and associated deaths in India occur at younger ages with attendant adverse health, economic and societal implications. This is mainly attributable to higher risk factor burden at younger ages, earlier disease onset (at least 10 years younger), premature mortality, and higher case fatality rate of CVD-related complications. Indians also have the propensity to develop CVD and diabetes at lower thresholds of overweight and obesity. Reports also indicate a progressive reversal of the social gradient, whereby the poor suffer increased exposure to risks such as tobacco use, hypertension and acquiring diseases such as CVD and diabetes, a situation similar to that observed in developed countries that already have undergone health transitions. Besides, in comparison to other countries, India suffers a very high loss in potentially productive years of life because of premature CVD deaths in those aged 35- 64 years: 9.2 million years were lost in 2000 and 17.9 million years are expected to be lost in 2030.These

factors are further compounded by the poor lacking access to expensive medical care once disease occurs, leading to widening disparities in care and social inequity.

Current responses

Though the disease profile has changed, the Indian health system is yet to fully re-orient itself, to effectively and efficiently confront the rising burden of NCDs, being still configured to provide acute episodic care and not adapted to providing chronic care. This has resulted in service inadequacies particularly at the primary and secondary care level. Diversity of providers, marked heterogeneity in the quality of clinical care, in availability and in accessibility, results in those belonging to higher socio-economic strata having access to the best possible care in modern tertiary hospitals and the poor lacking access to even basic primary care. Horizontal and vertical referral systems between the public and private sector as well as within the public sector are weak. Focus on early diagnosis and evidence based management approaches are also limited in both public and private settings. Of note, most people with NCDs spend out of pocket to meet healthcare costs with little or no financial protection.

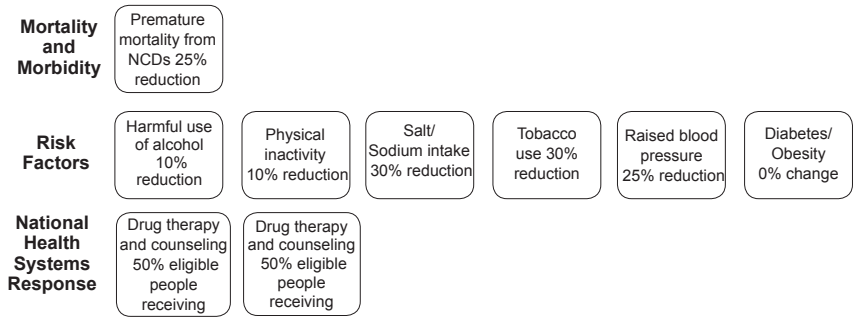
Several NCD related national programmes are now in place. These include the National Cancer Control Programme (NCCP) , the National Trauma Control Programme, the National Programme for Control of Blindness (NPCB), the National Mental Health Programme (NMHP), the National Tobacco Control Programme (NTCP), and the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS). Recently, the National Programme for the Healthcare of the Elderly (NPHCE) has been initiated. Of direct relevance to NCD prevention and control is the NPCDCS which has hypertension and diabetes as key focus areas and has incorporated the pre-existing NCCP. It is being implemented in 100 districts and expected to cover the rest of the country within the 12th 5 year plan period. NPCDCS aims at: a) assessment of risk factors, early diagnosis and appropriate disease management for high

risk groups b) health promotion for the general population. Deliberations are underway on implementing universal health coverage strategies and health sector reforms that can impact on NCD reduction. India is a signatory to the WHO Framework Convention on Tobacco Control (FCTC) and is implementing the Cigarettes and Other Tobacco Products Act, 2003 (COTPA), which mandates smoke bans in public and work places, ban on advertisements, prohibition of sales to and by minors, regulating the contents of tobacco products and placement of pictorial health warnings on tobacco product packages.

Pathways for addressing NCDs: way forward

Following the landmark United Nations High Level Meeting on NCDs in 2011 which mandated NCD prevention and control as a high priority issue, countries have now agreed to an ambitious goal of 25% reduction in mortality due to NCDs by 2025 and to establish a global monitoring framework to measure progress. This framework includes specific targets and indicators (Figure 3). Given the escalating burden of NCDs in India and the unacceptable gap between what is known and actually done in regard to detection, prevention and management, NCDs need to be addressed as a public health priority. Needless to emphasize this provides an excellent opportunity and the necessary impetus to energize and harmonize NCD prevention and control efforts in India so as to achieve the targeted reductions.

Figure 3: the WHO- United Nations Goal and targets for reducing NCDs



A comprehensive and integrated strategy that encompasses effective public health interventions to minimize risk factor exposure in the whole population and to reduce the risk of disease related events in individuals at high risk is warranted. This combination of the population approach and the high risk approach is synergistically complementary, cost-effective, and sustainable; and provides the strategic basis for early, medium and long term impact on NCDs in India in alignment with the aforementioned WHO-UN mandate.

Population based NCD prevention approaches

In developed countries where significant declines in NCDs have been observed over the past few decades, population wide preventive strategies, supported by an enabling environment, had contributed substantively as they have high impact, are cost-effective and sustainable over the long term given that they target lifestyle change. Recent analysis by leading health organizations such as the WHO and the World Economic Forum confirm the effectiveness and cost effectiveness of select population strategies (Table 1). However, implementation of these strategies calls for collaborating with non-health sectors where most of the NCD determinants lie, through multi-sectoral partnerships. Interventions that leverage the power of public health policies, for reducing excess consumption of dietary salt, fat, sugar and alcohol through regulatory and consumer education approaches; increasing physical activity levels by proper urban planning and creation of activity promoting environments; injury prevention promoting use of seat belts/helmets, reduction of drunk driving and inculcating safe pedestrian habits; increasing fruit-vegetable consumption through suitable agricultural and pricing mechanisms and implementing comprehensive tobacco control (effective implementation of COTPA,2003 under the aegis of National Tobacco Control Programme), have the potential to prevent a large proportion of disease events in the whole population, given that most disease events occur at modest elevations of multiple risk factors rather than at marked elevation of a single risk factor. For example, a 2% population-wide decrease of diastolic blood pressure, which

is easily achievable by modest salt reduction, was estimated to forestall 300,000 coronary heart disease and stroke deaths in India, with larger blood pressure decreases yielding higher reductions. As indicated earlier, population salt intake exceeds current WHO recommended levels and the recent global burden of disease study reported it to be the 7th leading cause of mortality in WHO's South East Asia Region, which is much higher than in rest of the world (11th rank globally), underlining the adverse health impact in countries like India. A 15% reduction in salt intake, through voluntary reduction in processed foods by the food industry and consumer education to encourage dietary change using mass media, was estimated to cost (in 2005) just Rs.2 per person/year. In addition to being cost-saving, reducing salt intake has the potential to improve hypertension control rates, reduce the need for anti-hypertensive medications and consequently curb associated healthcare costs. Given the rising burden of hypertension and related CVD, population-wide salt reduction is clearly a priority NCD intervention to achieve the global UN targets.

Other supporting legislative efforts should include policies for bans on misleading advertisement of junk foods and marketing to children, regulating food safety, mandating food labelling and ban on trans-fats.

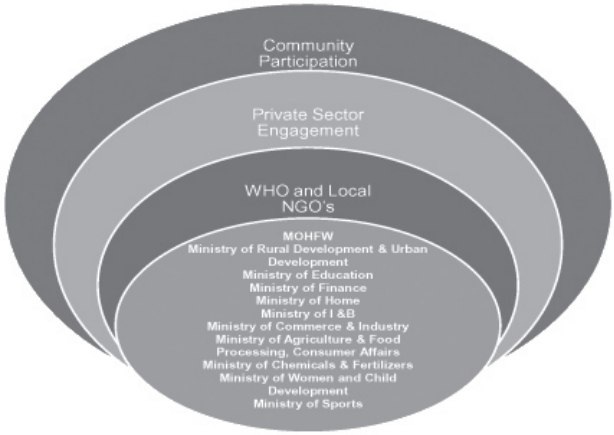
Table 1: Priority interventions and their costs

Risk factor	Interventions	Cost per person/ year (INR)
Tobacco use	Effective implementation of the National Tobacco Control Act	9.28
Dietary salt	Consumer education using mass media, action by food industry	3.48
Overweight, physical inactivity, unhealthy diet	Mass media campaigns, taxes on unhealthy foods, subsidies for healthy foods, mandatory food labelling, marketing restrictions	20.30
Excess alcohol consumption	Increased taxation, advt. bans and access restrictions	2.90
Cardiovascular risk reduction	Using low cost drug combinations for high risk individuals	52.20
Total cost per person (INR)		88.16

Leveraging multi-sectoral action for NCD prevention and control

Given that many determinants of NCDs are outside the realm of the health sector, such as poverty, education, social and cultural influences as well as economic and environmental factors determining diet, living and physical activity patterns, development and implementation of NCD control policies need to be comprehensive and ideally should involve a "*Whole of Government*" or "*Health in all Government policies*" or "*Whole of Society*" approach. This will entail involving multiple government ministries such as health, finance, home, education, agriculture, civil supplies, food processing, urban and rural development, transport, women and child development, commerce, environment, local self-government and panchayat raj, information, and communication (Figure 4). Further, participation of civil society organizations, private health sector, media, donor organizations and private companies is equally important to devise and implement multi-sectoral policies for NCD prevention and control. For example, the private sector can contribute to promoting healthy diets and physical activity, limiting levels of salt, fats, sugars, increasing availability of healthier foods and aligning market and advertising practices to facilitate NCD control.

Figure 4: Leveraging multi-sectoral collaboration Health system strengthening to promote evidence based clinical care



Effective interventions focussed on health system strengthening are necessary for reducing NCD related premature death and disability. To address the increasing demands of delivering NCD related care, there is a critical need for incorporating elements of prevention, surveillance, screening and management into all levels of healthcare (primary, secondary, tertiary). Further, skills of diverse healthcare providers involved in NCD care and management require regular enhancement, strengthening and updating. Given the large population that requires NCD services and the acute shortage of trained physicians, task sharing and task shifting of NCD care, by training of non-physician health workers, should also be explored. For instance, modelled estimates from India indicate that community health worker training in hypertension management is likely to be cost saving for the health system, in addition to averting numerous CVD deaths and hospitalizations. There is also supporting evidence from other developing countries with high NCD burden like South Africa and Iran on the feasibility and effectiveness of task sharing and task shifting in improving NCD outcomes.

Further, standardization of healthcare and accreditation of services are also necessary to improve the quality of care, in both public and private sectors. Improvement of the health system and integration of NCD related prevention and treatment services in the public and private sector will help provide more equitable delivery of services and are likely to have a large impact on reducing the disease burden and preventing much of the avertable mortality.

The initiation of NCPDCS offers a great opportunity for both health system strengthening as well as improving NCD management if leveraged appropriately. For example, the opportunistic screening planned in NPCDCS at the sub-centre level (first point of contact with health system) could be strengthened with provision of electronic decision support tools with screening and referral algorithms for the health workers to detect, refer and follow up NCD patients as well as facilitate reporting, utilizing appropriate data templates, and thereby contribute to surveillance and the development

of a health information system to track major NCDs and associated outcomes. Similarly, the NCD clinics mandated under NPCDCS could be leveraged to facilitate guideline based management with greater use of generic drugs, as recommended by the Indian Public Health Standards/ National List of Essential Medicines as well as capacity building of health personnel in delivery of chronic care. Training guidelines for physicians and health workers under the NPCDCS can be used, incorporating regular evidence updates where and when required.

Given the continued and long-term care required for NCDs, appropriate referral and follow-up pathways across various levels of care as well as public and private sectors are warranted. As medicines account for a significant proportion of expenses related to NCD care steps to ensure affordable, accessible and uninterrupted drug supply are necessary. Effective financial risk protection measures should be adopted to reduce the financial burden on individuals, as failure to do so will impede improving treatment outcomes. States can adopt the model of the Tamil Nadu Medical Supplies Corporation where it centrally purchases generic drugs at low prices and deploys a computer based drug inventory management system for optimal distribution. This system not only has reduced costs and increased efficiency and also has helped prevent stock-outs that were previously common. Similarly, properly validated and affordable devices to measure blood pressure, blood sugar and other clinical indices should be provided at all health facilities.

Given the low levels of awareness and detection of major NCDs, blood pressure measurement and possibly non-laboratory risk assessment using simple risk scores (based on assessment of age, gender, family history, blood pressure, physical activity) among adults should be mandated as part of all national health programs irrespective of the disease it deals with. To increase the awareness on major NCDs, the information education and communication (IEC) components of all national programmes can be leveraged to incorporate at least minimal health information and messages around NCD prevention and control.

Conclusion

The rising burden of NCDs in India needs to be tackled as a public health priority deploying an optimal context specific resource sensitive combination of the population and high risk clinical approaches. Numerous challenges lie ahead but there are also promising opportunities to galvanize efforts toward attaining the WHO-UN goal of 25% reduction NCD related mortality. India can ill afford to ignore this growing threat posed by NCDs to the health of its citizens.

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Governance in Government Health Programs

Introduction

India's major programmatic push to improve basic health outcomes since 2005 has combined efforts to increase spending, introduce effective interventions, and improve governance in essential public systems. Improving governance is a means to achieving all three dimensions of this increased effort – for example, additional funds may be allocated for health but without better governance they may not be spent on time or for the purposes intended.

Governance is a multifaceted concept that can be defined as "traditions and institutions by which authority in a country is exercised for the common good."(Kaufmann, Kraay and Martuzzi, 2004, 2007). Good governance can be thought of as a necessary element in the ability of public institutions to achieve their goals for improving health and social well-being. The design and planning of the National Rural Health Mission (NRHM) incorporated a number of different elements specifically intended to improve governance. This review will describe some of these key components and summarize some recent findings (and our views) on how well they have worked to improve governance and whether improvements in governance can be associated with improvements in program performance.

The stakes are high. Without better governance, widespread improvements in population health will likely be less, and less equitable, than they would be if programmatic efforts were better implemented. In addition, many in India strongly

advocate for a larger government role in health financing and delivery. The persuasiveness of their arguments depends greatly on being able to demonstrate that government is up to the task. Better governance in government health programs is a necessary condition for this to happen.

Brief history of Indian health sector and poor progress towards health improvement

India has been on a fast track towards economic growth but its translation of growth into improving the health of its more than one billion population is insufficient to meet the Millennium Development Goals (MDGs) by 2015 and the Government of India Eleventh Plan targets in reducing maternal, child (<5 years), and infant mortality. India's health profile is of global relevance as more than 78,000 (20%)of 387,200 maternal deaths, and more than 1 million (31%)of 3.4 million neonatal deaths worldwide occur in India (Rajaratnam, et.al., 2010) India is also ranked first in the world in total burden of disease detracting from the ability to achieve overall global health goals. (Ravishankar, et.al., 2009).

