

***Opportunities, Ecosystem Requirements
& Road-Map to Innovations in the
Health Sector.***



Report of the Sector Innovation Council for Health

Sector Innovation Council

Full Report

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On request: Background Papers/Studies contributing to the report.

- Case Studies of Pharmaceutical Innovation
- Identification of Gaps and Opportunities
- Public Health IT- study report
- Tele-ophthalmology -Tripura-
- Publicly Financed Emergency Response Systems

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The views expressed in this report are tentative, and subject to further discussion and modifications. This is very much work in progress and we look the further feedbacks to improve on the draft before it is finalised.

Section I: Background and Objectives

Objectives of the Council

The **Terms of reference** for the Sectoral Innovation Council on Health are as follows:

1. To map opportunities for innovation in the health sector.
2. Explore possibilities of encouraging and rewarding young talents for working in the health sector.
3. Prepare a roadmap 2010-2020 for decadal innovation in the health sector.

The context of this initiative is the setting up of a National Innovation Council (NInC) in 2010, to help implement a National Strategy and to prepare a roadmap on innovations for the decade 2010-2020. The N.In.C has 17 members and is chaired by Shri Sam Pitroda, Advisor to the Prime minister. The NInC leads a number of activities which includes establishing a National Innovation Portal (www.nationalinnovationcouncil.gov.in), catalyzing an innovation eco-system, developing 20 innovation hubs at universities in India, and building national and international collaborations.

One of the important roles of the N.In.C is to set up Sectoral Innovation Councils and State Innovation Councils. The Sectoral Innovation Councils are to identify opportunities for innovation. The Sector Innovation Council needs to identify areas where the health sector needs innovation for achieving its health outcomes. The Sector Innovation Council will also recommend and facilitate the policy and institutional structures needed for an eco-system that would promote innovation and absorb innovations, and build a sustainable Indian model of innovations for that sector.

The Sector Innovation Council set up by the ministry of health and family welfare has 15 members and is chaired by Shri PK Pradhan, Special Secretary of the Ministry and Mission Director for the National Rural Health Mission. Its first meeting was held on July 6th, 2011.

In its first meeting the council arrived at the methodology by which it would go about its work and allocated different themes to different sub-groups for mapping the current innovations and its drivers as well as identifying the constraints and making recommendations.

These **four sub-groups** were:

- I. Drugs and Pharmaceuticals- to be convened by Shri. Dinesh Abrol.
- II. Medical Devices- convened by Dr. Sujoy Guha
- III. Information and Communication Technologies- to be convened by Dr SK Mishra
- IV. Health Systems and Programme Designs: to be convened by Dr. Dileep Mavalankar

The Member Secretary with help of other members would contact experts identified and secure their participation in the sub-group. He would then circulate the names of those who have agreed to be on the sub-group and contribute to this process. NHSRC would facilitate the studies or meetings needed for the sub-groups to achieve their objectives. Subgroups could meet in the premises of NHSRC.

The task of the sub-groups would be to map the present status of innovations and the opportunities for innovation in their respective domains. Then they would look at the drivers of innovation, the factors that influenced uptake and scaling up of innovation, the incentives available and that were needed for innovation, and the constraints faced. Then they would look at the existing institutional framework for innovation and make suggestions for institutionalising or making institutional reform as needed. Background papers and inputs from each sub group describing the current situation, prospects and need for innovations, would be put together and presented to the whole group.

Definitions

Medical Devices: An article, instrument, apparatus or machine that is used in the prevention, diagnosis, or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means.

Medical Equipment: Medical devices requiring calibration, maintenance, repair, user training and decommissioning- activities usually managed by clinical engineers. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used alone or in combination with any accessory, consumable or other piece of medical equipment. Medical equipment excludes implantable, disposable, or single use medical devices. (WHO medical devices technical series based on Global Harmonization Task Force.2005.www.ghmf.org.documents)

Health Technology: The application of organised knowledge or skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life. It is used interchangeably with health care technology.

Needs Assessment: This is a process for determining and addressing the gaps between the current situation or condition and the desired one. It is a strategic activity and a part of the planning process that aims to improve the current performance or to correct deficiencies.

Health technology Assessment (HTA): HTA is an instrument to analyse the technical, ethical, social and economical impact as well as the clinical effectiveness of a specific technology.

Section II: Drugs and Pharmaceuticals

Innovation in Pharmaceutical products

1. Introduction

Drug discovery, development and innovation are critical to the road to be taken in respect of the journey to be made to approach the goals of fulfilling India's specific healthcare needs, pharmaceutical self-reliance for health security and preservation of export competitiveness in a knowledge intensive sector. Drug discovery and innovation are also an important part of ensuring universal access to essential drugs and diagnostics. While one part of the challenge of universal access is to ensure that there is universal access to already existing technologies, the other part of the challenge is to find new technologies to address unmet needs and provide better access by virtue of their being more appropriate to the health systems context.

Though at each stage in national development there have been important gains and some successes in drug development achieved, there are not very many drugs on the international market that India can claim as its innovation. Nor can it say that it is able to meet all its health care needs or hold down the rising costs of drugs. India has the potential to undertake product innovation at lower cost, develop the required S&T capabilities for drug discovery and development and become a frontline pharmacy for the developing world. However the nation needs to translate the potential into actual innovations, that would make the Indian pharmaceutical industry a reliable provider of the safest and most effective and affordable medicines. For this we need to examine the current regime of innovation with a view to understand its impact, and review changes underway in public policy and public institutions and propose changes in the eco-system that would lead up to the realization of the growth potential of the sector.

Indian Drug Industry:

India has the best developed pharmaceutical industry in the developing world and the fourth largest by volume in the world. It has the technical capacity to manufacture almost the entire essential drug list and all off patent drugs. It produces over 70,000 formulations. It has a highly diverse industry ranging from small scale domestic units, to emerging Indian multinational firms as well as a high presence of foreign manufacture from India and imports. The total value of drug production of this thriving industry is over one billion dollars per annum.

India has been investing in the development of biomedical research, medicinal chemistry and process R& D capabilities, both in the system of public sector science and in domestic industry, which can be leveraged upon, both in the interest of public health and for all round development of domestic pharmaceutical industry. It has access to one of the potentially largest skilled human resource pools in the world. It has traditional strengths in organic chemistry and herbal medicines. India also has a grim health situation, which remains a challenge and to address which we need increased investment in human and financial

resources, better governance and institutional reform. But we also need innovation, both in health systems and health technologies.

The area of innovation in pharmaceuticals - which encompasses not only medicines, but also vaccines, bioactive chemicals in public health, and in-vitro diagnostics, – is important to the country's interests for a number of reasons. The key areas where there exists a potential for the nation to benefit include:

- 1) Access to innovations that address public health needs of the country
- 2) Promotion of global collaborative R&D with a view to developing new products
- 3) Expansion of the role of Indian generics in the markets of countries of both, North as well as South
- 4) Enhancement of domestic research capabilities in a wide variety of areas.

Regimes of Innovation- Past and Present:

Pharmaceutical product innovations in today's world require the mobilization of state, industry and society for their accelerated development. Domestic pharmaceutical firms in India have been developing their own firm-specific capabilities and interactions to make the transition from a process to product focus and from imitation to innovation during the period of last two decades. Domestic pharmaceutical firms have access to the knowledge needed for innovation from multiple sources which range from foreign firms and universities to domestic firms and universities, Indian R&D laboratories to health care providers, and traditional sources of knowledge.

The drivers, motives, gate-keepers and financial support of innovations in the case of domestic pharmaceutical firms have changed over the years- and we can describe these as four distinct regimes of innovation. Soon after independence, Indian drug industry was miniscule, though even then we had great leaders in chemical sciences and a few Indian industries that were established specifically with nationalist objectives. The first phase, from the 1950s to the 1970 built up an Indian public sector in drug production, it built up a public health delivery system, and it also built up a number of public R&D institutions, and a few health research institutions established under ICMR. This was largely a state led period of public sector industry initiated capability development. An infant public sector industry coexisted with the foreign firms having a share in the domestic market.

The second phase, from the mid seventies to mid eighties represents the establishment of domestic private sector companies initiated with the help of the Indian Patent Act, 1970 and the National Drug Policy of 1978 and the CSIR laboratories which acted as an important source for process know-how for these companies. The Drug Policy reserved the production and distribution of 25 bulk drugs only to the public sector and 23 bulk drugs to the private sector. The remaining 66 bulk drugs were left out of reservations. During this period the foundations of Indian pharmaceutical industry came to be established for the benefit of Indian market. Its presence on international markets during this phase was not a priority of the domestic pharmaceutical firms. Most of the regulated markets were not opened till 1984 for exports by domestic pharmaceutical firms. One of the key motivations of development in this period was import substitution, not really new product development.

The strengths of CSIR laboratories in medicinal chemistry, synthesis and process know-how development began to be developed in this period.

The third phase, from the mid eighties to late nineties, was the period of internal liberalization. The Drug Policy 1986 was for the liberalization of import restrictions on technology and bulk drugs and intermediates. The Drug Policy stressed the need to impart a technological and productivity thrust to the Indian pharmaceutical industry so that it could harness export opportunities. For export production, companies only needed to inform the expansion plans. Capacity regulation was liberalized for exports. The Drug Policy of 1994 allowed only proposals involving foreign equity up to 50% through automatic route and considered participation above 51% on merits of each case. Foreign equity participation was further eased from March 2000 with 74% permitted on automatic route, in case of bulk drugs and intermediates. Investment above 74% was considered on a case by case basis in areas where investment was not otherwise forthcoming.

In the second half of mid nineties India gave commitment in WTO to change to a stronger pharmaceutical intellectual property regime. However the government chose to use the transition period provisions available to the country in the TRIPS Agreement, and delayed implementation of product patent till 2005. It was during the first half of nineties that the domestic pharmaceutical industry recognized that the change from process patent to product patent was now only a decade away. Since they were now quite certain that domestic market will not be exclusively available to the Indian firms anymore, domestic firms were much interested to exploit the lucrative generic exports opportunity opened by the 1984 Hatch-Waxman Act in the US market. The conditions for a new regime of innovation were ripe; the government was undertaking internal liberalization and incentivizing industrial exports.

The fourth phase, from 2000 onward, represents a period of globalization of the Indian pharmaceutical industry started formally with the Pharmaceutical Policy 2002. This policy abolished the industrial licensing regime for bulk drugs and formulations completely. The new policy permitted foreign equity participation up to 100 percent. The policy of price decontrol policy was extended further to many more drugs. Under such favorable conditions several Indian pharmaceutical firms chose to make an entry into the markets of US and Europe which had become available for generics. The sectoral innovation ecosystem had already come to acquire the necessary capabilities within public sector science. Further, as the product development capabilities were yet not mature in the country, it was not viable for many firms to make this journey and moving to off patent generic drug export was easier. At least some of the domestic pharmaceutical firms grew rapidly during this period. Today these firms are the third world's leading pharmaceutical giants- the Indian industry is being characterized by some even as the pharmacy of the third world- with a capacity to produce generics in almost all key health areas.

From the period of 2000 onwards the TRIPs Agreement became the basis of amendments in the patent legislation, leading to a transition from a process to product focus. Although under the post-TRIPs conditions it was expected that it would be possible for the domestic firms to interact with foreign sources of knowledge with greater freedom than before, in

practice it was the marketing and production related links that got encouragement. Marketing and production related international acquisitions, alliances and collaborations alone got a big push from the domestic pharmaceutical firms. It is apparent that in the absence of complementary policy and capacity actions Indian pharmaceutical and health sector could not take better advantage of the international interactions at the terms which were in the national interest. These were slow to develop and even conscious public act is required to be put these in place for the establishment of a new innovation regime in the future.

Policymakers seeking to put in place incentives for product innovation relied mainly on the force of a) stronger intellectual property rights system, b) external liberalization- opening the doors for foreign investment and participation, c) increase profitability through tax concessions and price and market decontrol. Coordination of industry, public sector science and drug regulation were designed to work essentially during this period through market coordination. Public policy action was being deployed to align the development of human resources and R&D mainly with the expectations growing in respect of the opportunities becoming available to the domestic pharmaceutical industry in the regulated markets of developed world becoming available and with the demands for the greater opening of the domestic markets and making the R&D supply side capabilities accessible to the global pharmaceutical firms.

Policies were also changed to encourage the global pharmaceutical firms to outsource the cheaper infrastructure, manpower and patients available from India for clinical trials and some portions of drug discovery. The policy assumption was that there would be 'technological spillovers' in terms of capability building. However there were no regulations regarding their obligations to interact with the domestic S&T organisations and industry for their capacity building. As a result spillovers have been minimal. There has also been some misuse by the CROs of the lax regulatory environment prevailing with regard to the ethical conduct of clinical trials.

While until quite recently the growth of domestic pharmaceutical industry was perceived to be a major success story of policy interventions initiated after the signing of TRIPS agreement, there is also now increasing concern. In the month of November 2011, the Department of Industrial Promotion and Policy (DIPP, November 30, 2011) issued even a discussion paper which clearly recognised that the government may have to undertake some course correction if the success achieved so far by the domestic pharmaceutical industry is also to be sustained for the benefit of access to essential medicines and for the development of R&D capabilities leading to new medical products in India. The discussion paper of DIPP notes with much concern that as some of the top domestic pharmaceutical firms have already made an exit from the market and others may also choose to follow the example and sell their stakes to the global pharmaceutical players. With such changes and with no major innovations in the pipelines, the gains that the Indian people had made in respect of getting access to essential medicines at affordable prices could soon evaporate if there is no timely action. It is clear that the overall performance of the drugs and pharmaceuticals sector is now under scrutiny from the side of the government and industry with this fresh perspective of the need for innovation.

This is a good time for the sector innovation council to re-examine the issue based on the evidence of the last 15 years. The sector innovation council should consider the steps needed to reconfigure the innovation policy both due to its immense significance to the country on account of the projected revenue growth from exports, as well as for ensuring that the domestic industry meets the health needs of the Indian population.

We therefore begin by describing the dominant market based innovation regime and examine to what extent it has been successful in innovation for export led industrial growth, in terms of developing Indian markets and serving Indian needs, and in being able to sustain its growth and Indian character in the future as well address the changing health needs of the future. Where there are gaps we discuss the barriers and constraints that could explain these gaps between expectation and performance.

Then we discuss the role of the public sector in drug R&D and the role it is playing in innovation under the changed regime of innovation and the barrier it is facing.

After this we describe the needs and opportunities for innovation and we conclude this section with the main recommendations or eco-system requirement, for making use of the opportunities and responding to the needs.

2. The Current Innovation Regime- a description.

Product development innovations (including all the three domains: therapeutics, in-vitro diagnostics and vaccines) can emerge from the different sub sectors of the industry large, medium and small domestic pharmaceutical firms and foreign pharmaceutical multinationals. There are also young biopharmaceutical firms emerging due to the efforts being undertaken by the government to encourage bio-entrepreneurship through the development of incubators and parks being setup for their support in selected cities where there already exist a number of research institutions and academic institutions. All these carriers have the potential to contribute to product innovation.

In this section we examine whether the outcomes expected of these policy changes of the last 15 years were realized with respect to innovations and use these insights to make proposals for how we need to shape our eco-system for the future.

The three policy changes were

- a) The relaxation of the drug price control order, reducing the number of drugs on it from 145, to 75 and an even further reduction proposed that got stuck by a court ruling. Higher prices and high returns for industry in the essential drug area were justified by the need to compensate for innovation expenses and to stimulate further investment in innovation by industry.
- b) Change from process patents to product patents. This was agreed upon in 1995 and enforced from 2005, giving time for Indian industry to adjust. This meant that Indian industry was to be encouraged to innovate in developing new chemical entities and contest for new patents- not merely make already discovered and validated molecules through a cheaper process.

- c) Permission of FDI for entry into pharmaceutical industry- including permission for mergers and acquisitions. This was expected to bring in newer drugs faster into Indian markets and allow greater capacities for development of drugs for Indian needs- as international knowhow could now be available for Indian health needs.

It was also expected that the strengths of past policy would be retained. The major strengths that were carried over from past policy thrusts were:

- a) A large very Indian manufacturing industry that grew from the 1970s – which had acquired adequate capacity in process innovation- and which drew a lot from the Indian public sector for its development. Almost all the domestic firms that lead now the pharmaceutical industry emerged from mid seventies onward. Most of them did grow reasonably well during the decade of eighties to become the competitors of foreign firms, first in the domestic market and then in the international market during the decade of nineties. Industrial and technological competence was also built by the Indian pharmaceutical companies in this period with the help of the environment of incentives created by the government by legislating the patent act 1970 and the drug policy of 1978 which clearly provided for domestic market protection and price control to the benefit of Indian companies and also promoted bulk drug manufacture within India.

In the 1990s, responding to the threat of product patents hanging on their head but making a good use of the grace period available due to delay the implementation of product patent in pharmaceuticals to the country, a number of Indian industries also chose to export off-patent generics to regulated markets, leading to a new chapter in Indian pharmaceutical sector growth and technological capability development. A good example of this growth is the story of Dr Reddy's Laboratory. There are at least now fifteen firms that can now claim to have developed the firm size. They have been able to acquire the in-house R&D capabilities required for undertaking incremental pharmaceutical innovations. The process of capability development for drug discovery and development can be said to have begun formally in the domestic Indian pharmaceutical industry in 1994 with Dr. K. Anji Reddy of Dr. Reddy's Laboratories (DRL), earlier a technocrat in the leading public sector firm namely Indian Drugs and Pharmaceuticals Limited (IDPL) opening the R&D laboratory for drug discovery in Hyderabad. DRL was responsible for setting up the first new private sector drug lab at Hyderabad as a distinct facility. There are also other examples. Companies like Ranabaxy, CIPLA, Lupin, Cadila, Sun Pharma, Wockhardt, Glenmark and Biocon.

- b) As the research laboratories working, mainly under the systems of CSIR and ICMR and DBT were also mobilized to provide relevant R&D support for select areas like chiral chemistry based process development, reverse pharmacology, etc., India was able to get an edge in the making of better products. Of the CSIR laboratories the most relevant and active on this issue of support were the Central drug research institute, Lucknow, the Central Institute on Medicinal and Aromatic Plants. Although all these laboratories were set up during the period of 50s, and 60s (Sri Chitra Tirunal Center for Medical Science and Technology was set up in the 70s), they were mobilized effectively during this period for pharmaceutical innovation.

- c) The Indian Council for Medical Research is exactly a 100 years old, and has recently been strengthened into a department of health research. The ICMR has a network of research laboratories- both regional and disease specific- for tuberculosis, for malaria, for other vectors- filarial, leishmaniasis etc, for viral diseases, for HIV, and three thematic- for nutrition, immunology and epidemiology. Most of these were set up in the seventies and eighties, though some of them are over a century old. Basic research laboratories and funding programs from DST contribute to understanding of disease and new molecule development. There are also the central Councils for research into ayurveda, unani, siddha and homeopathy. The current role of these research laboratories and the constraints they face is covered in a later section.
- d) Some of the other areas that were established and grew in this period were the department of biotechnology, which also became a lead sponsor and support to innovation in this area and which supported a cluster of new institutions. The creation of the department of pharmaceuticals was less clearly associated with any special focus on driving innovation forward.

However, it should be kept in view that this limited success in the upgrading of Indian industry for the start of in-house drug discovery capability building and the creation of export markets for the Indian off-patent generics in the markets of US and Europe is not sufficient for the development of new drugs. The Indian sectoral system of biomedical innovation could not be strengthened sufficiently because the three main actors, industry, science and government, could not steer and coordinate the development of capabilities and links required to be established for the benefit of indigenous product innovation.

Some of the assets created by past policy that had been allowed to decline during the decade of nineties and were left from the processes of innovation during this period were the public sector held capabilities of manufacturing in pharmaceuticals and vaccines. These assets were weakened during this period on account of their neglect in the policies under implementation.

3. Consequences of Current Regime:

Methods of Assessment:

In this section we present an assessment of how far this current innovation regime (2002 to 2012) was successful in its goals as far as the challenges of a) Meeting Indian health needs in terms of access to quality drugs relevant to the burden of disease and b) Leading to an ecosystem that is favourable to meeting its goals in the future, given the dynamic situation in global and national markets both with respect to supply and demand.

Methods to study outcomes in innovation all have limitations. We can study the number of research papers published and relate it to disease burden projections using some standard tools for the purpose, or we can study the patents applied (in India, in the US, and with the EU)- by Indian agencies, or we can study drugs going into clinical trials or applying for

registration and drug controller office or extra-mural research projects sanctioned by department of science and technology, biotechnology, health research and pharmaceuticals. Sources of information include the companies' websites, in addition to information from these offices and registers.

For the output of publicly funded R&D institutions we have studied the research programme funded by extra-mural funds, the papers they have published and patents they have filed and licensed out successfully.

We present below data from only some of these sources. Other sources we accessed show similar trends- but much greater work is needed to systematically analyze and collate data from all the above sources.

A. Emerging patterns of progress in pharmaceutical innovation :

The data from patents filed by the Indian pharmaceutical industry with the United States Patents and Trade Mark Office (USPTO) is given in table 1 and in terms of drug master files (DMFs) and abbreviated new drug applications (ANDAs) and new drug applications (NDAs) filed by the Indian firms is given in table 2.

Table 1 shows a gradual enhancement in the number of patents on processes, dosage forms, formulations. We have had few product patents, and even lesser patents of new chemical entities or drug delivery systems. What really grew most rapidly as a result of the post TRIPs regime change was a growth of dosage and formulation variants- which was over 558 patents being filed. In the field of product development the bulk of "innovative outputs" belong to mainly the areas of dosage/formulation/composition of matter.

Table 1: Emerging Patterns of Pharmaceutical Innovations 1992-2007

No.	Nature of patent	1992-1995	1996-1999	2000-2003	2004-2007	Total
1	Process patents	1	8	62	149	220
2	Product (other than therapeutics / diagnostics / vaccines patents)		6	18	38	62
3	NDDS patents			11	20	31
4	NCE patents		2	10	23	35
5	Dosage/formulation/CM	2	43	228	285	558
6	Method of treatment patents		1	19	16	36
7	New form of substance patents		5	85	195	285
	Total	3	65	433	747	1227

Note: NDDS - Novel Drug Delivery System; NCE - New Chemical Entity

Source: Data of emerging pattern of patenting activity of domestic (30) and foreign (5) companies active in India (Process, product, NDDS, NCE, dosage/formulation/composition, Salt/polymorphs/derivative) data collected from USPTO of 1992-2007. USPTO website URL <http://www.uspto.gov/>

Chemistry driven process research leading to "non-infringing processes" for "active pharmaceutical ingredients" (APIs), introduction of cost effective routes, identification and characterization of impurity profiling pertaining to APIs, reduction of impurity levels,

acceptable dosage forms and formulations came to be pursued as the main priority in the Indian pharmaceutical industry during the post-TRIPS period. This emphasis has continued to date. All of these are related to the development of process know-how and the upgrading of production capabilities for the off-patent generics.

The other area of R&D pertains to formulations where (novel drug delivery systems) NDDS based products were introduced.

Another major area of investment undertaken for the building of innovative competences in the case of Indian pharmaceutical companies related to the improvement of good manufacturing practice. This enables registration for off patent generics produced here to be permitted into the US and EU markets. Table 2 clearly shows the proportion of New Drug Applications (NDAs) as related to Drug Master Files (DMFs) and Abbreviated New Drug Applications (ANDAs) registered by the top 15 Indian companies.

Table 2: DMFs, ANDAs and NDAs received by the top Fifteen Indian Companies

Company	No. of DMFs*	No. of ANDAs	No. of NDAs	Sales turnover as of 2008 in CMIE Prowess Data base (in Crores)
Total (Top Fifteen Companies)	1242	1129	19	78963.13

Source: No. of DMF Data from <http://www.betterchem.com> (Drug master file database) and no. of *Abbreviated New Drug Application* (ANDA) from individual company website.

The economic opportunity created by the Hatch-Waxman Act of 1984 has been the most important stimulus for the domestic pharmaceutical firms to invest in the processes of learning, competence building and innovation making activity to be undertaken for the export to regulated markets of US and Europe. This act made space for a market in generics in the US. Analysis also clearly shows that the enhanced domestic investment in innovation making in India has so far been successfully directed mainly towards achieving the goal of competitiveness in the regulated markets of United States and Europe for off patent generics and not made a major impact on new drug development as such.

Since most essential drugs are off-patent, is the lack of leadership in new drug development a problem? In this regard, one long term consideration that we need to factor in is that in the recent period the pharmaceutical products on the market has had a trend of getting renewed by one third within seven to eight year period for the reason of the safer and therapeutically drugs being needed, patients developing resistance to older drugs, etc. Of course, there is also evidence that 'me-too' type of drugs or even trivial improvements is getting support. Therefore, the challenge is more responsible pharmaceutical innovation. India is faced with the problem of a double burden of disease; different treatment requirements could be different in many instances because of either the different strains of pathogens, or the genetic profiles. This throws up a different kind of challenge for the treatment of chronic diseases.

Further, there is also the issue of management and application of intellectual property on account of the global pharmaceutical firms being accorded in equal the access to domestic market. Even if these firms are prevented from taking over the domestic pharmaceutical

firms the imperative of innovation competition would drive the processes of pharmaceutical innovation. New Chemical Entities (NCEs) based product innovation is clearly a strategic requirement for the domestic pharmaceutical companies. Domestic pharmaceutical companies are dependent on the national ecosystem for learning, competence building and innovation making, and the national ecologies and systems for biomedical innovations of different types are still not mature. The pathway pursued during the last decade was not adequate to acquire the required scale and systemic framework.

Given our commitment to the goal of provision of universal access to essential drugs and diagnostics through the public health system in the 12th Plan, and our movement towards the larger goal of universal health care, we will have to therefore ensure that patents do not raise further barriers to the supply of cheap and state of the art generic drugs in every area of health care. Responsible pharmaceutical innovation is encouraged through appropriate incentives as part of innovation policy. There is also the challenge of growing concentration due to the consolidation underway in the pharmaceutical industry due to mergers and acquisitions. The costs of health care would become unsustainable if the medium and small scale pharmaceutical companies are not able to manufacture the pharmaceuticals on account of the patent barriers. We saw this for anti- HIV drugs- which we could afford only because we could internally manufacture them- and this was a great service not only to India but to the entire third world. Policies therefore need to assist small and medium scale companies as well.

B. Progress in New Process development:

Another question is whether we have retained the advantage we have had in process technology. Analysis shows that Indian firms could not enter into the areas involving cutting edge technologies in formulations and processes developed for the markets of Europe and the US though they could internalize competencies needed for those market segments which are technologically less advanced. These are also areas where Indian firms have mature production technologies- with know-how based on chemical synthesis and organic chemistry available to a large extent already within the existing national system of production and innovation.

The areas where Indian industry lags far behind are new process intensification (PI) technologies and green technologies.

Technologies of process intensification: Micro-reactor technology, Stimulated moving bed reactor technology, Oscillatory baffled reactor technology, Spinning tube reactor technology, Reactive extraction processes, Membrane crystallization, Ultrasound-enhanced crystallization, Microwave technology, Ultraviolet/sunlight in process intensification, Micro bioreactor technology.

Green chemistry or Green Manufacturing: Technologies that reduce energy and material use, lower potential for leaks, increased recycling capability, reduced byproducts in reactors, improved product purity: The list of such technologies includes: Reducing solvent consumption, Better catalysts, Bio-catalysis alternatives, Bio-renewable sources, Switchable catalysts, Nanotechnology, biological methods.

There are companies which are carrying out in-house research to develop these processes but their success has been limited so far. Even for domestic manufacture much of Indian chemical industry is affected, a large number of companies in cities like Hyderabad having to shut down for failure to comply with requirements of pollution emission and safety standards- even where other segments of the industry are shutting down due to changes to a product patent regime.

CSIR laboratories, have in the part demonstrated the capability to develop the know-how packages for a large number of process technologies, which have since diffused to the industry. The domestic bulk drug industry should be encouraged to collaborate with the CSIR laboratories to undertake the development of know-how for technologies identified as yet to be adopted. Implemented in the mode of a public mission, the CSIR laboratories can enable the industry as a whole to upgrade itself. Patented process technologies can be modified as necessary and be licensed using non-exclusive licensing to the medium and small scale companies. Today the country has in addition to the laboratories of CSIR system, the process development companies established by the retired scientists in the private sector. In many areas they too are quite capable of providing the packages of advanced know-how and advanced engineering capabilities to the small and medium scale domestic pharmaceutical firms.

C. Progress in exploitation of opportunities for product innovation

The Indian pharmaceutical companies, like their global counterparts, are also busy focusing their efforts on the therapeutic segments such as oncology, central nervous system, infectious diseases, lifestyle diseases, cardiovascular, inflammation and immunology. For further and full development required for market introduction New chemical entities (NCEs) being developed at home by the Indian pharmaceutical companies, have been out-licensed to the global pharmaceutical firms in return for a share in marketing rights. However Indian companies are experiencing failures in most of cases of such out-licensing agreements as their counterparts in the developed countries, are not ready to allow the Indian companies to ride on their shoulders. There is an urgent need to upgrade the national ecosystem and establish the required facilities for full development in India. (See Annexure for the case studies, illustrative of failures of this route for product development currently under use by the Indian companies)

Further, in India too, the traditional pharmaceutical companies are also shifting their focus to equivalent biopharmaceuticals otherwise known as bio-similars. For example, Dr. Reddys' Laboratories (DRL) is now aiming to invest in the delivery of equivalents of proprietary biopharmaceuticals through process-product- development by taking up relevant clinical research as well. Recently, the company launched a new product, Cresp, a biosimilar Darbepoetin alfa, for use in the treatment of anemia associated with chronic kidney disease and chemotherapy. This was the third biosimilar to be launched by Dr. Reddy's Laboratories. The company is known to be working on at least eight such biosimilars for therapeutic use in oncology and auto-immune problems.

Many Indian biopharmaceutical companies are working in the area of protein therapeutics to develop bio-similars for products whose patents have or will expire soon, for example, erythropoietin, human growth hormone, human insulin, interferon, streptokinase, etc. The Indian companies are also working in a major way on vaccine. The development of a variety of vaccines from conjugated to combination and recombinant vaccines is on the radar of Biocon, Serum Institute, Bharat Serums and Vaccines, and Panacea Biotech to name a few companies. The Indian industry is achieving better breakthroughs in this area.

Indian pharmaceutical companies are also pursuing technology development for new drug delivery systems which include skin patches, biologically degradable polymers for controlled drug delivery, injectable and implantable long acting drug delivery systems and site-specific drug delivery systems for enhanced efficacy and reduced toxicity. Delayed release, extended release, sustained release and pulsatile release systems in oral drug discovery segment are an attraction. Novel drug delivery systems are being developed mainly in the therapeutic areas like anti-infective, cardiovascular, respiratory and NSAIDs. Biocon has been successful in developing oral insulin, which is the first of its kind in the world to reach an advanced stage of clinical trials. This conjugated oral insulin is weight neutral, rapid acting and promises to cut down the risk of hypoglycaemia.

It is obvious that the domestic pharmaceuticals firms need to be facilitated to exploit these opportunities in a balanced way. Domestic firms have an obligation to contribute to product development to meet the unmet health needs of Indian population. We must encourage a balanced implementation of the patent system and use the policy space available in respect of the flexibilities available as per the TRIPS Agreement. There is flexibility available with regard to the implementation of norms and standards of patentability in the interest of developing indigenous pharmaceutical industry in which the firms, be large or medium or small have an opportunity to fully realize their potential.

The government has also much institutional space still available in respect the enforcement of patent opposition and court injunctions. The country is also yet to use the space available in the patent legislation with regard to the use of mechanisms of compulsory licensing, working of patents and control of patent duration through the route of fine tuning of patent renewal system by amending carefully the patent rules. The country has also withstood so far the pressure for the implementation of data exclusivity.

The Ministry of Health and Family Welfare and the Department of Industrial Promotion and Policy should be accorded a role in the implementation of the mechanism of compulsory licensing for government use as well as commercial use of the patents granted to the companies without any discrimination in the interest of improving public health and guaranteeing the Indian people their access to essential medicines.

As against the large companies, research in majority of the small scale companies is limited to process improvement and cost optimisation. Though government risk venture funds are available to support research in the small scale sector, they are not utilised to the fullest. The initiatives by small and medium scale companies are limited by the fact that they are unable to afford qualified persons. The government should prevent the large firms from raising the entry barriers to block the new firms from establishing themselves in the

domestic economic space. The drug regulatory agencies should not be allowed to link the process of drug regulation to the patent examination status. These processes must remain independent. Large firms have the financial muscle to file patent applications in large numbers independent of whether or not the patents would be ultimately granted on those applications. They will try to link the decisions in respect of drug regulation with the status of patent examination to prevent the small and medium scale firms from entering in the market. We should strengthen the provision available in the form of Section 3 (d) of the Indian Patent Act 2000 to ensure that the product patent incentive is available only to those inventions where the therapeutic gain is substantial.

D. Development for home market/national health needs

There are two ways of looking at the correlation between the focus of innovation and the burden of disease in the nation. In table 3 we present the correlation between burden of disease estimates by disease category and in table 4 we use the categorization of diseases into Type I, II and III as used by World Health Organization. Both have problems of categorization and problems with correlation with innovation, but even after making allowances for the details, they broadly indicate trends which are unmistakable.

Table 3 and Table 4 shows that though both domestic companies and foreign pharmaceuticals are both investing a larger proportion of their effort in diseases which are equally if not more common in developed countries, domestic companies make substantial investments in high disease burden areas as relevant to our nation and the so-called neglected diseases- which foreign companies do not. This is a silver lining, for even if there is growing imbalance, there is also hope and consolation linked to the possibility of getting the domestic firms to successfully respond to domestic demand.

Table 3: Pharmaceutical Projects and Patents and the Pattern of Matches with the National Burden of Disease 1992-2007.