Table 1: Key GOI and MDG Goals

GOI Eleventh Plan Target and NRHM 2012[+] Millennium Development Goals, 2015[++]	Recent Status
Reducing Maternal Mortality Ratio (MMR) to 100 per 100000 live births[+,++]	212 (SRS, 2007-09)
Reducing Child (<5 years) Mortality Rate to 38 per 1000 live births[++]	63 (SRS, 2008)
Reducing Infant Mortality (IMR) to 28[1] per 1000 live births[+]	44 (SRS, 2011)
Reducing Total Fertility Rate (TFR) to 2.1[+]	2.5 (SRS, 2010)

The focus on medical causes of diseases and technical interventions has diverted attention from the structures and processes of making the health care delivery channels operate effectively and efficiently. Some of the key drivers of India's underperformance in health gain are the shortcomings of the

public health system in implementing the well developed strategies and programs through its extensive institutional mechanisms within and across different levels of service delivery. The Government of India itself has identified health system weaknesses and stressed the need for urgent reforms in public institutions owing to their weaknesses in adequately fulfilling public responsibilities (World Bank, 2006). The addition of strong media, active civil society organizations, and the rising expectations of a growing middle class form a confluence of pressure groups for transparency and accountability of the public sector. The mid-2000s saw an unprecedented commitment from Government of India to redress many years of insufficient spending on health to remedy the overall dearth of resources in the public health system. Increased resources highlighted the problems in public systems of being able to make effective use of resources.

NRHM: Reforms to address poor performance of the health system

A major policy response to earlier shortfalls in public health service delivery was to launch the National Rural Health Mission(NRHM) in 2005. NRHM was the national government's key strategy to make use of a proposed doubling or trebling of government health spending (to "2-3% of GDP" from less than 1%) and it included a number of innovative approaches intended to remedy governance problems in the public sector. The leading framework for implementing NRHM was through integrating and decentralizing programs across various sectors and related state and local structures under the new NRHM organizational structure. Elements of this initiative were the creation of integrated district health plans, including "effective integration of health concerns with determinants of health like safe drinking water, sanitation and nutrition"; partnership with nongovernmental organizations (NGOs); flexible funds for state and local governments; strengthening of the "society mechanism" to improve use of increased funds; appointment of an Accredited Social Health Activist (ASHA) in each village; and

"strengthening of public health infrastructure." (Planning Commission, 2006)

Improvement of management infrastructure and practices

To enable the new NRHM decentralization strategy to operate effectively, the NRHM planned to create and strengthen health societies at the State, District and Block levels. Convergence at the state level required the inclusion and coordination of all centrally funded health schemes and additional guidelines for inter-sectoral coordination would ensure that key social, educational and economic programs that contribute to improved health are executed within the broader mandate of NRHM. The core instrument for defining needs and priorities that would translate into local budgets was the district health plan executed through an intensive bottom up, inclusive process. It was the responsibility of the District Health Society to propose annual work plans with related budgets to the State Health Society or Mission under the leadership of the Chief Minister.

In order to provide managerial support to track and monitor funds at the district and block levels, new Program Management Units (PMUs) were authorized. The capacity of the PMUs was to be built and supported by the proposed National Health System Resource Center (NHSRC) based in New Delhi and the State level equivalents. NRHM also provided funds for hiring on contract of managerial consultants at state and district level.

Increased use of block grants (untied funds)

The NRHM implementation plan included provisions to transfer funds, functionaries and functions to PRIs. To provide oversight, monitoring committees would be formed at every level, with participation of PRI leaders, CBO/ NGO representatives, and the community to plan and review the utilization of the funds.It was proposed that eventually at least 70% of the total NRHM expenditures would be supervised by the PRI and other community groups. (MoHFW, 2005).

Incentive payments for village health workers (ASHAs) and families

A major component of NRHM was the launch of Janani Suraksha Yojana (JSY) to promote institutional delivery through cash payments to families and to ASHA workers. This approach worked to reduce financial barriers that often prevent women from accessing skilled attendance at birth. The rules governing benefits varied by categorization of the state's level of development, urban/rural geography, parity and income status of the concerned woman. In the ten high focus states, all women residing in rural areas regardless of socioeconomic status and parity are eligible for the maximum cash benefit of 1400 rupees. The ASHA equivalent for accompanying women for an institutional delivery (a "supply-side" incentive) is 600 rupees.

Community accountability through PRI, the elected voice of the community

It was envisioned that the "NRHM would seek to empower the PRIs at each level i.e. Gram Panchayat, Panchayat Samiti (Block) and Zilla Parishad (District) to take leadership to control and manage the public health infrastructure at district and sub district levels." (MoHFW, 2005) At the village level, the Village Health and Sanitation Committee (VHSC) was to be established with proportional representation from all the hamlets and inclusion of people from the lower castes. The PHC and Sub-Center was also to have oversight by the VHSC in its area. Likewise the Panchayats would be represented in the committees of the respective health facilities through the Rogi Kalyan Samitis (RKS).

2. Previous governance weaknesses inhibited NRHMs performance

Incomplete implementation of Panchayati Raj

A history of decentralization initiatives preceded NRHM and laid the foundation for its ability to get fully implemented. In 1993, after decades of debate on decentralization, two constitutional amendments gave legal recognition, increased

political status, and greater expenditure responsibilities to urban and rural local governments. The main mission of the PRI remains: "empowerment, enablement and accountability to ensure inclusive development with social justice and efficient delivery of services." (MoPR, 2013) However, problems with the legislation and its implementation include lack of clarity, mismatches between revenue and spending authority, and lack of local administrative capacity. (Singh, 2008)The lack of more consistent functionality of the PRI infrastructure and the GoI's incapability to devolve more responsibilities and resources to the PRI affected the ability of NRHM to fully implement its programs. This, combined with the GoI's own deficits in organizational management and creation of functional funding channels for improving the infrastructure in facilities and providing skilled health personnel to deliver quality services, prevented NRHM from being fully implemented.

Under-spending and problems in funds reaching lower levels of service delivery

By the mid-2000s, overall government spending on health continued to be less than 1% of GDP. Of this,the state contribution had been around two-thirds in comparison to the central level funding of one-third. In contrast, total spending on health, both public and private, was around 4-5% of GDP, reflecting a high share of private spending, most of which was out-of-pocket. National surveys had indicated for some time the high burden of this spending on the poor where it accounts for a significant level of "medical impoverishment" (Berman,Ahuja, and Bhandari, 2010).

The efficiency and effectiveness of the flow of funds through the government bureaucracy impeded further the use of limited government funds. Poor quality infrastructure and gaps in essential equipment, drugs, and supplies combined with delays in disbursements, bureaucratic hurdles and corruption to undermine providers' motivation and performance and reduce the confidence of the population in government health services in many states. The consequence was a paradox of underutilization of mostly free or very low

cost public health services, creating undue hardships for the most disadvantaged who may delay or not receive vital health services or seek poor quality if not harmful care from less than fully qualified but accessible providers (Berman,1998).

NRHM contained a number of specific strategies to address these shortcomings.

Some of these measures specifically try to improve governance and in some cases, to be effective, these measures also require governance itself to improve. The society mechanism is an interesting example. By routing much of NRHM additional spending through state and district health societies and by merging different purpose-specific societies at these levels, NRHM put in place processes to improve the timeliness and appropriateness of spending. But for these processes to work effectively, state and local officials also needed to be willing and confident to expedite processes, for example by not requiring additional clearances for actions through the new mechanisms.

Evidence from the first few years of NRHM implementation indicates that overall such governance weaknesses persisted despite the new processes. This resulted in large gaps between what was budgeted and what was actually spent by NRHM – gaps that were larger in the NRHM focus states where need was greatest (Berman et al, 2010).It is likely that the reported gaps may underestimate actual delays in spending since funds run through the "society route" do not lapse each year which would allow higher level unit to report as spent moneys which may still lie unused in the accounts of lower level units.

Strong governance and financial management is also required to deliver on the large role NRHM assigns to performance-based payments for ASHAs and conditional cash transfers, such as the JSY Program. Studies have documented the state-by-state variation in the payment process, including the role of delays in payments to mothers and ASHAs. For example, more than three quarters of ASHAs in Orissa and Rajasthan reported getting their payment regularly. However, only nearly half of the ASHAs in Madhya Pradesh and Uttar

Pradesh and only 21% in Bihar were found to be receiving their payment regularly (UNFPA, 2009). As in many other national programs, the poorest and least educated women did not consistently have the highest odds of being part of the program (Lim, et.al., 2010).

In a survey of State Nodal Officers, many have reported that in case of delays in getting funds, even additional efforts to get other schemes to temporarily pay to the JSY beneficiaries and ASHAs, did not provide sufficient coverage to meet the demand in 2008-09. The most frequent reasons reported were: (i) non-availability of JSY funds at the service unit level, (ii) facilities not getting funds either due to non-availability of funds and non-submission of all the required documents needed with the report for the previous fund disbursement, and (iii) check book unavailability which was reported quite often.(UNFPA, 2009).

Ineffectual human resource policies and practices

The basic building blocks of health systems are human resources. The health personnel shortages continue to plague the public health system. The public health system has 1.35 health professionals per 1000 population, with more doctors than nurses and midwives (Rao et al 2011). The Joint Learning Initiative has estimated that 2.5 skilled professionals per 1000 are needed to attain 80% coverage by skilled attendants. (Paul, et. al., 2011)

The high absenteeism rate of medical staff posted to health facilities contributes to the inability of the health system to deliver services. In a nationally representative all India survey over 1400 public health centers across 19 states, on average 40% of doctors and medical service providers were absent from work on a typical day (Muralidharan, et. al., 2011).Doctors were more likely to be absent than junior staff, but all levels of staff were significantly less absent in facilities where the doctor in charge was more likely to be present. Doctors posted at remote facilities and at facilities with poor infrastructure and equipment were absent at significantly higher rates, as were those who lived further away from the work place.

Pervasive system-wide causes of health provider underperformance are many. They include poor compensation and benefits, inadequate housing and provisions for families, poor working conditions in under-resourced and under-supplied facilities, and the absence of a reward structure to garner loyalty and motivation. Overall, India has a low ratio of nurses to physicians relative to international comparisons (Rao, Bhatnagar, Berman, 2009). Rural health service design may be overly dependent on having physicians relative to their willingness to serve in rural areas given their social and class background and better private sector opportunities. Conversely, non-physicians including nurses, midwives, and other paramedical workers, have not been trained for leadership roles in rural health care.

There is also high turnover, which under mines performance. Doctors with greater connection to the community (as indicated by whether they have served over three years in the same clinic) are also less likely to be absent. (Muralidharan, et. al.,2011) The corruption factor in transfers and postings is widely discussed in India. Bribes may need to be paid in order to get or maintain a more sought after position or geographic location. The high "cost" of a particular position has a spin out effect, as lower level staff members are part of the chain of repayment that that has a cascading effect down to the village ASHAs.

Increasing government financing for health should result in strengthening human resources. For example, the ASHA program, a significant addition to human effort in public health programs, scaled up very rapidly with central government funding. But in states with weaker governance, funding for new posts may be a necessary but not sufficient condition for filling human resource gaps. A comparison of efforts in UP and Tamil Nadu to create and fill posts for rural nurses and physicians highlighted the barriers encountered in UP even when new posts were funded and created. There were long delays in recruitment and other processes, which resulted in low uptake of available positions. Many of these constraints were outside of the health department. (Raha, et al 2009).

Poor quality facilities and coordination of services

In 2003, only 32% of 9688 primary health centers and 63% of 1625 community health centers were judged to have adequate infrastructure. (Paul, et. al., 2011).NRHM did catalyze substantial investments in improving facilities. By 2007–08, operating theatres were functioning in more than 65.2% of community health centers, and 68.8% of district hospitals had fully operational blood banks. But poor governance in specific states has undermined this initiative. In a recent study in Uttar Pradesh,15 facilities were assessed that should have been should have been providing at least basic emergency maternal, obstetric and newborn care (BEmONC) services, according to government guidelines. The findings showed that none of the facilities met the recommended standards for BEmONC except the district hospital. This led the authors to conclude "Even in the face of vigorous commitment to improving maternal health services in India, in adequate staffing, supplies, and equipment at health facilities, as well as transportation costs and delays in referral, appear to contribute to a substantial proportion of maternal deaths in a representative district in Uttar Pradesh." (Raj, et. al., 2013)

Lack of effective accountability structures

In August 2003, the Central Council of Ministers of Health and Family Welfare had resolved "that the State would involve PRI in the implementation of Health and Family Welfare Programs by progressive transfer of funds, functions and functionaries, by training, equipping and empowering them suitably to manage and supervise the functioning of health care infrastructure and manpower and further to coordinate the activities of the works of different departments such as Health and Family Welfare, Social Welfare and Education which have functionaries in at the village and Block levels." (MOHFW, 2005) Although, there is variability in the functioning of the PRIs across different states and regions of India, in many of the high focus states, the PRIs lacked the capacity and resources to positively affect NRHM systems for planning, implementing, monitoring and injecting the

community's voice and power into creating the demand for better health services .After seven years of NRHM implementation, many of the Village Health and Sanitation Committee(VHSC) structures, the basic building blocks of accountability at the most decentralized level, still do not exist or are not fully functional.

The lack of accountability has also permeated the ASHA selection process. As per NRHM protocols, the selection process was deemed to be democratic with the inclusion of the entire community in putting forth and selecting the ASHA worker. However, many factors are thought to influence this process and include: 1) the educational requirements which exclude most of the poorest communities; 2) lack of information and community mobilization to follow-through on the proposed norms; 3) interest from the upper castes who may have regarded this position as an eventual entry into a regular salaried government position; and 4) influence and pressure of the more powerful sections of the community, including the Pradhan to select their relatives, friends or neighbours.

The combination of a flawed ASHA selection process with the lack of a representative community structure through the VHSC has reduced the ability of scheduled caste and scheduled tribe communities from equally sharing in the benefits of GOI schemes and services. The cycle then is self-perpetuating as the cultural and social dynamics of inter-caste communication affects community participation and exchange affecting knowledge about government benefits and structural restrictions in ASHA, ANM and AWW service delivery.

Innovations to improve governance

India has the resources, capacities, and a dynamic democracy to advance into a higher level of health system performance through the implementation of its well-designed programs and strategies. The engine of that take-off is the activation of good governance cutting through all the geographic levels and bureaucratic layers of the system. The direct participation of people at the lowest levels of the village community together with the advent of a functional PRI system can create and accelerate positive outcomes especially

when regular meetings are held with the inclusion of women and the SC/ST communities. In addition to a structure for information, feedback, monitoring and action, many parts of the full governance mechanism in the public health sector have been set in motion but require further support and monitoring to achieve better outcomes and to gain the momentum needed get over the tipping point in improving system-wide transparency, integrity leading to performance.

Improvement in financing

As noted earlier, NRHM early efforts to increase government spending on priority health programs were only partially successful. Government health spending increased from about .9 % of GDP prior to NRHM to about 1.1% of GDP in recent years. But this was far below the 2-3% of GDP that was targeted by GoI, to be achieved by 2012.

Several factors explain this shortfall. It proved difficult to get states to increase their funding as expected – the central government has limited capacity to affect state spending directly. Governance barriers prevented the society mechanism from being fully effective. And the demands placed on public systems by programs that required many small payments to lower level facilities, ASHAs, and individual beneficiaries were formidable. Systems were not in place to deliver on what was planned in many cases.

There has been positive progress however. NRHM and CAG have monitored budget realization and there have been significant improvements across the states. In many cases today spending exceeds 100 percent of annual budgeted amounts, which likely reflects spending of prior non-lapsed amounts as well as increased effort. There have been widely reported corruption investigations and criminal actions taken against offenders. And there are good examples of innovative efforts at state level to use e-banking and other financial management innovations to speed up payments to lower level facilties, providers, and mothers.

With greater financial constraints in recent years, budget increases have also slowed, allowing the gap between planned spending and actual spending to shrink.

Emergence of multiple accountability structures/ processes

The clear articulation of goals for the system provides the basis against which real performance can be measured, and accountability visibly present through documentation and action. Despite the emphasis on multiple data collection strategies and systems, the most comprehensive JSY study using nationally representative data, did not have the ability to assess the potential contribution of state or district level governance, or program implementation and oversight to the overall effect of the JSY because data for these indicators were not available. (Lim, et.al., 2010)

Clear mechanisms for downward accountability are essential in improving access to benefits and services when there is flexibility to make local decisions about resource spending. The demonstration of a functional local mechanism to address community concerns can lead to greater local legitimacy and community support. As mentioned in the original NRHM framework, the capacities of the members of village, block and district level committees have to be built for them to be able to function effectively. This process must be institutionalized and ongoing as people change their positions and new policies and programs are initiated requiring new information and training protocols that can translate into knowledge about how to take action to obtain new benefits or services.

For accountability to work, specific roles and responsibilities must be delegated to ensure that performance of specific functions is clearly understood. There currently exists a significant overlap of roles, responsibilities across functionaries, government departments and jurisdictions. The ASHA in NRHM, for instance, is accountable not just to her community through the VHSC structure but also to the multiple line departments at the state government level.

Greater engagement and pressure from local communities

Because of the strong media, active civil society organizations, and the rising expectations of a growing middle

class, the prospects for engaging the community in strategies to disclose information and hold providers accountable for their actions has great potential. The growth of women's self help groups and other forms of community collaboration through established groups and related structures can play a major role in improving the local environment for generating a more empowered community voice for demanding accountability from the government functionaries. The Right to Information Act (RTI) and the establishment of grievance cells can reinforce the local government through the PRI structure to be more responsive to engage in processes to create positive change.

Although there is great variability in the extent to which local communities are able to act in a cohesive fashion to solve their problems, a basic principle is that communities need to know about their entitlements and be able to provide feedback to the system and expect some results. They also need to know that there is a benefit to the community from the resources that they manage through local committees. Research has also demonstrated that people are more likely to participate when local governments are more responsive. (Surie, MD, 2010). In the long run, the community is the catalyst for ensuring that benefits, schemes and services reach the bottom of the one billion plus pyramid to promote a better future for all.

Some Conclusions

In 2005, the UPA government initiated bold new efforts to correct decades of underinvestment and poor performance in basic government health care. The National Rural Health Mission contained, in its design, many different elements which were intended to increase spending on priority health programs and to address governance inadequacies and to improve governance in specific ways that would improve health performance. It is worth noting that increasing spending and improving governance are also related – weaknesses in governance also resulted in shortfalls in actual spending on NRHM even when resources were available in the high growth years of 2005-07.

The evidence to date indicates that there has been much progress. But that progress has been uneven and it is likely that it is strongly associated with the underlying governance conditions in different states. In states with better governance, NRHM innovations were more able to improve performance. In states with weaker governance, NRHM innovations sometimes were not sufficient to correct or reverse the governance problems and consequently performance suffered.

This brief review has highlighted how some of the key elements of NRHM were intended to address perceived governance problems and provided some examples of both positive and negative experiences. Our review is by necessity based largely on examples. Governance quality is not so well-defined, certainly not well-measured with sufficient scale at a systems level, and almost never analyzed in relation to program performance.

This review suggests that government planners were correct in diagnosing governance problems as a cause of weak prior performance and in their emphasis on governance innovations as a key element in scaling up public health programs through NRHM. It also suggests that some of these innovations, when they worked, are associated with better program performance. Our review also notes that entrenched governance problems in some states were not easily overcome by the mechanisms put in place by NRHM and that some of those mechanisms themselves were only weakly implemented due to limitations in government capacity to carry out its own stated plans, which is also a governance shortfall.

NRHM is only one mechanism for governance innovations in public health being introduced in India – there are numerous other initiatives across the states. For those advocating a dominant government role in health in both financing and delivery, improving governance in public systems remains arguably THE major challenge. The struggle has been engaged, but the outcome is far from certain.

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Amarjeet Sinha

NRHM has Made a Difference: The Evidence from States:

Need to look at the evidence

This paper is an attempt to assess the impact of the National Rural Health Mission (NRHM). The misadventure for a few years by a handful of bureaucrats and Ministers in Uttar Pradesh[1], has tarnished the good work that NRHM has done in a large number of States. Even in Uttar Pradesh, some good work was done for a few years before the misadventure with public funds began. A fair assessment of NRHM needs to look at hard data more carefully. Much as what happened in Uttar Pradesh is reprehensible and condemnable, that is not the only reality of NRHM. Launched in 2005, the NRHM attempted to strengthen the public system of health care at all levels. It had envisaged significant increase in public expenditure on health[2]. Unfortunately, the increase has been very modest, with public expenditure on health improving from a little below 1% GDP before NRHM to a little over 1% GDP after NRHM. There is a slowing down on increases in allocation for NRHM in 2011-14, given the constraints of budgetary support on account of high fiscal deficits[3].

Assessing NRHM

Any new mission takes a few years to come into force and it will be safe to assume that nation-wide presence of NRHM interventions can be said to be in place 2007 onwards. The foremost presence has been in the form of the Accredited Social Health Activist (ASHA) linking households to health facilities. Being a Framework for Implementation (and not a guideline cast in stone) NRHM has permitted flexibility to States in deciding their course of action and priorities to

achieve the stated goals of the Mission[4]. Changes in health indicators take time even after adequate resource provision and it is for this reason that the initial plan was to craft NRHM as a 10 year programme instead of a 7 year effort (2005-2012). It is for this reason that NRHM has been extended as the National Health Mission (including urban health mission, for which only a token provision has been made in the Budget of 2013-14) in the Twelfth Five Year Plan (2012-2017)[5].

The Public Health Paradigm shift

While assessing and evaluating the contribution of NRHM, it is necessary to bear in mind the challenges in public health and how, many other developing and developed nations have tackled them. NRHM was clearly an effort to take health care from a narrow 'medicalized' perspective to a wider public health approach, from mere discourses on antibiotics to clean water and sanitation. The shift in approach was influenced by a systematic assessment of the current health scenario in India[6]. The thrust on public hygiene, clean water and sanitation as central to the public health approach has been the case in continental Europe as also many developing economies, whether it is China, Brazil or Malaysia, Thailand, Mexico, Iran, Sri Lanka. NRHM was clearly pursuing a paradigm shift in the perspective on public health and this required a consensus with other Ministries and Departments. Similarly, the efforts on fighting under-nutrition are central to public health as under-nutrition alone makes a 20-40% difference in the indicators of health and well-being[7]. Clearly, successes in the battle against under-nutrition, is integral to the public health approach.

Clear thrust on public systems

NRHM clearly advocated building credible public systems as it was felt that given the information asymmetry, health needs public systems and cannot be left to the private sector and markets alone. There was a clear policy articulation of strengthening public systems[8]. This is contentious in India post 1991, where successes in economic growth through a liberalized private sector participation has given a confidence

that even social development can be attained by a private sector led effort. This is clearly a misplaced notion as the challenges of public health are different from merely setting up secondary and tertiary care medical facilities. It is only the public system that can take care of primary health and the counter-veiling presence of a functional public system has consequences for the cost and quality of care in the private sector.

The Journey of NRHM - An assessment

The NRHM was launched by the Hon'ble Prime Minister in April 2005. Its detailed Framework for Implementation which gave it the mandate for large scale health sector reforms was approved in July 2006. In its journey NRHM has tried to push reforms with resources in partnership with the State and UT governments. Health is a State subject and NRHM has respected the leadership of the States and UTs in bringing about reform and improvement in health indicators. The NRHM Framework for Implementation has pushed 'communitization' of facilities, adequate and flexible financing with community accountability, monitoring progress against Indian Public Health Standards, innovations in human resources engagement, and building of capacity at all levels for effective and efficient decentralized management of the health system.

Sources for assessing performance

Besides the Annual Common Review Mission which visits 13 – 17 States with a team of public health experts, civil society representatives, development partners etc., the NRHM has been subjected to a large number of external surveys and studies. From the DLHS-III Survey 2007-08 conducted under the supervision of IIPS Mumbai to the Sample Registration System (SRS) and the Annual Health Survey of 284 districts in the 9 States with unsatisfactory indicators 2010 and 2010-11 (Assam, Bihar, UP, MP, Uttarakhand, Orissa, Rajasthan, Chhattisgarh, and Jharkhand) of the Census of India, the Performance Audit by the Comptroller and Auditor General (CAG), Citizens' Reports by Civil Society, Community Monitoring Reports through the Advisory Group on

Community Action, Planning Commission Study by Ms. Kaveri Gill, Jeffry Sachs' and Nirupam Bajpai's study in three North Indian States, evaluation studies on the Janani Suraksha Yojana programme in eight States, Unicef's Coverage Evaluation Survey 2009, Institute of Economic Growth and IIPS Mumbai led studies, studies undertaken by the National Health Systems Resource Centre(NHSRC) on the ASHA programme, emergency ambulance system, etc., have been brought out during this period. The Lancet journal has also published articles on child and maternal mortality and a number of papers in the Special issue on India in 2011 have looked at some of the NRHM initiatives. Action Aid and Save the Children have looked at some aspects of NRHM. It is actually possible to take stock of which way the Mission has moved during these years by carefully looking at the studies, the data and the Review Mission Reports.

Some early conclusions

Based on a careful evidence based assessment of progress as recorded by independent studies and review missions, it is clear that NRHM has led to increase in outpatient cases, inpatient cases, institutional deliveries, availability of ambulances, presence of community health worker in every village, better availability of drugs and diagnostics and most importantly a sincere effort to craft a credible public system. The weakness of the health system in India before NRHM is public knowledge and it is also well known that India was incurring one of the lowest public expenditure on health in the world with less than 1% GDP. It is also well known how public system had become dysfunctional in a large number of States and how new programme after programme for diseases and family welfare were working on the flawed assessment that there was primary care system waiting to deliver services. NRHM questioned this very basic paradigm and gave the maximum thrust to human resources for health and that too, specific to institutions and on a contract to enable greater community accountability of the human resource deployed under NRHM.

NRHM also provided an opportunity at each level from the Village to the Sub Centre, the PHC, the CHC, the Sub

Divisional Hospital, the District Hospital to create a community institution under the umbrella of the Panchayati Raj local government system, with provision of untied funds to meet institution and village specific needs for health care. Effective decentralized management is a difficult exercise as it always involves delegation of powers and financial resources to local community institutions. Large systems have a tendency to stall decentralization as many government systems perceive this as an empowerment of local level facilities. It is for this reason that in a number of States the utilization of untied funds at the local village, sub centre, PHC, CHC level remained slow in the initial phase[9]. Many institution heads at these levels had lost the confidence to spend as per their felt need on account of over centralization over the last five decades. However, even that has picked up very significantly over the last few years. That confidence has come by and by and today as the Common Review Mission reports indicate, a large number of institutions have made good use of these resources as per their felt need. The unspent balances pointed out by Performance Audit in the initial period are on account of this uncompromising priority of NRHM for decentralized management of the health system[10].

NRHM has a mandate to ensure that 70% of the financial resources get spent at the block and the below block level and only 20% at the district level. NRHM has pushed this quest for flexible financing with local level community accountability and this did indeed lead to slow utilization in the initial years. NRHM has successfully set up institutions for communitization and is engaged in the process of making them even more vibrant and effective government institutions. It has gone beyond the monopoly of PRI by also co-opting self help groups, women's groups or any one with motivation in the Village Health and Sanitation Committees constituted under the umbrella of PRI. These community processes take time especially in a sector like health where decentralization was not on the agenda at all over most parts of the country and PHCs, CHCs functioned without any control of local government in most States.

Impact of Janani Suraksha Yojana

The studies on JSY have brought out the fact that institutional deliveries have increased tremendously across all States and more so in States like MP, Orissa, Rajasthan, Assam, Bihar and over the last two years in UP as well[11]. Some other studies like one by Human Rights Watch in UP has also highlighted the issue of quality of care and the denial of good services to poor women at many facilities[12]. While resources are available with government facilities for improving the quality of care, it is also true that the pace of refurbishment and improvement of quality in health facilities has not kept pace with the demand for institutional delivery services in many States on account of the JSY financing. States like Jharkhand and Chhattisgarh have moved slowly on institutional deliveries and by and large their strength has remained at the sub centre and community health worker level rather than at higher level institutions.

Respecting the leadership of States

The journey of NRHM is one of State/UT government led reforms with resources. The Government of India only indicates the resource envelope to the States and it is the States that develop the detailed Programme Implementation Plan based on the District Health Action Plans in their State. There is a State Health Mission under the Chief Minister monitoring the progress of NRHM in the State. This has led to innovations on an unprecedented scale across the country. From Boat Clinics in Assam to partnerships with Tea Gardens for the health care to the poor, partnerships for diagnostics in Bihar and West Bengal, emergency transport systems designed as per local needs in Haryana, Andhra Pradesh, Gujarat, Rajasthan and many more States. There has been large scale innovation in human resource engagement with Rural Medical Assistants selected in Chhattisgarh and Rural Health Practitioners selected in Assam. Orissa has recruited Ayush doctors to provide services at PHC where there was no MBBS doctor. States have been encouraged to think through their problems and come forward with their own solutions.

Government of India has played the role of sharing good practices through thematic workshops across States so that States can learn from each other and emulate the best practice. Efforts to set up procurement and logistic systems like the Tamil Nadu Medical Service Corporation has been made in a few States like Kerala, Rajasthan, Bihar, Chhatisgarh, and a greater thrust is being placed on it to ensure availability of quality, drugs and equipment at all levels in a sustainable manner. Similarly, buildings are either being renovated or constructed in over 20% Sub Centres and 75% CHCs and District Hospitals under the NRHM.