No	Major therapeutic areas/Disease/Health conditions	Share in total burden disease (%)	Domestic Companies Pharmaceutical project (%)	Foreign Pharmaceutical project (%)	Domestic Pharm Cos. Patents as (%) of Total Domestic Patents	Domestic Pharm Cos. Pharmaceutical Patents Percentage (%) of Total Patents	Foreign Cos pharmaceutical Patents Percentage (%) of Total Foreign Patents	Foreign Cos pharmaceutical Patents Percentage (%) of Total Patents
1	Diabetes/ Metabolic disease	0.7	24.51	17.26	12.73	12.67	20	0.084
2	Cancer	3.4	10.05	8.81	5.6	5.57		
3	Tuberculosis	2.8 (2.4)	1.18		0.50	0.50		
4	Malaria	1.6 (0.2)	2.36		0.93	0.92		
5	HIV/AIDS	2.1 (1.3)	0.59	0.23	0.84	0.84		
6	Inflammatory diseases/Infectious disease/Injuries	16.2 (5.2)	11.83	5.21	44.56	44.36		
7	Respiratory diseases	1.5 (7.0)	4.73	5.61	1.1	1.09		
8	Bone disease	-	4.73	6.63	1.27	1.26		
9	Neurological	8.5		0.56	10.18	10.14	40	0.16
10	Ulcer	-			0.5	0.50		
11	Psoriasis	-			0.33	0.33		
12	Cardiovascular/ HT/Heart	10	0.59	10.12	8.05	8.18	20	0.084
13	MCH	16.0 (4.9)	1.34		0.25	0.25		
14	Diarrhea	8.2 (5.7)	1.77		0.08	0.084		
15	Depression	-			3.56	3.55		
16	Allergy	-			1.78	1.77		
17	Hepatitis	(0.3)		1.81	0.16	0.16		
18	Leprosy	.1						
19	Blindness	1.4 (<0.1)						
20	Oral diseases	0.5						
21	Prosthetic hyperplasia	-			1.01	1.014		
22	Others	25.4	30.17	18.18	6.45	6.42		

Source: USPTO from 1992-2007, Company Websites and data available on the Burden of Disease from GOI.
<http://www.uspto.gov/>

**Table 4: Disease wise Product Specific R&D Activities of Domestic firms Active in India
1999-2009**

Domestic Companies	1999-2001			2002-2004			2005-2007			2008-2009			Total
	DISEASE TYPE												
	I	II	III	I	II	III	I	II	III	I	II	III	
Orchid Pharmaceuticals Ltd				2			6			2			10
Sun Pharmaceutical Ltd							2			7			9
Biocon Ltd				2			4			6			12
Glenmark Pharmaceuticals Ltd				1			5		1	7			14
Bharat Biotech Ltd								1	1	3		2	7
Alembic Ltd													-
Dr.Reddy's Laboratories Ltd				7			2	1		15			25
Lupin Ltd	1				1		4	4		4		1	15
Cadila Healthcare Ltd							3	1		9			13
Piramal Healthcare Ltd							7			5			12
Wockhardt Ltd							1			2			3
Ipca Laboratories Ltd										2	2		4
Aurobindo Pharmaceutical Ltd													-
Torrent Pharmaceuticals										1			1
Ajanta Pharma										7			7
Natco Pharma										2			2
Granules India Ltd										1			1
SMS Pharmaceutical										10			10
Shanta Biotech							3		2	10	1		16
Panacea Biotech												2	2
Matrix Laboratories										3			3
Grand total	1			12	1		37	7	4	96	3	5	166

Source: Data collected from individual website & latest annual report of individual pharmaceutical companies and CTRI Clinical trial registry India *Disease type-(Type-I, Type-II, Type-III); *Type-I- Diabetes, Cancer, Metabolic Diseases, Hepatitis, Influenza, Cardiovascular, Infectious Diseases, Inflammatory Diseases, Allergy, Respiratory Diseases; *Type-II – HIV/AIDS, Tuberculosis, Malaria; *Type-III- Leishmaniasis, Trypanosomiasis, Lymphatic filariasis, Leprosy, Diarrhoea (Neglected diseases of the poor in developing world)

The reasons for this are elaborated in the subsequent section. Broadly stated innovation regimes led by manufacturing units respond to stimuli from the demand side. Currently these are stimuli from a) the higher profits/ rate of return from undertaking export of off-patent generics to the regulated markets of US and Europe as compared to the domestic markets. b) the need for Indian manufacturers to be able to meet the drug regulation challenges posed to the domestic firms on their entry in the markets of US and Europe and c) the absence of stimulation of home demand, especially for the diseases of the poor- snake bite, vector borne disease etc, and neglected diseases like acute flaccid paralysis and acute encephalitis syndromes and even in common international diseases like hypertension and allergy the need to keep improving on available drugs- while keeping them affordable. Unequal partnerships which Indian firms enter into with foreign firms – in its most extreme form acquisition of the Indian firm and then its subsequent development as part of the where the global firms markets are concentrated also contribute to this pattern of development.

Whereas table 3 and 4 provided data from US patents office, table 5 and 6 provides the details of disease focus of the new drugs under development in India as gleaned from company websites of the top 20 Indian pharmaceuticals and a report from a leading business newspaper. The picture we get from these sources is not only one of a limited level of efforts at new drug development, but that many of them had to be completely abandoned by the firms. Thus in the last 16 years of a new regime, no new drug has made it out of Indian domestic pharmaceutical firms..

Table 5: Disease Focus of New Chemical Entities (NCEs) based Drug Discovery Pipeline

Companies	Cancer	Metabolic disorders	Brain / Nervous system	Bone diseases	CVS	TB	Malaria	Skin	Other Infections	Total
Lupin Ltd		1	1	1		1		2		6
Dr Reddy's	3	5		1	2				1	12
Wockhardt								1	5	6
Glenmark		2			1				1	4
Torrent		1			1					2
Orchid		1								1
Zydus Cadila		6								6
Piramal HC	1								1	2
Alembic Ltd			3						1	4
Biocon Ltd	1	1								2
Sun pharma									1	1
Ranbaxy Lab							2		6	8
GSK Pharma	1		1						1	3
Total	6	17	5	2	4	1	2	3	17	57

Source: Companies' annual reports and websites, accessed December 2009.

Table 6: Current Status of NCE based Drug Discovery Pipeline

Companies	Compound Continuing				Compound Abandoned				Total
	Preclinical	Phase I	Phase II	Phase III	Preclinical	Phase I	Phase II	Phase III	
Dr.Reddy's lab		1		1	5	2	1	2	12
Glenmark	1	5	1					1	8
Lupin	2		3	1					6
Orchid			1						1
Piramal	3	2	4						9
Ranbaxy				1	2	2	1	2	8
Torrent								1	1
Wockhardt			1		1				2
Total	6	8	10	3	8	4	2	6	47

Source: Compiled on the basis of reported information in "Death of a dream", cover story in Business World, 30 January 2010. Available at: <http://www.businessworld.in/bw/>

In the absence of stimulus for augmentation of home demand within the country the conditions continue to favour the target of low value added products required by the global markets. It is this imbalance in the policy design which is now reinforcing skewed research priorities in the public sector research system too. From the point of view of prevailing

public health situation this certainly does not suit the country on whose shoulders the domestic industry still depends.

Table-7: Top 14 Domestic Pharmaceuticals: Areas of Commercialized /Launched Compounds as Generics in the Indian Market during 1999-2011

Disease Type	1999 to 2001	2002 to 2004	2005 to 2007	2008 to 2011	
Type I	5	27	52	79	163
Type II		4	6	20	30
Type III	0	2	4	3	9

Source-Data collected from individual website & latest annual report of individual pharma companies and Cygnus research, data accessed as on Nov 2011; *Disease type-(Type-I, Type-II, Type-III): *Type-I- Diabetes, Cancer, Metabolic Diseases, Hepatitis, Influenza, Cardiovascular, Infectious Diseases, Inflammatory Diseases, Allergy, Respiratory Diseases; *Type-II – HIV/AIDS, Tuberculosis, Malaria; *Type-III- Leishmaniasis, Trypanosomiasis, Lymphatic filariasis, Leprosy, Diarrhoea;

E. Persisting role of publicly financed innovation:

Though the dominant regime is market driven, there are some areas of national priority where programmes or publicly financed innovation established in earlier decades persist and have been successful. Publicly financed innovation, in the earlier phase focussed on the conditions and diseases that are understood clearly as national priorities. Take the area of contraception. This is an area of innovation that world over has been driven largely by public finance. Another area where public finance drives innovation is in the area of tuberculosis, malaria and filaria.

These are discussed in some detail in a separate section (5.3) on success stories in public sector drug innovation.

4. Barriers to Market-Based Health Innovation in Pharmaceuticals serving Health Goals.

These can be discussed under the following heads:

- A. Barriers to the lack of alignment of market-based Innovation with national health needs.
- B. Barriers due to choice of strategies of Innovation:
- C. Barriers due to nature of partnerships between domestic and foreign firms.
- D. Barriers due to Indian firms' inability to leverage strengths in Indian R&D institutions.

A. Barriers to the alignment of market based innovation with health needs :

One major and well recognised problem regarding the relation of health needs of the poor are that often not felt as market stimuli for drug innovation. With some neglected diseases like kala-azar, the market is inherently limited- as the population affected are relatively less, as compared to diseases like hypertension and diabetes that are global. With other diseases like malaria or tuberculosis, disease prevalence is high, but the scope for raising prices and profitability is limited, unless governments purchase and supply the drugs to the affected population in an affordable way. While such an intervention is required and under active

consideration of the government in the 12th FYP, complementary decisions to promote the innovation, delinked from monopoly pricing of new products would be essential. Monopoly pricing of new products is currently permitted statutorily under the system of strong patents. Instead increased R&D funding, prioritising of public financing for purchase and supply of essential drugs and strategic advanced marketing commitments from the public health system, would be required for innovation directed to identify needs. But there are a further set of constraints acting that should also be adequately addressed with a view to go ahead with the implementation of proposed measures.

One major constraint is that even the estimates of burden of disease are inadequate. Largely what is used is a 2004 mortality estimate from which a burden of disease estimate is extrapolated. When this is the situation at the national level, state specific data, is even less available.

The only area where public financing signals are currently operating are national health programmes where one is faced with considerable microbial resistance to already existing drugs- like in combination therapy using artemisin compounds in malaria, or from drug resistant tuberculosis or HIV or multi-drug resistance bacilli.

Another long term consideration is for India to ensure that drugs meeting latest standards in safety and efficacy are available at affordable prices, even for what is known as Type- I diseases. Given our commitment to provision of universal access to essential drugs and diagnostics through the public health system in the 12th Plan, and our movement towards the larger goal of universal health care, we need a balanced system of intellectual property rights to generate cheaper state of the art generic drugs in every area of health care, and Indian manufacturers who can be compulsorily licensed to manufacture them, to contain the rising costs of health care.

B. Barriers due to the limitations of current firm-level strategies of innovation:

The current strategies of product innovation are not good enough for making an impact on early stage drug discovery. Large domestic companies have been pursuing preferentially those areas of drug discovery and development that lowers their own risk.

This can be illustrated through one example from DRL which is still one of the most determined domestic companies working on drug discovery and development. DRL's main strategy is to find a new drug within an existing family that has been discovered, a compound analogous to an existing one from Sankhyo – like their work on giltazones for diabetes. This strategy cuts down the risks and uncertainties of new drug research though this may not produce a drug “blockbuster.”

Another strategy of risk reduction or sharing is out-licensing. The Indian company takes some leads to pre-clinical stage and then has a deal with an MNC which will have the right to market the compound in a particular market if all tests are cleared. The Indian company gets milestone payments for each stage of clinical trials the compound clears. All the big companies namely, Ranbaxy, DRL and Glenmark have followed the out-licensing route to developing new drugs. DRL has tried a deal with Novartis too, for further work on an anti-

diabetic compound DRF 4158. Ranbaxy entered into a deal with Bayer for Cipro NDDS and RBx 2258 (BPH). Glenmark has tried a deal with Forest of North America and Tejin of Japan for compounds that could provide treatment for asthma. But the level of success obtained by these companies through this route has not yet yielded the desired results in respect of new product development.

Further, as can be seen, most of these drugs which would come under such out-licensing would be drugs that have a global market- typically type- I disease. Thus in such conditions of competition in the 'global' pharmaceutical industry as is available today, domestic firms can be still expected to be lured by the multinational corporations to work for the western markets. While this may also be due to the fact that Indian companies consider the size of the domestic market as small and not sufficiently attractive for taking up the development of new products in the drugs and pharmaceutical sector and would rather go along with the global pharmaceuticals, the strategy is failing to click. (Annexures provide the detailed case studies).

There are some interesting exceptions to this trend. In recent years, ambitious new start-up discovery firms backed by private equity investors such as Pune-based Novolead and Indus Biotech have also come up with success stories. It is interesting that they could succeed whereas Indian pharma's goliaths faltered (Business world, 30 January 2010). Thus the problem may not be in the absolute lack of opportunity, but on the dominant trend that market-driven innovation leads to, and the discourse should be on why and how public policy in innovation could counter-balance this.

c. Barriers due to the limitations of scope of tie-ups of Indian firms with Foreign firms: Acquisitions, Alliances, Collaborations and Licensing Agreements:

Public policy in pharmaceuticals in the post-TRIPs period aimed for complete freedom to the domestic firms to enter into strategic alliances, collaborations, licensing agreements and consolidation/acquisitions, with the idea that such freedom would result in far more rapidly greater innovation which would be useful to the cause of Indian industry and Indian health services. The nature of relationships forged and their impact on innovation is assessed below.

i. Acquisitions by Indian firms: Table 7 provides the details of acquisitions made abroad by top 14 Indian firms. These 14 firms are a sample that could be studied for their relationships made public by the firms. 22 of the acquisitions were R&D driven and 75 were marketing or production driven acquisitions.

Table 7: Type of R&D & Marketing acquisitions pattern of Indian pharmaceuticals 1999- 2011

Companies	R&D acquisitions		Sub total	Marketing/Productions acquisitions		Sub total	Total of all acquisitions
	INDUSTRY			INDUSTRY			
	DO	FO		DO	FO		
Top 14 leading Indian Pharmaceutical	2	20	22	3	72	75	97

Source & Notes: individual Company website Press releases, News, Archive etc, data accessed as on Nov 2011; # Top 14 leading Indian Pharmaceutical Industries are: (*Ranbaxy laboratories, Cipla ltd, Dr. Reddy's Laboratories, Cadilla healthcare, Biocon Ltd, Sun pharmaceuticals, Lupin Ltd, *Piramal healthcare, Glenmark pharmaceuticals, Torrent pharmaceuticals, Strides arcolab, *Wockhardt ltd, IPCA laboratories, *Orchid pharmaceuticals).

If we then further analyze, the pattern of the 22 R&D acquisitions in table 7, none of the 22 are for drug discovery, or for clinical development- all of them were for research services-related to strengthening their foreign marketing and a much smaller number for manufacturing. See table 8. R&D facility acquisitions have been made largely for the establishment of research services function helping only generic entry through help in the host country for the preparation of dossiers and undertaking laboratory work.

Table 8: Type of R&D acquisitions with Industries 1999-2011

Companies	Discovery R&D		Sub total	Clinical development		Sub total	Research services		Sub total	Grand total
	DO	FO		DO	FO		DO	FO		
Top 14 leading Indian Pharmaceutical							2	20	20	22

Source and Notes: As provided in Table 7

ii. *Other forms of R&D tie-ups:* In the case of Strategic Alliances, Collaborations and Licensing agreements entered into by these firms during the period under observation research services function predominates. Thus these 14 firms entered into 106 tie-ups, of which 45 was for research services, 37 were for clinical trials, and only 24 was for drug discovery. Of this 24 ten were either with domestic research institutions or academics and 2 with foreign universities and one with a domestic industry. 10 of 24 drug discovery tie ups were with foreign firms. In contrast 28 out of 37 clinical research tie ups were with foreign firms and 38 out of 45 tie ups for research services are with foreign firms. Out of 80 tie-ups between these 14 companies and foreign firms only a meagre 14 were for drug discovery. (See table 9).

Table 9: Type of R&D alliances, collaborations and licensing agreements 1999-2011

Top 14 Pharmaceutical Industry In India		R&D alliances			R&D Collaborations			IN Licensing			OUT Licensing			Total
		DR	CR	RS	DR	CT	RS	DR	CT	RS	DR	CT	RS	
RI/Academia	Domestic	2		1	5	3	1			1				13
	Foreign				2	4	3							9
Industry	Domestic		1		1	1				1				4
	Foreign	2	2	8	12	17	19		5	6		4	5	80
Grand total		4	3	9	20	25	23		5	8		4	5	106

Source and Notes: As provided in Table 7

iii. Nature and Scope of Licensing Agreements:

Out-licensing is used by domestic pharmaceutical firms to undertake clinical development of their new chemical entities to the firms that have considerable market operations in the sector of drugs and pharmaceuticals in India, in return for a share in royalty and control over patents.

In-licensing deals for undertaking bio-equivalence studies in case of formulations and dosages

In-licensing arrangements are used to build up the portfolio of the foreign firm for the purpose of growing in the domestic market. For example, Nicholas Piramal has had arrangements with Roche for launching products of Roche dealing with cancer, epilepsy and AIDS. Glenmark has in-licensed Crofelemer, Napo's proprietary anti-diarrheal compound. Wockhardt has had arrangements for the in-licensing of Syrio Pharma SpA for dermatology products. Ranbaxy has had arrangements with KS Biomedix Ltd for EMRs to market Trans MID in India with an option to expand to China and other South East Asian Countries. These are good with respect to access of patients to these drugs- but not with respect to our capacity to innovate, or on holding down the cost of drugs or in terms of financial gains and control of future markets.

There is also an imbalance between the terms of in-licensing and out-licensing- and we may be conceding more than we need to in both cases. In terms of competency developing- we are out-licensing earlier stages of studies like pre-clinical toxicology as well, while when we in-license only the bio-equivalency studies before marketing comes- which requires less competency building.

In the case of in-licensing agreements payments to foreign firms are on a recurrent basis and are guaranteed returns. In terms of out-licensing it is a share of royalty, without much share of the risks.

iv. *Marketing Alliances:*

Marketing as a purpose dominates, in most cases alliances, collaborations and agreements have been signed by the domestic with foreign firms. (See table 11) Further, this needs to be compared with the number of alliances, collaborations and agreements made for R&D which shows the main motive of establishment of tie-ups was marketing and R&D had little importance in the relationships forged by the domestic firms with foreign firms.

Table 11: Pattern of Marketing alliances, collaborations and licensing agreements 1999-2011

Top 14 Pharmaceutical Industry In India	Marketing alliances		Marketing Collaborations		IN Licensing (Marketing)		Out Licensing (Marketing)	
	Domestic	Foreign	Domestic	Foreign	Domestic	Foreign	Domestic	Foreign
Industry	10	111	5	101		21	2	6
Grand total	10	111	5	101		21	2	6

Source and Notes: As provided in Table 7

v. *Strategic alliances and implications for the building of a new innovation regime*

In a number of cases tie-ups are also being generated by the domestic firms for the strategic development of export markets even by collaborating with global pharmaceutical firms. DRL has an alliance with Pilva, for the development and marketing of oncology products in Europe; DRL and Glaxo-Smithkline have a multi-product agreement; DRL is collaborating with Pharmascience Group for development and marketing of generic products in Canada; Glenmark's supply and marketing agreement with Lehigh Valley. Ranabaxy has also entered into a strategic tie-up with GlaxoSmithKline for drug discovery and clinical development for a wide range of therapeutic areas; Ranabaxy is collaborating with Eli Lilly, Pfizer and Novartis in drug discovery and with Vectura, a drug delivery company for the development of platform technologies in the area of oral controlled release system. Others who have agreements, collaborations and alliances for the R&D purpose are Reddy's Laboratories, Lupin, Glenmark, Torrent, Sun pharmaceutical, Cadila and Biocon. Certainly such strategic alliances where the whole segment is a target of the alliance reflect an element of strategic choice and longer-term relationship. At the moment among the domestic companies DRL, Glenmark and Lupin seem to be examples of long term strategy.

Some relationships with global pharma bring about also regular royalty payments to Indian pharma at minimum investments with a wider geographical coverage for their products. Strides Acrolab Ltd has entered into a number of such deals with companies in United States, United Kingdom, Japan and Europe. Clinical research in India is also being treated as a lucrative strategy for building relationships with foreign firms by some of the Indian firms. Cadila Healthcare has entered into alliances with Atlanta Pharma, Schering AG, and Boehringer Ingelheim. Lupin has a licensing agreement with Cornerstone Bio Pharma Inc for clinical development of NDDS for an anti-infective product. Torrent has entered into a

collaborative research programme for the drug discovery in the area of treatment of hypertension with AstraZeneca.

As tie-ups with foreign firms are largely as junior partners at adverse terms even drug discovery tie-ups can have adverse terms. Dependent or potentially compromising relationships would not benefit the firms as much and can affect the national system of innovation adversely when pressures are being mounted on the industry to accept TRIPS plus provisions of data exclusivity and so on.

vi Tie-ups for the satisfaction of Indian needs

R&D tie ups focussing on Indian needs and manufacturing advantage exist both in the form of collaborating with not-for-profit ventures, foreign university and domestic CROs, though very few. But these show that the government can incentivise and reward such relationships further to get the domestic firms to satisfy Indian healthcare needs. Examples: Ranbaxy's collaborative research programmes with MMV, Geneva for an anti-malarial molecule, Rbx 11160; Ranabaxy's collaboration with University of Strathclyde, United Kingdom in new drug delivery system (NDDS); Cipla's collaborative programme of risk sharing type with a domestic company set up by a non-resident Indian namely Avesthagen Laboratories to produce biogeneric drug for Arthritis, N-Bril. Although Avesthagen has an ongoing collaborative programme with Nestle, BioMereleux, France and other companies, but the relationship of Cipla with Avesthagen is unlikely to prove compromising and can be handled independently.

D. Barriers due to Weak Linkages between Domestic Firms and Publicly Financed R&D.

i. Few tie-ups with domestic R&D institutions:

Although domestic firms are the major beneficiaries of R&D undertaken for the development of process innovations sourced from the Indian system of public sector research laboratories, but there exist very few tie-ups between them for undertaking in a collaborative way the work on drug discovery and development. See Table 10 for the pattern of ties built with the domestic R&D institutions for clinical and discovery R&D by these firms during the period of 1999-2011. Just two firms used the domestic R&D institutions for the purpose of R&D alliances

Table 10 : Type of R&D alliances with Research Institution/Academia

Companies	Clinical & Discovery R&D		Sub total	Research services		Sub total	Grand total
	DO	FO		DO	FO		
IPCA laboratories	1		1				1
*Piramal healthcare	1		1	1		1	2
Total	2		2	1		1	3

Source and Notes: As provided in Table 7

Among 14 leading Pharmaceutical companies Ipca and Piramal have only concluded R&D alliance style cooperation with RI/academia.

ii. *Poor Utilisation of Existing Public R&D Financing:*

While the industry is known to be complaining of government funding for the direct benefit of R&D in industry being rather small, it can be however seen that they are not even utilizing the existing schemes in a big way to focus on high priority areas. Medium burden diseases, which also have global markets, are a major focus of the projects submitted by the industry. Table 16 shows the pattern of diseases covered by these firms while using the government funded programmes and schemes initiated for the benefit of pharmaceutical innovation.

Further Table 17 indicates that important domestic firms, seen by many as the emerging Indian pharmaceutical multinationals, have not been leveraging the government funding for undertaking industrial R&D. More than half of these firms chose to ignore the schemes formulated by the government industrial research financing altogether. There were only six firms out of top fourteen firms that took projects funded by the government for the development of facilities and activities required to be undertaken for the development of new drugs. But even they accounted for just 15 projects in the portfolio of 104 projects sanctioned by the government.

The reasons are unclear, but it could be that many firms which are tuned to the route of outward foreign direct investment for global markets are less likely to come forward to use the government schemes for R&D and innovation of therapeutics in priority diseases. Lack of interest in the schemes from the emerging Indian pharmaceutical multinationals is the case even when the government has agreed to cede to the collaborating firms the ownership of intellectual property rights (IPRs). Some of these firms have now been sold by its promoters to foreign firms. It is obvious that the national links of these firms are only getting weakened rather than being strengthened.

Table 16: Pattern of R&D projects obtained by the firms from the government and schemes in terms of their burden of disease orientation

Funding agencies Programmes/ Schemes	High Burden	Medium Burden	Low Burden	Total
DPRP	23	30	13	66
BIPP	6	5	1	12
SBIRI	2	14	10	26
Grand Total	31	49	24	104

Source: DPRP, BIPP, SBIRI website, data accessed as on Nov 2011; # DPRP- Drugs & Pharmaceuticals Research Programme; #BIPP- Biotechnology Industry Partnership Programme; # SBIRI-*Small Business Innovation Research Initiative*

Table 17: Pattern of R&D projects obtained by the firms from the government funded programmes and schemes in terms of their burden of disease orientation

Companies	DPRP			BIPP			SBIRI		
	High Burden	Medium Burden	Low Burden	High Burden	Medium Burden	Low Burden	High Burden	Medium Burden	Low Burden
Projects by dis. Burden	23	30	13	6	5	1	2	14	10
Torrent Pharma	-	1	4	-	1	-	-	-	-
Ranbaxy Laboratories	-	5	-	-	-	-	-	-	-
Strides Arcolab	1	-	-	-	-	-	-	-	-
Lupin Pharma	1	-	1	-	-	-	-	-	-
Cadilla Healthcare	-	3	-	-	-	-	-	-	1
Biocon Ltd	-	-	-	-	1	-	-	-	-
Total	2	6	5	-	2	-	-	-	1

Source: DPRP, BIPP, SBIRI website, data accessed as on Nov 2011; # DPRP- Drugs & Pharmaceuticals Research Programme; #BIPP- Biotechnology Industry Partnership Programme, # SBIRI-*Small Business Innovation Research Initiative*, #TDB- *Technology Development Board, DST*, #TDB- *Technology Development Board, DST*

iii. *Mismatch between the needs and capabilities of clinical R&D Infrastructure:*

Investment in product development activity is unevenly developing in respect of the use of national S&T infrastructure of hospitals and medical colleges. As compared to domestic firms, foreign firms are using available medical infrastructure in a far more intensive manner- as witnessed from the number of clinical trials by foreign firms as compared to Indian firms.

But as most of the clinical R&D activity is concentrated in phase III stage the gains for competence development are extremely limited. (See table 18 below). This means that the clinical research part of the national system of drug innovation is being far more valued for the patients India can provide, rather than for competencies that the system should be building. Because the competencies of clinical research organizations (CROs), medical practitioners, colleges and hospitals are not able to accomplish as yet the cutting edge drug innovation the domestic firms prefer to go abroad for Phase I and Phase II clinical research.

Domestic pharmaceutical firms are just starting to pursue their phase I clinical trials in India. An estimated 60 new compounds are also known to be in various phases of development and testing for the domestic firms. Some of these compounds have been licensed by the domestic companies from foreign firms. Needless to say, the activity of compound development and testing by domestic companies is quite small compared to world standards. However the proportionate share of phase I in their clinical trials is much higher than for foreign pharmaceuticals and it is growing. (See table 18).

Table-18: Pattern of Phase-wise Clinical R&D Activities in the Case of Domestic and Foreign Pharmaceutical Firms Active in India from 1999-2009

Companies	1999-2001			2002-2004			2005-2007			2008-2009			Total
	Compound Status/Phases												
	I	II	III	I	II	III	I	II	III	I	II	III	
Foreign (8 Companies)	1	2	1		1	1	2	4	2	10	23	69	116
Domestic (15 Companies)	1			9	3	1	19	17	12	27	21	47	157
Grand Total (23 Companies)	2	2	1	9	4	2	21	21	14	37	44	116	273

Source: Data collected from each company's website and atest annual report of individual pharma companies and CTRI Clinical Trial Registry India (CTRI)* Compound Status/Phases –I, II, III. (Status of involvement of domestic and foreign firms in the trials (Phase-I, Phase-II, Phase-III, Phase-IV)

Source: Clinical Trial Registry Analysis (CTRI) 2007-2009.url- <http://ctri.nic.in/Clinicaltrials/index.jsp>

In conclusion:

We have discussed how the networks being developed between domestic firms with foreign firms for drug discovery and development have so far failed to yield successful pharmaceutical products. Annexure 1-5 presents 5 case studies on this. These studies indicate not only that Indian industry cannot afford to rely on these agreements and collaborations to develop indigenous pharmaceutical products, but rather has to strengthen the collaboration between public sector science and industry which has had a better success. Also the evidence indicated that the policy assumption that outward foreign direct investment (OFDI) route based external ties and liberalisation would give access to overseas knowledge is not empirically borne out in experience due to the failure to put in complementary policies in place for the mechanisms of reverse knowledge transfer to be institutionalised. Nor has the pressure to face increasing competition from home and abroad given them either the market or the innovation edge. The complementary interactions and linkages for prior learning that the domestic firms needed to develop with the publicly funded Indian S&T infrastructure have failed to develop. Consequently the national system of innovation is yet to achieve the required scale of capabilities, complementarities and linkages between different knowledge domains, and build the institutional ecologies and incentive systems capable of giving the country its first indigenous new drug or diagnostic.

At the moment the national ecosystem is lacking in favourable institutional conditions and necessary arrangements for the prior learning and the development of capabilities needed for global market linked drug discovery and indigenous product innovation. With reduced public policy intervention, left to market forces, emerging Indian pharmaceutical multinationals were aligned to working for the easily available market opportunities and their strategic investment. Capacity building and linkage building became weak as they sought junior partnership positions with foreign firms, subservient to their goals or just sold out. Further the export based relationships of these firms are lacking in emphasis on the products needed for high burden diseases of the country. As goal misalignment and

weakened national identity manifest; quite a few of these firms including Ranabaxy, Nicholas Piramal, Wockhardt and others have preferred to shift investment from innovation and manufacture to hospitals chains and pathology laboratories.

The system of biomedical innovation is urgently in need of an innovation policy which will help develop and articulate the optimal system conditions for indigenous needs to be used as the over-riding consideration for the determination of all the other policies, be the policy for FDI, public sector manufacturing, competition, price control, regulation, industrial promotion, building of ties, interactions and links with domestic and foreign sources of knowledge etc. As the processes of publicly financed drug innovation would play a major role in a national ecosystem for biomedical innovation, we analyze below the current status of publicly financed biomedical institutions and their efforts for product innovation in India.

5. Publicly Financed Biomedical R&D and Product Innovation.

Publicly funded health research and development (R&D) and innovation activities being undertaken for the purpose of development of therapeutic products, diagnostics, vaccines and other relevant products are spread out in terms of contributing institutions into quite a few departments and agencies in India.

We cover in this report the R&D activities supported by the following agencies namely,

- a. Indian Council of Medical Research (ICMR),
- b. Department of AYUSH,
- c. Council of Scientific and Industrial Research (CSIR),
- d. Department of Biotechnology (DBT),
- e. Department of Science and Technology (DST),
- f. University Grants Commission (UGC)
- g. All India Council of Technical Education (AICTE).
- h. Department of Pharmaceuticals.

These above agencies act by financially supporting R&D activity in a large number of National Laboratories, Research Institutes, Institutes of National Importance (INIs), Universities, Medical Colleges and hospitals working in the area of health research.

We estimated the magnitude and composition of public health financed research effort as categorized into intra-mural activity and extramural research programmes and projects further classified by therapeutic and thematic areas using G-Finder Classification

5.1. Pattern of Intra-Mural Funding:

The current state of information available on the magnitude and composition of intra-mural R&D funds allocated to the sector of health can be characterized as patchy and poorly visible. Tracking of resources for health research requires systematic studies as health research is spread across a large number of research performers. At the moment there exists no mechanism in the government which can offer the policy makers comprehensive information on the magnitude and composition of health research expenditure.

Implementation of necessary action required in respect of tracking of financial resources for health research should be made a responsibility of the newly created department of health research in the Ministry of Health and Family Welfare.

Table 22 to Table 25 provide a picture of emerging structure and priorities of health R&D in research institutes of CSIR, ICMR and DBT in terms of ongoing projects. As the list of ongoing projects has been taken from the web sites and annual reports of latest period available, the profile analyzed here below covers the projects funded through both the modes of financing, intra-mural and extramural financing.

The efforts are diverse and distributed in all disease areas, but clearly we have a different pattern here from the market driven, industry led efforts. The focus is much more on diseases of national priority and infectious diseases. Some of the Type I diseases like cancers also get adequately addressed, though other like cardiovascular disease are clearly lower on the priority. Part of this is due the institutional framework and the mandate given to different organizations. Systems of innovations that the country needs to build for drug discovery and development would have to be created by using the strengths already embedded in these existing institutions. These diverse niches have seemingly different types of inputs, capacity and culture nurturing them.

Table 22: Therapeutic area wise projects in CSIR Institutes

INSTITUTES CSIR	Tuberculosis	Diabetes	Malaria	Cancer	HIV/AIDS	Cholera	Infectious Disease	Cardiovascular	Inflammation	Maternal & Prenatal Problems	Leis mania	Hepatitis	Filarial	Brain Disorder	Infectious diseases	Non Disease	Total
CDRI	9	14	13	18	17	3	12	5	16	19	2	5	3	15	23	52	208
CCMB	13	19	7	23	6	2	7	8	11	13	5	2	2	7	19	78	199
IMTECH	6	23	12	25	7	4	20	7	19	5	3	1	6	9	25	24	171
IICT	11	5		2	6	1		14	3	2			2	1	3	63	111
NCL	1	2			2			4		1				11	5	43	69
IGIB	6	18	13	12	14	2	21	3	6	12	5	3	10	4	16	27	160
Total	46	81	45	80	52	12	60	41	55	52	15	11	23	47	91	287	918

Source-data accessed from individual website of CSIR, dated jan.2010 @ infectious diseases including viral, bacterial, fungal infections etc.

Table 23: Pattern of Therapeutic area wise projects in DBT Institutes

INSTITUTES DBT	CANCER	BRAIN DISORDER	DIABETES	HIV/AIDS	LEISHMANIA	JAPANESE	TUBERCULOSIS	INFECTIOUS DISEASES	HEPATITIS	MALARIA	DENGUE	CHOLERA	CVD	MATERNAL & PERINATAL CONDITION	BONE DISEASE	NON DISEASE	TOTAL
NCCS	26		5	11	6	1	3	20	1	1					2	27	103
NII	16		6	1	2		9									21	55
CDFD	10		3	5	2		6	8		3					2	14	53
RGCBT	58	9					7	26			1	4	2	5		2	114
NIPGR								11								20	31
TOTAL	110	9	14	17	10	1	25	62	1	4	1	4	2	5	4	84	356

Source-data accessed from individual website of DBT, dated jan.2010

Table 24: Pattern of Ongoing Therapeutic area wise projects in ICMR Institutes

INSTITUTES ICMR	Tuberculosis	Cancer	HIV/AIDS	Malaria	Cardiovascular	Diarrhea	Cholera	Maternal & prenatal	Bone Disease	Leis mania	Hepatitis	Silicosis	Respiratory Disease	Leprosy	Filarial	Infectious disease	Non diseases	Total
JALMA AGRA	23	4	7											22	2	20	13	91
NARI, PUNE			25														14	39
NIE,CHEENAI			5		1												1	7
TRC CHENNAI	29	2	9														1	41
IOP, DELHI				3											2	2		7
RMRC DIBRUGARH					1												4	5
NICED KOLKATA						7	6										1	14
NIRRH MUMBAI		1	2					47								8	6	64
RMRIMS PATNA				1		1				12	2				3	7	6	32
RMRC PORTBLAIR	2														2			4
NIOH AHMEDABAD		2						7				2				27	16	54
RMRC JABALPUR	3		1	1												4		9
GRC,MUMBAI			5					11	2							23		41
NII,MUMBAI		2	3		1			1					1			5		13
TOTAL	57	11	57	5	3	8	6	66	2	12	2	2	1	22	9	96	62	421

Source-data accessed from individual website of ICMR, dated 4 Apr.2010

Table 25: Percentage of Therapeutic Areas wise ongoing activities / projects in public sector institutes

	Major therapeutic areas	Share in the Total burden of disease/health condition (%)	Therapeutic area wise projects in CSIR Institutes (%)	Therapeutic area wise projects in ICMR Institutes (%)	Therapeutic area wise projects in DBT Institutes (%)
1	Diabetes	0.7	8.82		3.93
2	Cancer	3.4	8.71	2.61	30.89
3	Tuberculosis	2.8	5.01	13.53	7.02
4	Malaria	1.6	4.90	1.18	1.12
5	HIV/AIDS	2.1	5.66	13.44	4.77
6	Inflammatory diseases	16.7	5.99		
7	Infectious diseases		6.53	22.80	17.41
8	Respiratory diseases			0.23	
9	Bone disease			0.47	1.12
10	Brain disorders	8.5	5.11		2.52
11	Cardiovascular	10.0	4.46	0.71	0.56
12	RCH	11.6	5.66	15.67	1.40
13	Diarrhea	2.1		1.90	
14	Hepatitis		1.19	0.47	0.28
15	Cholera		1.30	1.42	1.12
16	Leis mania		1.63	2.85	2.80
17	Filarial		2.50	2.13	
18	Jap encephalitis				0.28
19	Dengue				0.28
20	Silicosis			0.47	
21	Leprosy			5.22	
22	Others	25.0	9.91		0.84
23	Non disease	-	31.26	14.72	23.59

Source- Therapeutic area wise projects in CSIR Institutes data accessed from individual website of CSIR, dated 4 april.2010 #Share in the Total burden of disease/health condition (%) Source: Peters *et al.* 2001

In table 26 we describe the spread of these projects across institutions, and their outputs in terms of patents and publications. Clearly ICMR being more into clinical research does not score on patents and CSIR is most active in this area.

In table 27 to 29, looking at the patterns of collaboration, we find most collaboration in the ICMR projects and relatively much less in CSIR and even in DBT process. Active diverse collaboration at every stage may be essential not only for better outcomes, but for subsequent licensing, commercialization and uptake.

Systems of innovations are also therefore likely to need diverse types of support and incentives, with much better coordination and co-financing to harness a better return from these extensive national organizational structures of biomedical R&D.

Though the match with national priorities is closer than in market driven innovation, there are still many areas that have not attracted attention, and a very large focus on two or three diseases- tuberculosis, HIV, cancers, malaria – to the exclusion of almost all else.

Table 26

Diseases	ICMR					CSIR					DBT				
	Institutes	Scientists	Projects	Publications	Patents	Institutes	Scientist	Projects	Publications	Patents	Institutes	Scientist	Projects	Publications	Patents
Malaria	15	82	45	613	-	4	22	18	76	31	5	12	10	30	5
Tuberculosis	14	65	50	416	1	5	31	36	115	33	5	21	28	77	8
Leis mania	10	37	23	286	1	3	31	27	158	16	3	8	8	26	1
Hepatitis	10	36	11	188	-	1	2	2	-	6	11	38	12	188	1
Diarrhoeal diseases	13	44	4	271	-					1	3	4	7	25	-
Cholera	9	38	5	286	-	3	8	8	28	2	2	2	1	2	2
Dengue	11	39	11	109	-	2	2	-	3	3	2	4	4	5	-
Japanese Encephalitis	8	26	5	81	-	4	5	1	3	3	2	3	3	36	3
Chikungunya	10	37	14	78	-	1	1	1	1	-	2	3	-	9	-
Total		404	168	2328	2		102	93	384	95		95	73	398	20

Existing pattern of deployment of resources and outputs in the institutes of ICMR, CSIR & DBT

Source-Data collected from individual website of ICMR, CSIR, DBT, data accessed as on Apr.2010

Included no of projects is ongoing, selected publications & no of patents collected from USPTO FROM 1991 to 2007

Table 27: Disease wise Ongoing Collaborative & non collaborative projects in public sector research institutes

Disease	COLLABORATIVE PROJECTS	NON COLLABORATIVE PROJECTS
AIDS	40	42
Cancer	46	28
Brain Disease	3	
Bone Disease	1	2
Cholera	7	3
Adrenal Hyperplasia		4
Auto immune Disease	1	
CVD	2	
Chronic Obstetric Morbidities		1
Coronary Artery Disease		2
Dengue & Chickengunya	1	1
Dermatitis	1	
Diabetes	1	2
Diarrhea	8	2
Filaria	1	2
Gastroenteritis	1	
Hepatitis	3	3
Infectious Disease	4	7
Inflammatory Disease		1
Japanese Encephalitis	1	
Kala azar	7	1

Disease	COLLABORATIVE PROJECTS	NON COLLABORATIVE PROJECTS
Leis mania	8	8
Liver Disease		2
Malaria	3	11
Parasitic zoonosis	1	
Shigellosis	1	
Tuberculosis	37	24
Polycystic ovary syndrome	1	
Pediatric	1	

Source-Data collected from individual website of ICMR, CSIR, DBT institutes, data accessed as on Apr.2010

Table 28: Disease wise Pattern of Collaboration for Ongoing Projects in ICMR, CSIR & DBT

Diseases	ICMR			CSIR			DBT		
	Collaboration		Non - Collaboration	Collaboration		Non - Collaboration	Collaboration		Non - Collaboration
	Inter Departmental	Inter institutional		Inter Departmental	Inter institutional		Inter Departmental	Inter institutional	
Malaria									
Tuberculosis	10	27	17	11	6	19	5	6	17
Malaria	6	29	10	6	1	11	4	-	6
Cholera	3	-	2	2	1	5	-	-	7
Chikungunya	7	2	4	-	-	-	-	-	4
Leishmania	11	3	9	9	-	18	-	4	4
Hepatitis	4	-	8	-	-	2	-	-	3
Dengue	2	4	5	-	-	-	-	-	1
Diarrhoeal diseases	4	-	-	-	-	-	-	-	-
Japanese Encephalitis	-	-	5	-	-	1	-	-	3
Total	47	65	60	28	8	56	9	10	45

Source-Data collected from individual website of ICMR, CSIR, DBT, data accessed as on Apr.2010

Table 29: Disease wise ongoing collaborative projects of research institutes of ICMR, DBT and CSIR with other types of performers

Disease	Collaborative Projects					
	Research institute	Universities	Medical college/HO	Institute of national importance	Industry	Other
AIDS	21	12	7	1		7
Cancer	28	9	3			7
Brain Disease	1	2				
Bone Disease	1	1				
Cholera	9				1	
CVD	1				1	
Deng & Chi.gun		1				
Dermatitis	1			1		
Diabetes	1					
Diarrhea	8					
Filaria	1					
Hepatitis					3	
Infectious Disease	3	1				
Jap. Encephali	1					
Kala azar	2	4	1	1	1	1

Disease	Collaborative Projects					
	Research institute	Universities	Medical college/HO	Institute of national importance	Industry	Other
Malaria	3					1
Parasitic zoonosis	1					
Shigellosis	1					
Tuberculosis	23	4	5	1	6	2
Polycystic ovary	1					
Pediatric	1					

Source-Data collected from individual websites of ICMR, CSIR, DBT institutes, data accessed as on Apr.2010

5.2. Pattern of Extramural Research (EMR) funding

Information available on the EMR projects is better organized than what can be ascertained at the moment with regard to intramural projects in India. This would give us another insight into how members of Indian scientific community are managing their preferences and priorities in respect of biomedical R&D.

Analysis of extramural research (EMR) project funding (1990-2006) shows an improvement in terms of the relative importance being accorded to biological and medical sciences. The field of medical sciences is now the second most important area of research to be supported in the form of project funding in the country. In terms of average per project cost it was number one. Even the analysis of the composition in terms of allocations made to different types of research organisations suggests that national laboratories and institutes of national importance have been successful in receiving a major part of the resources allocated under EMR funding to the field of medical Sciences. Health related R&D activities through academic institutions, however requires more attention. Not all the schemes of technology financing are covered in the above analysis. In the schemes like TDB and SIBRI, industry and national laboratories happen to be the main beneficiary of resources allocated for health R&D.

A great majority of the EMR projects are either of basic research type or of epidemiological research type. Not too many EMR projects can be said to be oriented towards drug discovery. See the Figures 1-3 provided here below for the details of agency wise sponsorship of R&D work being undertaken in the field of biomedical research by the scientific community under the EMR projects. Again TB, HIV / AIDS, Cancer and Diabetes are the preferred areas of biomedical research. DST, DBT and ICMR provided for over 80 percent of the funds. CSIR provided only 1 % of EMR project based funds. In terms of loci of projects governmental research institutes (RIs) account for one third of the EMBR projects during the period 2000-2008. Hospitals account for 24 % of the EMBR projects during the period. In terms of grant-in-aid projects industry has only routed for HIV/ AIDS and Malaria in a significant way. It seems that the pattern of disease wise EMR projects undertaken and sponsored by the involved agencies is reflective of the ethos and preferences of scientific community which has a cosmopolitan orientation; rather than any conscious prioritisation of funds. .

Fig 1: Extra Mural Biomedical Research (EMBR) Fund Allocation by Type of Therapeutic Area (2000-2008)

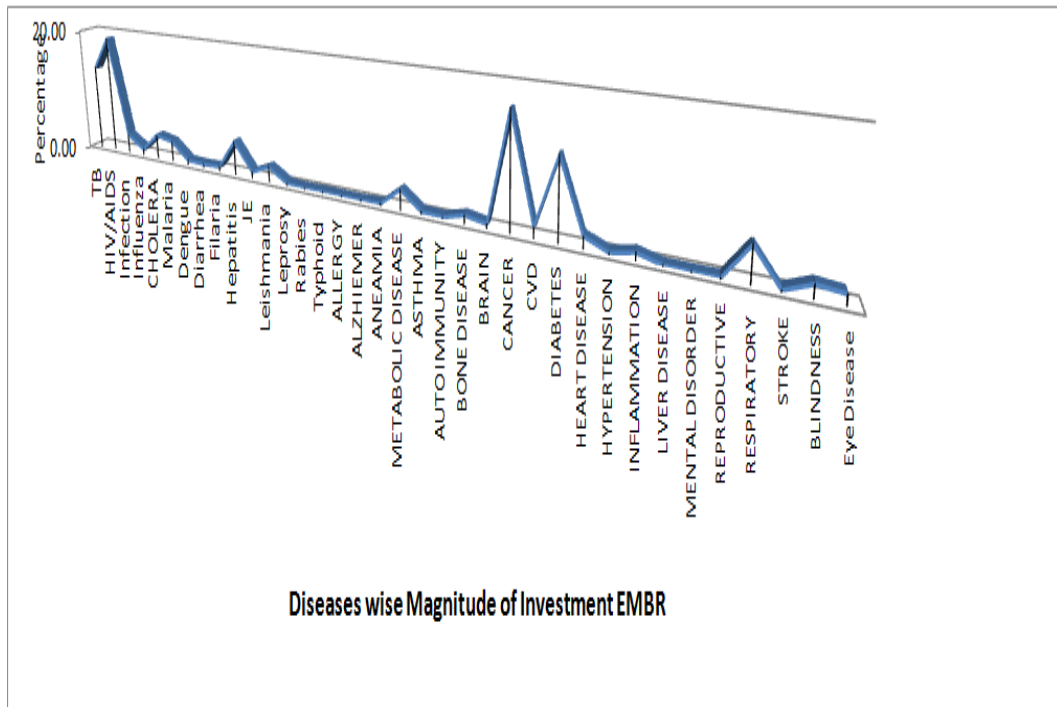


Fig 2: Extra Mural Biomedical Research (EMBR) Investment by Type of Therapeutic Area (2000-2008)

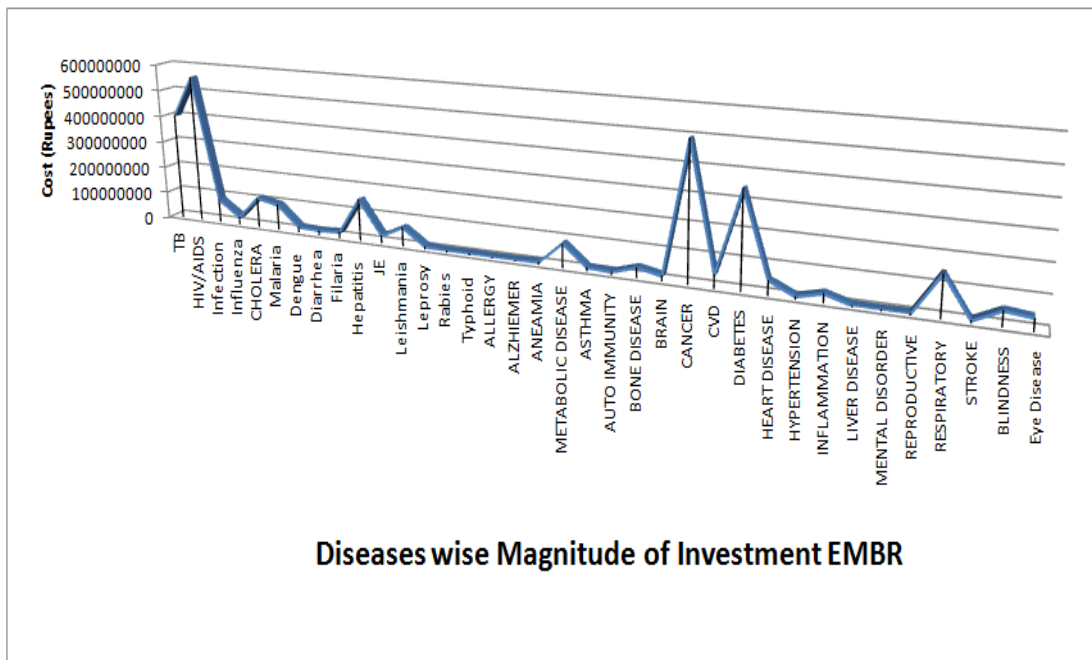
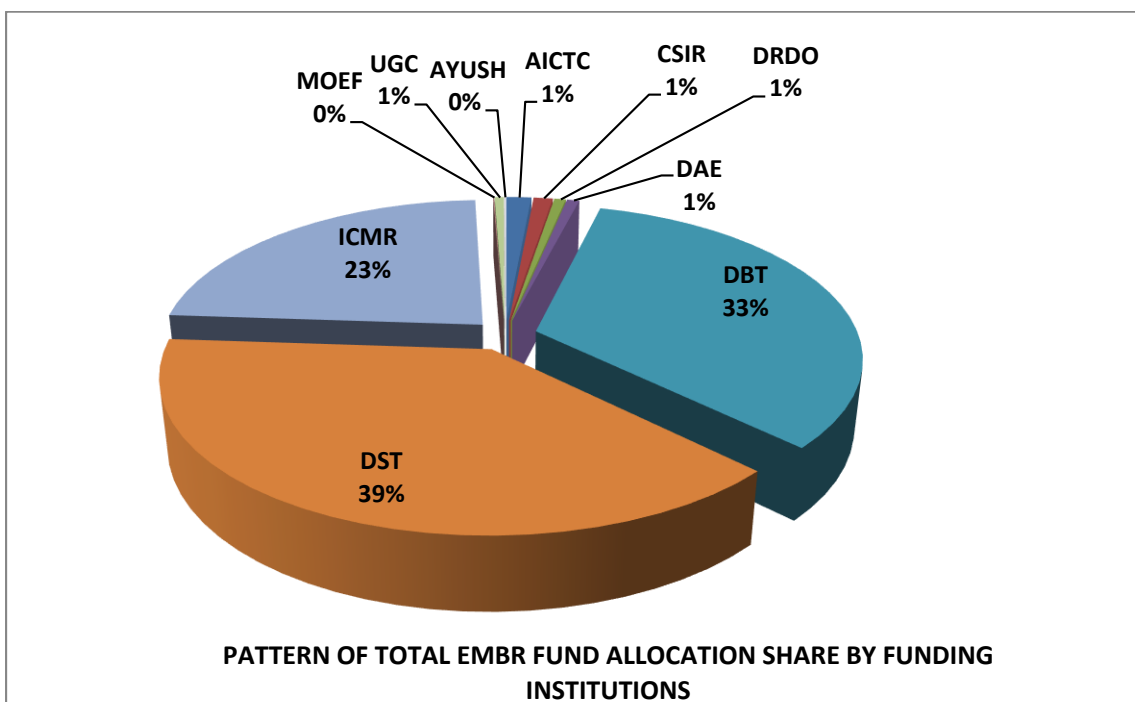


Fig 3: Extra Mural Biomedical Research (EMBR) Fund Allocation by Type of Funding Source (2000-2008)



5.3. Success Stories in Public Sector Drug Innovation show the potential for publicly financed innovation whose main beneficiaries have been domestic companies:

Public sector focus in the past has built capacities in addressing national priorities and on synthesis of compounds derivable from plants based on cues obtaining from existing uses and discovery by reverse pharmacology using knowledge from ayurvedic or other indigenous medical knowledge systems as leads. This area should be built upon to serve the markets available at home and abroad as shown by the success of Chinese and Taiwanese traditional medicines. Publicly financed innovations are not limited to merely the development of drugs out of compounds derivable from plants and synthesized in the laboratories. Now the success extends to the development of biopharmaceuticals. Below we give some examples of success to indicate that if the domestic firms and national laboratories are brought together for serving the priority areas of the nation success is possible and can be multiplied manifold:

1. Centchroman, a non-steroidal contraceptive for women, developed by CDRI in the 1980s.
2. Alpa, Beta-Artheter, a semi synthetic derivative of artemisinin, developed at CDRI in collaboration with CIMAP, Lucknow is useful as a second line of treatment for chloroquine-resistant P.falciparum malaria including cerebral malaria. Licensed to Themis Chemicals Ltd., Mumbai and is being marketed as an injectible formulation, under the trade name 'E-Mal'
3. Bulaquin, primaquine derivative, used in combination with chloroquine as anti-relapse, antimalarial and for prophylactic

4. Gugulip: cholesterol lowering properties using the lead available from the Indian system of medicine of Ayurveda. CDRI developed. Licensed to and marketed by CIPLA.
5. Picroliv, a hepatoprotective agent of plant, with antiviral and immunostimulant activities, CDRI developed.
6. NMITLI Collaborative Programme Based on Reverse Pharmacology: The expertise of 12 institutional partners (including CDRI and NIPER, Mohali) and Lupin Laboratories as the industry partner were synergised for the development of new targets, drug delivery systems, bioenhancers and therapeutics. This includes Sudoterb (LL-3858), has been for the treatment of tuberculosis, lysotaphin, a biotherapeutic,(with Bharat Biotech), a product against psoriasis, and Poly herbal formulations have been developed for diabetes, arthritis and hepatocellular protection .
7. At IICB Kolkatta, some natural products (dihydrobetulinic acid, luteolin, diospyrin and indolyl quinolines) were identified as inhibitors of leishmanial topoisomerases. In addition, researchers at IICB have been able to establish herbal formulations obtained from *M koenigii* and *Tribulus terrestris* as useful for the treatment of prostate cancer. This herbal formulation is being marketed under the brand name Prostalyn. IICB has been able to isolate another molecule from the flowers of *Woodfordia fruticosa* which has been found to be useful in the treatment of peptic ulcers.
8. Synthetic peptides are being studied at the Institute of Science (IISc), Bangalore. CDRI is looking at synthetic peptides to use them as anti-fungal agents. Peptides and peptidomimetics have a strong potential for use as novel drug therapeutics.
9. CCMB is studying the antibacterial role of human beta-defensin analogs, which exhibit activity against *E coli* and *Staphylococcus aureus*.
10. Streptokinase is a significant development in the use of proteins as therapeutics now available in the market for the purpose of clot-dissolving. IMTECH has been successful in transferring the same to Cadila for production and marketing in India.
11. In a collaborative effort from scientists at NCCS, NIO and ICGEB, two anti-malarial compounds from mussels have been found to have very specific activity against *Plasmodium falciparum*. The license to commercialize the drug process has already been transferred to a Mumbai-based company Shreya Life Sciences.
12. CSIR-IMTECH has succeeded in technology transfer of Streptokinase to Nostrum Pharmaceuticals, Inc., US; successful completion of technology transfer of recombinant staphylokinase to Strides Acrolab, Bangalore, with work on Phase II being started involving scale-up and animal toxicology; successful phase III of technology transfer of recombinant streptokinase to Sashun Chemicals and Drugs Ltd., Chennai; know-how transfer for the production of alpha-amylase and alkaline protease to Celestial Labs, Hyderabad.

5.4 Inter-institutional collaborative programmes in publicly financed R&D and their role in biomedical innovation

Intra-agency and inter-agency research collaborations are only beginning to be catalyzed in biomedical fields in India. A major collaborative effort for drug target identification and drug development using computational approaches has been launched as a joint project of several CSIR laboratories. This project aims to develop new software and strategies to enable identification of therapeutic targets; to develop and design new tools for predicting toxicity and drug response in-silico and to generate qualified and trained IT professionals for pursuing research in the area of bioinformatics. Rational drug design efforts are dependent on computer aided design methods which include the methods of structure based drug design, ligand based drug design, de novo synthesis to be used for the drug targets identification in the post-genomic era. A major collaborative effort for drug target identification and drug development using computational approaches has been launched as a joint project of several CSIR laboratories. This project aims to develop new software and strategies to enable identification of therapeutic targets; to develop and design new tools for predicting toxicity and drug response in-silico and to generate qualified and trained IT professionals for pursuing research in the area of bioinformatics. Peptides and peptidomimetics have a strong potential for use as novel drug therapeutics. Synthetic peptides are being studied at the Institute of Science (IISc), Bangalore. CDRI is looking at synthetic peptides to use them as anti-fungal agents. CCMB is studying the antibacterial role of human beta-defensin analogs, which exhibit activity against E coli and Staphylococcus aureus.

ICMR and DBT have come together to begin collaborative programme on HIV/AIDS and Microbicides to promote HIV/AIDS research. The programme aims to support a wide range of anti-HIV candidates including small chemically defined molecules, indigenous compounds, formulations, nucleotides, peptides and proteins targeting a range of relevant targets using a diverse range of delivery systems. In addition to iterative development of candidates, the programme aims to support studies in order to advance the understanding of HIV immunopathogenesis and host immune response. The programme also targets to accelerate research that will generate knowledge and develop state-of-the art technologies to provide the basis for the development of HIV vaccines and novel therapies against HIV including microbicides.

5.5. Industry-Academia collaboration:

In recent years, the Indian industry has been involved in the forging of collaborative programmes with universities. However, only few Indian industries are supporting such research projects. Most of the collaboration is in the form of consultancy, which is typically narrow problem based and does not involve large scale projects.

The reputed institutes like IISc, IITs, ICT and a few others have achieved success in establishing tie-ups with the industry. Majority of industry tie-ups have been person-driven, rather than system-driven, i.e. resulting on account of relationship between the researcher and a company. Industry-academia interaction is being perceived gradually as a key to

competitive advantage in select areas of infrastructure and expertise utilization for consultancy and training.

A major form of research collaboration is contract research programmes. For example CSIR-IMTECH has collaborated with thirty two companies including Ranabaxy, Cadila Pharmaceuticals, Lupin Laboratories and Panacea Biotech for contract research projects with a fair degree of success. Recently CSIR-IMTECH successfully transferred the technology in case of Streptokinase to Nostrum Pharmaceuticals, Inc., US; recombinant staphylokinase to Strides Acrolab, Bangalore, with work on Phase II being started by the collaborator involving scale-up and animal toxicology; phase III of technology transfer of recombinant streptokinase to Sashun Chemicals and Drugs Ltd., Chennai and know-how transfer for the production of alpha-amylase and alkaline protease to Celestial Labs, Hyderabad.

Some of the state governments are also now in the field of encouraging these linkages and collaborations between industry and academia. DBT-funded institutes such as NCCS, Pune, NII, New Delhi and CDFD, Hyderabad have also taken steps; one such example is the DBT funded project on developing HRP-II/ p-LDH based diagnostic kits for the differential detection of malaria parasites by Bangalore based Bhat Bio-tech in collaboration with National Institute of Malaria Research, New Delhi.

Business Incubators and Biotech Parks: Another area that has attracted considerable attention is the setting up of Business incubators. Many of the Indian incubators are sponsored by the DST and are generally hosted by reputed academic institutions.

The DBT is also setting up parks and incubators to foster bio-entrepreneurship across the country. The biotech parks and incubators in Lucknow, Chennai and Hyderabad are already operational. More parks and incubators are being established in Kochi, Bangalore, Guwahati and Bubhneswar.

However, despite these efforts, industry-academia collaboration is restricted to the few top institutes and a huge thrust is required to spread the culture across the country.

5.6. Barriers to Commercialization of Publicly Financed Innovations:

- a. *Poor orientation to commercialization:* in commercialization of the research carried out at the institutes has been reported as a deterrent to industry-academia collaboration. Availability of human resources having adequate knowledge as well as skills, should be considered a key enabling factor providing advantage to the industry in a knowledge intensive sector like the drugs and pharmaceuticals. Indian academicians have an inclination towards carrying out fundamental research and publishing papers rather than pursuing innovation, industrial research and transferring knowledge and technology to the industry. There needs to be affirmative action to develop human resource in universities for more active roles in collaboration with industry and innovation. This requires also redefining the mandate and mission of universities.
- b. *Institutional Reforms needed:* There is a need to relax or removing regulations that prevented faculty members from working with companies. There is also a lack of clear

policies on knowledge and technology transfer and lack of offices and guidelines for the management of intellectual property and putting in place clear rules and guidelines.

- c. *Lack of collaborations* – especially multi-disciplinary and across different types of institutions is an issue. World over research consortia have developed, but this is slow to begin in India. Collaborative approach is critical to increasing the R&D efficiency in India owing to the limited availability of resources. Research in public sector science system is carried out in silos, without active collaboration across the institutes. As a result, a number of institutes work in similar areas leading to inefficient utilization of R&D funding. Scientists willing to contribute should be given due recognition to promote this culture in the institutes. Inter-agency collaboration (CSIR-ICMR-DBT-DST) is absent and needs to be corrected by the adoption of mechanisms such as national health research management forum. Consortium approach to collaborations needs to be given a try to build the right kind of culture for industry-academia collaboration.
- d. *Adequate funding*: here is a need for funding schemes and ensuring adequate financial resources for R&D activities at universities. Limited focus on practical knowledge, lack of adequate faculty, inadequate infrastructure and growing competition for talent from MNCs, are some of the key impediments that the innovation policy would need to address.
- e. *Modernize University Curriculum*: The curriculum being taught in majority of academic institutes and universities does not match with emergent needs. People handling the biotechnology departments / laboratories are majorly biologists and not engineers, thus failing to harness the latest discoveries and commercialize them. There is an increasing requirement for functional genomics scientists, protein scientists, quality control analysts and clinical research associates- and our universities do not currently produce many of these skills. There is also lack of the skills in latest technologies requiring multidisciplinary principles and skills.
- f. *Testing Facilities*: Lack of access to pilot plants and testing facilities are also major problems. Strengthening of facilities for non-human primate testing, national testing facilities for biological testing would also be a step forward to encourage cross-domain interaction of some importance to biomedical researchers working in industry, academia and research institutes.

6. Needs and Opportunities:

One of the major problems facing both, market driven innovation and publicly financed innovation, is the problem in identifying the needs and priorities from the view point of health outcomes. We note that industry statistics on one hand shows us that as much as one half of all drugs on the market give way to new innovation was over a eight year period and on other hand the most urgent and prevalent diseases of the nation fail to attract adequate innovation over decades. For stimulating research by industry the needs have to be perceived as market opportunities, demand, and for publicly financed innovation it has to be

through both prioritization and mechanisms of financing, where national needs are perceived as project and publication and patent opportunities.

There are many problems with being able to identify needs and opportunities. For one, there is no clear burden of disease estimates available. The most commonly used source is a 2004 study of mortalities from the registrar general records- a source which is quite problematic.

Moreover this is a national average and extrapolation, and one would prefer to use state-specific estimates since some states have completed a demographic and epidemiological transition and others are on the way and still others have not. Even the patterns of infectious disease vary widely. In large states the variation between districts in the state, may be more than the variation between states- and there is a case for seeking dynamic district level burden of disease estimates.

The other problem is that a high burden of disease need not necessarily mean a need for innovation, for access to existing drugs and devices may be more than adequate for the purpose of control and cure. However a glib assumption, that it is a service delivery or system failure rather than a technology failure, may miss the point that technologies have to suit systems and not the other way around. For example severe iron deficiency anemia in pregnancy can be treated by blood transfusion. But given the problems of the latter, there has been always the effort to come up with an injectable iron that could give the total dose required in one, or at least a few doses. There are such options available, but none of these have been certified as safe for use under field conditions. This could be seen as a failure to organize blood transfusions, and iron injections in higher referral facilities, or it could be perceived as a technology gap, which innovation including novel drug delivery mechanisms could solve. Common sense and intuition are poor guides in deciding what part of the gap is attributable to technology gaps and what part to access to technology. And as we know with the development of resistance in malaria, tuberculosis and nosocomial infections, one may be related to the other.

An attempt to detect the programme gaps that technology could solve by survey questionnaires of providers working in different situations was not productive. Clearly a more intensive approach like clinical immersion as used for detecting gaps in non drug technologies in the Bio-Design Programme may be required.

Finally there are many areas like anti-hypertensives and anti allergics where a large number of safe alternatives are available- but the search for better and safer drugs goes on. There are reasons to participate in these- but even more urgent is to come up with better and safer cures for a large number of diseases that have cures with much older and outmoded technologies- like the anti-snake venom based on horse sera.

Another major opportunity for innovation is what is called "point of care" diagnostics. Quick rapid diagnosis in fevers without localizing signs or symptoms, in different systemic infections respiratory, neurological, etc, detection of antibiotic resistance and better anti-biotic choice, screening of newborns and infants for abnormalities, and specific population groups which are at risk for endemic diseases could all be revolutionized by the

development of such diagnostics. The development of RDK for malaria detection is an apt example, but even here further innovation is needed for a broader spectrum of diagnosis, longer shelf life, greater specificity etc.

We categorize and discuss below the clinical gaps and innovation opportunities.

1) Opportunities: Listed by Type of Clinical Gap.

A circulated questionnaire and a dialogue with practitioners drew the following insights regarding clinical gaps and opportunities.

a. For Diagnosis-

(i) There are many morbidities for which available diagnostic tools are inadequate. One category of such gaps is where sera have to be sent to a distant laboratory for virological/immunological studies and confirmation. A more robust diagnostic kit allowing diagnosis at the point of care- like rapid diagnostic kits for malaria would make a significant difference.

Examples include diseases like dengue, chickengunya and leptospirosis- but potentially the list is endless- since most diagnostics for infectious diseases can have better 'point of care' innovation.

(ii) Even current success stories like RDK for malaria requires new innovation to give it a larger shelf life, more specificity and for covering both types of plasmodia with the same step.

(iii) Innovations are also needed for greater reliability of currently used diagnostics. For example in the field, Widal is still the only test used for typhoid as cultures are difficult to organize. Yet Widal has low sensitivity and specificity. Tuberculosis still does not have a reliable diagnostic for active disease- a problem particularly in children where clinical symptomology is non-specific.

(iv) In snake bites management there is little laboratory support in terms of innovation, nature of venom to guide early treatment or levels of anti-venom-its effectiveness to guide better treatment.

(v) At another level treatment even for diarrhea, lower respiratory infections, meningitis remains guided by clinical examination with little laboratory support even in district hospitals. Improved microbial identification and resistance pattern testing with advisories to peripheral care providers would also be valuable.

(vi) There is also a need to design equipment for a larger number of public and clinical health laboratories-which are cheaper, more robust, requires less skill levels and training to handle and provide a range of in-vitro diagnostics for drug testing and drug levels in sera, for microbial and resistance pattern identification and for wide range of immune

markers. It should be possible to instal such a package of diagnostics at the level of every district hospital initially and eventually every block hospital, at much lower costs than is currently possible.

(vii) The entire area of diseases of veterinary infections and zoonoses has not been considered but they too need work up.

b. For Therapeutics:

(i) For the most well equipped diseases of national public health importance- tuberculosis, HIV, malaria, typhoid, kala azar due to constant emergence of resistance, newer families of drugs are essential. But in practice most of these 'innovation pipelines' are choked - or at best down to a trickle.

(ii) For a number of major problems- dengue, chickenguneya, hepatitis, even chronic malaria, acute encephalitis syndrome other than Japanese encephalitis, acute flaccid paralysis, scorpion stings etc. no therapeutic measures are available and treatment is only supportive.