Findings of the Coverage Evaluation Survey

The Coverage Evaluation Survey (CES)2009-2010 conducted by ORG on behalf of Unicef, has brought out key and dramatic changes since the launch of NRHM. Some of these changes are as follows:

		2005 As per NFHS	2009-10 as per CES
1.	Institutional delivery	40.7%	72.9%
2.	Safe Delivery by Skilled Birth Attendants	48.2%	76%
3.	Mothers who had 3 or more ANCs	50.7%	68.7%
4.	Institutional delivery in MP	29.7%	81%
5.	Institutional Delivery in Rajasthan	32.2%	70.4%
6.	Children with diarrhoea who received ORS	26%	53.6%
7.	Number of children breast fed within one hour	24.5%	33.5%
8.	Full Immunization	43.5%	61%
9.	New born had their cord cut by sterilized /new blade		86%

Source: Coverage Evaluation Survey 2009-2010; Unicef.

The gains recorded by the Coverage Evaluation Survey have been confirmed by the Annual Health Survey findings 2010 and 2010-11, carried out by the Census of India in 284 districts in India's poorest regions. Clearly, there have been

gains in the access to the public system of health care because of demand side financing under the JSY and by connecting households to health facilities by engaging the ASHA.

Did disease control really get neglected?

Some make the point that disease control programmes got neglected due to NRHM. The evidence is to the contrary. NRHM was not only about Reproductive and Child Health. It was about developing a horizontal platform of health care institutions like the Health Sub Centres, PHCs, CHCs, and District Hospitals. With improved availability of paramedics including Lab Technicians through recruitment and through partnerships, health facilties could provide a range of services in disease control as well. States like Bihar recorded a very significant increase in the Designated Microscopy Centres (DMCs) under the TB programme. The problem has been that the TB programme continued to maintain its verticalized approach. Similarly, there has been a significant improvement in malaria prone States like Orissa and Assam in the outreach services available at health facilities. Also, the ASHA and emergency transport arrangements, along with more hospital beds in States (of course much less than the requirement but then, was money as envisaged made available to NRHM?), helped in better detection and action in cases of malaria and other public health challenges. The ASHA has made a difference in the health seeking behaviour of poor households. There is now a tendency in many disease control programmes to explain their failure by neglect of those programmes by NRHM. The fact is that many of these externally funded programmes wanted to retain their 'verticalized' identities and both Project teams and funding agencies encouraged such an effort. While the NRHM made the effort to include disease control programmes as part of the Programme Implementation Plan efforts, there was reluctance from the disease control programmes to be accountable to a new structure.

Ambitious targets and over-modest funding

There is a tendency in some documents to criticize the National Rural Health Mission (NRHM) for not reaching

over-ambitious targets that were never backed with adequate financial resources. This needs to be protested on the basis of evidence. Mismanagement of NRHM funds for a few years (not the entire Mission period) in UP cannot be used to gloss over the success of the Mission in almost every State, even though the Mission was not provided the proposed amount of financial resources. Many States also needed a longer time to build capacities to spend. NRHM was launched in 2005, at a time when infant mortality rate had plateaued around 60 for a few years (2003-05). Any Mission takes a few years to be fully functional and it is safe to assume that by 2007 the Mission took roots in the field. NRHM's foot soldiers, the ASHAs started connecting households to health facilities and this process naturally took a couple of years of basic training and support.

Analyzing Infant Mortality rate

Analysis of the Sample Registration System Data on Infant Mortality Rate (IMR) for the 2003 – 2007 period and its comparison with the reduction in the 2007-2011 period reflects the success of NRHM, especially in hitherto backward States. The Table below records the Change in a few States –

		IMR 2003	IMR 2007	IMR 2011	CHANGE 03-07	CHANGE 07-11
1.	INDIA	60	55	44	05	11
2.	KERALA	11	13	12	02	01
3.	TAMIL NADU	43	35	22	08	13
4.	BIHAR	60	58	44	02	14
5.	GUJARAT	57	52	41	05	11
6.	RAJASTHAN	75	65	52	10	13
7.	UTTAR PRADESH	76	69	57	07	14
8.	ORISSA	83	71	57	12	14
9.	MADHYA PRADESH	82	72	59	10	13

The Table clearly brings out the faster rate in decline of IMR in the 2007-11 period, the period when the impact of

NRHM becomes visible. In States like Bihar, from a meager two point decline in 2003-07, the 07-11 period has seen a remarkable 14 point decline. Even a better performing State like Tamil Nadu made good use of NRHM funds to speed up IMR decline considerably. Except Kerala (which already has a very low IMR comparable to developed nations), all States including UP have shown a faster rate of decline. This is always more difficult when we move downwards.

The issue of attribution

Critics will say how reduction in IMR be attributed to NRHM. Let us look at the key findings of the Annual Health Survey 2010 and repeated in 2011, conducted by RGI's Census of India in 9 backward States. There is confirmation in improvement of key inputs that give better outcomes – immunization, institutional deliveries, ante natal care, post natal care, etc. in States like Orissa, Rajasthan, MP, Assam, Bihar, Jharkhand, Chhattisgarh, UP and Uttarakhand. The Annual Joint Review Mission of NRHM has reported increase in OPD/IPD cases, availability of drugs, diagnostics and doctors in most States. NRHM has clearly unleashed a revival of the public system in many States. Nothing signifies it as starkly as the per month OPD figures for Block Primary Health Centres of Bihar. From 39 per month in February 2005, it is over 8500 per month in 2011. The increase in institutional deliveries in public facilities in Tamil Nadu, shows the power of well functioning public systems to attract the people. Every State has made efforts to improve human resources, physical infrastructure and general functioning of government hospitals. Large number of Managers has been brought into the system to ensure improved compliance to protocols. For the first time government facilities have been subjected to NABH and ISO certification. For once, crafting credible public systems is the focus. Thrust on generic drugs through TNMSC like arrangement has also started in a few States. While a lot remains to be done, a meaningful beginning has been made in crafting credible public systems.

NRHM – only a beginning in public health approach

The public health challenges are many and only a beginning

has been made with NRHM. There is a need to deepen these reforms and continue to focus on crafting credible public systems. The public health challenges of clean water, sanitation, under-nutrition, have all to be attended to on a wider platform of community led human development. Purchasing hospitalized care through insurance company does not answer the public health needs. Dengue, Encephalytis, chikanguniya, all require community led responses by the public system. Even hospitalized surgical care requires the counter-veiling presence of a functional public system to regulate the cost and quality of the private sector. The gate keeping role of the public system is required in any insurance based scheme to ensure that unnecessary surgeries are not being resorted to. Mass scale hysterectomies have been reported in many insurance schemes in many States.

Partnership with the non-governmental sector

There is room for partnerships with the non-governmental sector to meet the needs of hospitalized care. Here again, a Trust Model like Karnataka's Yeshasvini, without insurance companies and the State providing reinsurance, is better as in this model all monies are spent on health care. The vagaries of claims ratio unnecessarily pushes up the cost of health care in the insurance company model. A country struggling to reach even a modest 2% GDP public expenditure on health, cannot afford high cost of care models. All partnerships require a strengthened public system with the capacity to get into partnerships. There is evidence under NRHM of PPPs working well, if intensively monitored at the local level and with transparency, in provision of diagnostics and in management of ambulance systems. A cautious and careful approach is required in partnerships as the health sector does not lend itself to market principles very easily.

Evidence from States

The clear evidence from the States is that public systems need to be strengthened. Accountability frameworks need to be further strengthened so that flexibility in programme implementation (which is required for results) is not converted into a licence for misadventures. Greater community and

Panchayat links with a wider human development approach and a common institutional framework for health, education, water, sanitation, nutrition, women's empowerment, and for the development of marginalized social groups, is established from the habitation to the State level. It is high time that the ASHA worker, the Aanganwadi Worker, the School teacher, the habitation level and elected Panchayat leaders, the women's groups, the youth groups, all work together for human development. Health sector needs public systems. Let us continue the NRHM thrust to make them credible.

The trends in fertility reduction

The Registrar General of India has come out with the Sample Registration System (SRS) Statistical Report 2010. The good news is that the Total Fertility Rate(TFR) that stood at 2.9 in 2005 is down to 2.5 in 2010, with 10 States attaining replacement level fertility. As per 2011 SRS Data, it is further down to 2.4. The better news is that decline in fertility has been significant even in hitherto States with unsatisfactory health indicators, referred to as BIMARU States at some point of time. Though still 3 plus in most of these States, the decline is faster than the decline in the national average. There were a few hardcore 'family planning types' who thought that sterilization and sterilization alone is the way to population stabilization. They actually considered the demand side incentive for institutional deliveries under the Janani Suraksha Yojana as retrograde as it would lead to more child births. They argued that the compensation for loss of wage for Vasectomy and Tubectomy is lower than the JSY dole of Rs. 1400 in rural areas and that this was sending a wrong signal. The evidence, is completely to the contrary. Population Stabilization is much more a development issue, reflected best in the replacement level fertility rates in all States, be it Bihar or Kerala, when it comes to TFR among women who are Class X or Class XII Pass. **The strong correlation of Secondary completion among women and low fertility is conclusive proof of the population as development issue. One has to look at fertility rate declines in the wider frame of human development thrust.**

Reforming family welfare programmes

This does not mean that the family planning programme does not need attention. It needs priority as survey after survey has highlighted the very high unmet need, both for temporary and permanent family planning methods. Male participation is still very, very low and States like Tamil Nadu also needs to celebrate their low Total Fertility Rate with caution – they have made family planning completely the responsibility of the woman of the house. That is not how it ought to be. We need to encourage male participation more effectively, just as we need to encourage reversible method more widely. There are a range of skill and service quality issues. The demand is so high that even when quality is compromised there a large number who want to avail of the services. Poor women have voted with their feet for small families. We need to provide quality and guaranteed services. We also need to promote counselling and popularization of reversible methods and other forms of contraception more effectively. The Accredited Social Health Activists, the ASHAs, the foot-soldiers of the National Rural Health Mission, have been ably connecting households to health facilities. ASHAs as depot holders for condoms and Oral Contraception Pills, more thrust on training of nurses and Auxiliary Nurse Midwives' for Intra Uterine Contraceptive Device insertion, a strong Post Partum Intra Uterine Contraceptive Device programme, counselling for family planning, birth spacing, a strong Information, Education Campaign, increased thrust on No Scalpel Vasectomy, fixed day guaranteed quality family planning services, accreditation of quality private providers who follow the protocol, are all important components of an appropriate strategy for family planning.

Women's well – being through a human development thrust

Women's health has to be seen in a wider frame of women's well-being. It is a gender empowerment issue as well. Increasing age at marriage, opportunities for participation in secondary and higher secondary education, provision of basic necessities to take care of life cycle change in adolescence, organization of forum for adolescent girls and women,

sensitization of men to women's rights and care needs, recognition of pregnancy as a period of care in a woman's life, survival of children, availability of basic primary care and free referral transport arrangements, are all factors that contribute to well-being. Under-nutrition too has a gendered history and societies where gender equality is organic to social relationships, the gaps are narrower. India needs to recognize gender and social equity and entitlement of the poor, the vulnerable and women as inalienable, for the country to make rapid progress on human development indicators. Hierarchies of access to services and selective participation in human development opportunities are not the way to improved well-being. Entitlements have to be universal and quality has to be guaranteed.

Need to focus on Under 5 mortality and reducing under - nutrition

The SRS has also brought out the need for better care of the 6 month to 36 month children. While India's infant and neo natal mortality has been declining significantly in the last few years, there is still a need for a faster pace of decline in the under 5 mortality. The health care deficits of all boys in the 0-14 age group and of girls in the 0-18 age group need to be removed through guaranteed health care programmes for them. With one third of India's population in this age group, India needs to ensure that the emerging young population does not suffer from physical and mental disability in childhood, compromising the human development potential itself. The war against under-nutrition is necessary for population and development as it is only through better survival and removal of irreversible debilitating impact of under nutrition in the 6 to 36 month children that the country will be able to move towards the cherished goal of population stabilization. The battle of sex ratio will have to be fought through gender empowerment and well-being. Male participation in health at the family level has to be considerably increased to challenge the stereotype of women alone grappling with health and population issues.

Simultaneous improvement in health indicators

It is interesting that the decline in Infant and Maternal Mortality, Crude Death and Birth Rates, and TFR are all taking place simultaneously, highlighting the inter-connectedness of all these health indicators. The efforts by the States with NRHM resources and State led leadership over the last 7 years are beginning to show. An increase in government spending from a little below 1% GDP to a little over a percent GDP has started showing results. Surely, if 3% GDP public expenditure is made on health as has been promised for long, and if under-nutrition issues are addressed in a wider human development framework and not through narrow departmentalism, population stabilization also will become easier and faster. Population is really a development issue and just narrow family planning efforts is not the answer to the challenges of gender empowerment, women's rights, and entitlements of the poor. Human development needs internalization of equity and destruction of hierarchies of access and services. Gender empowerment, social equality, and provision of basic health care services of good quality across the million hamlets, villages and towns for over a billion people, is the answer to population stabilization.

Millennium Development Goals in the realm of the possible?

The decline in death rates and birth rates also confirm the impact of NRHM. While the 2009-12 data on Maternal Mortality Ratio is not out as yet, indications from the Annual Health Survey 2010-11, analyzed for Revenue Divisions in 284 districts that there is a very significant decline from the 301 MMR in 2001-03 or the 212 of 2007-09. It is likely to be lower than 150. If that were to happen, the 2015 Millenium Development Goal of less than 100 MMR appears in the realm of the possible. Similarly, a one point acceleration of the annual rate of decline of IMR (3 for the last three years) which is at 44 in 2011, will also make the MDG of 28 achievable by 2015. This seemed impossible when NRHM was launched. Given the limited financial resources made available to NRHM, it is a significant achievement. While there are many

parameters on which NRHM can improve, hard data bears out the impact of the Mission. We are always miserly in acknowledging a contribution if it made by a discredited public system. While the unfinished agenda in the health sector is enormous, a small beginning has been made by NRHM.

NRHM has unleashed a lot of positive synergies and the Ministry should make all the efforts to further deepen such processes of community health in a manner that every household is able to seek its entitlement to care. The 800,000 ASHAs across the country have demonstrated their ability to link households to facilities. The challenge in the coming years would be to honour the entitlement of every household for quality health care that is accessible, accountable and affordable. NRHM is very much on a right track and it only needs to further put pressure for better governance and for larger civil society involvement at all levels through public hearings and community monitoring. NRHM started an excellent community monitoring system in nine States and the challenge is to make it universal in the XII Plan so that local communities begin to demand health care in a rights and entitlement framework. This would also call for behaviour change in the way public system interfaces with poor households and particularly the women. The challenge of NRHM is to craft credible public systems and this would also call for new systems of public recruitments which are institution specific and based on service guarantees with complete local level accountability. NRHM has promoted this culture of local recruitments and local accountability through contractual appointments. There is a need to develop a new paradigm of public recruitment based on the learning of the last few years. The process of ISO and NABH accreditation of public system health facilities has also been a very useful step forward. It has rightly brought the focus on processes and provisions in public facilities.