(iii) For some major causes of death like snake bite the available product is horse serum based, poorly standardized and outdated technology, but no bioengineering products have arrived. For neonatal sepsis an effective oral antibiotic is a long felt demand- but none is available.

(iv) In the area of chronic diseases and cancers we know that genetic profile make a difference to drug responsiveness. However there is little work in either looking such differences or building innovation that build around these difference.

2. Opportunities: Listed by Major Disease Types Examined: Annexure.

3. Opportunities: In the Export Market Driven Scenario:

This is in line with current regime, but even here there are opportunities, which even as we swing to addressing national health needs, we should use as part of promoting industrial growth. Many of these opportunities listed below would also make some categories of drugs much more affordable.

a. Market opportunity for the sale of generics in OECD nations will continue to grow: At the moment global generics market is estimated at US \$ 120.6 billion (2009). Generics sales rose 10.2 % in Japan, 16.9 % in France, 12.5 % in Italy and 10.5 % in Spain. This market opportunity has been growing and increasing its size at a CAGR of around 18 % over the last few years. Besides tapping the generics market in US and Europe Japan is also expected to be the new target for the Indian generics manufacturers.

- b. Drugs and pharmaceuticals with sales worth over US \$ 100 billion are expected to lose patent protection. This includes the blockbuster drugs like Lipitor, the number one product by sales revenue in the global pharmaceutical market. Many of the Indian firms are already spending millions of dollars on the filing of ANDAs to gain rights to produce this drug for the regulated markets of US and Europe.
- c. Similarly, biosimilars seems to be offering a new opportunity. With the promised approval of the US Biosimilars Bill the emerging policy environment is likely to create a new market opportunity for this industry just as the Hatch-Waxman Act did for generics earlier. Along with the changes in law regarding biosimilars, a number of biopharmaceutical drugs including Erythropoietin, human growth hormone, Granulocyte colony stimulating factor (G-CSF), insulin and Interferon, will be going off-patent in the coming one decade. All of this will open up a whole new market and start occupying the Indian firms in innovation making for the marketing and sales of biogeneric drugs.
- d. Therapeutics in diabetes and oncology will also form big attractions for Indian biopharmaceutical companies.
- e. One concern would remain that with the huge market opportunity represented by the above developments, especially with respect to biosimilars, we need to establish a policy for bio-manufacturing such that we are not limited to process innovation in already mature areas, and keep pace with the required competencies in both new process technologies and product development. Another concern would be how the country should go on to maximize the gains for the Indian poor from the opportunity that the industry will certainly be taking.
- f. Another major market cum technology opportunity becoming now available to the domestic companies is the possible application of new platform technologies that are now available for the production of new drug delivery systems (NDDS) for namely oral, nasal, pulmonary and intra-ocular formulations of drugs in type II and III diseases where generally international firms do not get interested. Since the development time and cost for NDDS development is much less than NCE development, identifying and articulating the demand for right kind of needs is certainly another definite opportunity.

4. Innovation in Vaccines:

Production of vaccines at low prices for the benefit of low income groups with higher margins of safety and stability, even when used in difficult climatic and health systems contexts, is another need and opportunity. Recent trends in the vaccines industry reveal a shift towards combination vaccines such as pentavalent vaccines. Further, the industry can also be expected to move away from largely whole cell pertussis based combinations to acellular-based combinations in the coming decade. Vaccine production is now an R&D based private sector industrial segment which has competence to participate in the processes of learning, competence building and innovation for the supply of new vaccines. There is considerable Indian capacity to enter this area- and make a difference.

However unless there is a conscious effort to build a favourable eco-system to respond to these opportunities, the trend would be to follow the current pathway of being driven by mainly the foreign markets for off patent generics which have we have seen will have

diminishing returns over times – in terms of being able to address our health priorities, of being able to maintain the nature of innovation that is necessary for Indian pharmaceutical industry to survive and about securing the future movement towards universal health care.

7. Building Eco-Systems To Support Innovation:

7.1. Steering, Coordination and Alignment of R&D/Innovation with needs:

- a. Creation of an authority/ Or empowered mechanisms: for alignment, steering and coordination of biomedical R&D and innovation, which prepared a 10 year plan, which is suitably included in the overall healthcare R&D and innovation plan. This plan will indicate the priorities to different agencies in respect of the sector of drugs and pharmaceuticals, diagnostics and vaccines. These priorities would need to be divided into short, medium and long term plans for the deployment of required financial and human resources. It would submit its report to the NIC every year, and parliament every three years. The National Innovation Council may create this group by consulting the representatives of all the relevant agencies, academia, domestic and patient groups.
- b. Extramural research fund for the initiation of publicly financed biomedical R&D and innovation activities, to seed the product development partnerships and the new activity / technology groups. This is an additional instrument and not a substitute for the arrangements already existing in the country.
- c. Nodal groups / organizations for planning and financing activity / technology-wise activities: for the determination of strategy to be followed / work on new chemical entities (NCEs) discovery, new biological entities (NBEs) discovery, new drug delivery systems (NDDS), innovative and novel formulation development, biosimilars and biogenerics, genetic and proteomic research, vaccines, regenerative and reconstructive medicine, preventive medicine, diagnostics, herbal, ayurvedic and other traditional medicines, interventional devices and instruments, bioinformatics, etc.
- d. Product Development Partnerships : Publicly funded development project proposals, each of which is governed by a separate board having all the relevant knowledge domains and stakeholders including clinicians, biomedical researchers and patient groups' representatives as members. These would steer and coordinate mobilization of human resources, financing and continuous monitoring.
- e. All these boards will be guided in their decision making by the provisions stipulated in the policy with regard to the decisions on the management and application of intellectual property and incentives to be obtained and utilized for the success of the programmes.

7.2. Action against foreign acquisition of domestic pharmaceutical firms:

There is a need for urgent action to protect Indian Industry from being completely taken over. This is a clear and present danger as a number of major Indian pharmaceuticals have been taken over by International Pharmaceuticals and others are lined up. Even the top

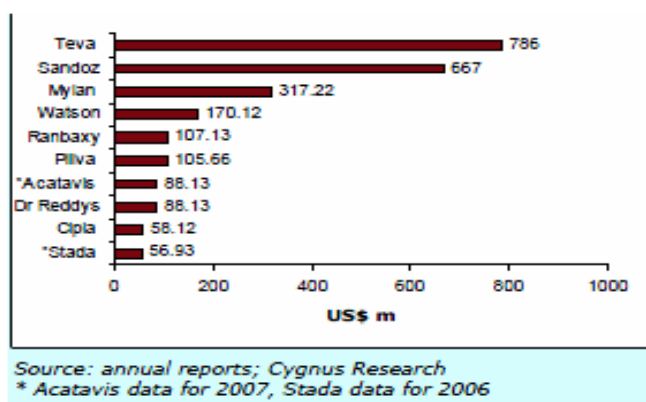
ranked domestic company Ranbaxy is now no more a domestic company. It has been sold by its Indian promoters to Daichi Sankhyo, a Japanese MNC. Moreover, even the other leading companies viz. Dabur, Nicholas Piramal, Wockhardt and Shanta Biotech have divested important parts of their pharmaceutical business to foreign companies. In many cases these divestures have also involved R&D based segments. The latest news is that Cipla is also negotiating the sale of its assets with foreign firms.

The Indian pharmaceutical industry is the child of state; the Indian government cannot look the other side when the promoters are choosing to take an easy route to get out of the business of new drug discovery and development and invest far more in the establishment of hospitals and pathology laboratories. India's health and essential medicines security is dependent on the activities of domestic pharmaceutical firms in the area of drug discovery and development. The government should strengthen the competition policy and include direct provisions which should protect indigenous innovation from hostile takeovers and prevent the industry from being sold to foreign pharmaceutical giants who have shown far less interest in innovating for the benefit of developing nations and the poor.. The FIPB should be used to regulate the brown field investment in the sector of drugs and pharmaceutical industry. The national competition policy should be used to monitor and regulate the collaborations, agreements and alliances being entered into by the domestic pharmaceutical firms in India and abroad.

7.3. Increase public investment in R&D and innovation financing :

R&D intensity of domestic pharmaceutical industry is of the order of merely about 1-2% of sales to 5-6% of sales. This, as we have shown is not focused on new drugs or on health priorities and all this can worsen further. Global pharmaceutical companies spend on average at least 9-10% of sales. The existing level of R&D expenditure of the top fifteen Indian pharmaceutical firms is nowhere near the expenditure being incurred by the generic companies of Israel and Europe as shown in figure 4.

Fig 4: Top generic players by R&D spending -2008



Pharmaceutical research and product innovation demand large investments over extended periods of time. Indian domestic pharmaceutical firms being smaller in size as compared to international standards, lack the financial might to absorb the cost of failure. Majority of them expect a quick return on their investment. Small biopharmaceutical firms have also had less success in fostering a culture of innovation and there is high level of risk aversion among venture capital and private equity players. Development finance has been on the retreat.

All this makes a case for much higher government investment in innovation. All three of the main departments- CSIR, DBT and DST has been providing grant-in-aid projects and also loan finance, but there is not much interest among the large companies to use the facilities of these three departments. The DBT is making a concerted attempt to encourage the biopharmaceutical firms to take innovative, high risk R&D projects for establishing proof of concept as well as for development and commercialization of research leads.

Due to the fast growing contribution of large domestic private sector companies the share of private sector in biomedical R&D is certainly on the rise in India- but as we have shown this means that all the national priorities would not get addressed adequately.

Table 22: Estimation of Biomedical R&D expenditure of Public & Private Sectors in crores

Year	2010-11	2009-10	2008-09	2007-08
Total Central Government Grant-in-Aid	2279.17	1983.15	1738.13	1285.52
Private Sector R&D Expenditure of 673 companies listed in CMIE	4267.17	4162.5	3653.39	3053.44
Total Health Research Expenditure	6546.34	6145.20	5391.52	4338.96
Share of private sector in research and development expenditures	65.18	67.74	67.76	70.37
Estimated as a % of Total National Level Health Expenditure	1.36	1.5	1.66	1.68
Estimated as a % of total National level R&D Expenditure	15.22	16.49	22.22	15.26

India is developing this skewed configuration at an early stage of development of the system of innovation. Public and private sector are known to play a different role and function in the organization of knowledge production in health research. Arising out of the decline in the share of public sector there will also be an adverse impact on research productivity and reduced emphasis on basic science. In all the countries public sector research organizations are known to play a major role in the activities of basic research, drug discovery and pre-clinical work. Thus there is an urgent need to increase in public financing of both, biomedical research in general, and drug innovation in particular.

In US and Europe the share of public sector research has been for quite some time persistently fifty percent. In India it is about 30 to 35%. Further total health research expenditure as a percentage of total health expenditure is as low as 1.5%, whereas by recommendations of the National High Level Expert Group it should be in the range of 8%.

7.4. Financial Support and Fiscal Incentives

Government's contribution in all respects including R&D Expenditure for Discovery/ Clinical/ Pre-Clinical/Wet Lab work shall be maximized keeping in mind very low success rate of Discovery.

- I. Government of India shall obtain undertaking from companies that in case the company is sold to foreign control, all grants and other fiscal incentives provided shall have to be returned with interest to the GoI.
- II. Technopreneurs led enterprises have more enthusiasm, have stronger commitment, take faster decisions, have inherent fiscal prudence and thus if their research proposal after "brutal scrutiny" merit funding, they should be committed grants for the entire period of development, whatever be the duration.
- III. Incentives - following actions are identified to overcome the challenge of R&D:

(a)	The fiscal benefit of weighted deduction for expenditure on scientific research u/s 35 (2AB) of Income Tax Act expires on 31 March 2012	<ul style="list-style-type: none"> ▪ This should be extended for a period of at least 10 years up to 31 March 2022. It should always remain valid for 10-year period.
(b)	The expenses incurred on clinical trials, bio-equivalence studies, regulatory approvals and patent filings outside are not eligible for weighted reduction u/s 35(2AB).	<ul style="list-style-type: none"> ▪ Section 35 (2 AB) should be modified to include these expenses.
(c)	S. 35A offers 200% weighted deduction for <i>in-house</i> R&D. However, with the imposition of Minimum Alternate Tax [MAT] of 20%, companies are unable to avail full benefit of weighted deduction. Though the law provides for carryover and set off, the ongoing and ever growing investment in R&D does not allow benefit of weighted deduction to R&D intensive industry.	<ul style="list-style-type: none"> ▪ Modify MAT to allow companies to take benefit of weighted deduction of 200% for R&D. ▪ Alternatively, the amount spent for R&D should be treated as TAX CREDIT [Investment Tax Credit] and be allowed to be set off against Tax and/or MAT Payable.
(d)	The weighted deduction u/s 35(2AA) allowed on sponsored scientific research undertaken through an approved national laboratory, university, Indian Institute of Technology and other specified institutions was increased from 125% to 175%. The weighted deduction u/s 35(1)(ii) on contributions made to approved scientific research association, university, college or other institutions was also increased from 125% to 175%.	<ul style="list-style-type: none"> ▪ Similarly, the weighted deduction on contributions made u/s 35(1) (iia) to a company engaged exclusively in R&D and approved by the specified authority, should also be allowed.
(e)	Grants and Interest Subsidy	<ul style="list-style-type: none"> ▪ Allow grant of upto 75% for capital investment in technology development. ▪ Offer soft loans for capital investment and working capital for technology development.
(f)	Exemption from Duties and Taxes: Input credit is available only if R&D equipment and raw materials are used in the same premises where excisable goods are manufactured Several companies have set up R&D centres away from their factory premises. They are	<ul style="list-style-type: none"> ▪ The rules should be amended to allow CENVAT credit on all inputs used for R&D purposes even if they are used in a location outside the factory premises. ▪ All inputs including capital goods and equipments

not eligible to claim credit for inputs/capital goods procured for the purpose of research and development. Thus, there is a distinction between R&D units within the factory premises and outside the factory premises.	necessary for carrying out research and development should be fully exempted from all duties and taxes.
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7.5 Better Balance between basic research and medical sciences.

One of the objectives of public financing of R&D should be to ensure a better balance between basic research, and research in medical sciences. The impact of the decline of share of basic research on the processes of drug discovery and development could be even higher in intensity because of the crisis of R&D productivity in biomedical R&D has much to do with the challenge of low hanging fruits having been already picked up by the global pharmaceutical firms and the system being required to push the frontiers of biomedical innovation. History also tells that radical innovations or even episodes of rapid progress in medical research in the past had much to do with the developments in physical, information and biological sciences. In India, the research system is still in its early stage of development on account of biological sciences having not only a low level interaction with the domain of physical and information sciences but also with the domain of medical sciences. Much attention would have to be given by the Indian policymakers to the issue of how we can achieve a better balance within and between the activities of private and public sector. This has implications for the shaping of coordination of R&D among the biomedical fields and specializations which are today required to be collaborating among themselves far more strategically and systemically.

7.6 Improve Coordination between Government Agencies in Health Research Financing.

In the 11th FYP the policymakers saw the area of health research mainly as a responsibility of the Ministry of Health, for example, the Planning Commission Working Group noted that “the health research is to a large extent funded by the Govt. of India through Ministry of health, the funding for health research depends on health budget----”. But there is a need to pose the department of health research, not as financing all the areas of health research by itself, but more important as coordinating and acting as a node with which all the other departments and agencies must coordinate to bring about the necessary coherence and flexibility and responsiveness to national needs that the system of biomedical R&D and innovation must possess.

Coordination and financing of research are intimately interlinked. There needs to be adequate mobilization of financial and human resources available with all the other departments, the health research policy which provides for the establishment of national health research management forum should be used to enhance resources for the benefit of health in these agencies and departments in a coordinated manner. The health research expenditure of ICMR, CSIR, DBT, DST, UGC, AICTE and industry support must all follow a pace of increase in health research expenditure to match the increase in health expenditure that is envisaged during the 12th Plan. Ideally, as spending on health research should be at least

8% of the total health spending. It is our recommendation that all the departments and agencies are motivated and mobilized by the government to enhance their level of funding for biomedical R&D and that the department of health research acts as the center for coordination in both, priority setting and financing.

The draft document of National Health Research Policy was ready in 2007 in the Indian Council of Medical Research (ICMR). In this document, the draft prepared by ICMR also suggests the establishment of national health research forum. It suggests, 'The forum will have to be established as an institution for reaching consensus on identifying national health research agenda and priorities based on the policy framework laid down by the national health research policy. The forum will review, from time to time, the performance of national health research system within which the policy is implemented.' This requires to be implemented in the earliest.

7.7. Leveraging public sector R&D strengths in drug discovery and innovation:

There are some areas where the public sector R&D has built up considerable competencies and capacity. The most important of these is the route of reverse pharmacology using leads from traditional and indigenous systems of medicine. Systematic efforts to build a data base on traditional systems of medicine are ongoing and needs to be strengthened a much larger programme for searching these data based for innovation opportunities could be built up. This would also leverage our strength in process re-engineering appropriately.

7.8. Overcoming impediments to human resource development and scaling up

Availability of human resources having adequate knowledge as well as skills, should be considered a key enabling factor providing advantage to the industry in a knowledge intensive sector like the drugs and pharmaceuticals. There needs to be affirmative action to develop human resource in universities for more active roles in collaboration with industry and innovation.

Based on global experiences such measures could include:

- redefining the mandate and mission of universities,
- relaxing or removing regulations that prevented faculty members from working with companies,
- developing policies and offices and clear guidelines on knowledge and technology transfer, management of intellectual property rights, and research collaborations,
- creating funding schemes and ensuring adequate financial resources for R&D activities at universities.

Modernizing the University Curriculum: This must include practical knowledge, and introduce skills in scaling up and laboratory trials, and in latest technologies requiring multidisciplinary principles and skills. There is an increasing requirement for researchers and scientists, functional genomics scientists, protein scientists, quality control analysts and clinical research associates.

7. 8 Building R&D Consortia:

Consortium approach to collaborations needs to given a try to build the right kind of culture for industry-academia collaboration and collaboration across the institutes.. Inter-agency collaboration (CSIR-ICMR-DBT) needs to be promoted through adoption of mechanisms such as national health research management forum. Industry, clinicians, research institutes and academia need to come together to define the challenges and set up clear priorities for research collaboration. Financial incentives and the provision of dedicated facility for collaborative research for all those researchers who are willing to cross their domains and collaborate across domains can be the way forward for rewarding such activity. Consortia would also be able to build and maintain better access to testing facilities- for non-human primate testing, facilities for biological testing, material testing, pilot plants etc. and this would also be a step forward to encourage cross-domain interaction.

7.9. Promotion of open access movement

The National Knowledge Commission has made a recommendation for open access. Key institutions in the advanced countries - including funding agencies such as the NIH and the Howard Hughes Medical Institute in USA, the research councils and the Wellcome Trust in the UK and university faculties such as the Stanford School of Education and the Harvard faculties of Arts & Science and Law - have mandated open access to publicly funded research.

Action should be initiated by the Department of Health Research with a view to strengthen the OA initiatives as desired in the resolution of World health Assembly and in consonance with NKC recommendations.

As part of this one immediate measure should be to establish compound libraries- when every institution has a repository and these repositories are linked with ease of access across institutions and to public.

Establish national level data bases on key knowledge components like a data base on small organic molecules (300 compounds available in published sources) which would contain data on structure, physical data, activities, etc. A repository of organic compounds is another proposal. Also for a system of facilities for storage, purification, generation and retrieval of data and for screening of compounds in the CSIR the agency wide programme is now being formulated in the CSIR system by the concerned scientists. NCL-CDRI-IICT have been asked to constitute a group, under CSIR which establish repositories for bar coded organic compounds. Benefits from such a facility can be immense. With one input multiple outputs (orange books, chemical genomics and compound revalidation data) would be facilitated. It is estimated that additional 400 crores would be required for the setting up of all these facilities. URDIP would have to be strengthened to foster the chemical information service. The team to be constituted with CDRI-NCL-IICT is in the process of preparing the vision and strategy including information on who are the likely users of these repositories. In order to

give a fillip to this activity action may be initiated by the Department of health research in collaboration with CSIR and Department of Pharmaceutics.

7.10. Stimulating industry to undertake R&D in priority areas.

In the case of domestic markets, a large part of pharmaceutical innovation is devoted to undertaking only product differentiation rather than the introduction of new, appropriate products for affordable health. To counter such a tendency it is now necessary to create demand pull policies in the way of a) procurement of generics from small scale pharmaceutical firms and in priority areas b) development of advance market commitments, c) prize fund or challenge funds for innovations in priority areas, and d) larger public procurement and distribution through public services or Jan Aushadhalay for the marketing of affordable medicines to reach the poor. Encouragement to the building of capacity for R&D and innovations that suit local health needs requires the issue of small market size to be appropriately tackled if the local firms are to be stimulated into contributing to the priority health needs of the Indian poor in an affordable way.

Domestic firms should be incentivized for the development of appropriate product targets by using the instruments of public support to fill gaps in capabilities and activities for innovation to be undertaken by the private sector in a targeted way. As an example, the n the Department of Pharmaceutical plans creation of infrastructure and physical facilities which the industry would be able to use on payment (Department of Pharmaceutics, May 29, 2009).

7.11 Information on Innovation:

Efforts to be undertaken for the establishment of mechanism for systematic tracking must be comprehensive and provide actionable health research intelligence. Persistence of fragmentation, gaps and mismatches, duplication, misdirection, are some of the problems that are required to be urgently overcome. To create the system of collection of health research intelligence a health research project registry should be established in the Department of health research.

Information is also essential for government to design push and pull incentives to align appropriately the directions of R&D and innovation in the system with the national priorities in respect of disease focus and stage of development of research.

There is a need to systematically track the financial resources being devoted to R&D. Actors involved in the system of health innovation come from many communities of practitioners; they are not limited to the community of biomedical researchers or doctors. Resources devoted to the making of health innovation in public and private sector contexts are required to be estimated separately through a survey of innovation expenditure for different types of health innovations.

It is an area of contention and cost audit may be made mandatory for the entities claiming to be working for the introduction of different types of innovations, especially when they are getting concessions and subsidies on that score.

Regular surveys of innovation expenditures for different types of health innovations can also be undertaken with a view to understand the gaps in capacity and policy instruments needed for capacity building in the public and private sectors context.

Agreements being signed between domestic and foreign firms and institutions need to be registered and documented appropriately. It is currently not possible for the policymakers to even know who is doing what in the sector of healthcare. Information flows in only when the entities involved themselves decide to share information for their own benefit (mobilization of finance, market development, etc.) with regard to their own investment activities. Private sources like Prowess of CMIE, Pharma Express, Pharmabiz, Cygnus and other such sources in the form of trade journals have become the main mechanism of information for everyone including industry. Currently there is none and we learn about this only from occasional reports in trade journals

Technology transfers between laboratories and industry need to be tracked. These new activities involve the development of mechanisms of strategic technology sharing alliances, joint technology development agreements, public-private-partnerships (PPPs) for collaborative R&D, business incubation centers, training institutions, product development partnerships and many other such forms. There exists no mechanism in the ministry of health for the management of technology transfer activities through these mechanisms for the benefit of health sector.

In PPPs contract agreements should be developed with safeguards being built in them for price controls, institutionalization of the government's prerogative of intervention for the introduction of sufficient competition, automatic march in rights, etc. Dispute resolution mechanisms can specify a participatory and transparent system of decision-making, public accountability and just governance. The GSPOA demands that if the government is desirous of putting public health as a supreme objective in the management of PPPs the challenge of facilitation of technology transfer is tackled at the stage of formulation of PPPs. A study on the above raised subjects would enable the country to identify the emerging barriers to technology transfer in the context of meeting of the public health needs.

7.12. For a better management of intellectual property

India must learn to manage and apply intellectual property with the aim of minimizing the barriers to innovation arising out of the implementation of TRIPS compatible scenario of innovation.

One space that can help innovation is the use of compulsory license. India is well placed to utilize the limited TRIPS Agreement flexibilities in this regard for export of pharmaceuticals to LDCs. So far just one application for CL under 31 (f) has been filed by an Indian company, namely Natco Pharma; it intends to export two anti-cancer drugs Roche's erlotinib (brand name Tarceva) and Pfizer's sunitinib (brand name Sutent) to Nepal, a LDC with no manufacturing capacity. Indian generic drug manufacturer Cipla is already supplying low-cost antiretroviral drugs AIDS drugs for 50 percent of the 700,000 HIV patients taking in developing countries. These drugs cost about 5 percent of the price of similar drugs sold by US and EU pharmaceutical firms

Within India there is no instance of its use with preference given to foreign firms voluntarily licensing the intellectual property.

To ensure the achievement of public sector goals, particularly those related to health products like vaccines, drugs and diagnostics, the country needs to establish a system of intellectual property alerts. Monitoring, legal aid and public policy support will have to follow if the goals of public health are getting violated. Further, it is important for any institution engaged in product development to have adequate capacity in contract and license drafting, and negotiation. Above all, this requires sufficient staff time for detailed preparations. Using milestones in contracts requires a good understanding of the technologies, business processes, and regulatory issues. Continued investments in training of intellectual property and technology transfer personnel are important if India is desirous of taking maximum advantage of the flexibilities of TRIPS Agreement.

Concrete measures to make use of TRIPs flexibilities include the construction of public databases that provide accurate and current information about disclosures made in Patent filings and Patent Grants. Such databases can be mined to identify potential candidates for generic manufacturing, using TRIPS flexibilities.

Decisions on the pharmaceutical and biotechnology patenting must involve the department of health research, to ensure no infringements of health rights and interests. It should promote the setting up of an expert group whose job would be to provide technical support to the department on management and application of intellectual property.

The department of health research should take steps to concretize the development of a database of technologies for the production of essential health products and a mechanism to provide support for technology transfer.

Patent pools may be used to give greater access to patents by domestic firms. Information on purchase of IPR and licensing should be studied. Technology transfer systems would be much improved if the country can get the international community to establish a Govt-to-Govt system of monitoring of technology acquisition.

Patenting of microorganisms need not be allowed in the interest of preventing monopoly in a growing area.

There are important alternatives developing to patent driven regimes internationally which may be of improved relevance to us. Also the evidence that patents and IPR drives better innovation and commercialization needs more evidence. Clearly there are areas where it is not very efficient. One way of maximizing benefits from publicly funded R&D is to patent the knowledge and transfer it to industry under exclusive licenses with the aim of earning maximum possible revenue. But there are other ways in which the patents could be worked up – ways that go along with the concept of the knowledge commons- and these should be explored first.

7.13. For regime shifting through open source drug discovery (OSDD)

One major innovation in drug innovation is OSDD. With the convergence between computing and biology on a fast track it is quite clear that open source methods can also be used to organize early phase drug discovery. This new approach, which can be rightly called

as “open source drug discovery (OSDD),” approach, would significantly reduce the cost of discovering, developing and manufacturing cures for neglected diseases in India. First, when it would give hundreds of scientists a practical way to donate urgently needed expertise and advice required even while continuing in their present jobs. Second, this approach would even permit the sponsors to award development contracts to the companies and university departments offering the lowest bid for the provision of a solution to the identified research problems. Finally, because open source discoveries would not be patented competition from generic drug makers would keep manufacturing prices at or near the cost of production.

India is willing to take global leadership in the area of open source drug discovery (OSDD). It is clear from even the limited experience of OSDD on TB of CSIR that it is a new unique initiative. It has much potential to involve researchers (over 1000 scientists are already engaged in contributing to this project) from all over the world including India in product development for the benefit of neglected diseases. OSDD is a web-enabled interactive platform that will list the current design challenges for developing drugs to treat drug-resistant tuberculosis, malaria, and HIV. The first step in CSIR’s OSDD initiative is the launch of an open source website hosting information about *Mycobacterium tuberculosis*, the bacterial pathogen that causes tuberculosis. This information includes gene sequences, expression, function, activity, and the response to drugs of all *M. tuberculosis* proteins as well as host-pathogen interactions (<http://mtbsysborg-igib.res.in>).

7.14. South- South Cooperation:

Currently international collaborations are skewed and tilted in favour of building relationship with the developed countries. The countries of South seem to have a place only in the sphere of traditional medicine and protection of traditional knowledge. Much effort would be needed with regard to the building of health research capacity in a joint way in the South through a systematic development of international collaborations in R&D from India to enable the least developed world to also enjoy the fruits of health science and technology which would be hopefully now better oriented to meeting the objectives of public health in the world as a whole.

India can take initiative in the establishment of international R&D centers on the lines of international agricultural research centers and in this even make the foreign firms to contribute personnel and resources to develop the capacity needed to be set up for the implementation of health R&D and related innovation activities to tackle the neglected diseases R&D and innovation gap in the South.

There is also a need to pursue the goal of a Global R&D Fund for Essential R&D in neglected areas. While such a fund can and should seek contributions from different sources, its governance should be public in nature. Several innovative ideas to raise resources for such a fund can be suggested, for example a cess levied on companies (based on value of sales) that sell products that are IP protected, with a clear understanding that the impact will not be passed on to consumers. Country Governments should also be required to contribute to this fund, and the contributions can be calculated on a sliding scale based on the

country's GDP and Purchasing Power Parity. Such a fund should be utilised to support direct grants for funding of knowledge as a global public good.

7.15 For the strengthening of regulatory framework

Much progress has been made in the country on the front of actions being taken for establishing and strengthening of mechanisms to improve ethical review and regulate the quality, safety and efficacy of health products and medical devices. Under Schedule 'M' for GMP have become mandatory in the country w. e. f 1.7.2005; the requirements are comparable with WHO GMP norms. Many companies have already complied with GMP norms. But while the strengthening of Schedule M with a view to improve the level of good manufacturing practice is taking place it is also true that not all the segments of Indian pharmaceutical manufacturing industry are able to undertake the required investment on their own. The SSI units are of the view that the requirements specified for physical space and air conditioning must be reviewed to make the implementation feasible. However, it needs to be ensured that more and more companies, particularly the small-scale manufacturers adopt these standards.

Several Small Pharma units (total number estimated to be 8000) need financial help for upgrading their infrastructure to meet GMP norms. These units play a vital role in supplying low priced drugs. As per the information from Office of the Development Commissioner (SSI), contribution of SSI in Indian Pharma Market is 50% by volume and 30% by Value. It is therefore, essential to safeguard their interests. A scheme of interest subsidy has been proposed for providing interest subsidy @ 5% on the loan taken by the drug manufacturers (SMEs) for implementing Schedule M. The requirement for funds for this purpose is estimated to be Rs.560 crores during the 11th Five Year Plan (2007-12).

For Ayurvedic, Yoga & Naturopathy, Unani, Sidha Homeopathy (AYUSH) units, Schedule- 'T' requirements are already enforced and one third of 9,000 odd Ayurvedic units have reportedly complied with these norms. Department of AYUSH is providing financial help for Schedule 'T' compliance. Department of AYUSH has also notified the draft guidelines on GMP, which will take care of the GMP aspects pertaining to Ayurvedic, Unani and Homeopathic drugs. Draft rules concerning approval of laboratories for carrying out analysis of Ayurvedic medicines have also been issued.

The Drug Controllers Office should be strengthened into an Autonomous Drug Regulatory Authority at the National level for control over manufacture, quality & supply of drugs needs to be strengthened. In both traditional and modern medicine, regulatory infrastructure would have to be suitably strengthened to ensure good quality of products and check production of spurious drugs. States need to constitute legal cum intelligence cells for carrying on campaign against spurious drugs for which the Central Government should assist State Governments, by extending funds to them. This needs appropriate human resources and a network of laboratories. It also needs a health technology assessment center that can advice the authority on the scientific validity of the claims before it is allowed in the market. It can help this office both issue advisories where needed on what the drugs are approved for and cautions.

India must be however quite careful about the proposals that the developed countries are making with regard to the harmonization of processes employed by the regulatory authorities, and to promote in particular the implementation of clinical trials using “global” standards for medicines evaluation and approval. Similarly, while the country is involved in the strengthening of the WHO prequalification programme, it should not be used to scale down indigenous production. There is evidence that in the case of vaccine production the WHO prequalification programme was used to close down some of the units that have been producing essential primary vaccines since the pre-independence period.

7.16. Incentives for Innovations that are not premised on Monopoly Pricing

The present framework for innovation is premised on high monopoly pricing as an incentive for drug industry to get into innovation. This has been shown to lead to products that attract high prices that can be sustained because of the monopoly over production and distribution that IPR regime allows. But there are many diseases which would not be market choices, but which are no doubt essential. For example antibiotics against multi-drug resistance bacilli have to have highly restricted and regulated sales- and can never pay back the cost of its innovation- unless the government subjects itself to huge payments for very uncertain benefits. This could be said about innovation in a wide variety of other developing nation needs and needs of the poor. There is therefore a need to financially reward innovations by other means so that the innovation costs need not be a part of drug pricing. Many such mechanisms are under discussion and some are already being put into operation. There is a need to evaluate and prepare a menu of possible mechanisms. This may include the following:

Open Source Drug Discovery: The CSIR in India has launched an initiative called “Open Source Drug Discovery”, to develop new products. As a first step, the initiative targets new products to be developed to treat Tuberculosis. The initiative involves utilization of the principle of “open licensing” and decentralized collaborative product development, which has been so successful in the software sector. While the process is still in its infancy in India, the potential is huge, and India has a special interest in promoting it as a model that can be adopted in different settings. Specific contributions that are evaluated as significant steps forward could attract awards.

Prize Fund: This is a mechanism that was suggested by some countries (Bolivia and Barbados) at the IGWG. It is a model that has been developed by the global think tank on innovation and public health – Knowledge Ecology Initiative (KEI), the mechanism complements and, in fact, overlaps many features of the OSDD initiative. It suggests mechanisms where the process of innovation is broken down into small discrete steps, and each step attracts a Prize”. Different entities (including for-profit Pharma companies) can bid for the Prize. Married to this is the concept of open licensing of the outputs of such Prizes.

Patent Pools: This is a concrete mechanism suggested by UNITAID. While Patent pools have the limitation that they work within an IP framework, their judicious use and focused intervention by Governments, can result in such a mechanism being more effective in promoting innovation and discovery of useful products.(need to explain – what is a patent pool)

It is necessary to also map other possible methods of promoting innovation that delink the issue of pricing of a product from R&D costs, but still retain sufficient incentive for not only individual innovators- but also for members of an innovation consortia. The financing of such mechanisms needs a collaborative effort and commitment from member countries of the WHO.

One may also re-visit the possibilities of off patent innovation being taken to scale production for the public health system through public sector units. Certainly in some essential products adjudged to be a health priority, and in areas where limited quantities are needed, but it is life saving, this may be the only option to both support innovation and affordable manufacture.

7.17. Policy for the development of human resource and capacity building for R&D and innovation

While India can boast of large turnover of science graduates and even engineers, the human resources required for modern day pharma research are severely lacking in key areas like toxicology, bioinformatics etc. Universities and educational institutions have been unable to update their syllabi in tune with high speed changes taking place in the world of technology. Hence, the students graduating are not equipped to meet the current industry requirements and often companies have to incur additional expenses (time and monetary) to train new hires.

One of the approaches to tackle the problem of job readiness is partnerships between industry and of precise research skills oriented Finishing Schools/ Training Programs, specially in academia. A link between academic curriculum and industry requirements will prepare students in pharma research for the industry by completion of their qualifications. Establishment of a large number collaboration with involved industry/ institution can make human resource more handy and useful.

The Government of India must initiate and install “Visiting National and International Pharma Professors / Technologists Forum /Panel” for training in Pharma Innovation Research with attractive incentives.

There is need to create/ develop adequate critical mass within Drug Regulatory Authority with necessary qualifications, expertise and experience to meet the requirements of “Harmonization of Guidelines” in line with international requirements keeping Indian situation in view.

Moreover, India needs to develop a concept for the development of a product in more arduous way as elsewhere in the world. Indian Scientists are good at concepts and proof of process strategy and thus lot of patents are being filed in India and abroad. However, taking the proof of process to proof of technology is quite lacking in India. Once it is accomplished, products will reach to the market in most competitive and cost worthy way making affordable and quality medicine accessibility a reality.

To improve the knowledge about quality aspects, certificate courses for GLP, GMP and GCP shall be initiated.

- I. Website with depository of information of Scientists & Researchers with their qualification and expertise shall be launched to facilitate contacts to draw global expertise.
- II. Discovery research requires initiatives to draw expertise from the basic science disciplines of universities, national institutions, IIT's, IISERs, private companies and wherever possible even from funding agencies.
- III. To develop discovery ecosystem:
 - a. Research institution faculty shall be allowed to work on sabbatical in the private sector lab.
 - b. Private company Scientists be allowed to work as adjunct/visiting faculty in the companies
 - c. In both above arrangements, experts from abroad and NRI's shall also be encouraged to enrich the knowledge resource.
 - d. Institutional R&D infrastructure shall be improved and accountability be enforced to encourage out-sourcing of work from industry to institutions. This will prevent wasteful expenditure on equipments and make India cost-effective R&D destination.

7.18. Placing Drug Innovation in Context:

However, health interventions must not be reduced to just the discovery and development of medicines. Lessons from the findings of health system research are very clear. Appropriate innovations are needed at the level of nutrition, water, sanitation, environment and social security but also in respect of the choice of technology for agriculture, industry, transport, energy and habitat.

Health is a product of the pathway of development which impacts on the status of public health, communicable, non communicable and chronic diseases.

Actions would have to be therefore guided by a broader conception of research even for building and improving of the innovative capacity.

Health system research based policy review is recommended with a view to identify the instruments of demand articulation for health sensitive innovations and their implementation to pursue the pathway correctives across all the relevant sectors. Innovation in pharmaceuticals, especially priority setting and even specification development, must be firmly embedded in larger health policy and health systems research.

Section III: Medical Devices

India has less than 1% of the global market share in medical devices despite having 1/6th of the world's total population. Poor access to technology contributes both a lesser quality of health care and to a poor environment for innovation and growth in this area.

India's medical equipment market is estimated at 2.75 billion dollars and of this only 29% is domestic production. As much as 71% of our medical devices and equipment needs is met by imports- as compared to about 10% in a nation like Brazil. Medical device imports to India increased to approximately 51 billion rupees or \$1.13 billion by 2008- a 1300% increase over 20 years. Domestic production accounted for about \$700 million or rupees 35 billions, but of this, about half is exported- much of it of low priced products like needles and catheters. This excessive reliance on imports for much of our medical devices needs has implications for costs and access- and in a changing patent regime, the costs are only due to rise further.

The use of medical devices grows rapidly. Comparing NSSO figures of the 54th and 60th rounds, we find an increase of utilisation from 3.8% to 8.3% of all outpatients and from 46% to 57% in case of in-patients. Even today, this industry represents 0.16% of the GDP, but this would rise at least five times. The predicted CAGR is 15%. And whether this would be met by domestic production or by import would have considerable implications for our economic growth. There are approximately 700 medical device manufacturers in the industry, mainly local device makers focusing on low-value products such as needles and catheters. Most high value products are often imported. Much of Indian industry is centred on exports. For the public and private health sector to meet the health care needs and the resulting demand for medical devices there is a need to build an ecosystem that fosters innovation, manufacture and rational utilisation of these devices.

The area of medical devices includes a vast and diverse range of products. An effort at categorisation of these could arrive at the following:

i. Diagnostic devices

1. Imaging (X-Rays, CT scans, MRI, endoscopes)
2. Laboratory:
 - a. Basic blood and urine and microscopy tests
 - b. Biochemistry
 - c. Pathology including hematology
 - d. Micro-biology
 - e. In-vitro diagnostics- rapid diagnostics.

ii. Therapeutic-

1. Drug delivery systems: eg injection syringes, Infusion pumps, catheters
2. Medical lasers, Lasik surgical machines
3. Surgical supports: instruments, stents, valves, prosthesis
4. Monitors: - EEG, ECG, oxymeters
5. Medical Textiles:
6. Life support equipment : ventilators, anesthetics, dialysis, pacemakers,

7. Ancillary equipment- beds, transfer trolleys, I.V. stands, laundry equipment, lighting equipment, sanitation measures, sterilisation methods,

Each of the above categories could be made up of a number of similar areas and within which we have different players and regimes in operation.

One category in the above which has an over-lap with the earlier section on pharmaceuticals is with respect to in-vitro diagnostics. This includes tests for infectious disease (HIV, hepatitis sub-types, typhoid, STDs, malaria dengue etc), diabetes, hormones, cancer biomarkers, pregnancy tests, blood grouping, and increasingly molecular PCR tests. The IVD market is globally about 40% of the total medical devices market. India has over 150 firms active in this area of which 50 have a substantial volume. Many of these are pharmaceuticals.

Biomedical textiles have uses ranging from hygiene and healthcare (gowns, caps, sheets etc.) to implantable (vascular grafts, hernia repair mesh) and non-implantable surgicals (dressings, plasters and other barrier protectives) and extracorporeals like artificial kidney. With advances in technology, traditional fabrics and yarns have been replaced by non-woven materials with specific features like antimicrobial properties, extreme fluid absorbency or repellancy, flame retardant properties etc. Estimates of the Indian market in medical textiles range from INR 15¹ - 46² billion to 60 billion by 2016/17. So far, their use has been restricted to corporate hospital chains. The advantages of non-wovens are obvious but decision makers- doctors and administrators- balk at the high costs. The apparent unaffordability is exacerbated by lack of domestic manufacturers (only 2 Indian manufacturers exist, and most of the country's supply is imported).

SITRA (South Indian Textiles Research Association), Coimbatore is an autonomous body supported by Ministry of Textiles, and has been declared a Centre of Excellence for medical textiles in 2011. It is involved in formulating standards and developing prototypes in Meditech products.

The Innovators

The organisations that are active in innovation in India could be categorised into four groups as shown below:

a. Government Research labs:

- i. Sri Chitra Tirunal Institute for Medical Science and Technology Services, Trivandrum,
- ii. SAMEER, Chennai,
- iii. CEDTI, Mohali,
- iv. Central Scientific Instruments Organisation, Chandigarh,
- v. Center for Cellular and Molecular Biology,
- vi. Center for DNA fingerprinting and diagnostics, Hyderabad

¹ http://www.sitrameditech.org.in/website_files/Compendium%20on%20Centres%20of%20Excellence.pdf

² <http://www.sitrameditech.org.in/projects/>

- vii. Inst of Physiology and allied sciences (defense) lucknow,
- viii. BARC,
- ix. Innovative Product Development Center, National Physical Laboratory, New Delhi.
- x. Institute of Aerospace medicine CSIR,
- xi. Defense Research Development Organisation,
- xii. ACTREC, Navi Mumbai- high end cancer diagnostics, (with Tata Memorial Hospital)
- xiii. Institute of Life Sciences, Bhubaneswar, cancer therapy and infectious disease biology and kits.
- xiv. International Center for Genetic Engineering and Biotechnology(ICGEB): Diagnostic kits-
- xv. Indian Chemical Lab.
- xvi. National Institute of Immunology- HIV, typhoid. (DBT funded)
- xvii. National Institute of Virology- Pune
- xviii. Central Council for Research in Ayurveda, Homeopath, Unani, Yoga, Siddha,- AYUSH products and delivery systems.
- xix. National Centre for Biological Sciences, Bangalore and its parent organization Tata Institute of Fundamental Research, Mumbai

b. Academic Institutions:

- i. The different IITs- in particular those with biomedical engineering programmes such as IIT Kharagpur, Delhi, Madras, Rupnagar(Punjab), Roorkee, Guwahati.
 - ii. Also in Indian Institute of Science, Bangalore and BARC
 - iii. Other Engineering Colleges: Manipal Institute of Technology, Vellore Institute of Technology, Bengal Engineering and Science University, Shibpur, Jadavpur University, College of Engineering, Osmania University, ICT Engineering dept, Anna University, Guru Gobind College of Engineering, Nanded, and in NJTs and other engineering colleges and universities. Medical Colleges: AIIMS, PGI, SGPMER, CMC Vellore, St. John's Research Institute with St John's Medical College, PSG Institute of Medical Sciences and Research.
- c. Industry sponsored:** specific innovative laboratories: GE-Healthcare, India, Seimens, Phoenix Medical Systems, Dabur, South India Drugs and Devices, TERUMO, TTK Health Care limited and specific responses to productions, Dabur Research Foundation, Supra Research Foundation, Pune, Sai Medical Foundation, Ahmednagar, Anapana health Center, Bangalore, Samvedana Hospital and Research Centre, Noida, KM Cherian Health Foundation, There are also a number of companies in the area of in-vitro diagnostics. Of the 150 listed companies active in this areas, 50 constitute the main part- most of them being pharmaceutical manufacturers with a branch in these product range. The major players are given in the annexure. A number of these are more into import and sales, often assembly and marketing and often not into any level of innovation.
- d. International collaborative programmes** with multi-disciplinary Indian institutions: Stanford Biodesign, Johns Hopkins, etc,

Of these SCTIMST has a good track record which has brought a number of products into the national market and subsequently into the international market. Their most well known products are the prosthetic heart valves and blood bags. Their main driving principle was import substitution as a form of cost reduction and better availability but once these were available, there was international interest in their use. SAMEER has made limited forays into medical electronics- but no major product that has been successfully commercialised. (to check). CSIR laboratories too have introduced innovative products, but faced difficulties in their scaling up either through commercialisation or through public systems uptake.

Academic Institutions, especially the IITs have been pioneers in this area. A number of their products have been fully commercialised. Their strength is that they bring in many young minds into the process. But there is an inherent weakness in a programme that is based on students- for products requiring longer development times are weak and even in commercialisation of others there is insufficient interest of investment. Yet the large number of opportunities that these programmes have identified and worked on provides valuable learning lessons. They also play a major role in building indigenous capacity for biomedical engineering and innovation.

In industry, the major form of innovation may have been the *jugaad* of the small scale entrepreneur of concentrations as in Punjab or Tamilnadu. This has particularly contributed to instrumentation. Though small scale units they gain considerable strength from being clustered and informally networked, so that they are able to draw upon tacit knowledge and unstructured experiences from a surprisingly wide catchment area.

A more recent development is the coming of large scale innovation establishments that aim to tap Indian skills and talents in innovation for an international market, as also take advantage of the huge and hitherto latent potential of the Indian market. Leading amongst these is GE and Siemens established firms in Bengaluru.

There is also another recent development, - of small start up techno-entrepreneur led companies, as exemplified by Remidio, Embrace, BigTec Xcyton and ReaMetrix, in Bangalore. There are similar companies in Mumbai and Delhi as well. These are very small, very innovative, of the home-grown companies in the diagnostic and/or device space. These are focused on being innovative and bringing out low – cost devices for the Indian market.

The fourth major development is a sort of academic driven, international collaborative efforts at multidisciplinary team- led innovations. The leader in this is the Stanford Bio-Design project. This is a collaboration between IIT Delhi, AIIMS and the Stanford University and has the patronage and financing of the Department of Biotechnology (DBT). Other examples are the Johns Hopkins University collaborative programmes- again with IIT and different medical colleges. These have substantial USAID support. A third successful example (which is really part of the next section – but is discussed here along with institutional arrangements) is the University of Oslo, NORAD supported effort at development of health informatics- which has a tie up with NHRIC and an Indian not- for-profit organisation, created partly for commercialisation.

The basic pattern of how these collaborations work is to have a strong academic component where a number of students are identified and trained by immersing them in the process of themselves developing an innovation. This goes along with a robust process of identifying opportunities for innovation which requires them to be immersed for various lengths of time in clinical situations and dialoguing with users and gatekeepers and potential commercializers. A third component is that after the prototype has been developed to bring it into commercial markets through a business enterprise model. In the Stanford Biodesign project, the innovator is himself/herself encouraged to transform into a commercial entrepreneur. In the Johns Hopkins model, it is the aid agency that picks up the scaling up role. And in the HISP-NHSRC model, it is the technical support institution that supports the uptake of the product into government programmes.

The current drivers of innovation include the following

- i. Industries searching for new markets/products - business opportunities. This includes international companies, which would have substantial markets for such new products back home- like automated BP apparatus, and easy -to- use cheap glucometers, non invasive or rapid testing kits.
- ii. Academic programmes: Institutes of technology that hope to push the frontier of technology, and that seek to make useful products from new knowledge that has been generated.
- iii. Import substitution- which is both a form of cost reduction and an opportunity for local industry .
- iv. Increasing access to technology for rural and remote use. Paradoxically whenever this is done, the simpler more robust design makes it an attractive option even in the urban setting. Reduction of costs as a mechanism of increasing access outreach. This could be done by de-featuring- (reducing unnecessary features which add costs without commensurate use values), or by re-engineering the product. This driver overlaps the first, when it is deafeaturing or reducing costs of the same design, and overlaps with the second when re-design is attempted. Also be reducing the level of skills required to operate it- by removing for example language barriers.
- v. To give new therapies or diagnostic tools- more effective, or safer than current available options. Innovations are often identified with this driver, but in fact it is really a less important consideration. Part of the problem is in identifying areas where such needs exist.

Current Innovation Regime and Constraints faced:

Is the current regime of innovation adequate for our needs? Does it lead to innovating products that match public health and clinical priorities? When innovations sprout, are there barriers to their commercialisation and uptake in public health systems? What are the barriers to innovation itself?

We look at a few well known examples as case studies to understand and discuss the strengths and constraints of the present situation in innovation.

Case Study 1: Government Led Innovation: The Chitra- TTK Heart Valve

The Sree Chitra Tirunal Institute of Medical Sciences and Technology (SCTIMST), founded in 1976, had a clear vision statement: “Become a Global Leader in Medical Devices Development, High Quality Patient Care, and Health Sciences Studies by 2020.” Its organisation was to design an advanced centre for device innovation in a tertiary care institution which also had a wing dedicated to health systems studies- so that the three could fertilise each other. Medical technology was leaping forward and the seventies and eighties were still the period when indigenous S&T capacity to keep pace, and import substitution as a form of integrated technological and manufacturing capacity development as an assertion of national sovereignty was an inspiration. Shri PH Haksar, deputy chairperson of the Planning Commission inaugurated the institution.

The institute has been instrumental in establishing a medical device industry base in India by successfully developing and commercializing technologies of a number of devices and implants. Some of the commercialized technologies include blood bag, membrane oxygenator, hydrocephalus shunt, artificial heart valve, dental materials, hydroxyapatite based materials and implants. It has specific laboratories for device testing, modelling and prototyping, artificial organ development, dental products, polymer processing, instrumentation, precision fabrication, clean rooms for technology packing and dissemination. It has a state-of- the- art section related to biomaterials and it is doing considerable work in this area, as well as in stem cell and tissue engineering. It also has an animal laboratory – but though intended to support researchers nationally is largely adequate only for its own internal needs. An implant biology division gives it a lead role in development of prosthesis.

The Biomedical Technology wing has implemented a quality system meeting international standard ISO/IEC 17025 and is accredited by Le Comite Francais d'Accreditation (COFRAC), France.

One of the first challenges it took up was to develop an indigenous heart valves. Valvular heart disease, largely rheumatic was very common, the burden of the disease was often on the poor and artificial valves were very costly and difficult to get.

The first artificial valves project initiated in 1978 was fully developed and commercialized by 1990. To commercialize it, TTK health care was chosen and they were licensed to manufacture it. To begin with there was considerable problem is acceptance and it took time to build confidence that an Indian product, which was priced much less could be as effective. But once it was established, it became the mainstay of such use, not only in India but abroad in other South Asian countries and in South Africa as well. As of today this heart valve has been installed in over 50,000 hearts. One of its specifications developed was for it to last a life-time, even the youngest recipient and not need replacement- whereas many earlier valves would require replacement after 10 to 15 years. For this it had to go through specially designed accelerated durability tests.

Even now the innovation path is to develop a product, then find a commercial partner and then license and handhold them to commercialize it, and even after successful partnership continue to come up with improved versions of the product to keep ahead in the game.

The big questions of the institute are what is the market share of its products on the domestic market, and what percent of the export market are from its products. Also we need to ask how successfully and in what areas has SCTIMST gone beyond import substitution to leading in innovation for new products –as implicit in its vision? One indicator of this is the number of patents it has drawn and the number and percentage of its patents which are being worked by domestic or international agencies. The answers to these questions should then be linked to the current pattern of needs identification, and to the strategy of commercialization.

Currently we could state, that this is one of the best success stories of a government laboratory leading a program of medical device innovation and developing a global leadership role in health technology development.

Case Study- 2: Industry Led Innovation: GE Healthcare's Healthymagination.

GE Health care has an ongoing programme called Healthymagination. As part of this it will spend \$3 billion over the next six years on healthcare innovation that will help deliver better care to more people at lower cost and a further \$2 billion to drive healthcare information technology and health in rural and underserved areas. These are part of GE's global commitments of reducing costs, improving quality and expanding access for millions of people.

Under healthymagination, by 2015 GE will launch at least 100 innovations that lower cost, increase access and improve quality by 15%. A further 15% reduction would come by working with hospitals on performance improvement tools like the six sigma strategy that would reduce their costs. It is also aimed to increase access to services and technologies by 15%. It would also expand its employee health efforts. These measures are expected to strengthen GE Healthcare's business model and increase the "value gap" between its health spend and GE Healthcare's earnings to drive new value for GE shareholders.

"Healthcare is an important industry that is challenged by rising costs, inequality of access and persistent quality issues," GE Chairman and CEO Jeff Immelt said. "Healthcare needs new solutions. We must innovate with smarter processes and technologies that help doctors and hospitals deliver better healthcare to more people at a lower cost. Healthymagination is our business strategy that seeks to help people live healthier lives, support customer success and help GE grow,"

To reduce the impact of technology on costs, GE will launch 50 low-cost products that offer powerful technology capabilities with simple operation and applications targeted to achieve the 15 percent reduction in costs. These "only what is needed" products will be tailored to areas where access to healthcare technology is limited. The main strategy in this is likely to be 'defeaturing'- simplifying a number of machines by removing features which are not required by users in low resource settings.

Another major part of the innovation is to make health IT faster and more productive, by improving the capability of electronic medical record (EMR) technology and other information technology that speed communications, limit variation and control costs. By

accelerating EMR and HIE adoption, GE expects to help remove \$28 billion in cost from the health system while improving access to better and more affordable care.

To address the health care access needs, GE has created a suite of maternal and cardiac care products for rural and developing markets. GE will expand its maternal infant care product offerings by 35 percent and will invest and scale its work with Grameen Bank to 10 countries by 2015.

GE previously partnered with the Nobel Prize-winning organization, Grameen Bank, and has now agreed to the joint goal of creating a sustainable rural health model that reduces maternal and infant mortality by more than 20 percent. To achieve this, GE will develop low cost products specific to maternal and infant health using the latest technologies and go beyond technology development to co-create clinical protocols, patient workflows, training curriculum and business models supporting healthcare quality and access for the world's poorest women. Neonatology expertise gained through working with GE partners in India - the NICE Foundation & Cradle, Bangalore - will support the future extension of Grameen's rural program to include much-needed newborn care. GE's Lullaby Warmer*, designed in Bangalore for use in developing nations, helps reduce infant deaths from hypothermia and asphyxia. It provides newborns with vital overhead heat and improves access to care through easy-to-use technology. According to the WHO, at least 50% of global births occur in underserved rural settings where access to affordable technology remains limited.

This is an industry driven innovation model which is largely but not exclusively aimed at the private sector. Notably it looks at innovation in technology development and in access to technology as a continuum. In its package therefore is not only business models for maternal and child health to the poorest based on its learnings with Grameen Bank, and what it calls point of care process change in the way services are delivered, but also the application of quality management techniques to hospitals which would help reduce costs by increasing efficiency of hospital performance. The aim of innovation in technology is cost savings so as to reach to a greater market and by the same logic for more people to access the technology. One of their main products is a de-featured simpler more robust ultrasound which can be used in rural areas, though in the current social context that may have its own problems.

The questions of this model could be the same as we asked in the earlier case study. What is the mix between me-too products meant to capture a market (market innovations) and new value innovations? What choices were made in both which need to address and how it is addressed? When innovation needs are driven by cost saving and market extension- what are the sort of gaps that get left behind.

Case Study- 3 Gaps In Innovation : The Non-Invasive Hemoglobinometer.

A non-invasive low cost haemoglobin measurement device that can measure anemia levels instantaneously.

Perhaps the single highest prevalence disease in the country today is iron deficiency anemia. This is also the most easily treatable and detectable disease. It has a significant mortality, especially in pregnancy. The public health programme to address this focuses on correcting it as part of identifying and treating anemia in schools, in pre-school Anganwadis, in pregnant women and in adolescent girls. The current test to identify anemia and classify it into mild, moderate and severe depends of Sahle's hemoglobinometer which is a small glass

tube within which a drop of blood is interacted with a ml of hydrochloric acid of specified strength and then diluted by distilled water till a reference colour is reached. Though it is a simple test, there are three huge problems. First, the logistics of supply of this small quantity of acid to remote schools, Anganwadis and sub-centers is most difficult to manage. Secondly it needs a prick with a sterile lancet, making for reluctance to test again and again, and third the test is liable to wide subjective misreading and the apparatus is fragile and breaks easily. For these reasons less than 20% of facilities who should be doing the test, ever do it, and in schools and Anganwadi centers it is never established. Reliance is this on prophylactic iron and folic acid treatment- but when everyone has to be given, there is a high degree of carelessness and loss of focus, and as a rule preventive doses are of no use when higher doses for treatment are required.

A simple non invasive test preferably one that can run on battery supply would be ideal. There is an easy way to measure the oxygen content in haemoglobin, using a light ray and a spectrometer applied non invasively to the finger tip. By a slight re-engineering the same principle could have been used to measure the haemoglobin. Measuring haemoglobin could then become as simple as measuring weight of a person. Yet this innovation has not happened.

Markets for this are immense- and anemia is a huge public health problem where the public health programme to address it is a non starter. Such an innovation could have made a difference. But yet this did not start up? While the more difficult pulse oximeter is available today , even with telemedicine connection. What could the reason?

A possible reason is that the failure of the public health programme, and the failure to test for anemia by ANMs were attributed to errant workers and poor supervision- even though over 80% were not doing it. The system failed to search for design failures- which it should have been alerted to once the failure was so widespread.

Another possible reason is that technology is perceived as a “given”- a black box- which sets the rules by which the game must be played. The design of the technology itself is not questioned. This test works very well in some contexts- and it is assumed that it would therefore work well in all contexts. Faced with a systems problem in delivery of a technology, few go back to examine the design.

This test was the best available once upon a time. But since it was developed, perhaps in the fifties if not earlier, science and technology have leapt forwards. However there has been no application of these advances to this peripheral use. The intensive care setting attracts attention and investment in a way the needs of the people in the periphery do not.

There have been efforts to improve this test, and there is currently a prototype which is available. But this a priority only for the public health programme, not for advanced private clinics where this is part of the autoanalysers battery of tests. The innovators behind these prototypes have no access to the decision makers. For that matter it is not clear who the decision makers are on such a decision and what is the pathway they will need to take to a) independently test the claim of the innovator as regards its efficiency, robustness, accuracy

etc and b) arrive at a decision to make it part of the public health programme and c) price and procure the product and d) ensuring universal access to the technology.

When discussion for alternatives to this test come up, the available alternative of a cyanmethemoglobin method for estimation is proposed. This test was suggested in the tenth plan, but was never implemented. The reasons are not known- but perhaps they are the same as now for the non invasive test. However, now it brings forth the need to compare between not just two, but three options, and there are no systems in place or institutional mechanisms or capacity to do so.

Case Study- 4. Stanford India Biodesign Programme.

This is collaborative programme between Stanford University, USA and AIIMS, and IIT, Delhi, funded on the Indian side by DBT and supported by corporate partners and the Indo- US Science and Technology Forum.

This programme selects four candidates each year through an open advertisement and interview process- one from each of engineering, medical, design and industry backgrounds and puts them into a one year fellowship programme leading to the development of a completely innovative medical device. The four work as a team. The first six months of their training is in theory. In the next six months, they go through a process of clinical immersion, where they spend time in the hospital corridors and wards, observing and learning and discussing, and come up with a list of close to over 300 gaps from which they choose about a 100 requiring innovation.

Then from this short list they come down to just two or three choices, by applying a few filters. What filters are applied, depends on the programme and context. In the US programme the filters could be profitability for the manufacturer, the levels of risk, the delays in regulation etc. In the Indian programme, the potential positive social impact of the innovation is one of the most important criteria. Lesser requirements of regulatory clearances- given the fact that even the pathway of approvals is often not defined are another criterion. Less investment, less time and less complexity are also filters used, since this is a fellowship programme, where results have to be quick and large teams of scientists cannot be assembled.

Once the need is identified, the next steps is the need specifications and developing a solution, then prototype development and testing with improvements to finalise the design.

After this come the stage of larger clinical trials where they are needed and approvals, and then commercialisation and marketing of the product- or its uptake into public health programmes.

Despite these challenges the first four years of the programme have turned up a few very interesting innovations:

1. A novel device to manage fecal incontinence that improves clinical outcome and reduces operating costs

2. A simple cost effective device to access intra-osseous cavity in long bones to administer fluids and drugs during emergency. – When it is difficult to access veins due to shock/collapse.
3. An easy to apply and robust splint for pre-hospital care of trauma patients.
4. Low cost novel device to screen neonates for hearing defects in resource constrained places.
5. Neo-natal resuscitation; simplifying a life saving procedure.
6. Patient transfer sheet- a simple and cost effective way to transfer non ambulatory patients from one bed to another.
7. A novel device to dislodge mucus to strengthen aspiratory muscles for patients with respiratory disease
8. A trans-illumination device for peripheral vein detection in paediatric patients.

But these innovations continue to face a number of problems with uptake.

To illustrate:

- a. There is no clear authority to whom they must turn for its approval for use in private or public sector.
- b. There is no authority or mechanism in place who/which could approve a new and innovative product for purchase by the government.
- c. There is no easy way to procure these products under government rules. Government rules require a number of bidders applying for an open tender. Though officially single vendor purchases could be allowed in practice there is much hesitation, and price fixation becomes a problem.
- d. These are low cost products and most of these need low pricing – which means profits could come only from large volumes. Either government must commit to placing a large order or the company must be willing for investing a large sum for a low rate of return.
- e. If the product innovation is patented and then sold to a firm, then the firm could develop the patent or choose not to do so- since it has similar, but higher margin products on sale, or could develop it and cost it out of reach for the larger public. Although we associate patented with higher costs- this is not inevitably so. A patent holder could use his or her rights to license it to many, therefore introducing competition. Governments could acquire patents of public health importance and license these to three or four firms against advance marketing commitment- with which initial push they could subsequently develop the market.

Discussion

Student driven programmes bring young minds into problem solving. They also create social and human capital that has great long term spinoffs. However the student driven (PhD) and engineering programs for innovations have serious limitations. The end product in a student programme is a paper. In a innovation programme it is a product that gets marketed

on a regular basis. Significant innovations would require long term strategies and institution building.

Many device requirements could be categorized according to cost into low cost 'Me Too' devices. These could be handled in student programmes, but even these require sustained support for commercialisation and scaling up. Considerable market innovation occurs in this area which could just be allowed.

Medium cost disposable devices are largely market driven. Here the issues are mainly related to regulation for safety and assessment for taking into public programmes. Government has only to enable innovation, but it need not direct it.

Then there are high-cost lifesaving equipments which are relatively inaccessible even in large cities and therefore would require optimal long term funding mechanisms. The SCTIMST is a good example, but we would need many more such institutions or consortium of institutions which could work on a sustained long term basis – one consortium at least for one major area of medical devices. Sustained government funding would be required for high cost life saving equipment development.

The problem with innovation happening within corporate laboratories or even where government choose competitive selection process is that it heightens the mindset and organizational culture of secrecy.

Both national labs and corporate labs have pros and cons. Non-performing scientists could become a drain. Their conversion of innovations to the market has been limited, though in tie-up with our generics-labs like NCL and IICT have made good contribution. Programmes like CSIR800 have made innovations but had limited success because there is no agreed pathway to productise and introduce innovations as products in the markets.

Even in markets (competition) being able to pick up innovation rapidly- different sectors and even different products have different experiences. Mobiles is an example of how rapid such uptake can be. But not every product does so. In health technologies- where regulation, and safety issues dominate, and there is considerable information asymmetry, the ability of markets to do so is limited. It needs some stewardship from the government.

There is therefore in the area of medical technologies, a much greater knowledge commons- a pool of needs and innovation opportunities, knowledge of what worked and unsuccessful innovations, and ideas from across disciplines that can lead to new ways of looking at new problems. But when some of the players would institutionally require appropriating from the commons for a secretive patent based product development, the commons would need to be protected innovatively. Otherwise the affordability of new products was not sure, and there was no way to ensure that patents leading to substantially cheaper alternatives would be worked at full capacity.

The lack of animal laboratories, the lack of biocompatibility guidelines, similar to clinical trial guidelines, for testing in animals were other constraints which not only prevented innovation in some areas, but also shaped choices in what was considered an opportunity for innovation.

Another problem in this area, was of unfair competition from international corporations which have been known to kill research by patent contestations. The SCTIMST's initiatives in blood bags for open heart surgery, an innovative cost saving product was held back due to its threat to a multinational firm's interests. Unfair marketing could also raise questions of safety and credibility of new products and prevent low cost innovations in the market. This is not as much a problem with screening/diagnostic devices, but where invasive or therapeutic procedures (e.g. cardiac stents, implants or staplers) are concerned, patients would be more concerned about quality and given a mindset of superiority of imported products over their domestic counterparts, choose the imported one. There is a role of government in ensuring a level playing field for all domestic and international players – and the best way to do it is by ensuring a transparent quality assurance and regulation system, as well as watchfulness and action against monopoly practices.

The lack of any clear pathway by which an innovator could get a product tested, approved or taken up within public health systems was another major constraint that emerges. These institutional constraints need to be addressed. Government rules that act as barriers to uptake of useful and safe innovations need to be identified and amended to allow this.

Finally service providers and managers in health systems need to have greater skills and capacity for technology needs for health care assessment, as well as health technology assessment. Health technology assessment requires a distinct institutional framework with capacities, much like NICE in UK. Technology need assessment is however a general skill that every health programme manager- mid level and top level should possess.

Needs and Opportunities

One of the aims of the council is to lead to a regime of innovation that is driven by health needs. Not every need or opportunity gives rise to a technological solution and not every solution is an opportunity for commercialisation, or even for publicly financed large scale production. Every technology is a social construct and its successful incorporation into health care practice is also a social process. Nevertheless the starting point must be needs identification.

Needs assessment is a process for determining and addressing the gaps between the current situation or condition and the desired one. Needs assessment for innovation in medical devices, is identifying a gap which available technology does not solve, or where there is a potential for carrying out a current health care function with greater efficiency, effectiveness or quality, or where there is greater access to technology. Each of the needs so identified is a potential opportunity for the innovator.

Given such a definition, what we need, is to put in place a system where health care providers and health systems managers can work with technologists to identify opportunities for innovation in a continuous manner and then as a next step work with manufacturers, regulators and public health systems and user groups to identify which of potential opportunities must be prioritised and how the technology must be shaped so as to fulfil the social need. No doubt many manufacturers would like to be associated with the first stage of needs identification, and to the extent that they are technologists, this could be

useful. However, manufacturers would have existing products and priorities, and a needs identification which interacts with, but is not driven by manufacturers' perceptions has its distinct advantages.

Having said that, in the current context, examining the areas of health policy, the working group and expert group reports leading up to the 12th Plan, and the common review mission reports and other evaluations, the government may however choose to focus its money in two or three areas where it should show results and where there is an immediate policy priority.

Three such areas which emerge on the basis of where needs are most articulated and where capacities for innovation and uptake is much better in place. We propose that these three areas are seen as thrust areas for the 12th Plan and taken together we should make a dent over the 10 year period. We note that there are many other areas like medical imaging, surgical equipment, medical textiles, where there is considerable ongoing research, innovation and development in India and this needs to be supported and encouraged. The three listed below therefore refer to only three areas of public health care priority in the context of the National Rural health Mission.

The **three thrust areas for the 12th Plan** could be listed as follows:

- a. Re-design of the Sub-Center Health Kit (not limiting ourselves to the ANM kit- which is the current set of drugs and equipment provided to the female worker of the sub-center- and around which there has been relatively a greater dialogue.).
- b. Improved Quality of Care in Low Resource settings
- c. Improved Emergency Care- care in transit.