Adopting the human development approach

We can today visualize Universal Health Coverage for all only because a beginning has been made. There is a very long, long way to go and India needs to recognize the contribution

that Universal Health Coverage can make in India's human development and in making it more inclusive. One also has to recognize the multi – dimensionality of health challenges and the need to recognize a wider human development approach to health. Education, nutrition, clean water, sanitation and public health, have to be brought on a common platform of human development for a faster rate of improvement in human well-being.

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5 Budget document 2013-14.

6 7 Expert Groups were constituted with the finest public health experts to finalize the draft Framework for Implementation of the NRHM.

7 The Lancet; Special Issue on Under Nutrition; 2008.

8 NRHM – Framework for Implementation articulates this unambiguously, more clearly than even the Universa Health Coverage High Level Expert Group.

9 Kaveri Gill's study on Andhra, Bihar and UP; 2007.

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K.K. Talwar and Meenu Singh

More Doctors for Healthcare Services in India

Introduction

The provision of top quality health care services, at affordable cost, is a critical issue facing the country today. The system must be in a position to ensure that every individual has access to affordable healthcare.[1] However, the country appears to be facing a shortage of doctors, both general and specialists, who can provide care to all sections of the society. To address this issue, we would inevitably be required to look at the related subject of maintenance of standards in medical education, so that an increase in numbers is not at the cost of quality. The present article seeks to address these twin facets, and offers a roadmap for action.

The Nature and Scope of the Problem

The Indian print media, based on High Level Expert Committee Report (HLER), has highlighted the fact that India will need 6-7 lac more doctors by 2025. This has serious implications for the system of medical education in the country, since an increase in the number of doctors can only be met by enhancing the capacity of the education system to produce more doctors. One needs to carefully estimate the requisite increase in number, and ensure that there is no compromise whatsoever in the quality of education and training provided in our medical colleges.[2]It is worth noting that India already has 363 medical colleges (the highest number as compared to any other country) admitting over 45,000 medical graduates every year.

The projected shortage of doctors is based on a minimum doctor population ratio of 1:1000, as recommended by the

Planning Commission Task Force (High Level Expert Group).[2] The current norms on the doctor population ratio emanate from a report of the Joint Learning Initiative (JLI), a consortium of international health experts, given in the year 2004. The researchers of JLI concluded that effective workforce strategies can boost health service delivery, even under difficult circumstances.[3]The recommendations of the JLI were, more or less, accepted by the WHO. The recommendations have limitations which have also been recognised by the JLI itself. Many countries have achieved health status indices of global standard, even with lower doctor-population ratio.[4] Malaysia and Sri Lanka are two examples not far away from our country who have achieved much better health care indices, matching western standards, with doctor-population ratios of 1:1400 and 1:1800 respectively.[4]

Under the government health system as on March, 2011, there are 613 district hospitals, 985 sub divisional hospitals, 4809 community health centres, 23887 primary health centres, 148,124 sub centres and 1825 mobile medical units working in the country (Rural Health Care System in India, 2012). All these health care facilities need deployment of trained work force. We need not only general duty medical officers but also specialists viz paediatricians, obstetricians/gynaecologists, anaesthetists, physicians and surgeons for effective delivery of health care and achieving health care outcomes. The NRHM programme has drawn guidelines (IPH standard) for number of general doctors in PHC, CHC and also specialists in community health service (CHS) cadre.[5] Regarding district hospitals, there is need as per the bed strength of the hospitals. At present, 80% of the OPD patients and 40% of the indoor patients are being treated by the private set up. Even for the existing medical colleges, we need teachers and residents in various specialties to meet the minimum required numbers for faculty and residents. Thus, we need to plan and develop programmes to fulfil the requirement for general and specialist doctors.

A major limitation, in this regard, is the non-availability of reliable data about the exact number of existing trained medical professionals in the country. The Indian Medical

Register (IMR) is maintained to keep a record of the registered medical doctors in the country. At present, as per IMR register there are over 8.5 lac medical doctors registered. However, the IMR does not have any provision to find how many may have migrated out of India, or are no more in active practice. There is also some duplication in the registration, as the doctors registered in their parent states get re-registered if they shift their regular workplace to another state. The doctors are required to update their registration details for additional qualifications, but these have also not been strictly tabulated. Thus, we are not aware of the exact number of specialists in different disciplines in the country. Unfortunately, these limitations have only been recently realised in the Medical Council of India. The Medical Council of India is now making efforts to address this issue, including through computerisation of the IMR.

Based on the available data, the doctor-population ratio in India is presently (approximately) 0.5 per 1000 persons. We have no data of the exact number of specialists in each branch, though a rough approximation can be reached based on the membership of the various associations of specialists. But how many of these are in active practice in India may not be certain. Another facet is the skewed distribution of the existing medical professionals, with many more doctors being available in/around urban areas, and very few in the rural areas.

According to the estimates and recommendations given by HLEG of Planning Commission of India, 187 new medical colleges may be opened which will yield a ratio of 9.4 doctors/10,000 population, in order to meet the WHO standards. This entails further increase of large number of medical colleges which involves huge resources, including the availability of quality teachers.

Sudden expansion of the medical colleges in the last 15 years has resulted in the recruitment of poor quality teachers, and even spurious teachers,thereby affecting seriously the quality of training. Most of these colleges are in the private sectors and are adopting irregular means in admission processes leading to meritorious students being deprived of

admission. Most of the Government Colleges also have not upgraded their facilities and infrastructure for a long time, and this has led to deterioration in the teaching standards in the Government sector. The addition of such a large number of colleges,without addressing these concerns, may lead to a further decline in standards.

Some General Suggestions

It is often said that having a bad doctor is even worse than having no doctor. In order, therefore, to ensure quality training for doctors, we need to look at the following aspects first:

a. To stabilise and improve the existing colleges with good infrastructure and faculty to ensure quality training.

b. To implement measures to ensure admission through merit. The national common entrance test shall help to achieve this objective. There should also be a common exit, at least at the state level, to ensure minimum standard of training.

c. To implement measures to revive the status of the profession so as to attract bright youngsters back to the profession. Indian doctors who graduated till the 1990s have made their professional impact and brought laurels to the country while working abroad or at home. This indicates not only superior quality of training during the relevant period, but also that bright youngsters opted for the medical profession.

We already have 45,000 students getting admitted to medical colleges and it is hoped that another 5000 will increase from the new session (2013-14). In the next 5 years, we need to ensure further increase of 10,000 students to make 60,000 admissions every year. This will result in 6 lac more doctors in the next 10 years to obtain the desired doctor population ratio. A better doctor-population ratio, as well as better healthcare services, can be achieved by taking the following steps, instead of hurriedly opening so many new colleges:

- A majority of the government colleges still have 100/150 seats, which can be increased to 200/250, with the

addition of infrastructure and facilities. This will provide the increased number of seats required over the next 5-10 years.This may drastically cut down the need for new colleges.

- Some new colleges should be opened in underserved regions or states which lack educational facilities. This will also strengthen health services.
- The practice of mandatory rural posting for graduating doctors before joining MD/MS,already prevalent in some states, needs to be adopted in other states also. This will also give exposure to young graduates to rural medicine. A step in this direction to make one year compulsory rural posting as eligibility criteria to join the postgraduation is already being envisaged by the MCI and the Ministry of Health and family welfare. This may become a national policy and will help continuous availability of doctors in all PHCs even with the presently existing medical admissions.
- The utility of middle level health workers has never been stressed and a concerted effort to have quality skilled middle level health workers has not been undertaken. Efforts need to be made, urgently, to this end.

Specialists and Superspecialists

The projected need of specialists in the country has not been worked out. The Indian Medical Register (IMR) does not have accurate data regarding the exact numbers of specialists and superspecialists. At present, more than 70% of specialist positions in the CHCs and district hospitals are lying vacant. For instance, we have over 25,000 paediatricians (as members of Indian Academy of Paediatrics) but still out of approximately 4800 positions required in CHC – approx. 74% are lying vacant. This is also true of other disciplines. To some extent, this gap is because of imbalanced and asymmetric distribution, coupled with the lack of attraction for these jobs. It is important to take steps to make these positions attractive and also ensure optimum infrastructure in the hospitals so that the specialists have the professional satisfaction of using their skills.

An exercise to assess the need of specialists and super specialists in different disciplines is seriously required, in order to plan for the expansion of facilities for training in these disciplines. It is also essential to estimate out of the total doctors what proportions are desired as specialists.

We need to make family medicine attractive amongst the medical students. Today every doctor wishes to do post graduation as mere graduation has lost its respect and status in the society. The curriculum in family medicine should be made attractive and steps taken to motivate practising general doctors to do family medicine. This will not only enhance their prestige in the society but will also allow them to learn skills to effectively function as general physicians. Special training programmes may be considered for doctors in regular service for over five years, by reducing the training period to two years.

Networking or Health care linkage of Secondary and Tertiary Health Care with Primary Health Care

The referral system should be properly implemented and strengthened, so that only patients needing advanced care come to the referral institutes. It has been seen, over the years, that due to the lack of facilities at most of the public sector medical colleges and civil hospitals, the common people crowd into the few existing public sector referral institutes like AIIMS and PGI that still enjoy the confidence of the public.

There is a dire need to strengthen the health care delivery in other medical colleges and district hospitals, and also to upgrade 10-12 medical colleges in various states apart from setting up of the eight AIIMS like institutes. Each state can upgrade one or two of their medical colleges to the level of an AIIMS like institute that could serve as a nodal medical college for others. All medical colleges should also be equipped to provide the standard of care available in a tertiary care centre. The colleges should be linked to district hospitals. The district hospitals should be integrated with CHCs/PHCs. The linkage process should not simply be transferring a patient from primary health care facilities, nor does it end with the

discharge of the patient from the hospital. An effective referral system should have good communication and coordination between the different levels of care, and support from higher to lower levels to help manage patients at the primary health care facility. This leads to improved patient outcomes and optimum utilisation of the available resources. Telemedicine can also play an important role in integrating health care delivery.

Attracting Doctors to the Public Sector Healthcare System

Attractive packages, including monetary and non-monetary incentives, are crucial to encourage qualified doctors to join public sector institutions. Such packages could include salary increases, reservation for postgraduate seats in return for rural service, and improved housing, transport and other facilities. Postings in remote areas should be in the early stages of the professional career, for fixed tenures and with the provision of adequate facilities and infrastructure in the health centres to make these postings professionally satisfying. It has been observed that, often, doctors are handicapped because of the lack of facilities. Networking with district hospitals and medical colleges will help them to gain professional growth during this period. At the specialist level, it is important to ensure optimum remuneration and availability of infrastructural facilities to do their professional work with full satisfaction. Permitting private clinics within the hospital, in the evening hours, can be considered, to make public sector employment less unattractive.

The Problem of 'Brain Drain'

Many doctors, nurses, and technicians emigrate from India, which contributes to the country's shortage of health workers. Indian doctors constitute the largest number of foreign trained physicians in the USA (4.9% of physicians), and third largest in Canada (2.1% of physicians). The Planning Commission cites WHO to emphasize that about 100000 Indian doctors work in the USA and the UK.[6,7] Migration seems to be substantially higher for the brighter among the professionals, as they are able to compete for their licensing examinations. Our doctors abroad can be considered our ambassador/asset to help other

countries attain global health outcomes. It is also a matter of national pride that Indian doctors are excelling in other countries. They have a potential to contribute significantly even to the Indian medical scene.

At the same time, given the shortage of medical professionals in our country, we should try to retain our talent, and innovate means for discouraging migration of medical professionals.

Quality of Medical Education/Training

Quality of education is an issue which, of late, has become an important point of discussion. Increasing quantity, without improvements in quality, can have serious negative consequences and lead to wasted manpower and resources. The quality of medical professionals has deteriorated for various reasons. One reason is the fact that the medical profession does not appear to attract the best and brightest among the youth anymore. This is coupled with the lack of top quality facilities and infrastructure in many new medical colleges. In some of the privately run institutions there may be infrastructure available but there are very limited patients for medical students to learn the essential skills. Teaching faculty is in short supply and many colleges are hiring professionals who have other jobs also or in worst case scenario - they even reflect dummy faculty. Although the MCI under its existing structure is trying to ensure quality at these institutions, but it encounters problems due to several loopholes that are existing in the administrative and assessment process. This often leads to expensive and time-consuming litigation.

The need to improve the teaching and training of medical students cannot be ignored. The curriculum should address the health need of the society. A look at the current pattern of medical education shows that skills and knowledge acquired by medical graduates do not adequately equip them to deal with the health problems of the community. Undergraduate medical education focuses almost entirely on theoretical aspects, rather than imparting practical skills. A new undergraduate curriculum has been prepared by the MCI, which seeks to integrate clinical and basic training, and will be implemented from the next academic session.

It is important that the curriculum move away from being teacher-centred, and towards being student-centred, with emphasis on self directed learning. It is also important that teachers should be kept abreast with new teaching methods viz problem based learning, evidence based medicine and competence based medical education.

The following are some other steps that can be taken for improving the quality of medical education:

a) Making efforts to motivate our 'brain drain' professionals settled in Europe and America to come back and join various medical colleges/institutes. Countries like China have done this. To attract them we need to change our approach towards recruitment. Those who wish to come back may be offered positions based on their bio-data and professional eminence, rather than asking them to apply through the conventional route. A special search committee can be constituted to explore and work on this option. Talent search is an accepted norm in other fields, and medicine should be no exception.

b) AIIMS/PGI like institutions be linked with adjoining medical colleges to strengthen the training programmes. We have failed to create the integration of these eminent medical institutions with other colleges for academic development. This should be an important mandate of these institutions. The faculty from these institutes can periodically go as visiting faculty to these colleges. Equally, faculty members from the medical colleges should also be required to upgrade their knowledge and skills at the AIIMS/PGI like institutes.

c) Strengthening of telemedicine facilities to use tele-education from training programmes is also required. The National Knowledge Network, being established by the Principal Scientific Advisor's office has linked many colleges and will tremendously help in spreading higher education and address, to some extent, the paucity of good teachers.

d) Regular updating the teachers in new methods of training. The MCI has set up various Regional Training Centres for this purpose. Each centre is assigned the adjoining colleges. Regular workshops are being held to upgrade the skills of the teachers in newer teaching methodology and efforts be made to make these courses mandatory for updating.

e) As already pointed out earlier in this article, a common entrance test to ensure admission by merit, and merit alone, will help to attract meritorious students and will avoid unfair admission practices. Even to ensure uniformity standard, a common exit examination is required – may be the steps be initiated at state level at the beginning.