Another thrust area for development over a longer ten year period is "In-Vitro, Point-of-care Diagnostics."

Cluster 1: The Sub-Center kit:

- i. Non Invasive spot testing for haemoglobin levels of anemia
- ii. Automated testing of blood pressure
- iii. Automated testing of blood sugar
- iv. Dip sticks for urine sugar and protein.
- v. Improvements in weighing machine designs for newborn, for infant and children below 5. Could link with height and age and could show the BMI/grade of malnutrition/LBW status automatically. Leaves a record of weights taken
- vi. Rapid diagnosis of fevers which are life-threatening- but admit of specific anti-microbial drugs that could be given by protocol. Includes malaria, kala-azar, typhoid, hepatitis, even diseases like leptospirosis, rickettsial diseases where relevant. In most situations an immune-diagnostic based RDK of the sort that is available for malaria, needs to be put in place.
- vii. Common fungal infections of skin.
- viii. Automated Labour record- partogram included- tablet based?

- ix. Facility Work Organiser – and data base manager- tablet.
- x. M- Health communication tools- the mobile projector and training aid.

Cluster 2: In hospital care:

The thrust areas would be related to improved quality of care in low resource settings:

- i. Innovations for improved patient amenities, patient comfort and safety.
- ii. Innovations for Infection control
- iii. Improved clinical quality of care, through better support systems- ranging from EMRs, diagnosis support, easy access to protocols of care , tele-medicine facilitated consultations, medical audits etc.
- iv. Improved affordable diagnostics for the PHC-CHC level from imaging equipment to immune-diagnostics that are affordable, have only such features as can be used at that level, are robust – so as to achieve the 12th Plan goal of universal and free access to diagnostics for all.

Cluster- 3 : In emergency systems:

- i. Rapid assessment and diagnosis tools
- ii. Patient stabilisation
- iii. Telemedicine/ specialist consultations to support paramedics.
- iv. Training programmes/tools for paramedics in emergency situations.

Cluster 4: In-Vitro Diagnostics

- i. Rapid and reliable tests for TB- good enough to use for screening, and for population prevalence studies. Also with special reference to TB in children.
- ii. Rapid Detection Kits for Malaria- next generation- longer shelf life, more specificity, multiple species tests,
- iii. Rapid tests for etiological diagnosis in common fevers.
- iv. Bites and stings and poisonings- toxicity level measurements and guidance for appropriate treatment
- v. PCR for HIV for infants (currently only >18 months can be tested)
- vi. 5 in 1 test kits for blood banks
- vii. Early detection of DM, arthirits and breast cancer.

In the Indian public health context all of the above should have the following specifications other than high specificity and sensitivity- they should be affordable, should require less skill levels which translates into less training and lesser qualifications, it should be rapid, it should be robust, it should withstand wider climatic ranges in terms of temperature and humidity, and require as little refrigeration as possible, withstand long distance transport, should have a long shelf-life and be easier and safer to dispose.

Ecosystem Requirements

1. For Identification of Product-
 - a. National Registry of needs and requirements, work in progress, new innovations etc.
 - b. Involvement of clinicians and healthcare workers with centers of innovation for identifying opportunities. The role of clinical immersion or field level immersion of the innovator to find the opportunity and conversely the sensitization of practicing clinicians and health care workers to the potential of device innovation as a means of problem solving.
 - c. Look at public health programmes reviews to identify areas of non improvement in implementation of protocols of care or standard treating procedures and go beyond obvious answers to identify technology gaps.
 - d. Also patent searches and market surveys.

2. For Development of Specifications-
 - a. Participatory process where innovation institute-Clinicians-Industry- User community- participate. Ensure gender representation.
 - b. Building up digital libraries with ease of access.
 - c. Database on success and failures

3. Financing of Innovations-
 - a. Joint funding from DST, DBT, DHR, state or national depts. of health. Funds given to about 15 to 20 collaborations/consortiums. Each of these address a package of issues- some long term, some intermediate and some short-term. The minimum composition should be between a hospital network and a biomedical engineering dept and a university with good depts. with basic sciences and a department with public health and health systems understanding. Each of the members of the consortium would have some intra-mural funding for one level of development work. But for the rest it should be related to contribution/expenses that each have to incur.
 - b. Attractive schemes to encourage young innovators.
 - c. Funding to University B.Tech/M.Tech students as part of their programme- upto stage of developing prototype at least
 - d. Long term funding for implants (medical implants take about 7-10 years for development) and commissioned problem solving approaches.

4. Organisation of Multi-disciplinary Teams/Organisations-
 - a. Need to develop Technology Innovation labs which have consultants and mentors for young innovators- and which develop concepts.
 - b. In addition and distinct from the above one needs product incubation center to support commercialization, scaling up and uptake in government centers.
 - c. Computational and analysis facilities.
 - d. Short term courses for new entrants.

5. Prototyping and Testing Materials and their characterisation-
 - a. Need to have access to machine shops, rapid prototyping and moulding facilities to meet the biocompatibility requirements
 - b. Mould flow analysis facilities. Availability of certified biomaterials, sample preparation and test facilities
 - c. Bench top Development evaluation & In-vitro evaluation
 - d. Technology parks & test facilities,
 - e. Testing for safety: Availability of accredited animal testing facilities, Large & Small animal breeding - more scientific and humane set of rules Has to be more scientific while protecting the animal welfare with Long term maintenance of animals. Provision like if no reply is received within three months investigator can proceed with the experiment
 - f. Packing and sterilisation validation, Electrical as well as other safety issues

6. Clinical trials-
 - a. Ethics committee approval – through approved bodies
 - b. Support in preparation of documents, with approved panel of Clinicians and Protocols
 - c. Insurance

7. Scaling Up
 - a. Technology Parks and Training Schools.
 - b. Continuous improvement – need for doing so and being able to provide for it.
 - c. Vendor Development: National registry of vendors, Marketing Incentives
 - d. Commercialisation as approach to scaling up
 - e. Advanced marketing commitments by public sector and uptake of product in public systems as key to scaling up.

8. Regulation and Quality Assurance-
 - a. Indian Medical Device Act: This is proposed by DHR, and DBT.
 - b. Strengthening drug controller offices to be able to undertake medical device regulation: Guidelines are needed for assessment of a medical device manufacturing organisation- both for registration and auditing. The scope of assessment would depend on risk classification. There are four levels A to D. with D having the highest risk – like heart valves, and cardiac stents. Manufacturers need to have certified quality management systems in place. And compliance with essential principles of safety and performance.
 - c. Medical device Quality assurance: Requires Training facilities in Biocompatibility; Good Manufacturing Practices; Clean-room protocols; Sterilisation; Material preparation; Cleaning validation; Package validation, certification of good manufacturing practices.

9. Intellectual Property and restrict trade practices:

- a. Support for identification, drafting & filing of IPR; PCT filing
 - b. Technology Transfer Support for agreement drafting Industrial partnership Panel of Industries:
 - c. Incentives to Industries for/and protection from unhealthy competition
 - d. Regulations encouraging indigenous products
10. Uptake in public sector programmes:
- a. Technology Assessment Institutions- modelled on NICE UK- to comment on safety, cost effectiveness- relative and absolute, contribution to health goals.
 - b. Negotiating procurement rules- purchasing from single vendor, purchase and development of prototypes.
 - c. Post marketing surveillance.
 - d. Develop Technology Needs Assessment capacity in mid level and top level health programme managers. (this is distinct from technology assessment capacity)

Section IV. Information and Communication Technologies

The area of information and communication technologies is innovation driven. There is not only a continuous stream of innovations, both private and public sector has a very rapid uptake. In the public sector, every state government is working on sourcing innovations and putting in place one or more systems. And similarly every division of the health department has deployed or is put in place a large number of IT based systems. This is in contrast to both the situation in devices and the situation in health systems and programmes.

The innovations in this area could be broadly divided into three areas

1. Management Information Support Systems.
2. Hospital Information Systems.
3. Telemedicine and E-learning systems

Management Information Systems:

There are a large number of systems deployed currently in public health management. A tentative list of these is given below, with the caution that the list is not exhaustive.

National Systems

1. National HMIS Web Portal-NRHM*
2. Integrated Disease Surveillance Project –IDSP*
3. National Anti Malaria Management Information System-NVBDCP*
4. EpiCentre –Revised National Tuberculosis Control Program
5. Strategic Information Management System –NACO*
6. Mother Child Tracking System (MCTS)-NRHM*
7. Tally ERP 9- NRHM Financial Management.
8. National Cancer Registry Program
9. Procurement Management Information System (ProMIS)- NRHM
10. Rashtriya Swasth Bima Yojana.

State Specific Systems

1. Gujarat

- a. eMAMTA*
- b. Birth & Death Entry Application & Reporting System
- c. GPS Mobile Van Monitoring System
- d. Drug Logistic Information & Management System
- e. Hospital Management Information System
- f. GVK EMRI 108 – support to emergency response system.

2. Tamil Nadu

- a. Hospital Management System (for District Hospital & sub District Hospital)
- b. Hospital Management System (for Medical Colleges)
- c. Health Management Information System *
- d. IT system for procurements
- e. Pregnancy and Infant Cohort Monitoring and Evaluation

3. **Andhra Pradesh**
 - a. Family Health Information Management System (FHIMS)*
 - b. MDR-TB Tracking System
 - c. School Health Program
 - d. GVK EMRI 108
4. **Himachal Pradesh**
 - a. Hospital Information System
 - b. Name Based Information Tracking System
 - c. District Health Information Software
 - d. Personnel Management Information Systems.
5. **Punjab**
 - a. Mobile-Based Sub Centre Data Reporting System
 - b. District Health Information Software
6. **Odisha**
 - a. e-Blood Bank
 - b. E-Swasthya Nirman
 - c. MHU Tracking System
 - d. Human Resource Management Information System
 - e. District Health Information Software*
7. **Chhattisgarh** - E-MAHATARI and GVK EMRI
8. **Rajasthan**- Health Pregnancy Child Tracking System (PCTS)
9. **Maharashtra** - PHD
10. **Karnataka**-
 - a. Human Resource Management System (HRMS)
 - b. Private Clinical Establishments Regulation
11. **Jharkhand**- Human Resource Management Information System (iHRIS)
12. **Assam (Dhemaji)**- PALNA
13. **Delhi**- Online Birth & Death Registration System
14. **Kerala**- District Health Information Systems

Note: Systems studied for this background paper are marked with asterisk (*) sign. Also note that there are many more district level innovations like PALNA which have not sustained- which does not necessarily mean that there was a problem internal to the innovation. However for reasons of focus, we limit ourselves to the state and national level innovations.

Innovators: In almost all the above examples- the prime movers were government departmental leaderships. The financing was often from development partners, central governments or state governments. A notable exception to this is the EMRI support software which Satyam had made as a central component of EMRI – itself an innovative business enterprise model. Another notable exception is the RSBY, which uses a smart card to delivery the keep track of utilisation of entitlements under the scheme by beneficiaries and ensures that it is capped at the sum assured and also uses it to pay the claims of the providers.

In those that are related to public health management, the role of development partners has been important. HMIS was seen as a key component of sector reform in all the nine World Bank funded state health sector development programmes of the nineties. There was no need to argue or impose this particular component- this was one of the most readily and widely accepted components of the reform.

The key innovators were software consultancy firms like TCS, iBilt, Fergusons etc and the public sector NICNET.

How effective are these? A study of public health IT systems concludes that on the whole all these systems have failed to achieve their own objectives. Their value addition to the process of management, which is the main output expected from a functional system is as yet far from certain. The first generation of HMIS under the state health sector development programmes of the nineties were judged to have performed inadequately across all states- the best progress being reported from Andhra Pradesh and Maharashtra. When the new round of development of systems started up in 2006-07 under NRHM support, all of the states except Maharashtra were non functional. The Maharashtra system was functional but could not be configured to meet the new requirements and even its old data base was not accessible even to its own users.

At the national level a system for malaria was sanctioned in 2002, a system for a more general HMIS in 2007, a centralised tally based system for financial management and PromIS for logistics management in 2009 and a mother and child tracking in 2010.

Every product that has been deployed seems to go through a clear cycle. There is a phase of introduction, rapidly growing into a peak utilisation and then gradually tapering off into a very low level of use where it remains for a fairly long period- before finally being replaced by the next generation product. Our concerns are that at its peak utilisation most systems are no where near their objectives. Further there is a mis-match between the company's perceptions of its targets as having been achieved and the actual use on the ground. The low level of use is usually attributed to lack of motivation, lack of sincerity, lack of supervision, and at best lack of human resources or training.

Case Study 1- The National Malaria Information Management Systems.

The malaria system was sanctioned in 2002, started functioning near 2004, peaked in 2005, when 517 districts had received training and most started reporting. This impressive start was temporary, and it declined soon after and has ever since been at very low level of functionality. Currently only three states, and two union territories continue to report and this too incompletely. The study highlights many reasons for this but one key element we highlight is the abrupt increase in granularity of reporting and frequency of reporting- premature shift to facility based reporting and to fortnightly reporting, which was far out of proportion of the capacity of the systems to manage it, and which led to the decline. Out of a total of 24 mandatory fields only 2 or 3 were ever utilised, and the portal was very difficult to negotiate for even the more dedicated user. Analytic capability was only at the highest end. Finally when the national web-portal came electronic connectivity with it was impossible to establish and for the malaria officers used to reporting on their system, migrating to it was neither possible nor desirable. But administrative interest in this innovation reduced and the system went into hibernation. Currently there are ongoing efforts to replace or renew. The system for malaria improved and at its peak most of the districts were reporting on one of the nine modules that it contained. From which it is declined to only a set of 5 districts reporting incompletely even on this.

Case- Study-2: HMIS National Web-portal:

The product was sanctioned in 2006, became operational in November 2008, peaked as early November 2009, and then remained at that level till 2011 and then has been slowly declining. Its design was to create a portal where every district and eventually every facility could upload its data, directly and online. The web-portal would post analysis of the data on some standard formats, and when required other users could use a SAS analytic engine to do their own analysis. Upto the point when the portal was receiving district level aggregate data its was functional- in that it could receive all the data. Then somewhere offline the data was analysed and posted. A few rudimentary analysis was also provided. The ability of local users to get the analysis they required was never established and its main analytic package SAS was never used even at national and state levels.

Towards late 2010, the system began to insist on direct entry of facility level data into the system- exactly as it happened in malaria. Most states could not or did not comply. But even with those that did comply, the web-portal slowed down greatly. There were problems of hierarchy- which group of sub-centers and PHCs belonged to a block and it was difficult to add in all sub-center data. Often facility level providers who uploaded data did not keep a copy, and inbetween levels had neither paper data to use nor any electronic data- for the portal had only raw numbers. The recent study concludes “report generation is not user friendly. Many reports cannot be seen online. To view they have to be downloaded onto the local disk. User cannot slice, dice or drill down or drill up. Although SAS is a very powerful analytics engine, Web-Portal doesn’t come across as using the power of SAS in the back-end. All the 634 districts were uploading data during 2010-11. The user-base has dwindled after the facility wise data entry was started. Facility level data entry increased the load from consolidated data of 634 districts to more than a lakh sub-center data. The human resource at the district level was not matched to take the increased data entry load, leading to fatigue.” If the main use of the system was to empower local management, wherever this is the sole system- there is a long way to go. If it is policy support then far too much data is incomplete and unreliable and all policy purposes continues to be dependent on DLHS and similiary survey data with HMIS almost never being used. If it is accountability of sevice providers, there is no instance of increased granularity of data having helped this and analysis of facility level patterns at national and state level has never been even attempted. However in that data definitions, indicators, and flow of information has been standardised, and data can be downloaded from the web and analysed and presented in excel sheets or DHIS2, the last five years of HMIS is still a step forward, though far short of its objectives,

Case-study 3: Mother and Child Tracking Systems

Another major effort is the mother and child tracking system. The aim of the system is to be able to record every pregnant woman and track the care she receives and the health events she encounters through her pregnancy, and similarly to track every child through infancy for immunisation. This is often highlighted as one of the more important government initiatives. Over one crore records of pregnant women have been added in. However after a year of

efforts the 5th CRM report cautions that “the MCTS data is not currently integrated with HMIS, and it remains a parallel stream. The huge backlog of data to be entered in many districts, leads to a situation where the data entered is not usable for service delivery follow up. More clarity and systems design inputs are needed at the field level for the high burden of this task to add value to programme implementation.” Further there are even more fundamental questions about the programme and calls for a base paper that spells out- how exactly MCTS would contribute to either improved maternal survival or facilitating service delivery and how it would be integrated with other systems.

There are eight more case studies that the report covers, but these could be taken as typical. An exception to this pattern of innovation and use is the DHIS2 system- but we present that later, after completing the discussion of the main problems.

The problems are the following:

- a. Poor Systems Design:** There is insufficient understanding of the needs and requirements of the system.. Public health leadership is poor equipped to guide them or even articulate their needs adequately. Also the perception of what is important and usable information differs- both at different levels of the hierarchy (block, district, state, national) and of different stakeholders at the same level (statisticians, public health leadership, IT managers, administrators etc). As the desired skills are not available program managers excessively depend on vendor for requirement gathering and system design which may not be in accord with the objective of computerisation. In all the systems developed there is pressure to go on increasing the data collected without reference to use of information. System developers are under pressure to be responsive to client preferences irrespective of their own insights and cautions. Clients are not fully aware of their own needs and these tend to change as they see the system roll out. There is also a mis-match between the amount of data collected, the level of infrastructure(hardware, connectivity) available, the level of human resources (numbers, skills available) and the software deployed. There is no clarity on the level of granularity of data which is optimal, when to use EMRs and the relationship between EMR based data and the use of aggregate numbers in different operations.
- b. Integration** - The need for integration between the public health IT systems was noted by all stakeholders, but was not implemented due to technical and administrative structural rigidities. All the public health IT systems have been developed in silos and they lack integration standards. Also the master data is not tuned for integration. Each IT system has a different way of looking at the master data. Public health data makes more sense when integrated across different programs. There is a need to facilitate exchanging of health information across systems such that the big picture can emerge e.g. Malnutrition data of a block in one system and the deaths and incidence of acute respiratory infection from another system. But in current designs there are immense problems of sharing data with existing systems or even with other systems being deployed in parallel. Newly developing systems start by asking all others to shut down and shift over or just continue in parallel, duplicating the earlier system and doubling the burden of work, such that one of the systems get undermined. Thus the rise of MCTS in Gujarat undermined its own HMIS which till then was generating a very good quality of facility based reporting- just as earlier facility based reporting on HMIS web-portal, undermined the DHIS2 system it had established. Thus the

granularity of HMIS information and use of information Gujarat makes today is significantly less than what it did in 2009!!

- c. Coping with dynamic requirements:** The requirements of most of these systems are never frozen and are constantly changing. This has technical repercussions, as well as adoption, maintenance and continued usage issues. Most public health IT systems were built as an application for a single purpose rather than a flexible product capable of evolving over time. These can't be adapted for any other disease program. With the exception of one product, all the public health IT systems don't provide flexibility for defining data elements, forms, reports etc. Even the system objectives can keep changing. There is no evidence of product life cycle management, configuration management and release management. No evidence of version control for each release. The systems have turned into applications that are constantly in flux. In this respect DHIS2 has a different experience, as it is specifically designed both for responsiveness to local needs and for a dynamic development path.
- d. Administrative Constraints:** Procurement is insensitive to software lifecycle and technology obsolescence. The software development lifecycle documents were not traceable in most of the public health IT systems - requirements document, functional and technical design documents, test plans and test reports. Most of the systems didn't have any documentation or rather the documentation was limited to user manuals. Either the sponsoring Directorate didn't ask for the documentation from the vendor or the vendor didn't maintain the documents. In either case - Technically this is a dangerous situation because it renders the system unviable for the long-term use. A detailed technical evaluation was out of the scope of this study; however except DHIS-2 which has been tested and certified by STQC, none of the other systems had been technically audited. Procurement processes of some of the instances studied are hostile to open source systems as pre-qualification criteria would effectively rule many of the potential suppliers out. There is also no space in procurement to see a product as continuously evolving.
- e. Data Entry Problems:** Currently almost all systems are grappling with poor data entry status. Most systems provide manual data entry interface and no other interfaces are enabled such as Excel, Imports, Mobile, and IVR etc. Users also don't have the flexibility to switch to aggregated data entry when patient based details are not available. Most of the systems also don't have the flexibility to change hierarchy of data entry when disaggregate facility data is not available. User-friendliness on the data entry side is weak with poor and heavy form designs – especially in context of slow speed networks. Forms take a long time in loading on slow connections, and have multiple drop-down and options that need to be loaded from the server. In some systems lot of horizontal scroll forces the use of mouse and thus slows down the work. In a good design, all the forms should be of approximately same length and similar data element types and should take approximately the same amount of time to fill. It's a bad design to have forms of different lengths. A long form should be split into 2 if it needs a lot of scrolling. Long and heavy forms are slow to load on a slow speed network connection. It is frustrating for the user to keep waiting for a long and heavy form to load.
- f. Ability to Serve Local Data Analysis Needs –**

 - i.** In the paper based system, the analytics was not available at every level, but manual aggregation at each level, made for some level of local analysis. But with computerisation even this gets lost. . Data analysis is not geared to meeting needs of the decentralised user –

and therefore they have little to gain, except reprimand if there is poor performance. DHIS-2 alone had this ability.

- ii. Planning, based on this data, at district level is not established for any of the systems. Data flows up to higher levels [Centre, State & in some cases District] and there is analysis capability only at these levels. The lower facilities would be informed only on need to know basis and that too on some fixed formats. Therefore there was no motivation in the lower hierarchy to enter truthful data in electronic systems. Most of the systems are currently working as an accountability tool rather than program management information systems. Even where the product in use had the ability to provide feedbacks, as in DHIS-2. the actual instance of use of this function was very limited, since the culture had not been established.
- iii. Part of the problem is due to the excessive burden of unnecessary data elements and lack of program monitoring indicators in the system. Indicators and reports which are available, merely focus on data entry and reporting completeness rather than supporting program management.
- iv. Wherever the functionality to generate reports is provided, Report generation is not user friendly. Many reports can't be seen online; to view they have to be downloaded on the local disk. User can't slice, dice, drill down or drill-up. Some systems use SAS in the back-end for data analysis. Although SAS is a very powerful analytics engine; but these systems don't come across as using the power of SAS in the back-end.
- v. The systems have fixed predefined report formats. The flexibility to produce your own reports is lacking in the system. Lots of ad hoc reports are required which couldn't be thought of at the time of software system design. The support team spends a lot of time producing these ad hoc reports. Rather an online analytical processing [OLAP] functionality would have gone a long way to enable the users to produce their own reports.
- g. **Data Privacy & Security** - Most of the Public Health IT systems don't follow common data security norms and have not been built with a purpose to ensure confidentiality, security & privacy of public health data. It is easy to identify a community from aggregate numbers; whereas a patient can be identified from Patient based reporting systems. Therefore data security & privacy need to be maintained in aggregate number reporting systems as well as patient based system. Whenever Data Security Bill becomes a law, protecting health data will become mandatory in India. Therefore it is prudent to design public health IT systems to ensure data security and privacy.
- h. **Hardware and Network issues** – Lack of knowledge on hardware, its rate of obsolescence and the build up of systems where it could be periodically upgraded or replaced. Support is also needed for basic procurement and maintenance of computers. Network connectivity below the district level it is problematic in many states, and below the block level it is terrible in almost all states. A much better connectivity is needed if it has to reach upto the PHC and sub-centers level.
- i. **Knowledge Management** : There are resource centers operating in this area, with some useful experience, but typically they are brought in after the designs are frozen, and not before the tender documents are made. Then too they are seen as only an aid to training, and not in decision making . Decision makers are administrators who turn to individual consultants based on their perceptions of who should be knowing about it, or who by the definition is the officer or department head in charge. There is no site of institutional memory, no site where

learning from past experiences are stored, and more likely than not the same mistakes get repeated.

Case Study -4. The District Health Information Systems -2.

This is an open source system, which began its evolution in South Africa in the late nineties and now has different versions deployed in over 15 countries. This product is now also offered as part of a bundle of free and open source solutions offered by WHO for public health management. In India it was introduced in Gujarat and Kerala, by Health Information Systems Project- India, a not for profit organisation set up with NORAD support and collaboration of the Department of Informatics of the University of Oslo.

When NRHM rolled out its HMIS programme in 2007-08, its national technical support organisation, NHSRC entered into collaboration with HISP to introduce this system to provide the tools for district and state level analysis of data. This was to complement the national web-portal which at that time was geared only to receive aggregate data from the national level and which offered no intra-district analytic capabilities. Since the theme of health sector reform under NRHM was decentralisation, such a complementary system was welcomed.

Deployed in November 2008, within a matter of six months, the DHIS2 had been used to bring all data of the year 2009-10, including data of the 8 months prior to its launch into the web-portal. By March 2010, which would be at its peak, over 22 states and union territories were using this system. However by March 2011 it had dropped to 17 and of today there are only 10 states which are still using it as their main system- Kerala, Bihar, Odisha, Maharashtra, Madhya Pradesh, Punjab, Himachal Pradesh, West Bengal, Jammu and Kashmir and Nagaland. Tamilnadu and Karnataka use this system in a more limited way- as an addition tool for analysis and display of data. Still it could well be as an article in Lancet points out- the largest single deployment of open source in public health IT anywhere in the world. However the use has not stabilised. Some of the states that had opted out like Andhra Pradesh and Karnataka are veering back to using it, while others like J&K are still moving out.

The strengths of this system are many and these have been pointed out by the IT assessment study. First all states could customise it and add in their own data elements, create their own indicators and make their own data sets and analysis formats. Secondly it could work both offline and online- though the problems of working offline were many and online was preferable. Thirdly it had very robust and simple analytic capacities which could be easily taught and which could cater to every use as required at the level of the facility, the block, the district or the state. It had also a wide variety of ready to use displays of the analysed data. Fourthly it had no license fee and the customisation costs per paid on the basis of developers time and as a rule would be about Rs 4 lakhs for a state. Fifth the software was part of an international open source network which constantly released new versions with newer features. GIS was added on. The ability to provide information on completion of reporting, timeliness of reporting and utilisation of validation checks by all reporting units were added in—and so on. There was an effective and good version control. Finally there was a strong knowledge management institutional support- to organise capacity building, to create standard data dictionaries, to train reporting units, to produce

manuals and most important for advocacy and change management. With all these strengthen, this should have been a clear winner. That it was not so, is interesting and we need to understand the constraints that act on such a system.

Constraints: One major problem was in the process of procurement and contracting in. Though HISP was already in operation in two states, it got excluded from the development of the national system by the stipulation of a minimum annual turnover clause and because of software development certifications that were asked for. Most open source developers face these problems. It was only because HISP became a partner of NHSRC and because NHSRC did the work for the states without charge, that even this level of scale up had been possible. NHSRC selected it initially on the basis of there being no other person with a ready solution for district level analysis, but it also signed an MOU with HISP where it only paid HISP India the costs and that too piece-rates- for training and development, so that it could be reasonably safe in terms of procurement practice. In 2010 when the partnership was made more explicit, and when there were new products to develop, NHSRC itself tendered for open source developers who could provide solutions starting with the suite of open source products being made available by WHO. Only two agencies qualified. As more and more states got interested it was becoming difficult to find competitors and as a consequence finalising or negotiating rates became a problem. We need to find more innovative ways of allowing other providers to enter, and even of building their capacity. With just one or two providers, fixing rates is also a problem because the whole quantum of work is not always known before-hand and state departments start increasing or changing their requirements with a vendor at hand. Even today it is not possible to procure or cost open source work easily within government rules- and when it comes to participatory technology development based on prototypes- the ideal solution for such systems- the rules become even more of a constraint,

The other major problem was the lack of an electronic bridge between the national web-portal and the DHIS2. The DHIS 2 underwent a rigorous testing and was certified for user friendliness, security and functionality. It meets a number of open standards. But the national web-portal is not inter-operable. The DHIS 2 had to provide an output as a coded excel sheet that was then uploaded into the web-portal. This was cumbersome, but with a number of hiccups, it still worked. When however the web-portal shifted to facility based data entry- uploading over 1.8 lakh facility data was a much more difficult task than uploading 600 district forms- a 300 fold increase in work load. It was not as if most states found it easy to shift to such facility based reporting, and we noted earlier that many states and the system as a whole got set back by this move- as had the malaria system just three years earlier. But this raised the already present demand for shutting down all systems except the dominant web-portal- and many states, for example Chhattisgarh, Karnataka, Gujarat which had been reporting very well even at the facility level stopped. Of course they lost the ability for local analysis that they had and in Gujarat facility based reporting which was well established with feedbacks just collapsed- and the state went back to paper based reporting upto district level, manual aggregation and entry on the district format directly. There were many other reasons given for shutting down the HMIS- for example if the figures were changed directly in the web-portal, they would not change in DHIS2 from which it had been uploaded, leaving a trace of what the original pre-change data was. Or that these are

two systems and duplication, or simply that the web-portal was the official ministry system etc.

If these were the external constraints on DHIS2, there were some major internal ones also. One was that one needed to invest on a continuous basis in troubleshooting and support and upgradation and someone had to pay for it. Further no state invested in IT personnel to manage their servers and to manage the applications on the server. The states who never had to pay for these aspects, could not begin now and the old problems of how to justify such payments became major. Also the level of readiness of the software under such scaled up conditions had been under-estimated and a lot of work had to go into bringing out improved versions. Given the pressures, each difficulty encountered could become an argument against a duplicate system, and there simply wasn't enough space to make mistakes and learn from it. Third the problems related to rationalisation of data elements, organisation of flow of information, recurred during state requests for customisation and adaptation, and often the national resource centers advice on not introducing unnecessary or irrational data elements or some inappropriate features or uses were just ignored by the states, while the IT technical partner felt obliged to go ahead and provided the functionalities requested of it, by the state which was its primary client.

Finally, the capacity to use information had not developed and therefore states which gave up the system under pressures were largely states which had not begun using the full power of the system for programme management.

The good news is that as the problems of direct reporting grow, and as the capacity for local use of information grows, the open source product may make a comeback.

Hospital Information Systems:

There are many efforts to develop this in both the public sector and in the private sector.

Most major private sector hospitals have some software or a set of products in place for functions like registration, billing, laboratory services and so on. In the public sector hospitals in Gujarat, Punjab, Tamilnadu have progressed in this. The ESIC has also made considerable progress in this.

The central challenge is however to build a system that allows case records to be maintained and updated in electronic format, and from this cull out data required for improved hospital management and clinical quality of care as well as health statistics needed for the purposes of public health. This clearly very few have succeeded in doing. The heart of the problem lies around the construction of the electronic medical record- the EMR.

EMR is defined by Healthcare Information and Management Systems Society as an application environment composed of the clinical data repository, clinical decision support system, controlled medical vocabulary, computerised provide order entry, pharmacy and clinical documentation applications. This is used by health care providers to document, monitor, and manage health care delivery within a care delivery organisation. The EMR is also a legal record of what happened in the encounter with the hospital and it is owned by the hospital (or care delivery organisation- CDO- in generic IT language). (In practice the current EMRs are shaped around the needs of billing and insurance and is not as efficient a clinical support or public health tool).

A subset of the EMR, presently assumed to be summaries, like continuity of care record (CCR), is owned by the patient and has patient input and access that spans episodes across multiple CDOs. EMRs are used for quality of care, for generating bills and care statistics, for management inputs and for research and education. Where the same EMR needs to be used across facilities and different hospitals with different IT systems in working, there needs to a standard format of making the EMR. This is also important for insurance companies.

The ministry of health in October 2010, constituted a committee for standardization of Electronic Medical Records. This set up three sub-task groups, for identifying interoperability standards, clinical standards, data sets and specifying hardware network configurations and for specifying ethical, legal and social issues guidelines for ensuring security and privacy of data. Though the draft is ready, the effort is currently at a stand-still.

Telemedicine

This is another area where continuously for over ten years there has been active innovation ongoing. In 2001 the Department of Information Technology, Ministry of Communication & IT, Govt. of India initiated a Project called “Development of Telemedicine Technology and its application towards optimization of Medical Resources.”

- The project was awarded to Center for Development of Advanced Computing (C-DAC), Pune & Mohali and three premier institutes (AIIMS, New Delhi; PGIMER, Chandigarh and SGGIMS, Lucknow). The objective of this project was to develop indigenous telemedicine technology and its validation by three premier medical institutes. Two telemedicine softwares – Mercury® and Sanjeevani® were developed and three institutes got networked with each other and each developed network with one medical college at Rohtak, Shimla and Cuttack respectively. This effort led to technical capacity development in the country.
- Subsequently DIT funded several research and development projects to its own scientific agencies and academic institutions around the country keeping the focus on indigenous technical capacity development.
- Then IIT Kharagpur developed systems for transfer of patient data over telephone lines and brought out a telemedicine software called Telemedik® which was deployed in a pilot project in Tripura and developed another software dedicated to telemedicine applications in Tropic Diseases which was deployed in a pilot at School of Tropical Medicine, Kolkata linking few district hospitals in West Bengal.
- Similarly, C-DAC, Trivandrum in collaboration with Regional Cancer Center, Trivandrum developed software dedicated to Cancer care applications. Media Lab Asia, an agency of DIT focused their R&D project funding on development telemedicine technology for grass root applications.
- Around the same time, the Indian Space Research Organization (ISRO) stepped in to develop telemedicine technology and application models using satellite communication under their societal development focus. In partnership with state governments and corporate hospitals, ISRO developed around 400 odd number of telemedicine nodes across the country in an hierarchical model reaching upto district hospitals in some states e.g. Kerala, Karnataka, Rajasthan and Maharastra. With the ISRO efforts the islands could be

connected to mainland leading to healthcare accessibility to people residing in Andaman and Lakshdweep group of islands.

- For the first time in the history of global telemedicine India could develop innovative models of Telemedicine infrastructure on Wheels based on Indian satellite technology focusing on applications in the national public health problems like Blindness Control, Diabetes, rural healthcare access.
- One of high points of the development of telemedicine has been the development of a National Resource Center for Telemedicine & Biomedical Informatics by enhancing the capacity of the School of Telemedicine and Biomedical Informatics at SGPGIMS, Lucknow. This institution is positioned to be able to provide leadership and guidance and documentation of telemedicine efforts throughout the nation.

“Technically telemedicine involves transmission of information on audio channels, as text, as still images, and as video . It could range from simple speech to heart sounds, from visual images of the doctor and patient, to the real- time CT and MRI images”.

There are many reports of telemedicine efforts from the different states. We list some of the better known efforts below:

1. Tertiary Care Support to secondary Care sites:
 - i. ISRO- Narayana Hridayalaya project- the focus is on cardiology.
 - ii. ISRO – Dept of health project across 11 states- focus was on all specialty care.
 - iii. Telemedicine support to three medical colleges by SGPGIMS and a similar programme for Punjab and Himachal by PGIMER, Chandigarh.
 - iv. Tele-ophthalmology projects by MOH&FW under National Blindness Control Programme- in partnership with Tripura Government, Shankar Nethralaya and Aravind Eye Hospitals.
 - v. Tele-oncology project in Kerala.

There are also important telemedicine initiatives that network advanced tertiary care facilities for sharing information and second consultations.
2. Business Enterprise models that seek to establish new paradigm of primary care through telemedicine.
 - a. Telemedicine model of World Health Partners.
 - b. 104 services of Andhra Pradesh.
 - c. MIT media-lab ASIA projects in telemedicine and e-health.
3. Emergency Response by Paramedic on ambulance supported by telemedicine linkages. (Building on EMRI systems or based on paramedic on motor-cycle – the AIIMS project starting up.)
4. E-Learning Models.

Of late there are changes in the technology in use. For one more and more Communication has shifted from space routes, to the standard internet. Much of the communication can be done on standard broadband but for higher facility networking dedicated lines are required. Mobile telephony with video channels is also possible. Simple

hand held options for recording heart sounds, ECGs, ECHOs and transmitting them over wireless communication have also become available.

5. National Medical College Network: Ministry of Health & Family Welfare, Govt. of India is launching a green field project which is going to link all the medical colleges of the country enabling the medical and paramedical professionals to enhance capacity through distance learning, tele-mentoring, digital library access, tele-surgery etc. using high speed optic fiber back bone of National Knowledge Network (NKN). Six Resource Centers have been identified in premier medical institutions located strategically in six different geographical regions of the country with the mandate to mentor the medical colleges around them.
6. National network for Cancer Care. Ministry of Health has launched a dedicated project for improving cancer care by linking all the 27 Regional Cancer Centers with each other and each with four peripheral hospitals to take cancer to district levels and beyond.

Case Study 1- Tertiary Care support to the District Hospital.

Karnataka Integrated Telemedicine and Tele-Health Project:

Satellite based- the project links select district hospitals to the Narayana Hridayalaya Hospital. If there is an emergency, the telemedicine links allows senior cardiologists to make an assessment and guide admission into a Coronary Care Unit at the DH. If surgery is needed it is taken to the NH Hospital. The telemedicine components consists of being able to transmit the electronic medical record of the patient and recordings made of vital signs and key investigations especially ECG and if possible ultrasound to the specialist and seek a specialty consultation.

This model has been replicated in many instances. This model requires availability of doctors, technicians and equipment that can do the tests and basic examination at the primary care site- and then a specialist available to respond to the request for consultation and provide advice. In the district hospital model the initiative is clearly with the DH and the tertiary care hospital is responsive. The rationale is to close the service provision gaps of a district hospital through telemedicine linkages.

Case Study 2

The model World Health Partners have put in place actually places the headquarters unit in the driving seat with the peripheral service providers as relatively more passive extensions of the center. The peripheral worker, mainly in two districts of Uttar Pradesh, follows a protocol and is guided to do the tests as per an algorithm through a mobile to call center link. The call center is located in South Delhi. A doctor at the call center provides advice. If specialist consultation or admission is needed then the patient is referred to a nearby specialist. User fees are expected to cover running costs of the scheme. The peripheral provider was often an RMP, but could be a paramedical chosen by the project. The rationale was to close the gaps due to non-availability of a basic doctor by using a telemedicine link up.

In the 104 variant, the call center operates to provide health advice and counseling to those who would call up. A mobile van provides fixed day services in villages with a focus on non-communicable diseases. Both of these were to be linked up with telemedicine links to specialists who would add value to the primary care process. Before this phase was rolled out the programme ceased. This was not user fee based.

Case Study 3:

The Tripura Tele-ophthalmology project

Tripura Tele-ophthalmology project was started as a joint collaboration between Government of Tripura, IL&FS Ltd & Aravind Eye Hospitals. Service delivery model has been derived from Aravind Eye Care, project management is being done by the IL&FS and funding support is provided from the Government of Tripura.

There are 40 Vision Centers (VCs) established in each block of the State and are connected to the secondary care center at IGM Hospital, Agartala through intranet (TSWAN) & internet (Tulip). Each Vision center has Ophthalmic Assistant who does primary examination and uploads patient details in the VCMS software. Patient specific data is then reviewed at the IGM Hospital by the specialist, who based on the details and images of eye, diagnose the case and decides on treatment modalities. Simple ophthalmic instruments and imaging instruments are used in the VCs. For patient-wise data transmission software license is purchased from Aravind Eye Care and for Audio-Video chat software license has been purchased from Argusoft Communicate @Work. AMC for the maintenance of hardware, network and VCs is with IL&FS.

The project has basically computerized and enabled by telemedicine, one component of the whole Blindness Control Program – the screening for cataract, diabetic retinopathy & glaucoma cases and this has helped in identification of cases with preventable blindness.

Challenges

Follow-up linkages are weak: It is not possible to identify whether the patient referred to the higher institutions has actually reached there, meaning even if the cataract cases are identified and referred it is not possible to ascertain whether s/he has undergone surgery or not. VCs are functioning vertical to other telemedicine initiatives and other programs in the State and there is no linkage exists between telemedicine centers in SDH & DH and VCs at the block means patients visiting SDH/DH, can't avail eye care services through Tele-consultation. Medicines are not provided in the VCs and spectacles are provided with some cost which increases patient's out of pocket expenditure. Capacity building is not systematic and requires to be strengthened further. Project is based on cheaper technology however one time investment cost of network and maintenance cost is high. Over the years VCs has improved screening, but impact on actual cataract surgeries against target is limited pointing to supply side constraints. But there is clarity on what the project value adds on and for this reason it has achieved its objectives.

Case Study 4

Kerala Tele-oncology Case Study

Kerala Tele-oncology project has started as a joint collaboration between Regional Cancer Centre (RCC) Trivandrum, C-DAC & ISRO. Where ISRO has provided bandwidth, hardware & software for Tele-communication, C-DAC has developed IT application for patient based data entry & transfer and RCC manages the project. The project received funding support from the Ministry of ICT, GOI.

Regional Cancer Centre Trivandrum is connected with five peripheral centers through V-SET for high quality video conferencing and audio-video data transfer. Each peripheral center organizes one day special cancer OPD on monthly basis, where specialist from RCC visits these peripheral centers. During patient examination, the specialist does Tele-consultation if s/he requires expert opinion. Patient records are transferred electronically from the RCC to peripheral centers as and when patient visits the peripheral centre for follow-up care. For patient-based data entry, C-DAC has developed software and for picture and video data transfer licensed PACS software is used, both software are not integrated and function parallel to each other. Project functions on V-SET connectivity with additional ISDN connection as back-up. In addition each center is connected through Kerala State Wide Area Network (KSWAN) for access to the application and server at RCC.

Project supports follow-up cancer care for those patients who are staying far from RCC. Project also helps in cancer diagnosis, follow-up services, side effect monitoring and pain management besides appointment scheduling for RCC. Developed as hub & spoke model; RCC Trivandrum functions as hub & five peripheral cancer centers work as spokes. From spoke patients can communicate to the doctors sitting in the hub.

Challenges

Telemedicine services are not utilized to its full capacity and are mostly used to support follow-up care, which was already going on without telemedicine also. User fee is charged for every service except Tele-consultation. No protocol for the program implementation is in place moreover also no program management structure in place hence there is no routine program review mechanism. The entire project is functioning vertical to other District health system and there is no integration exists. There is a need for continuous capacity building.

Constraints and Issues:

Telemedicine appears to be an area where there is active linkage between government, academics, and private sector. The number of patients handled through this chain are impressive. However despite the advantages, telemedicine also shares the problem of an initial euphoria and rapid expansion, followed by a slow decline and major problems in sustaining it.

Telemedicine as tertiary care support to secondary health care seems to have worked best and longest. There is a much higher degree of capacity and both ends of the communication channel. This includes human capacity, organisational capacity and technical capacity. Both the district hospital and the tertiary care centers have the skills, the equipment, the infrastructure and the connectivity for it to work. Is the lack of sustenance due to a lack of a business model? Why does the initial interest wane off? Or is the need for such support and what can be done with such support more limited than the projection of such need?

When it tries to support primary care, there are problems of capacity at both ends. Connectivity is weak at block level and almost non-existent at the PHC and sub-center level.

Skills too are weak and equipments and infrastructure in the old models were costly and difficult to establish. However with Skype and equivalent becoming so readily available, it should be possible to link the primary care provide- doctor or nurse with the basic specialist at the CHC or district hospital or in a unit created solely for this purpose.

Here the next challenge would be the culture of providers where they seek to investigate and affix causes, rather than rely only on symptomatic care and excessive referral.

That applies to the public sector? What is the relevance of a business enterprise model linked to a call center? Could it sustain? Would it serve the purpose of provision of health care. This we do not know as yet.

Telemedicine as e-learning certainly has a future- especially in any scenario of continuous medical and nursing education. Every distance learning mode could be substantially improved by e-linkages. The challenge here is to institutionalise continuing medical and nursing education itself. Also a general programmes of skill upgradation and reinforcement. However e-learning will not be a substitute to class room interactions, much less to mentored, supervised skill learning. What it does is add value to usual class room and clinic based learning. It systematised learning and ensures a core message transmission, it makes for better evaluation and identification of gaps, and can provide a much larger access to learning situations than the usual ward rounds.

Needs and Opportunities for Innovation in ICTs

There is a tremendous scope for innovation in this area. At least the following essential functions of a public health system and of related departments need to be computerised. These could be clustered into five overlapping clusters. All of these are urgent needs- and in many states there is ongoing work to develop these. The point is how to make it more productive and sustainable than has been the experience in the past.

Cluster- 1: Epidemiological

- i. Registration of births and deaths with special emphasis on maternal and child mortality- as also disease specific mortality beginning with notifiable diseases and those of national health programme importance. (linked to registrar of births and deaths)
- ii. Disease surveillance to detect and act on disease outbreaks and epidemics as well as to assess burden of disease in different areas and communities. This is based both on specific disease reporting as well as on hospital based information on morbidity and mortality.
- iii. Nutrition surveillance - Monitoring under-nutrition and wasting and acute changes in nutritional levels.(linked to ICDS programmes).

Cluster- 2: E- Governance: Decentralised Health Planning and Management:

- i. The critical information requirement in this is a record of services delivered, and the nature of morbidity and mortality encountered. Ideally it should cover service delivery in both public health system and in the private sector. This helps estimate

burden of disease and better allocation of human and financial resources as well as director supervision and support activities. Placed on a GIS platform it could identify geographic concentrations- endemicity- of disease.

- ii. As collateral to this effort such a district level information system would also be able to generate the data on service delivery and progress on national disease control programmes needed for planning at national and state levels. Necessarily this would be linked in the least to human resource management, and financial management and drugs and supplies logistics- as well of course to hospital management information systems.
- iii. Human resource management within the public health system- recruitments, deployments, salaries, transfers, postings. More important would be linkages to services delivered and workforce performance.
- iv. Financial management – from resource allocation, resource transfers, accounting and utilisation to financial services – making of payments to facilities, providers, beneficiaries.
- v. Logistics: Management of drugs and supplies procurement and logistics and equipments purchase, installation and maintenance.
- vi. Support regulatory functions of the state- by creating a nation-wide registration of clinical establishments, manufacturing units, drug testing laboratories, licensing of drugs, approval of clinical trials.

Cutting across these 6 objectives are two more- which are equally important principles of design: The systems deployed must reduce the burden of work of Service providers in record keeping, and easy retrieval of records relevant to their Work. It must improve transparency of government systems.

Cluster 3: Improved Quality of Care:

- i. Provide electronic medical records that could be used to improve the quality of care to patients, and support referrals of patient from primary to secondary and tertiary care centers and more important enable their follow up at primary care levels after specialists consultations.
- ii. Provide electronic medical records to support the development of registries for disease specific programmes- in particular cancers, blood dyscrasias, organ retrieval and transplantation programme, renal failure, and even mental diseases.
- iii. Hospital Information systems would also – as an additional gain, improve hospital administration and provide data inputs to the district health management information system
- iv. Support to emergency response systems and referral transport arrangements and blood banking.

Cluster 4: Improve public and provider access to information:

- i. Provide a platform for continuing medical education and nursing education and skill upgradation. This includes many aspects of telemedicine.
- ii. Improved access of public to public health information and of individuals to their own health records.

Cluster 5: Telemedicine.

- i. Telemedicine- tertiary care support to secondary care providers.
- ii. Telemedicine- as secondary care referral support to primary health care.
- iii. Telemedicine- in the emergency transport setting

Eco-system Requirements:

1. Administrative- clear guidelines for procurement with model tender documents which allows for prototype development approach, for long term dynamic products and which provides at least a level playing field if not a preference for open source solutions. It should also make it less required for the public health sector to seek funding support from international aid development agencies, on these grounds.
2. Putting in place a National E-architecture blue-print to which any development in this sector must conform. Such a blue print would specify in the least:
 - a. Data definitions and Standards for data quality,
 - b. Standards for interoperability- for EMRs, and for transmission of aggregate numbers.
 - c. A Data Policy: How long to store data, in what format, who has to be allowed access, what safeguards for privacy, what is the ownership over the information.
 - d. The creation of information warehouses, with or without portals, at the district, state and national level- at least- to enable users of information to be able to get information from multiple sources. Also for these warehouses to allow entry of information through multiple means- in the form of direct entry, in the form of excel sheets, and other standard formats as specified.
 - e. Information requirements of the national level, along with systems of verification, and the degree of granularity of data sought.
 - f. Information requirements of the public domain- the principle should be Ensure that service providers who report on data would only have to provide data at one format/data entry screen- and from that screen different systems can electronically acquire the data that they require
3. Capacity- Building:
 - a. Encourage more courses and qualifications on health informatics- as a combination of skills in public health, information technology, evaluation methodologies, demography and statistics.
 - b. Build up teams, located in suitable institutions, who are able to play the role of resource persons/designers, trainers etc, for health information uses.
 - c. Build up institutional and regulatory framework- enabling rules and guidelines, by which there is clarity on who is responsible for which sources and verification of information, for aggregation, for display and dissemination.
4. Connectivity: Build up a optical fiber based connectivity between all health care facilities, as well as a mobile/wireless connectivity- both of which are robust and broad band enough to allow sustained transmission of video packages. Satellite communication will have limited supplementary use to remote facilities where even mobile transmission has not been established and as a back up to wireless and broad band.

Ultimately a dedicated health grid on cloud for national e-health programme may be envisaged.

5. Build a system for testing/evaluation/certification of software products and applications. For this reason insist on functional design, and technical design documents of each product as well as a statement of project objectives. This is not licensing- but at least the buyer would know the quality of products received and this would help low cost open source vendors to enter the market.
6. Ensure every innovation in this area is objectively evaluated in terms of how well it met programme objectives and how this in turn improved health care or health status or the efficiency of health systems.
7. Build up resource centers who can interface between IT developers and public health users and clinicians to ensure that the needs assessment is well made and that there is institutional memory of past experience and learnings that go into the design of new systems. Also which keep themselves abreast of technological developments in this area and which are able to share evaluations and learnings from innovations all over.
8. Adequate financing- that looks not only at start up costs – but costs over a five year period or longer and estimates for continual upgradation and capacity building.
9. Strategies of scaling up successful prototypes. The prototype or pilot itself should be on a scale and design that lends itself to scaling up.
10. The work of developing prototypes should take place in parallel in all the 5 clusters with a nodal center for each of the 5. To develop fast, but surely without the wastefulness of past efforts, it may be useful to sanction 5 prototypes in each of the clusters in different parts of the nation, learn from them and go to scale. This approach could build on what already exists and also allow space for new de novo initiatives.

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Section V:1 Health Systems and Programme Innovation

Defining Innovation in the context of health systems

Given the ongoing challenge of poor health indicators across the country, the wide divergence of capacity, competency and context and the multitude of actors in the health field, there is an almost constant emergence of “innovations” within health systems to improve health care outcomes.

Innovations in pharmaceuticals and in other medical technologies make a difference only if health systems and programme designs can ensure increased access to such technologies. Given the fact that most existing causes of ill health and cures thereof can be addressed by existing technologies, improvements in access to these could lead to significant improvements in health outcomes. And improvement in access depends on programme design and on the architecture and functioning of health systems.

There has been some discussion on what would be the definition of innovation in the health systems context. Not every change is an innovation. But a change (incremental or transformational) which (a) meets a need or solves a problem; (b) is creative – involves a new approach or a new application of an existing approach; and (c) brings significant benefit to one or more groups can be called innovative.

“A health systems or health programme innovation is one where the model, or practice demonstrates a solution to a hitherto unsolved problem in a specific context, if it contributes to new knowledge in the area; if it is able to be successfully scaled up within large and complex health systems (even if it is locale specific) ; and any adaptation for local context is achieved with little loss of effectiveness”.

An innovation must be based on new knowledge and/or a different approach to addressing a known constraint in programme design, implementation or health systems functioning. Innovations related to service delivery could be a comprehensive business model, or could involve select elements of the implementation chain. An innovation need not be altogether a new idea, it is possible to have some elements which are new combined with existing elements, or a different configuration of the existing elements. But mere replication of an existing model in a new area cannot be construed as an innovation.

Thus for example, addressing workforce issues through increasing salaries or expediting recruitment by the public service commission, or rotational postings, or compulsory rural postings do not qualify as innovations. These measures are necessary, but they are not sufficient to create the change. An example of an innovation in addressing workforce issues is seen in the state of Himachal Pradesh where a package of financial and non financial incentives for doctors was able to demonstrate significant reductions in high vacancies. Likewise a legal enactment in Karnataka to ensure a rational and fair system of transfers is also an innovation. Here, the institution of a transparent, efficient and fair system of a web based roster of employees and vacancies was employed to ensure that postings and transfers were made without bias. Yet another innovation in addressing the issue of

workforce constraints is seen in the state of Haryana. Here the state, employed “walk in interviews” for recruitment of specialists and doctors. The role of the public service commission was only in confirming and formalising appointments instead of doing the actual recruitment which had contributed to long delays.

Too often individual zeal in enabling action, such as an efficient administrator begin able to implement rotational postings, or organizing a public event such as a *health mela* to raise awareness about health services or even provide selected services, may represent an interesting activity, but cannot rightfully be called an innovation.

Positioning the role of innovations in health systems strengthening:

The immediate questions that arise consequent to this discussion are these:. Are the distinctions made above mere semantics? What purpose do they serve? Does it matter whether this is an innovation or not? How important is innovation or the lack of it critical to health systems strengthening?

We postulate here that health systems improvements and effectiveness of health programmes could occur because of one or more of the following:

- a) Increased Investments: Financial and/or Human resources
- b) Improved Administration: doing the obvious and the routine, but using management resources more efficiently.
- c) Institutional Reform and Institutional Capacity Building: Changing the rules of the game and enabling more effective performance of institutions.
- d) Innovation: Going beyond the obvious, and creating knowledge resources

These four elements is interdependent, but also has an independent effect. Each of these four is necessary but not sufficient in itself. Thus at any level of investment, improved administration, institutional reform and innovation, can each lead to improved results. Similarly there are many problems where increased investments are not enough and even the most determined and competent administrator cannot solve the problem without innovation. Innovation could be impeded by institutional structures but facilitated by reforms. There could be innovative institutional reforms too, but not all institutional reforms are innovations and vice versa.

This note discusses how innovation has contributed to health systems strengthening and improved programme outcomes and where more such innovation is needed. It also described the enabling factors for successful innovation and the constraints or barriers that need to be overcome.

We examine a set of “successful” innovations to identify the key drivers of the innovation, understand the context and environment within which such innovations arise and are implemented, and the constraints they need to overcome to be called successful. One criterion that has been used to call an innovation successful is (Samuel Paul’s) “the potential for scaling up to national or global levels, a long lifespan, and multiple agencies identifying

the program as successful". We compare these examples of innovations with others which were not successful in that they either did not sustain or failed to scale up.

Health Systems Innovation Databases:

As a starting point, we reviewed existing innovations databases to understand what had been included in these data based and the rationale for inclusion. We could identify the following databases:

1. PROD data-base : Created under the European Union's - Sector Investment Programme, it is managed by the Central Bureau of health Intelligence, with participation of the Indian Council of Medical Research (ICMR). It has not been updated since 2007. The entries in this database focus on health systems innovations. It has 18 categories and 208 entries.
2. USAID data base of 36 entries, focuses on community level interventions and those that involve public –private partnerships. The USAID funded Vistaar database also conducted an evidence review of innovations in maternal, newborn , child health and nutrition. .
3. Extracts from NRHM PIPs- proposals for funding under NRHM/RCH-II Innovations budget line.
4. MOHFW's Directory of innovations: supported by DFID: This included seven categories, and had 229 entries. All themes in this database corresponded to those in RCH-II and NRHM Framework of Implementation, and was completed in 2008. There are also databases from Assam (16 entries) and Madhya Pradesh (19 entries) which list innovations in several areas of health systems without categorisation.
5. Health Market Innovation Directory: - 2011: Directory compiled by Center for Health Market Innovation- an organisation which is part of the Washington Based Results for Development Institute. This profiled 1015 innovations across 107 countries. Of these 356 related to organising delivery, 234 to financing care, 79 to regulating performance, 468 to changing behaviours and 45 to enhancing processes. (with some programmes represented in more that one group). In terms of themes- 264 were on general primary care, 256 on HIV, 190 on family planning and RH, 181 on MCH, and about 60 each on TB and malaria and a lessor number of a larger ranges of themes. Of the above list 215 were from India. Summarising the study notes five innovative models which appear round the world (the examples below are all from India)
 - a. Generics Pharmacy . Medplus, India with 880 outlets and Like Jan Aushadhalyas.
 - b. Affordable Primary Care clinic chains- usually hub and spoke wit a central cilinic.
 - c. Vouchers for health services- purchasing specific services from the private sector.Eg Chiranjeevi:
 - d. Telemedicine used to provide medical care from a distant node linked to peripheral para-medical workers: Eg World Health Partners, E Health Point.
 - e. Health hotlines: Mera-doctor,

Most of the innovations recorded from India, are NGO led and usually donor financed. Very few of the innovations in this list have gone to scale. The few that are on scale are government led and did not begin as a small scale innovation.

Findings from review of databases:

- (i) Of these data bases the relatively more robust data base was the MOHFW directory of innovations. Relatively more recent than the others, it was intended to assess the scalability of the listed entries. This Directory included 229 innovations, which spanned the areas of improved service delivery, through improved access, multi skilling of health care providers, provision of incentives, expanding the package of entitlements for mothers, community participation, enhancing the involvement of local government in health service promotion and delivery, strengthening health systems through improved procurement and logistics systems, health management information systems, social protection through insurance and contracting of services to NGOs or the private sector.
- (ii) The focus of innovations studied in these data bases was essentially on maternal and child health services delivered through the public sector or through public private partnerships and HIV/AIDS. For maternal health the emphasis was largely on interventions surrounding the processes of labour and delivery. There are hardly any listed entries for the so called neglected diseases or neglected populations. Gender and adolescent health (school health and outreach services) are covered but have very few entries. Issues such as intersectoral convergence also get short shrift. The database also did not include private sector initiatives, communicable and non communicable disease. Partly this was because a majority of the innovations listed in the database were developed in response to the flexibility of programming and financing that was accorded by the NRHM and RCH 2 flexi-pool approach. The innovations were all in the context of substantial investments from national and state levels on improving the health infrastructure, strengthening health systems, promoting social mobilization and community participation, enabling decentralized health planning and implementation, incentivizing performance and quality to retain and attract human resources, and strengthening programme management and monitoring. Architectural correction was an NRHM purpose and NRHM was actively gathering innovations many of which were pre-NRHM for incorporation into NRHM.
- (iii) Some innovations spanned several states, while many were state specific. Though Innovations are reported from all states, there were higher number of innovations being tried out in Tamil Nadu, Chhatisgarh, Madhya Pradesh, Andhra Pradesh, and some of the North Eastern states. The state of Tamil Nadu has a strong public health system and all the innovations implemented here were led by the state, with no funding partner or external donor. In Chhatisgarh and the NE states, the presence of the EU supported Health Systems Reform project was an enabler and the presence of a concomitant strong Regional or State Health Systems Resource Centers appear to be key drivers.
- (iv) Public private partnerships or different forms of engaging with the private sector are another major category of innovations. These included contracts for management and maintenance of facilities, especially in remote areas, emergency response and referral transport systems especially for obstetric care, and purchasing specialist care from available private sector units. The stimulus for such contracting out at least to the private sector in some states appears to be external donor support, as in Uttar Pradesh, West Bengal, Madhya Pradesh, and Assam, supported by USIAD, DFID and the EU. In contrast contracting out PHCs to NGOs appears to be a state led innovation in Karnataka, Arunachal Pradesh, and Meghalaya.

Implicit in the choice of what made the above list as an innovation, is that it is small scale, implemented within the public sector, with the potential to be scaled up. Such a definition is too restrictive. Many of the large newly designed programmes -those that went to scale from the outset- either supported by corporate finance, or because they were introduced as a policy imperative from above do not make the list. In actual terms of extent and budgetary allocation some of these may be much higher spends than scaled up version of a pilot innovation or small scale intervention.

The notion that “best practices happen” through practitioner innovation, then attract the attention of policy makers, and are supported for scaling up by governments may be desirable- but in practice could it be the exception rather than the rule? We needed to explore this further. . We also noted that many innovations were not best practices waiting to be scaled up- but rather local adaptations of scaled up programmes in other contexts. Our approach here is not to categorize and assess the scalability of innovations. Our focus of analysis is on identifying the pathways through which well known innovations, have successfully gone to scale and analysing the reasons on why this took place. We then compare these with innovations that have not been scaled up. We limit our review to the last ten years, and go beyond the examples we found in the databases.

Innovation Pathways:

We detected a few general patterns that lead to innovations and new programme designs. A pathway is taken as a particular correlation of the innovators, (individuals and institutions), the gatekeepers, and the financing sources. We also consider the perception of these players on the need, objectives and mechanisms of innovation, the validation of the innovation, and finally the scaling up. The four major innovation pathways we identified include:

- a. The “Best Practices” Pathway: Innovations are developed at local level (district or below), either consciously as a planned effort by a knowledge agency to find a solution to a problem or by an implementer to overcome a constraint. The agency could be an NGO, district officer, or private concern. The innovation gets noticed, generalised and then is adjudged as having the potential to scale up. Sometimes it does scale up, but often it does not. The nature of the innovation ranges from just the tweaking of a programme component, and sometimes it is a relatively comprehensive alternative model of producing a health outcome or delivering a service.
- b. Business Model Pathway: This is usually, corporate or private sector led, and appears to be based on the twin objectives of addressing an area of need and enabling a profit through creating a market for the innovation.
- c. Policy Priority Pathway: Development and scaling up of new schemes by government in response to policy priorities. Here the logical pathway is that of development followed inevitably by scaling up.
- d. Local Adaptations Pathway: This pathway is often seen in local adaptations of large scale programmes, where a context specific innovation is developed in response to a local constraint.

Examples:

1. Best Practices Pathway:
 - a. Small scale NGO innovations that were subsequently scaled up: examples:
 - i. Gadchiroli approach to Home Based Newborn Care. (HBNC)
 - ii. Purulia Sick Newborn Care Unit (SNCU) model
 - iii. Multi-skilling for Emergency Obstetric Care
 - b. Small Scale innovations which did not scale up:
 - i. The Nabrangpur referral transport model- (local govt led)
 - ii. Transport of slides for malaria testing by Jan Swasthya Sahayog (JSS) (NGO led)
 - iii. Voucher scheme- Haridwar and Agra, Kanpur- (External donor led).
2. The Business Model Pathway
 - a. Emergency Management Research Institute (EMRI), Emergency response system model (led by a corporate business house, as a non profit venture)
 - b. The Health Management Research Institute (HMRI): Mixed method approach to expanding service access (Corporate- not for profit model)
 - c. Arvind Eye Hospital- Corporate- not for profit model
 - d. Janani programme- Corporate- not for profit model
 - e. MerryGold scheme- External Donor led)
3. Policy Priority Pathway: all state led
 - a. Enterprise models:
 - i. Chiranjeevi Scheme: contracting services to the private sector
 - ii. Rashtriya Swasthya Bima Yojana (RSBY)
 - iii. Velugu
 - b. Programme Design Innovations:
 - i. Integrated Management of Newborn and Childhood illness (IMNCI)
 - ii. Janani Suraksha Yojana (JSY) and Janani Shishu Suraksha Karyakram (JSSK)
 - iii. Introduction of Gambusia, Long Lasting Insecticide nets (LLIN) for malaria control programmes.
 - iv. Directly Observed Therapy, Short Course (DOTS) for the treatment of tuberculosis.
 - c. Health Systems Innovations
 - i. Tamil Nadu Medical Services Corporation (TNMSC)
 - ii. Retention Schemes for skilled health professionals-
 - iii. The Mitanin and ASHA programmes.
 - iv. Establishing Quality Management Services in public hospitals.
4. Local Adaptations Pathway
 - a. Boat Clinics as mobile medical units to reach riverine islands on the Brahmaputra.
 - b. Maternity waiting homes for promoting institutional delivery in remote tribal areas.

Understanding the Pathways of Innovation:

1. The Best Practice Model:

One of the most well known pathways of innovation is where a small scale pilot provides a proof of the concept or demonstrates the possibility of alternatives. This “best practice” is then scaled up. Much of the literature on innovation considers what factors lead to the emergence of such best practices, and what a health system can do to identify and scale it up.

Case Study- 1: Gadchiroli model of Home Based Newborn Care (HBNC) and scaling up to a national level.

This innovation is a classic example of how a small scale pilot to address the specific issue of high neonatal mortality, implemented in 30 districts of a resource depleted district in Maharashtra was scaled up to the entire country. The originator of the innovation in this case was an NGO, Society for Education, Action, and Research in Community Health.(SEARCH) led by a couple, both public health professionals with specialist clinical skills, inspired and guided by Gandhian ideals. The essence of the innovation was the provision of care for the newborn within the setting of the home, through a trained community health worker (CHW) which resulted in a 60% reduction in neonatal mortality. The genesis of the innovation lay in the fact that the period for vulnerability to sickness and death of the newborn spanned the first week of life to the first month of life, that recognition of illness required a certain skill set, and that facility based care was beyond the geographic or economic means for poor rural families. The original model comprised training CHW in a set of interventions including what are considered “medical” skills, that of antibiotic injections for sepsis and management of birth asphyxia through the use of a bag and mask. It also included a strong element of on the job mentoring, monitoring of case records and formats, supervision, regular provision of supplies, and payment through a performance based mechanism. The innovation was scaled up first by other NGOs and then through state support in a number of blocks. Both were evaluated and demonstrated effective reductions in neonatal mortality. . Published internationally, and disseminated and championed at various national fora, the HBNC was listed as a major component of the XI Five Year Plan and a key strategy for reduction in Infant Mortality Rate. Despite all this, it was formally included into the ASHA programme only in late 2010. The terms of inclusion even then, were a modified model in which the components of sepsis and asphyxia management were dropped. The training of ASHA in providing HBNC, and the provision of an incentive of Rs. 250 for a set of six visits form the core of the scaling up strategy. Three key elements that appear to have led to scaling up is the recognition that despite increases in institutional delivery a substantial proportion of newborns tended to die at home, the availability of 800,000 ASHA that provided the delivery system for the innovation and the learning and confidence in scaling up from the Mitran programme. All in all it took 15 years and overcoming a high degree of resistance from both professional concerns and alternative models of HBNC with its own champions and alternative programme theories of the ASHA before HBNC was finally scaled up.

Case Study- 2: Purulia Special Newborn Care Unit (SNCU) model:

In 2003, with support of UNICEF the neonatology department of the BC Roy Medical College in Kolkata took up the development of a intensive newborn care unit in Purulia district hospital. Faced with a human resource crunch they had to improve skills of existing medical officers and develop a cadre of para-nurses to supplement the scarce nursing strength that was available. Using appropriate intensive care practices and protocols, they demonstrated that a substantial reduction in neonatal mortality could occur through an appropriately designed Special Newborn Care Unit.

Scaling up of this model was slow. Even though this model was well established in 2005 when RCH 2 was being designed, the Purulia model was not included, since the rationale for provision of facility based newborn care in the RCH 2 design was that the state would successfully be able to recruit private providers to play this role. This proved to be a false assumption, and by 2008 SNCUs in public health facilities became part of the planning processes. In 2009 UNICEF developed a guideline to enable replication of the SNCU. From 2009 it became an integral part of the programme, but it was only in 2010 that scaling up to every district became the official plan; even in West Bengal where the proof of concept was first established. Purulia functioned as the inspiration and training ground for scaling up..

Case study -3: Referral transport for malaria slides:

A key constraint of the malaria control programme is to ensure timely examination of blood slides (from the village) to better guide treatment and public health action. The time lag of seven often 14 days between the time the peripheral worker takes a blood smear in the field and obtains a report, is often too late for either improved clinical care or for public health action.

The Jan Swasthya Sahyog (JSS), a NGO working in the district of Bilaspur in Chhattisgarh, has a field area spread over an entire block, and with its laboratory and headquarters located some 10 km from the town of Bilaspur. JSS entered into an arrangement where village volunteers who made the blood smears sent it to the nearest bus stop (of local buses). The staff of these buses were instructed to get the smears to the laboratory. The report of the slide followed the reverse direction and the volunteer was able to get the report back on the same evening.