Conclusion

The need of the hour is also to optimally use the available resources, and to adopt a holistic and multi-pronged strategy in order to best tackle the problems that we are faced with. It would be counterproductive to chase numbers, as it were, and merely seek to achieve pre-determined statistical levels. The approach must be need based and pragmatic, with constant and regular evaluation and monitoring. The system must be strengthened, and must be made robust and smart enough to meet future needs. Any expansion without planning proportional and optimum facilities in the PHC, CHC and district hospitals would be wasteful and futile, and may result in underutilisation of expert manpower and also even to unemployment as seen in the dental discipline.

It is high time that we undertake the necessary reforms, without any further delay, to treat the ailing medical education and healthcare system.

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Anu Garg

The Odisha Experience in Improving the Outreach, Quantity and Quality of Health Care Services and Facilities

Introduction

Odisha, with nearly 42 million population[1], of which 22.1% are Scheduled Tribes and 16.5% are Scheduled Castes[2], faces myriad challenges in improving the health and nutritional status of its people. With about 40% of its population below poverty line and high out-of pocket expenditure on health, the health situation has been difficult. While there has been a steady decline in maternal, infant and child mortality rates, as well as deaths due to communicable diseases such as malaria, diarrhea and TB; the fall has been at a rate that would make it unlikely for Odisha to achieve the Millennium Development Goals. However, the last few years has seen Odisha working towards more efficient health systems through effective planning, financing, human resource management, infrastructure creation, supply chain management, community participation and e-governance. Though some initiatives have been taken earlier, it was with the introduction of the National Rural Health Mission (NRHM) in 2005 that many of the innovations and change initiatives were mainstreamed; as well as new ones initiated.

Recognizing the major challenge of high Infant Mortality Rate (IMR)/Neonatal Mortality Rate (NMR) in Odisha (second highest in the country), before launching of NRHM, two major State initiatives had been taken up. The **IMR Mission** was set up in the year 2000 for developing and implementing strategies aimed at accelerated reduction of IMR. The key interventions

of the IMR Mission included strengthening the ongoing child survival intervention plus malaria chemoprophylaxis during pregnancy, improved newborn care and improved community knowledge and practices. The main objective of the second intervention, **Navajyoti Scheme** was to improve home based neonatal care in all remote villages of 14 high focus districts with high IMR. This intervention included training of Traditional Birth Attendants (TBAs) for safe home delivery, distribution of Disposable Delivery Kits (DDK) to these trained *dhais* and postnatal care. Around 12,500 *dhais* were thus trained and 63% of home deliveries were conducted through them towards the end of the scheme.

Challenges to Health Care in Odisha

There are several factors that make health care administration in Odisha challenging and daunting.

- Odisha's population of around 42 million includes large numbers of Scheduled Tribes (22.1%) and Scheduled Castes (16.5%). The data from NFHS – 2005-06[3] reveals that Scheduled Tribes have the highest rates of infant and child mortality as well as the highest burden of anemia and under-nutrition in Odisha. Odisha is also home to several PTGs like Bondas, Dongria-Kandh who have worse health parameters, even more limited access to health and different health seeking behaviours as compared to the general castes.
- With an estimated poverty rate of 57.2%[4], Odisha has large number of poor people with limited financial capacity to access health care.
- Southern districts of Odisha, often referred to as 'KBK' (Kalahandi – Bolangir – Koraput)[5] districts have a difficult, hilly terrain; poor road connectivity; low food security; more SC/STs, and more poor. Poverty levels in KBK + districts are high with Nabarangpur district having highest poverty rates at 80.6%[6].

KBK districts of Odisha

These districts are the farthest from the State Headquarters making monitoring a lot more difficult.

- Odisha has one of the highest percentage of area under forest cover - bringing in issues of poor road connectivity, rampant malaria, making health care delivery that much more difficult in these areas.
- These are also areas where there has been deepening of the Naxalite problem, further affecting delivery of health care services.
- These are districts with poor human development indices (including female literacy) and poor health and nutrition parameters. Weak infrastructure, deficient and demoralized human resources in health, higher burden of diseases viz. malaria, diarrhea, Acute Respiratory Infections (ARI) and inadequacy of other "social determinants of health" e.g. drinking water, sanitation further mar efforts to improve the health status in these regions.
- The paradox is that while these areas have greater need and require more inputs; they also have lesser absorption capacity. This is as enunciated in Harts' 'inverse care law' that health care resources are distributed inversely to their need[7].
- Apart from topographical and economic, social inequity related challenges, Odisha also routinely faces natural disasters like floods and drought, diverting energy, time and resources on disaster response rather than strategic

health management. Poor sanitary conditions perpetuate vulnerability to diarrheal/dengue outbreaks which too absorb disproportionate levels of resources and time of the health care providers.

Reaching the Unreached

In this backdrop of complexities and challenges, **efforts were made by health administration to improve the outreach, quality and quantity of health care services and facilities in Odisha**. Perhaps, the single biggest challenge in Odisha is reaching the unreached. Access to health services has been defined in different ways. While some feel that access relates to timely use of services according to need[8] others differentiate between the supply and opportunity for use of services and its actual use[9]. A conceptual framework[10-13] for assessing access to health services is used here which appears relevant in the context of Odisha (see Figure 1).

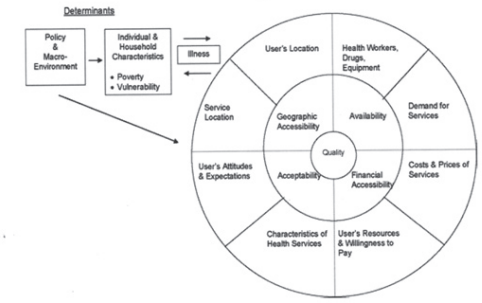

Figure 1: Conceptual framework for assessing access to health services

In this conceptual framework, four dimensions of access are detailed:

- Geographic accessibility
- Financial accessibility
- Availability
- Acceptability

"Quality" of health care is in the middle as it contributes to each of the dimensions of access to health services and is fundamentally related to influencing people's health. The 'distal determinants' (policy and individual/household

characteristics) are to the left of the circle. To extend outreach of health services in Odisha, attempts were made to address each of these dimensions:

Geographical Accessibility: Connectivity is essential for people to reach the health services as much as it is critical for the distribution of drugs and supplies, for emergency referrals and for monitoring by supervisory staff. Lack of it impacts access; more so for the poor and the marginalized[14]. Government of Odisha took the following steps for improving geographical accessibility:

Mobile Health Units

Odisha has a total of 350 **Mobile Health Units (**MHUs**)** in 27 districts of the State, to ensure availability of at least 2 MHUs in all blocks of the vulnerable Kalahandi-Bolangir-Koraput-Kandhmal (KBK+) districts. These are mandated to deliver diagnostic, curative and referral health care services at the doorsteps of the people living in inaccessible and remote areas of the State, especially in the 50 'Most Difficult' Blocks and 36 'Difficult' blocks, identified through a vulnerability analysis undertaken by NRHM. With MHUs in place, more than 21000 investigations have been conducted benefitting over 7 million persons from 2005-06 to 2012-13. Added to this, and in order to improve access to health care in left wing extremism affected areas of the State, a specially designed, outsourced and branded Mobile Health Unit called **Arogya Plus** has also been put in place. Similarly, a programme called ***Swasthya Sanjog*** provides health services at all outreach treatment points on a fortnightly basis through 114 MHUs, located in tribal and remote blocks. This initiative is funded by the State through its own resources. Likewise, **mobile boat clinics** are used for outreach services in areas that have waterway access only. A recent study[15] shows that mobile health units have become a major source of health service, meeting 80% of the health care needs of families reporting illness in last 6 months and saved Rs. 170-250 on travel costs.

Health Camps in difficult areas

The **Biju Gramina Swasthya Sibira (BGSS)** is an initiative geared towards organizing health camps in each assembly constituency of the State, where higher level speciality health care is provided. A total of 137 health camps have been held till December 2012 benefitting over 2.8 lakh patients.

Box 1: Geographical Focus on KBK+ districts of Odisha

Geographical Focus on KBK+ districts of Odisha

Expenditures of the National Rural Health Mission reflect the prioritisation of KBK+ districts as shown in Table[1]. In the KBK districts, aggregate NRHM expenditure grew by 70% between 2008-09 and 2010-11 – from INR 49 Crore to INR 125 Crore. In comparison, growth in expenditure in the Non-KBK districts was lower.

Table 1: District Specific Expenditure Trends under National Rural Health Mission

across KBK+ and Other Districts of Odisha (INR Cr)

Source: Financial Management Reports, State NRHM, various years.

Multiple initiatives have been undertaken to improve access to services in

Period	KBK+	Other Districts	ODISHA All Districts
2008-09	48.6	143.9	192.5
2009-10	108.7	254.2	362.9
2010-11	125.4	274.3	399.7
Average Expenditure (INR Cr)	*94.2*	*224.1*	*318.4*
Average Annual Growth (%)	*70%*	*42%*	*49%*

KBK+ and the state more widely, drawing on a variety of budget sources. Apart from Mobile Health Units, Arogya Plus, Mobile Boat Clinics in Malkangiri, the health infrastructure deficit in KBK+has also been prioritized with sub-centre buildings (the lowest facility in the primacy health centre system) given the highest priority. The challenge of bringing and keeping qualified health staff in rural underserved areas of India where working and living conditions are difficult is well known. To start to address the gaps, newly appointed doctors were posted to KBK+ as a priority. Financial incentives for peripheral (INR 8,000 per month) and district hospital doctors (INR 4,000 per month) in KBK+ were given. Contract doctors prepared to work in peripheral institutions also received higher incomes than those in district facilities. Odisha also initiated a policy of preferential entrance to post-graduate training. Scholarships for female nursing students from SC/ ST backgrounds pitched at INR 15000 and INR 50000 per annum for non-KBK+ and KBK+ districts respectively were important incentives approved in 2011.

Various approaches were tried to improve the motivation and performance of frontline workers, such as financial incentives for paramedics working in difficult areas; enhanced incentives for ASHAs working in vulnerable geographical pockets given the additional challenges they face in mobilising families and the low revenue potential for workers in small catchment populations; and the creation of ASHA Gruhas, rest homes in the vicinity of hospitals for the use of ASHAs accompanying pregnant women.

While it is too soon to see results from these multifaceted efforts, they present positive steps forward in addressing the complex human resource issues in the State to achieve a more appropriate human resource portfolio for delivering more accessible services.

Alternate Vaccine Delivery System

The State also has a unique mechanism of vaccine delivery, appropriately named **Tika Express** to ensure timely vaccine delivery in difficult to reach areas using two-wheelers, three-wheelers and four-wheelers, outsourced to NGOs/local people. This not only ensures faster vaccine delivery and return of unused vaccines/logistics; but also increases the time for actual vaccination freeing potential vaccinators to do vaccinations rather than the job of carrying vaccines.

Empowering the Community

Recognizing that in difficult areas with sparsely populated hamlets dispersed over a large area, one ASHA for 1000 population would not be adequate, the State took a special initiative to have more ASHAs in such areas @ 1 per 1000 population. Acknowledging the differences in female literacy levels in these areas as compared to other areas; educational requirement for recruitment of ASHA was also reduced in these areas. Another initiative that the State took was to provide **bicycles to ASHAs in these areas** for improved mobility, efficiency and for their empowerment. Village Health and Sanitation Committees at the village level and Rogi Kalyan Samitis at the institution level were also constituted and strengthened for greater participation of the community.

Vulnerability Mapping

Building on the NRHM district planning process, the Government introduced **vulnerability mapping**, a first step

to district wise analysis of health inequity and disadvantage as part of the planning process. This categorised all the blocks of the state according to levels of vulnerability using a composite vulnerability index. Based on the assessed level of vulnerability, flexible funding was provided to block and district managers for reaching vulnerable populations. Categorisation of sub-centres by remote location also provided a basis for prioritising development of these facilities.

Box 2: Reaching the Unreached - Malaria prevention and treatment

Reaching the Unreached - Malaria prevention and treatment

The interaction between poverty and incidence of communicable diseases is well known. Here, malaria is highlighted in the context of equity given the major share of the disease burden borne in KBK+ districts. Odisha accounts for nearly 25% of deaths in India (and 0.4 million of the 1.5 million cases in the country recorded annually). Within the state, eleven southern districts which constitute 25% of the population of Odisha, contribute 66% of reported malaria deaths in the state[16]. Malaria morbidity and mortality is highest where the penetration of health service is weakest, and where the majority population are from adivasi communities.

In the last few years, the Odisha National Vector Borne Disease Control Programme under NRHM aggressively tackled malaria control, with a focus on the most affected districts. Community-based diagnosis using rapid diagnostic tests for P. Falciparum malaria (85% of cases are caused by this parasite) with immediate treatment was a major plank of the control strategy. More than 50% of ASHAs (25, 500) were trained to treat malaria at the village level. A second major effort has been distribution of Long Lasting Insecticide Treated Nets (LLIN) in villages where the incidence of malaria is highest.

The Village Health and Sanitation Committees, known as Gaon Kalyan Samities in Odisha, were given the responsibility of distributing LLINs to all families in their village and ensuring adequate nets to cover every member of the household.. An evaluation of an additional scheme to provide LLIN to all pregnant women in five of the KBK+ districts found that 91% of the women had slept under the net in the night prior to the survey[17]. Among these women, anaemia was lower and BMI higher compared to non-LLIN households. Three-quarters of pregnant women given LLIN belong to ST or SC communities, reflecting the demographic profile of the area.

Affordability or Financial Accessibility: is an important determinant of access. Costs in health care are both 'direct' (cost of treatment, and 'informal payments') and 'indirect'. These include opportunity cost of the patient and those accompanying him/her, transportation cost and cost of stay etc. Both these direct and indirect costs can have economic consequences, including 'catastrophic spending' or 'distress financing', impoverishing the poor further. In Odisha, representative sample surveys from 1999-00 (NSS 55th Round) and 2007-08 (NSS 64th Round) show that monthly per capita household spending on health has increased from INR 22 to INR 32 in rural areas and INR 31 to INR 60 in urban areas[18]. Hospitalisation costs are often impoverishing; in 2004 the average amount spent per household on hospitalisation in a one year period was INR 4625 in rural Odisha[19] set against an average per capita annual consumption close to INR 6,000[20], it is not surprising that over 50% of hospitalization costs were financed by the sale of assets or loans. In 2010, the Government commissioned a study in 8 districts to take stock of the current level of Out-Of-Pocket Spending (OOPS) on health – Public Health Beneficiary Survey (PHBS 2010). The survey collected data on OOPS from three types of users of the public health system: (i) hospitalised treatment or indoor patient care, (ii) outpatient medical consultation, and (iii) child delivery (see Table 2). The findings from the study show that patients spent INR 775 at median level (INR 1,145 at average) from their own pocket for hospitalised treatment in a public health facility. For outpatient consultations OOPS was around INR 100 at median level (INR 180 at average). For child delivery, a family spent more than INR 650 at median level (INR 809 at average). As found in earlier NSS studies, the 2010 survey found that the biggest share of OOPS on health was spent on medicines. More than half of the OOPS incurred during hospitalised treatment was on medicines, and almost half of the OOPS for outpatient consultation was on the purchase of medicines.

Table 1: Out of Pocket Spending (OOPS) on Health in Odisha

Type		Median
Per Day Expenditure for Hospitalised Treatment (for Indoor Patients)	1,145	775
Expenditure per Medical Consultation in Outdoor Department	180	100
Child Delivery	809	653

Source: Public Health Beneficiary Survey, 2010.

Despite persistently high OOPS in Odisha, there are signs of progress. Comparison of data from the 2010 survey with the National Sample Survey data of 2004 shows the average OOP expenditure on institutional deliveries in 2004 at 2010 prices stood around INR 1,800 for rural areas and INR 1,200 for urban areas respectively. In comparison, the level of spending on institutional deliveries has fallen to INR 800 as per 2010 data. This is a significant drop in the cost to the family and has contributed to the rapid increase in institutional deliveries in rural areas from 35% in 2005-6 to 79.85% in 2011. Undoubtedly, the conditional cash incentive scheme for institutional deliveries, Janani Suraksha Yojana, has contributed to the reduced OOPS on institutional deliveries and their steep rise. Encouragingly, the PHBS found that the burden of OOPS for institutional deliveries is lower for poorer families compared to middle and high income ones. Nevertheless, the out of pocket cost for institutional deliveries are still too high for some, especially where this is inflated by poor physical access and low service availability. Poorer, more underserved and vulnerable women have lower take up rates of JSY benefits[21]. To address this equity gap, the Government is prioritising service delivery improvements in the most underserved parts of the state, the KBK+ districts. The Government's new cashless delivery scheme, Janani Shishu Suraksha Karyakram is expected to eliminate OOPS on institutional deliveries. Such measures reflect the commitment to better reach excluded groups and ensure universal access to maternal and newborn health care. To reduce this, and the high levels of Out of Pocket

Spending (OOPS) in the State some initiatives that were taken include:

Janani Express

Acknowledging that transport to the health facility is one of the three delays highlighted in the 'Three Delays Model of Maternal Mortality', the State put in place 304 ***Janani Express*** vehicles. These branded vehicles have been used to transport over 9.12 lakh pregnant women till December 2012, proving free 24x7 transport for maternity care on call.

Ambulance on Call - Dial 108

The State has recently (in March 2013) launched the Odisha Emergency Ambulance Services (Toll free number 108; with State-of-the art ambulances fitted with GPS and having advanced life support systems) for 15 districts in the first phase, which would soon be expanded to the entire State.

The Odisha State Treatment Fund (OSTF) is a unique scheme under which financial assistance is provided for treatment to poor patients suffering from life threatening disorders and diseases, provided they are BPL/RSBY card holders. As of Feb 01st 2013, a total sum of ` 30.00 crores have been sanctioned under OSTF, out of which ` 20.86 crores has been utilised.

Janani Shishu Suraksha Karyakram (JSSK)

Apart from Janani Suraksha Yojana (JSY) where around 23.44 lakh mothers have benefited (2006-2011), receiving incentive payment for institutional delivery; JSSK was launched to provide for "Zero expenses" delivery and care for mother and neonates including free transport, free drugs, free diagnostics, free blood, free diet, etc.

Rashtriya Swaasthya Bima Yojana

Department of Labour and Employment, Government of Odisha rolled out the scheme, in active coordination with Health Department.

Augmenting capacities of Public Health Institutions

Apart from equipping referral level institutions; efforts were made to significantly augment facilities at District Headquarters Hospitals (DHH) as Special Newborn Care Units (SNCUs) (like ICU for neonates) were set up in several DHH. There are 20 SNCUs set up across districts.

Availability: is measured in terms of the opportunity to access health care as and when needed. This could include proximity to health care institution, availability of health personnel, of drugs, equipments and even hours the health centre is open. To ensure better "availability" of health services initiatives taken include:

Augmenting health care proposal

Government regularly recruited doctors through the Public Service Commission; allowed recruitment on 'adhoc' basis; appointed doctors on contractual basis at the district level. Apart from doctors, additional ANMs, more than 1000 AYUSH doctors and several logistic support officials like District Health Information Officer, etc. were posted.

Multi-skilling of health personnel

To extract the most from scarce human resources, personnel were trained on anesthesia, Basic and Emergency Obstetric care, etc.

More ASHAs in vulnerable areas

Since 2005-06, when 11500 ASHAs had been selected, Odisha now has around 43000 ASHAs. The norm of one ASHA per 1000 population was modified for difficult areas.

Increase in drug budget

Realizing that largest chunk of Out of Pocket Spending (OOPS) is on drugs, State Government significantly increased the drug budget to provide free medicines as far as possible.

24X7 facilities in remote areas

478 health facilities were identified to provide emergency

obstetric care round the clock. In view of shortage of staff only 258 could be operationalized.

Acceptability: Declaration of Alma Ata[22] had proposed that primary health care needs to be aligned to prevailing cultural norms. In Odisha, as in India, pluralistic medical system prevails including Indian Systems of Medicine and Homeopathy (AYUSH), apart from informally trained providers, or local faith healers. Efforts made towards this include:

Mainstreaming AYUSH

Acknowledging the shortage of allopathic doctors and recognizing the faith of people in alternate systems of medicine, Government recruited around 1400 additional AYUSH practitioners and posted them in rural areas in PHCs.

Maternity Waiting Home in tribal areas

These were set up through local people in tribal areas for expectant mothers to come to district hospitals before time of delivery. Food, transport, etc. were provided. Till 2012, 2631 expectant mothers had availed this facility.

Increasing women's access to health services

Women's and girls' low social status and their lack of empowerment impact their health and well-being. Deep rooted gender discrimination requires multi-sectoral and broad societal efforts. More modestly, health efforts in Odisha over the past few years have focused on increasing women's and girls' access to health and nutrition services, and responding to their specific health needs. Implementation of the Pre-Natal Diagnostic Techniques Act has been a priority, with low Sex Ratios concentrated in the more developed areas. Making facilities more gender-sensitive through the construction of female toilets, partitions in labour rooms for privacy and dignity, and waiting rooms have been relatively easy improvements. Increasing the availability of female doctors in rural areas is less straight-forward. Faster progress has been made in strengthening female frontline workers.

New programmes have been started to address adolescent anaemia, and new ways of delivering services, through for example **Pustikar Diwas** (referral to a PHC for diagnosis and treatment of severe malnutrition) and mobile health units, are increasing reach and female access. **"Mamata", a new conditional cash transfer scheme for pregnant women and their infants** living in all rural areas of the state (85% of the population), will incentivise care during pregnancy, post-partum, and the child's first year of immunisations. Payments are made by e-transfer to the woman's bank account and a large part of the thrust at start-up has been supporting the opening of these accounts; empowering action in its own right. The roll out of Janani Sishu Suraksha Karyakram, the Government of India's programme to provide cashless deliveries and the treatment of sick neonates will further contribute to increased access to maternal and neonatal care. But much more is needed to tackle the gender discrimination and disempowerment that underpins the gender inequalities in health in the state, to stop the violence against women and girls, and the negative personal and public health consequences that result.

Quality of Health Care

At the centre of the conceptual framework is the quality of health care which is ultimately related to the ability of health services to influence health of the people. In Government systems, grappling with improving quantity and outreach; and in managing issues that may be urgent but not necessarily important; often quality of health care is the first casualty. Nonetheless concerted efforts were made to bring out qualitative improvements in health institutions, health care personnel, health care services (drugs, diagnostics, ambulances, referrals, blood banks etc) as follows:

Health Care Personnel - Quality improvements

The State Human Resource Management Unit (SHRMU) was established in to strengthen management of human resources in the State. Its mandate was to create

and update HR databases, restructure the cadres, undertake capacity building and promoting research. Restructuring of the Odisha Medical Services cadre was done with promotions of 353 doctors. Further, 800 doctors were posted on ad-hoc basis. Research and ethical committees were formed and a web-based health workforce Management Information System was established.

Multi-skilling of health personnel: For optimal utilization of the existing scarce health resources, multi skilling of doctors through short courses for MBBS doctors in anaesthesiology, Basic and Emergency Obstetric care, Public health and ICU management have been undertaken in a big way. Similarly, multi-skilling of laboratory technicians has also been initiated.

The Nursing Management Support Unit (NMSU): was established with focus on realignment of structure and cadre reform,address nursing issues and support nursing establishment. The cadre of nurses and paramedics were made district cadres with an objective to create smaller, more manageable cadres for lower level functionaries. Creation of more number of nurses and paramedics as per IPHS standards is under active consideration of the State government. To take the activity forward, **the first Nursing Directorate in the country has been established** in February 2013.

Health Care Services - Efforts to improve quality

Drug procurement and distribution: A centralized procurement system with an essential drug list (EDL) cuts down the purchase of unnecessary drugs, and resulting in rational drug prescription. To make this system more effective and streamlined, a **Procurement Corporation** is at present under active consideration of the State Government.

State Equipment Maintenance Unit: This was set up in 2009 with a mandate to ensure existing equipments function properly.

Using IT in health care: e-Swaasthya initiatives were

undertaken to improve efficiency and transparency in delivery of health services.

Box 3: Using IT in Health Care (e-Swaasthya)

e-Swaasthya - the e-governance initiatives

i. ***e-Blood Bank:*** Stores data about collection and availability of blood, using a bar code system for efficient handling and use within optimal storage dates. 52 blood banks are on the system. Any person can access the information as to the availability of blood in any specific blood bank through toll free IVRS (18003457777), SMS (BSNL:54323 Others:56767) and through NRHM website.

ii. ***Contraceptive Information System:*** A mobile phone SMS system for strengthening and streamlining the contraceptives supply chain, to ensure regular supplies as needed and support decision making.

iii. ***Odisha Drug Inventory Management System:*** Implemented in 30 district headquarter hospitals, all CHCs and three Medical Colleges as a quality control system, recording real time warehouse information and order processing system, to facilitate drug indenting, forecasting and budgeting.

iv. **e-*Swasthya Nirman:*** A web-enabled system that tracks the physical and financial progress of all construction activities undertaken by the National Rural Health Mission within the State, facilitating regular monitoring and decision making.

v. **e–*Sanjog*:** A GPS based system for tracking the location and movements of Mobile Health Unit (MHU) vehicles, which has been piloted in one district, Rayagada. It will support faster access to vehicles in an emergency and monitor fuel use, mileage and speeds, to ensure proper deployment of vehicles.

vi. ***Mission Connect for a closed user group:*** Provides post-paid SIM cards for designated field staff, to improve communications and services, especially during emergencies and epidemics.

vii. ***Telemedicine:*** Supports delivery of health services in remote inaccessible areas that have no services or very limited services. District and State level hospitals are linked through the State telemedicine network to a national level super speciality academic medical institution in Lucknow, enabling patients with complicated problems to access high quality care, as local health workers can discuss diagnosis and treatment regimes with specialists, using computerised records.

viii. **e-payment** - Odisha became the first State in the country to start e-payment for ASHAs (covering almost 60% ASHAs) on a fixed day of the month.

4.3 Health Care Institutions-Qualitative Improvements tried

Healthy Hospital Hygiene Hospital (H4) initiative focused on client satisfaction and non-clinical aspects of health service; like environmental security, housekeeping, laundry services, waste disposal based on a score sheet of 400 points. Any institution acquiring more than 300 points was declared as a H4 hospital.

ISO Certification: Quality Improvement Plans have been initiated in 6 hospitals, building up on the H4 hospital drive and the quality of care study. 8 District Headquarter hospitals have been taken up for ISO certification and one hospital at Puri has already been ISO certified.

Other Initiatives

Other initiatives taken up during the period include institution building like operationalizing AIIMS Bhubaneswar (which has since started its academic session w.e.f. 2012), setting up of Indian Institute of Public Health and Planning for Regional Institute of Paramedical Sciences which is in the pipeline; expansion of various disease control programmes like AIDS, malaria (19 lakh Long Lasting Insecticidal Nets distributed across 26 districts), TB (DOTS plus strategy initiated); reforms in drug control administration (augmenting testing and laboratory facilities and creating posts for supervision and laboratories); improvements in medical education - augmented infrastructure and equipments; increased number of beds and UG/PG seats; introduced new Departments like Transfusion Medicine, Hepatology, Rheumatology, Emergency Medicine; started kidney transplant, etc.; thrust on health promotion activities - developed Centre of Excellence for Health Communication; health 'walls' across villages; focus on community participation - Village Health, Sanitation and Nutrition Committees constituted in most villages, Rogi Kalyan Samitis activised across health institutions, etc., among others.

Improvements in health outcomes

The health outcomes have shown improvements in these years. While these improvements cannot alone be attributed to the steps taken; and perhaps it is too early to comment on the impact but the response has definitely been encouraging. Odisha has shown a steady and sustained improvement in most of the key impact level indicators of health sector performance over the last 6-7 years. The infant mortality rate has reduced from 97 per 1,000 live births in 1999 to 75 in 2005 and 57 in 2011[23]. Maternal mortality has declined from 368 per 100000 live births in 1998 to 303 in 2006, and further to 237[23] in 2011. Neonatal mortality has shown a rate of fall similar to that of IMR over the period from 2006 to 2011, although post neonatal mortality rates have remained at the same levels. Child Mortality Rate has shown an accelerated decline by 6 points from 2009-10 and 2010-2011 .

What is more interesting to note is the commensurate decline of 13 points (53 to 40 from 2005 to 2011) in neonatal mortality rate (NMR) of Odisha, which is ahead than the all India average decline. During the period under reference, in many of the larger States, there has been a decline in IMR but neonatal mortality mostly remained unchanged .

Public health facilities are being better utilized, reflecting the increasing confidence in public health institutions While in-patient attendance almost doubled from 2008-09 to 2011-12; the out-patient attendance also increased from 1 crore to 1.8 crore in the same period. Institutional deliveries have shown an increasing trend over the years

What is perhaps most satisfying is that there has also been a reduction in the equity gap for uptake of health services, an indicator that bodes well for large proportion of the ST/SC and BPL sub-groups in the State. This has been evident through a concurrent monitoring survey conducted in 2011 through DFID support.

Comparing utilisation of institutional delivery between DLHS-3 (2007-8) and four quarters of concurrent monitoring in 2011[24], we find that coverage has grown at a faster rate in KBK+ districts compared to the state average; resulting in a

declining gap .The gap in child immunisation between KBK+ districts and the state average has also declined .

State-wide, concurrent monitoring data shows that significant gains have been made in reducing the social gradient of key health indicators. There has been a quantum leap in Scheduled Tribes using maternal and child health services over the past 5 years. Moreover, the gap between Scheduled Tribe women and children and the total Odisha population for key marker maternal and child health services has declined remarkably.

The wealth gradient of institutional deliveries has also declined with the poorest women experiencing the fastest rate of increase since NFHS-3.

The Annual Parasite Index (API) and Case Fatality Rate (CFR) for malaria have shown a decreasing trend over the years with an accelerated decline in the last few years .Declines in morbidity and mortality are also consistent and clear

Way forward

Odisha is on the right track, a case made out by successive Common Review Missions, constituted by Government of India and consistent improvements in key indicators like IMR, MMR, CMR, TFR, etc. However, there is still a long way to go before it achieves National and Millennium Development Goals. Major policy decisions/initiatives which could strengthen Odisha's response to health challenges could be:

i. Development and implementation of a strong HR strategy and policy.

ii. Saturation of Human Resources requirement at "Delivery Points" by rational postings, filling up of vacant and creation of vacant posts, wherever required.

iii. Strengthening quality of care and maintaining standards through mentoring and supportive supervision.

iv. For supervision, the Directorates headed by doctors need to be strengthened with fixed tenure for the top

posts of Directors and of Chief District Medical Officers.

v. Setting up of a 'public health' cadre.

vi. Sustaining Units set up for systemic improvement viz. State Human Resource Management Unit; State Equipment Maintenance Unit; Centre of Excellence for Communication, among others.

vii. Establishment of a dedicated Civil Wing, to give thrust to inadequate and incomplete health infrastructure .

viii. Availability of free generic drugs at all health facilities, as per institution specific essential drug list. A dedicated procurement corporation could help in this endeavour.

ix. Strengthening critical units such as SNCU, NBSU, ICU, trauma care centres with skilled HR, equipment, maintenance and quality of services.

x. Developing output based monitoring systems.

xi. Strengthening primary health services and referral institutions to handle increasing load of non-communicable diseases.

xii. Continued thrust an primary prevention (health promotion) and secondary prevention (early screening). Given the increasing costs of treatment this is the most cost effective option. Utilizing the State Institute of Health and Family Welfare (hitherto used for capacity building) as an institute of Health Promotion is a possibility.

xiii. Simultaneous focus on other social determinants of health especially nutrition, drinking water, sanitation, women's literacy which directly/indirectly effect health indices. "All for Health" to achieve "Health for all" should be the mantra.

xiv. Strategic planning to continue to encourage more medical colleges in Govt. or seats of existing medical colleges as far as possible under prevailing norms etc.

xv. Geographical focus on KBK and other tribal districts has proved useful and could be continued. Separate focus an health of PTG groups through collaboration

with Scheduled Castes and Scheduled Tribes Welfare Department could be tried as they are the most vulnerable.

xvi. The e-Swaasthya initiatives need to be strengthened and built upon to bring greater efficiency and transparency in the system.

Conclusion

There is no doubt that the poor and the marginalized bear a disproportionately high burden of disease and yet have least access to health care. However deep insight into the various determinants of access along with a determined effort to augment services for addressing them can lead to improvements – even if incremental. As the nation prepares to achieve the Millennium Development Goals on health; and as it initiates the planning process towards Universal Health Coverage[25], Odisha will have to invest much more in health - funds, human resources, efforts and time. Given its historically weak delivery mechanisms; its disproportionately high burden of disease; its difficult and often, hostile terrain and its continued vulnerability to natural disasters, Odisha will have to go the extra mile. In the last few years, the Government has demonstrated political will and administrative drive even as the platform of NRHM provided the funds and the flexibility for health services to be increased, improved and innovated upon. This has kept the health agenda, justifiably, in the forefront of the development agenda of the State. Odisha must build on this momentum generated.

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Amarjit Singh

Improving Maternal Health Care through Public Private Partnership Gujarat

In a recent article in the 'Outlook', Jean Dreze and Amartya Sen compared the increase in Gross National Income (GNI) per capita on a purchasing power parity (PPP) basis during 1990 and 2010, and Maternal Mortality Rate MMR and IMR, between India and her neighboring countries and found that although there has been a substantial increase in the per capita GNI, the improvement in MMR and IMR was not commensurate. While China and Sri lanka had done considerably better on most indicators, even countries like Bangla Desh and Nepal had a better track record on some of the health indicators.

Indicator	Year	India	B'desh	Bhutan	Nepal	Pakistan	Sri Lanka	China
GNI per capita (PPP, US $)	1990	877	543	1280	513	1210	1420	813
	2010	3560	1800	4950	1200	2780	4980	7570
MMR	1990	570	870	940	870	490	91	110
	2010	212	340	200	380	260	39	38
Infant Mortality rate	2010	44	38	44	41	70	14	16

India clearly, had a long way to go. They lamented, "The progress of living standards for common people as opposed to a favoured minority, has been dreadfully slow – so slow that India's social indicators are still abysmal."

"Only five countries (Afghanistan, Cambodia, Haiti, Myanmar, and Pakistan) do worse than India in child mortality rate, only three have lower level of "access to improved sanitation" (Bolivia, Cambodia, and Haiti) and none have a bigger proportion of underweight children. Almost any composite index of these and related indicators of health,

education and nutrition would place India very close to the bottom in a ranking of all countries outside Africa".

Obviously, we have to think of out of the box solutions to improve our social indicators. The following case study brings out one such initiative to reduce maternal mortality in Gujarat.

The Issue

India accounts for the largest number of births (27 million) worldwide every year. Majority of these births are in rural areas and take place at home in absence of skilled birth attendants. Though trained Auxiliary Nurse Midwives are positioned in more than 30% of the villages, they are not skilled enough, in most cases, to handle even ordinary deliveries, not to speak of complicated cases. Generally, she has no expert gynae/obstetric back up to rely upon in case of a complicated delivery. The lack of availability and access to essential health services results in death of 1,17,100 mothers and more than a million infants within critical 28 days of birth. The irony is that most of these lives could be saved!

There are several reasons attributed to this, including as mentioned earlier, the non-availability of skilled birth attendants in rural areas. The trained obstetricians are available in the country but they are mostly in the private sector. For diversity of reasons- lack of amenities, constraint of salaries as well as government policies, only few functionaries actually work in the Government, and serve the population in remote rural areas. For example, of the 2000 obstetricians in Gujarat, only 7 were practicing in the rural areas in the block level hospitals which serve the poorest population. A similar situation exists in many other States of the country, like U.P., Bihar, Rajasthan, Chhatisgarh and Jharkhand. As a result, the maternal mortality ratio in the rural areas of the country actually worsened during the decade of the 90s from 448 to 619 per 100,000 live births. Those lucky to survive, may in many cases, suffer from incontinence, chronic pelvic pain, dismenorrehea and other complications of a badly handled delivery!

Setting the Scene

After several unsuccessful attempts to improve institutional delivery rate in the public sector, the Government of Gujarat tried an innovative approach in 2005-06, to involve the private sector to ensure safe deliveries for the Below Poverty Line (BPL) population. Under the scheme called 'Chiranjeevi' for long life of mothers and children, the private obstetricians were contracted to provide skilled birth attendance and comprehensive emergency obstetric care free of charge to poor women in rural areas. In return, the Government paid the obstetricians Rs.1,79,500/- for a package of 100 deliveries including treatment of complications. The average price per delivery came to Rs.1795. The criterion for selection of private obstetricians was kept simple to get good representation. The scheme was developed in consultation with IIM, Ahmedabad; Sewa Rural, Jhagaria and the Federation of Gynecological Societies of India (FOGSI)

The payment to the doctors was worked out in consultation with FOGSI on the basis of the actual cost in a rural setting - for Sewa Rural, a reputed non-Government hospital in a tribal area of the state. The scheme assumed a fixed rate of caesareans of 7% based on local experience in Gujarat. This financial arrangement removed the monetary incentives for doing more caesarian sections; a common problem in the private sector in India. The scheme covered cost of transportation from rural area to the city and a small reimbursement for the person accompanying the expectant mother.

Goals of the Initiative

The major aim of the initiative was to make safe delivery facilities available to all the below poverty line women in the State through the active involvement of private obstetricians. The broader aim was to achieve the Millennium Development Goal 5 for reduction of Maternal Mortality Ratio (MMR) by three quarters. Put simply it implies a reduction of MMR from the level of 301 to 75 per 100,000 live births.

The scheme has a wider significance for the country as India accounts for a quarter of all maternal deaths. India has to play a pivotal role if MDG 5 for reduction of maternal

mortality ratio (MMR) by three quarters is to be achieved.

The Experience

The Chiranjeevi scheme was started as a pilot project in 2005-06, in 5 districts of the State. To promote the scheme, regular meetings were held with community leaders, District Health Teams, members of the local Gynecological Societies to promote the scheme; however, no incentive was paid to anybody for the purpose. The procedures were kept simple and the expectant mothers with BPL cards could use the scheme without any other requirement of vouchers/entitlement. The scheme was managed by the District Health Officers. To allay the fears that the Government would not pay dues on time, doctors were given an advance payment of Rs.25,000 on signing the contract. As deliveries occurred, obstetricians were reimbursed promptly by the District Health Office.

It needs however, to be clarified that Chiranjeevi Yojna was only one of the components of the state strategy for improving maternal health. Simultaneously, steps were taken to; upgrade peripheral health infrastructure, effectively implement Janani Surakasha Yojna, train MBBS doctors in emergency obstetric care and auxiliary-nurse-cum-midwives as skilled birth attendants. These efforts were also supplemented by the 108 Emergency Trauma Care Service, which was mandated to carry the poor expectant mothers from the villages to a safe delivery facility in the public or private sector.

Outcome and Impact

The responses in five pilot districts were phenomenal; 75% of the private obstetricians in these districts joined the scheme willingly. Some 3.73 lac poor women delivered in private hospitals from January 2006 to March 2012 under the scheme. On an average each obstetrician performed around 2145 deliveries and earned up to Rs.3.5 - 4 million. The scheme turned out to be a win win situation for the poor women, the private doctors and District Health Authorities.

The initial efforts of the Government were rewarded with Asian Innovation Award. This encouraged the State Government to extend the scheme to the entire state. More

than 800 private obstetricians are currently engaged with State Government; they have performed 8.26 lacs BPL deliveries in the last six years. The coverage of deliveries under the scheme scored out 53% of the total BPL deliveries. The beneficiaries of the scheme included 52,120 women who underwent caesarian deliveries and 41,633 women who had complicated deliveries; at no cost to them. This prevented destitution and indescribable misery with substantial evidence that rural families had gone bankrupt because of undergoing complicated deliveries!

The scheme helped save precious lives; in normal course 1,651 women might have lost their lives during these deliveries, however, due to skilled birth attendance, only 107 maternal deaths were reported under the Chiranjeevi Scheme. Similarly, a large number of early neo-natal deaths were prevented because of skilled care during birth.

Consequent to these efforts, institutional delivery rate, the better proxy indicator for safe delivery, which was increasing at a snail pace rate of 1 to 2% annually, shot up from 55% in 2005 to >90% in 2009. An independent evaluation by UNFPA mentions about significant improvement in institutional deliveries among BPL population with high levels of clients' satisfaction.

An evaluation by IIM, Ahmedabad tells that most of Chiranjeevi users have income level of less than Rs. 12,000 per annum indicating that scheme did target the poor families. The users were relatively young mothers with less number of children. ANMs, anganwadi workers and female health workers provided information to 82 per cent of the Chiranjeevi clients.

The Chiranjeevi experience has been figured in state of the world's children report 2009, published by UNICEF, as unique initiative to improve maternal and child health. The South East Asia Region of WHO invited eleven countries at a workshop in Ahmedabad to visit private partners and learn about the scheme. The learnings from the scheme have been published in many internationally reputed journals such as International Journal of Obstetrics and Gynecology as well as the Bulletin of the World Health Organization.

The total cost to the State for 8.26 lacs deliveries has been around Rs. 1486 million or Rs. 248 million annually, which is a tiny component of state health budget.

Lessons Learnt

The Chiranjeevi scheme provided the first real time case of engaging private obstetricians on a large scale to provide skilled birth attendance and emergency obstetric care to poor women in a western giant State of India. It demonstrates the feasibility to involve private sector to provide skilled birth attendance to poor at minimal price. It reflects a replicable strategy to other States of the country to help achieve the UN Millennium Development Goals connecting to mother and child health.

The Chiranjeevi Yojna has lessons for other States. Despite tremendous success of Janani Surakasha Yojana (JSY), even today 55 lacs births that take place in Uttar Pradesh annually, only 21 lacs occur in SBA institutions. Thirty four lac births still take place in unsafe surroundings making expectant mothers and the neonates vulnerable. State Government finds it difficult to provide safe delivery facility to remaining 34 lac expectant mothers in Government set-up as most of existing hospitals are fully utilized. On the other hand, more than 4000 private obstetricians are working in U.P. who could be involved to provide safe delivery facilities to the poor women. Similar situation exists in many States; in Jharkhand, only 20% have access to safe delivery facilities. In the national capital, more than 32% women in slums and other areas deliver in unsafe surroundings. There is a real need to engage the private sector for safe delivery to poor.

The logic that involvement of private sector would compress the scope of Government is unfounded. The illustration of U.P. shows enough work for public and private sector. The Gujarat experience shows that after 4 years of partnership with private sector, the public sector deliveries have been increased in percentage and in absolute terms.

Efforts need to be made to ensure that safe blood is made available through network of rural blood storage centers, which are linked to and supervised by regional blood banks.

This is a critical component as a large number of women, especially in rural areas are anaemic. Most of the women who died under the Chiranjeevi scheme, could not be saved due to non-availability of safe blood in the remote areas.

Future Plans

This initiative shows that it is possible to involve private sector obstetricians to provide safe delivery facilities to the poor BPL women. To facilitate this, Government has to ensure that private doctors are paid on a regular basis through an effective review mechanism which includes representatives from the private sector. Similarly, efforts have to be made to revise the rates for the private doctors on a regular basis. These rates fixed in 2005 were revised to 2800 per delivery in 2010.. We need to put in place a system to ensure revision of rates once in three years based on inflation.

There is a need to ensure that contract doctors provide quality services; with infrastructure and manpower; follow standard operating procedures so both mother and child could get quality care.

Further efforts are required to market the scheme; despite efforts of the state Government we could reach only 53 per cent of BPL women. There is a need to ensure that remaining women are aware of the scheme and arrangements put in place to transport them to safe delivery facilities in time.

There is also a possibility of extending the scheme to cover screening for cervix cancer, HIV/AIDS and provision of high quality sterilization services. In Gujarat 258 private paediatricians are already working with the State Government under the Bal Sakha Scheme to provide expert care to critically ill neonates. This needs to be explored further.

Many states in the country could benefit from a Chiranjeevi like scheme. Such efforts would however, require a proactive and a dynamic leadership from the top health managers at the state level and committed team work of peripheral health staff including nurses, health facilities, medical officers as well as private obstetricians. The returns, in terms of maternal and neonatal deaths averted, would however be very worthwhile.

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