This innovation was highlighted in the 11th Five Year Plan document- and was disseminated within Chhattisgarh by SHRC, but it almost never replicated. Part of the issue was of course that rapid diagnostic kits had been introduced and the government attention had shifted to this.

Case Study- 4: Referral Transport in Nabrangpur, Odisha.

A key barrier to women's access to institutional delivery is the availability of transport that is affordable, readily accessible, and is able to shift women from home to facility within a maximum of thirty minutes. Innovations to address this barrier abound in the country, with state governments either expanding their own emergency transport fleet, (Kerala) contracting out the entire operation to the private sector, (EMRI) or using private sector vehicles but retaining the management within the public health system. The Janani Express scheme in Nabrangpur district of Orissa, is an example of the last mechanism. This is an innovation that was piloted in the district, by programme managers who used locally available solutions to address a key barrier. A recent study³ drew our attention to the fact that in Nabrangpur nearly 68% of all pregnant women that accessed institutional delivery had used these services in comparison to only 5% to 25% in all other districts studied, some of which had much more expensive and elaborate options.

The set of activities through which the district was able to ensure this level of usage includes: a systematic zoning of locations- villages and facilities, to plan for positioning of one vehicle within half an hour distance from most villages, ensuring sufficient density of vehicles so that there are at least four to five in each block; contracting local private vehicle owners, location of a vehicle in the district hospital and CHCs and in 22 of the 32 peripheral PHCs, provision of cashless service to the beneficiary so that they are not required to make any payments, creating a mechanism so that the amount of Rs. 250, (the transport component of the JSY) is deposited into the Rogi Kalyan Samiti account so that no additional funds are sought for some the district, fixed rates for each vehicle based on facility distance, focused publicity and local networking by ensuring that the ASHA, beneficiary, transport provider, ANM and health care facility in charge are all linked by mobile numbers and can coordinate action, and finally , a blended form of financing package that includes a fixed monthly rent and reimbursement for recurring costs and fuel charges which appear to be a sufficient incentive to retain interest of the vehicle owners in the programme.

The core of this innovation is the ability to use public financing to create a business model but one that is regulated by the system to ensure universal coverage, speedy access, and free to the end user. No doubt the success was also due to a relative lack of other service providers. Despite its success this model has not been scaled up in the state or in other districts.

One reason is that it is not adequately noticed and acclaimed by traditional gatekeepers who decide on acclaim status. The other is that other, more centralised models, have a greater draw amongst decision makers. A third is the problem of audit allowing such a flexibility in payments. But perhaps with time and support and advocacy it could pick up. It is still a young innovation.

There is a similar example of referral transport innovation from Dhemaji district in Assam, where a set of vouchers issued to pregnant women can be used for payment to boat/bus or taxi providers who in turn can cash the vouchers. Packaged along with a communication booklet and a soft toy, the distribution of these vouchers to pregnant women itself acts as a promotion of more appropriate health behaviours, such as use of antenatal care.

³ A programme evaluation of the Janani Suraksh Yojana, Fill in

Case Study- 5: The Boat Clinics of Assam.

This is a local adaptation of the mobile medical unit. For riverine islands the mobile unit is a boat which is suitably equipped. Though an interesting and very viable innovation, the question of scaling up is relevant only for similar geographic areas and is thus likely to be limited.

Case Study- 6: - *Voucher Scheme to Increase Institutional Delivery- Haridwar, Agra, Kanpur*

The genesis of the innovation is an internationally promoted model of public private partnership built around vouchers. These are a way of the government assisting the poor, without intervening in market dynamics- an approach that mooted by neoliberal economists as one of the few permissible ways of state intervention. In this context it would mean the provision of vouchers to women in the Below Poverty Line (BPL) category that would entitle them to a maternal health package or newborn care package of high quality free of cost, and increase the involvement of private sector providers to serve women in this category. NGOs have been appointed as independent agencies, to co-ordinate between the public and the private sector and to supervise and monitor the quality of care, and train and supervise the ASHAs. The vouchers (serially numbered, with holographic stickers to prevent counterfeiting) are provided to pregnant women through a chain involving NGOs, and ASHA. The private hospitals receive supplies (contraceptives, IFA and vaccines) from the government. In case of delivery complications, the patient is transported to the district hospital. A voucher management agency (VMA), which functions under the project advisory committee (PAC) chaired by the District Magistrate (DM) or Chief Medical Officer (CMO), is in charge of the following functions: identification of the beneficiaries, identification and accreditation of private nursing homes interested in participating in the voucher scheme, conduct training programs for staff of accredited institutes on quality standards, develop a financial disbursement system for advancing and/or reimbursement of funds to private hospitals, manage project MIS, conduct periodic quality audits, and carryout beneficiary feedback.

The entire voucher scheme is implemented through SIFPSA (a government based Society to improve family planning services in the state of Uttar Pradesh, created by the United States Agency for International Development (USAID) with substantial technical support from ITAP (Futures Constella).

A review of the scheme one year post implementation demonstrated several operational problems in the voucher scheme. These relate to the high proportion of caesarean deliveries, long waiting period, segregation of the BPL patients, low inventory of vouchers in stock, and variable quality of services in the private hospitals. Part of the poor quality stems for limited monitoring and supervision of the private hospitals, lack of grievance redressal mechanisms, and lack of newborn care services.

The Voucher scheme is an example of an innovation driven substantially through an external donor and external technical support and the private sector, but using the ASHA and the District Chief Medical Officer as part of the strategy. The complexity of the innovation partially explains the limited scaling up. The premise of the innovation that the engagement of the private sector through a contracting process

is the solution to poor access and universal coverage is likely misplaced for the context in which it was implemented, i.e the state of Uttar Pradesh, with poor regulatory mechanisms and substantial socio economic disparities in access and coverage.

Discussion:

From the set of case studies discussed above, it appears that in the case of NGO led innovations, the innovators are usually health professionals working with communities. Where it is within the government, it is usually the IAS cadre or at least those technocrats/mid level bureaucrats that enjoy a close relationship with them. This is not surprising since technical persons would have very limited space within the government system to act independently and innovate. Innovations originating outside the government, in an NGO, - as a rule appear to have several constraints in scaling up, but as the Nabrangpur or Purulia model show, state led innovations do not necessarily perform better from the point of view of scaling up. Most NGO led innovations addressed specific health problems. The motivation for the NGO is usually the urge to create new knowledge; knowledge that is immediately applicable and has great social relevance to the needs of the poor. Ideology plays an important part in such innovation- often Gandhian in the Indian context, but also other pro-poor ideologies in international contexts. More recently, many corporate social responsibility initiatives have recognised the importance of such funding either for building their own pilots or even as advocating as models for scaling up by the state.

NGO led programmes which have innovation content are largely funded by private funding or external international aid funding. Government funding for innovation in health systems, that too routed through NGOs is negligible. They require long periods of gestation and considerable trial and error to get it right. The funding agency should have the vision and patience to support this. There are examples of government funding for innovation. One of the most innovative and productive of such programmes is the Department of Science and (DST's) Science and Society Programme, but there is no such equivalent in the health sector. It is worth recording that one of the less known forerunners to the ASHA and Mitani programmes is the Women's Health Activist programme supported under this scheme.

As for small scale innovations taking place within the public health system, one of the main drivers for this category of innovation is that those who work at the cutting edge feel that impact of inefficiencies in the system the most. Faced with these inefficiencies they either develop an indifference to the work they are supposed to do, and services which they are supposed to provide or try to resolve or at least cope with their day to day problems with "Jugaad"- improvisation. It is this "Jugaad" which has resulted in many innovative practices which has at times resulted in far reaching changes and improvements in health systems. These innovations may be far more ubiquitous than is generally recognised.

We may therefore infer that a large number of innovations in health systems have resulted from efforts of the field functionaries of the health system to manage the system

well using the “given resources”. In this perspective, those higher in the hierarchy of the health system have more often been seen as hurdles in the path of innovations, rather than being the originators of true innovation. Many innovations do not see the light of the day because of the negative attitude of the “Gate Keepers” – the higher health bureaucracy, the audit authorities and holders of knowledge or professional privilege. In this perspective, innovations are likely occurring in health systems all around us all the time. The need is to discover, support and promote them.

Many very useful ideas do not get scaled up. Though the context of innovation is plural and the origin of the innovative idea is often unexpected, the context of validation which is acceptable to authorities, the approval for scaling up by gate-keepers, and the strategy of scaling up needs considerable knowledge and change management, and negotiation with institutional structures. Innovations which are programme tweaks- like the transport of blood smears in Bilaspur, and others which are innovations of service delivery designs like Nabrangpur, should be possible to scale up if there is adequate decentralisation and empowerment of districts to make such changes. The problem here is that there are other alternative top-down models which compete- sometimes with good reason and sometimes just because they are top-down which displace these possibilities.

The Business Model:

The innovators of the Business Model Pathway belong to the corporate sector- either acting with a business motive, or as part of corporate social responsibility. The holy grail of this innovation pathway is to come up with a business model which is self sustaining, at best requiring initial capital costs. This implies a model where there are user fees, but affordable enough for 80 % of the population, and where the business is remunerative enough for reasonable salaries, if not actually bring in a good profit, and also provide access to quality services which are otherwise not available.

In practice, however, many of these models require not user fees but public financing and the rationale for such public financing is that it is less expensive and more effective than comparable options. Most of these are geared on the principle that high volumes with low margins can still lead to substantial gains- the dollar to be made at the bottom of the pyramid-framework.

Case- Study -7” EMRI case study:

Under the auspices of Satyam computers, the EMRI was set up as a company to deliver emergency response services modelled on the 911 service in the US. A call center having the number 108 would respond to all emergencies- fire, crime or medical- diverting calls to the fire department, police or in case of a medical call to the ambulance services. Within 20 minutes of a medical emergency, the ambulance would reach, and with first aid administered by a trained emergency para-medic would transfer the patient to a private or public hospital in the vicinity. Satyam started it with an intention to explore building a model based on cost recovery, but shifted to a publicly financed venture once it was clear that a paid model was unlikely to work out. The government paid whatever it cost to do so- and there was no cap on the costs. The partnering private firm promised a 5% share of costs but this promise remained unfulfilled. The planning, technical know-

how and the software used at the call center were all provided by the corporate house. During the course of the programme the corporate ownership shifted to the GVK group, after a period of crisis in Satyam Computers, which related to governance issues.

Evaluation showed high public appreciation at the availability of a service which had hitherto not been available. It also showed that only about 30% of emergencies were availing the service and the more distant and vulnerable the population the less likely they were to access it. It was most effective in trauma care. For pregnant women transport also it is effective, but perhaps cheaper alternatives would have been more efficient. To really provide timely coverage the number of vehicles needed to be much more, and the costs that were already rising would become prohibitive. The real problem in calling it a business model was that there was no costing- it worked on the principle of “whatever it takes to give quality service.” And further it sought a monopoly.

But on the whole it worked and it has expanded to over 12 states and in another four states similar programmes run by other firms are in place. In terms of innovation we can see multiple drivers and gatekeepers shaping the course of innovation. Initially it is a corporate in search of a viable business model. Then it shifts to a completely government financed ambulance model. Then issues of corporate governance, the intervention of courts, changing public policy informed by an evaluation study leads to the introduction of competition and better public governance. This leads to another round of innovations, this time focussed more on institutional reform rather than on technical novelty. And now with better governance, the space for further technical innovation opens up again. (For a detailed account of these developments- refer – NHSRC study on publicly financed emergency response systems and patient transport systems).

Case Study -8: 104 services:

This innovation was also piloted by Satyam Computers. Here the model was composed of four inter-related components- a 104 medical help-line for telephonic medical consultation, a mobile medical unit to provide medical consultation through para-medics, a training programme for Registered Medical Practitioners (RMP) and a telemedicine link. The programme understanding was that much of the care could shift to the para-medics with local follow up by RMPs, but where required, the fixed day services run through the vehicle, would provide first referral support and telemedicine links would provide secondary care support. The mobile medical unit was geared to detect and follow up for the common non communicable diseases and was equipped with adequate drugs to do so. This component of the model appeared to have worked and made drugs for the poor accessible, but other than this, the actual gains and the cost benefit ratios were far from clear. Health outcomes too were not measurable, and most important, the financing of this model, as for EMRI was on the “whatever it takes” principle. Potentially it was a business model for primary health care. In such a model a user fee could have been charged by the RMP, and by the specialists who got the referred patients , and only the call centre and the mobile unit would need to be financed either from hospitals who received the referral or the government. But there was no costing of services and the contract had no clarity on deliverables. It also drew away considerable resources and attention from the public health sector without any commensurate benefit. Eventually the main point of referral was the government health sector itself- and there was no commensurate plan to strengthen the public system.

By early 2011, the programme lost support in the government, its workers went on strike, wanting to be made regular government employees and the programme shut down. Faced with increasing costs and no clear outcomes, the government took over the scheme. It

functions now like the mobile medical units elsewhere- as an outreach service linked to the primary health care network. Even as it shut down and at the peak of its problems, two states undertook to scale up the model, raising the question of the dependency on scaling up decisions for business models on health outcomes.

Many variants of this model have focussed on the telemedicine connection to a network of primary care providers- who are not mobile units- like the WHP model discussed earlier.

Case study -9 :Janani and the Merry-Gold variant.

Janani is an NGO working in Bihar to reduce the high unmet need for quality family planning services. To date, Janani has tried to achieve these goals through a combination of a network of its own clinics, franchising of providers and clinics in the private sector and the social marketing of branded contraceptives. Janani provides family planning (spacing and limiting) and abortion services through charging user fees. The most innovative part was the social franchisee component wherein, it recruits private clinics to provide a standard package of core RCH services where all costs and quality are standardised, and there is a clear fee for services that each clinic charges. There is a robust monitoring system that enforces this. In return for the franchisee fee, the clinic gets management and training support, and a volume of patients that helps it to do well. Linkages with government demand side financing for sterilisations, helps bring in substantial volumes and income, and this is now one of the main providers of sterilisation services. The fulcrum of the programme is now based on safe abortion and sterilization services provided as a fee for patients who access services directly and free of cost for those referred to by government. Franchisees have often not stayed loyal once their custom is built up- and there is a trend to shift to more a network chain of hospitals where investment and management is directly by the organisation itself, rather than recruited providers. The Janani innovation was implemented in a context when the government was simply unable to meet the high need for family planning, It was based on a premise that the unmet need was for both spacing and limiting and that the private sector would welcome being part of a franchise enterprise. But that is not really established and a shift to a greater reliance on public financing became necessary. The whole model depends for viability on major international NGO aid support. It is a model which worked well without any link to government, but does better contribution to public health sector goals after such linkage is established.

Merry-gold was an effort to replicate a similar concept in Uttar Pradesh and was funded by USAID and implemented through the Hindustan Latex Family planning Promotion Trust (HLFPPT), a public sector undertaking. Because of its funding support, it excluded safe abortion services from its package. The response however has not been as positive as in Janani, though a few peri-urban facilities are doing good business. However since alternative private sector providers are available in these areas, at comparable rates, the value addition is not as clear.

Case Study- 10: Arvind Eye Hospitals

This is a business model based on para-skilling to make eye care affordable to the poor. All non –critical procedures are left to skilled para-medics, largely trained in-house, while specialists handle surgery and final diagnosis, also ensuring a eight fold increase in number of surgeries a doctor performs. By carefully leveraging government schemes for cataract surgery, and developing its own outreach services, its central hospital performs over 3,00,000 eye surgeries every year, nearly half of which are free. It is a model that is

essentially independent of government support, but where support is available and leverage it is a welcome addition.

One clear factor emerges about business models. They are not self sustaining if they are to serve the poor and these often require substantial public financing. These could range from a minimal amount required only to provide access to the poor for one or two select public health priority services as in the case of Janani (for sterilisations and institutional delivery) or Arvind eye hospitals (for cataract surgery), or it could be almost complete as in the case of EMRI and the 104 service. The EMRI survived because it could establish that it provided a service for which there was no alternative model. The 104 perished because it could not prove its claims against the routine alternative.

Here it does seem that the models that do best are the models which sustain are those where the investment is private and there is no actual transfer of resources to private hands. Rather government is only purchasing services in areas where it has gaps- as against models where from the start it is built around almost complete public financing. In the latter context none of the efficiencies that are gained from having to recover the investment are in place, nor are there the efficiencies imposed by audits and the usual government decision making process.

Where it is completely public financed based there needs to be a much greater involvement of the government and its resource institutions in design and management. We need to coin a new term to capture this category- perhaps we could call it Government Organised/financed Social Enterprise models of service delivery. They are social enterprise models as different from programme component tweaks in that they are a package consisting of technology elements, capacities, work flow patterns and financing leading to a measurable, health system or programme deliverable that can be expressed in terms of unit costs.

We next consider below two case studies of such government organised and financed social enterprise models which were from the beginning government led.

Government Organised Social Enterprise Models:

Case Study- 11: Chiranjeevi Scheme and replication efforts

The innovation that appears to have set the stage for contracting out maternity services to the private sector is the Chiranjeevi Yojana in the state of Gujarat. Several states have replicated this innovation as seen in Saubhagyawati Scheme (Uttar Pradesh), Janani Suvidha Yojana (Haryana), Janani Sahyogi Yojana (Madhya Pradesh), Ayushmati Scheme (West Bengal), Chiranjeevi Yojana (Assam), and Mamta Friendly Hospital Scheme (Delhi). However the replication of the innovation was instituted even before there was definitive evidence of improved maternal and newborn mortality. It appears that several so called innovations often get high visibility, because the positive perception of the process is so high that it is often scaled up for implementation in health systems despite lack of objective evidence. The concern with Chiranjeevi is first about the seriousness with which costs and quality are monitored. Both, if we go by CRM reports and community groups – are not assured. Secondly, that this has largely only drawn away from the public sector, the actual new entrants if far more modest. Also that though it provides a viable private sector

alternative for one crucial service, that is too narrow a range of services, and a weakened public sector has to cope with all the rest.

Case Study -12:L RSBY core package, the Kerala variant and the MMJRK variant.

This is a social insurance model. The government recruits a insurance service provider through a tendering process to deliver a standardised insurance package. The sum assured is Rs 35,000 per year, the cover is for a family of five, the premium is decided by the bid but is in the range of Rs 700, and the co-payment by the insured for enrolment is in the range of Rs 30 only. Coverage is only for hospitalisation.

The coverage for this model has increased rapidly and is driven by political will. Objective evidence that it is providing social protection against catastrophic illness is limited, and there is both a trend of the private sector to use the information asymmetry to its advantage in both unnecessary care and unnecessary costs. Initially there are low claims ratio, but where there is public awareness and providers are available, (as for example in Kerala) everyone tends to claim the sum assured and the insurance company take a beating. In Kerala, most claims are from the public sector institutions.

Given the problems with moral hazards- Rajasthan tries a insurance like mechanism to transfer funds like an insurance agency would to public health facilities providing care packages to the insured.

The innovator in this case is the government department and led by a civil servant. But the department is able to command the state of the art in technical support- from all sources- World Bank to community insurance projects. The programme is driven by policy priorities and is planned and implemented at scale from the very outset- with relatively modest room for state level adaptations. Programme evaluations are largely internal and the data to judge the programme is not easy to access, but nevertheless, the programme expands and even is proposed as the main model. Clearly ideology has much to do with the drive. Also like EMRI and 104 high degrees of visibility and public acclaim promote scaling up. Though we still have to measure how much it is providing social protection where it is needed- in catastrophic health events- and to what extent payouts are for rational and essential care, to the poor family which is locked out of all private care due to financial and social barriers, any increase in access and social protection would be welcome.

Case Study- 13: The Velugu Model:

This model is unique in that it is the social enterprise principles to an almost entirely preventive and promotive health care effort. The programme addresses the social determinants of nutrition, women's empowerment, maternity entitlements and incomes and rural employment in an integrated manner. The village community and self help group establishes a kitchen with trained cooks who supply two meals which pregnant women and young children can access at a subsidised charge. The pregnant women are provided income generating activities that helps them to be withdrawn from farm labour to more sedentary work and also to pay for the increased nutrition. Other women and even men could access to kitchen with payment at reasonable rates. Eventually the entire cost of the diet is

recovered over two years- which means that the system could recover most its running costs. Only the initial capital and capacity building costs and later some management costs is external. Considerable decline in malnutrition and improved women's health and empowerment status is recorded. The financing was based on external assistance- most likely due to the flexibility that such funds afford for innovation and because the fund source in this case the World Bank that had its own preference for social enterprise models. The innovators were senior civil servants with a track record of working with innovative pro-poor options. Scaling up however remains a challenge since the perception is that this approach requires much higher levels of institutional capacity and social capital than most other places would have. But then- why not build up the institutional capacity and social capital in other places also? There is a political choice to be made.

The social enterprise models of service delivery as initiated by the government have been largely efforts at securing participation of the private sector in health care delivery. They fulfil our earlier definition in that they are a package of technology, work flow, capacities and financing leading to clear measurable, costed deliverables.

Their strengths are in that they have been able to harness some of the private investment for public health goals. In the case of Chiranjeevi it is a very narrow range of services that they harness, and it is posed against public sector provisioning. In the case of RSBY it is a broad range of services that they harness and there is adequate space, and in some states, like Kerala, a preferential basis for public sector participation. In Rajasthan the same insurance like approach is tried, but exclusively as a way of differential financing for the public sector. In the Rajasthan variant it could be a tweak of a systems component- in this case financing- rather than a full fledged social enterprise package as defined.

The innovators, gatekeepers and financiers in such innovations are the same. Unfortunately even evaluators tend to be the same. However the innovators do utilise considerable knowledge inputs from public health institutions and indeed all possible sources for designing the package, or workflows or evaluation. Though there has been no clear pilot, there has been a careful phasing up. However scaling up is driven by political and administrative hard-sell usually led by its original innovation leadership- and not too much informed by evaluations or by any efforts at re-contextualisation where replication is undertaken.

The comparison of the process of innovation and scaling up of this needs to be compared with other government initiatives which from the very outset are started on scale and often scale up even further- but only a programme components- not as social enterprise models.

Programme Design as Innovation:

Case Study 14: Integrated Management of Newborn and Childhood Illnesses (IMNCI)

IMNCI is the adaptation of a WHO/UNICEF recommended package for improving child health through improved case management of illness delivered at primary health level and introduced in India in 2005, as part of the national RCH 2 programme. The adaptation of the global innovation for India was to integrate newborn care through postnatal home visits by the Anganwadi Worker, a field functionary of the ICDS system that lies within the domain of another Ministry. This was despite the availability of the ASHA within the NRHM. IMNCI also includes case management protocols for the ANM and the Medical Officer. The IMNCI was piloted in phases and has now been scaled up in 223 districts but progress is slow. Globally the IMCI strategy has not been able to demonstrate reductions in infant and child mortality in many countries and everywhere it has had problems in implementation. One problem with the model is that it requires a good quality of referral support – both transport and institutional facilities- which in many contexts is just not available. Community mobilisation component is also weakly planned for. The tardy progress in implementation has been attributed to the huge numbers of workers to be trained, the lack of institutional training capacity, and supervision and support. The issue with IMNCI implementation in India is the delivery of the package at the field level, (particularly for newborn care through home visits) by a worker who is not a functionary of the line department, and the high reliance on referral for all sick newborns in the context of a low availability of facility based newborn care at all levels.

Subsequently, as a course correction, the IMNCI training was expanded to include the ASHA, but this was variable and little attempt was made to synergize the training content with existing training modules for the ASHA which included a more well defined package of skills and competencies for newborn and child health. This is currently included in Modules 6 and 7 for the ASHA, which is also being re-named IMNCI plus to express the close proximity between the two approaches.

IMNCI is an example of an innovation whose main drivers were multilateral agencies, acting in collaboration with the medical community both within and outside government. IMNCI was expected to be scaled up across the country, without a careful scaling up strategy that included consideration of institutional capacity for training and for referral, adaptation to include the ASHA programme, and convergence planning. The innovation in the Indian context was the inclusion of a component on neonatal care- and then much later a further adaptation to the ASHA as health worker.

Case Study 15: Janani Suraksha Yojana and the Janani Shishu Suraksha Karyakram.

The Janani Suraksha Yojana is a cash entitlement for pregnant women that enables institutional delivery as a means for reducing maternal mortality, and is a major initiative of the NRHM, in place since 2005. Its origins had three roots. There was an earlier National Maternity Benefit Scheme where pregnant women were given Rs 500 which was improved nutrition- which had a poor record of implementation. There was another referral transport scheme, funded by the RCH-I programme, where pregnant women were to be given Rs 500 for transport expenses to enable them to come to delivery. There was also a considerable demand from many states for a link worker or some form of community health worker

under the sector investment programmes and under RCH. From Chhattisgarh came in the report of many Mitans voluntarily providing escort to pregnant women to come to institutions and that this service was much welcomed. There was also the understanding that incentivising for promotion of sterilisations and institutional delivery could be a way of supporting the ASHAs. These diverse needs came together and were woven into the current design of the JSY programme where all the benefits were woven into enabling institution delivery. The Supreme Court innovation reiterated the maternity benefit aspect and ensured that the Rs 500 was paid irrespective of place of delivery. The sterilisation payments to ASHA was de-emphasised through civil society protest action- leading to the JSY payment as the main pillar of support to ASHA.

Within a year, it was clear that the JSY programme was gaining a great response, enabling and empowering women for institutional delivery. About this time the conditional cash transfer theory also became popular and the main explanation of why the programme worked. Large scale national surveys demonstrated substantial increase in institution deliveries, though it was never very clear, considering the quality of care as to how much of MMR reduction could be attributed to this. A programme evaluation of the JSY demonstrated that the entitlement had resulted in high institutional deliveries and the barriers appeared to be low density of facilities, poor service quality, high out of pocket expenses for transport and drugs, and lack of newborn care services. The JSSK represents an attempt to correct some of these barriers. It was designed to respond to two perceived weaknesses of the JSY: high out of pocket expenses for families accessing JSY and the provision of newborn services in addition to institutional delivery. The latter has no cash benefits and is completely a supply side intervention. But it entitled mothers and newborns less than one month of age to free care, more patient amenities at the hospitals, and two way transport between home and institutions.

This is clearly a policy driven innovation with senior officers as the innovators. Academic inputs and evidence comes in later to tweak the programme and offer theories of how it works. The JSY was also launched in a context of intensive inputs for system strengthening which were substantial if not sufficient, enabling the realization of the goal in a large measure. Though it is often said to have been neutral between public and private facilities, it is both in design and in roll out a major measure of strengthening delivery in public health facilities- and much of the revival of public health service delivery under NRHM can be attributed to it. Also, whatever the record on safety and outcomes of the institutional delivery strategy, women were clearly making a choice to come, enabled by the support and the availability of services. Even on outcomes, though one may argue that it could have been even better, the consensus today would be that it has made a significant positive effect.

Discussion on Programme Designs as innovations:

In the case of IMNCI, the design is imported and then tweaked from IMCI to IMNCI to suit the Indian context. But was the tweaking only because of India had a specific neonatal mortality problem that other countries around the world did not have, or because it had to negotiate its space with the more robust home based care model. The home based newborn care model, despite the considerable weight of evidence behind it, took upto 2010 to become official policy- and that too after considerable changes. And this, despite it having been a major component of the eleventh five year plan. Critical to this is the role of the gatekeepers of technical authority- both the international and the national. DOTS too has a

similar path- an international package arriving on shores, tweaked to adapt to some important Indian concerns and then tweaked here and there. In terms of projects own process targets it is relatively successful, but in terms of impact as measured by tuberculosis prevalence the jury is still out.

The JSY and the JSSK are home grown. It is constructed out of a combination of earlier programmes and new ideas coming from the field assembled together based on logical assumptions. The conditional cash theory explanation follows the establishment of the model- which at the time of RCH-II was not even a major part of the programme. Evidence follows even later in implementation and indeed few expected success (in terms of outputs- we do not know about outcomes) on such a scale. But evidence also shows serious drawbacks some of which are attended to by further tweaks and in all likelihood even more are needed for it to achieve its objectives. These policy driven to scale innovations do not face the hurdles of scaling up- but they require far more evidence and process in designing and considerable knowledge and change management inputs to optimise and ensure outcomes.

Health Systems Innovations:

Case Study 18: TNMSC:

One of the first and most successful of all health systems innovations in the Indian context, this a state government led affair that started up as part of an external assistance support for health sector reform in 1996. Subsequently sustained internally, the core is the creation of an institutional structure and organisation for procurement and supply chain management for the supply of essential drugs and supplies to all public health facilities- getting the best of rates and a high degree of quality assurance. The details are well known. What is important to understand is how despite overwhelming acceptance of the workability and desirability of this model, it has been so difficult to replicate and scale up in other states. Fifteen years after the model was established only one other state has a comparable model and three other states have diluted variants of this model. The barrier seems to be focussed on being able to secure the political and administrative will to establish a transparent system that leaves no room for leakages within the prevailing atmosphere.

Case Study 19: Retention Schemes for skilled health professionals-

The Approach to the Eleventh Five Year Plan literally despaired of getting doctors to work in rural areas. Yet the eleventh plan period has been rich in innovations to get this going. Till 2005, compulsory rural postings was about the only effort, and as a rule, this did not work. Since 2005 there was a slew of measures. These could be listed as follows:

- a. Incentives for working in difficult areas, and even higher incentives for more difficult and inaccessible areas.
- b. Non financial incentives- especially preferential admission to post graduation.
- c. Making rural service a mandatory condition of admission to post graduation.
- d. Innovations in recruitment process- by walk in interviews with public service commission playing the role of confirmation and regularisation.

- e. Preference to candidates from under-serviced areas, preferably with communities actively involved in selection for professional education and deployment- the second ANM programme in West Bengal.
- f. Special courses leading to new cadre dedicated to rural service, like the three year course leading to a rural medical assistant in Chhattisgarh and Assam.
- g. Multiskilling medical officers in specialist skills for emergency obstetrics and anaesthesia.
- h. Distance education based approaches to building up necessary skills in situ- epidemiologists, family medicine, district health management etc.
- i. Creation of a separate cadre with extra benefits to promote rural service.

Learning from these the central government got the NHSRC to work on a detailed scheme, where it would provide the incentive for doctors in difficult areas. As part of this effort the difficulty level of every single public health facility was scored, and about 10% identified as difficult and with most states consensus on such identification was also reached. A package based on both national and international learnings was devised.

It never got further. The point of the case study is two fold: First, we do not quite know- what happened in the states. Many innovations have been tried- but what worked, where and to what extent remains to be decided. Secondly, unlike JSY, this innovative programme design did not come through, and the question is why. A tentative answer is that its time has not come, the discourse requires to built up much more before decision makers will take the plunge. And there is every evidence that this discourse is building up and therefore change would follow. But for now this is relegated to being a field for lamenting the failure- not innovation to solve it.

Case Study 20: Mitanin and ASHA.

The Mitanin programme is an innovation of improving health outcomes through community health workers. It was scaled up in phases from 2003 to 2005, and now covers every hamlet in Chhattisgarh state, with 54,000 Mitanin in place. The premise of the programme is not new. Situating one CHW at the level of every habitation, whose orientation and training was built on a health rights framework, and who was able to provide community level care and facilitation for access to services- is an approach that has worked in many small scale NGO programmes. But scaled up and government led, it had failed in the past. The Mitanin programme, not only managed this scale up, it was also the inspiration for a nation-wide scale up to the ASHA programme, which is now over 800,000 CHW strong and growing. Large scale surveys in Chhattisgarh state showed striking improvements in those indicators related to maternal and caretaker behaviors particularly for child health. In 2005, Chhattisgarh a sharp reduction in 11 points in the Infant Mortality Rate drew considerable attention to this programme.

The Mitanin is an innovation for it found a way to scale up the conventional NGO led CHW programme into a state level version. To do so it had to innovate ways to institutionalise a dedicated leadership, design a capacity building plan backed by human and financial resources, and devise appropriate monitoring strategies, and build respect for community processes among technical leadership and managers and most important accommodate political interests and different stakeholder priorities. While the ASHA programme draws some of its design elements from the Mitanin programme, a recent evaluation demonstrated that the promise of the potential was not realized in the ASHA programme. Fundamental to

this is the role of different and contesting understandings by stakeholders who would seek to limit her role in community care and empowerment by reducing her level of skills and shape her more as a commission agent or at best facilitator for health services and health goods on the market. Even now the Mitanin programme continues to actively innovate and evolve- there is a Mitanin Kalian Kosh introduced, Mitanin help desks, Mitanins are taking advantage of literacy and equivalency programmes, Mitanins training to become ANMs, Mitanins active in panchayat level planning, in nutrition and a large number of innovations. In contrast the pressure on ASHA is to freeze it , to be continuously apprehensive of its growth and seek ways to cap it.

Here is an innovation that arises from small local area best practice, that has been incubated over a long time, with a high degree of innovative inputs of a different sort to scale up and then will continue to require a high degree of innovation to sustain and evolve. One of the major differences between the major failure with this programme in 1978-1985 and the success of 2006 to 2012, is the role played by a resource organisation like SHRC in Chhattisgarh and NHSRC at the national level in providing the knowledge management- in terms of guidelines, evaluations, component designs, as well as constant advocacy and championing of the programme and continued inputs to further and further innovation.

Case Study 21: Establishing QMS in public hospitals.

Quality assurance has been a central concern of RCH-II and NRHM. The proposed model was the setting up of quality assurance committees in every district. Such committees would visit facilities, and perhaps using a check list, note problems in quality of care and then exhort them to resolve these problems. Subsequent monitoring visits would ensure that they have done so. The problem with this intuitively sound approach is that across the states this did not really happen in any serious way. In the 5th CRM meeting, one key presentation called on the states to make this a reality. What needs to be noted in this context is that are many states which with the support of many technical support agencies had fully applied themselves to this task- and yet have had not found an effective or sustainable solution.

In such a context some states opted for either a NABH accreditation or an ISO process. The NABH accreditation proved too input intensive, and too costly with relatively low outcomes in terms of successful certifications. The ISO approach was too loose-ended and fuzzy so that almost anyone could get it. In such a context NHSRC tried to build on the ISO approach by adding on 24 processes that had to be brought under standard operating procedures and certified. These included a number of processes related to administrative efficiency, patient amenities, patient safety and satisfaction. At the heart of the innovation is the understanding of what a QMS is- an approach to seeing quality as a set of processes, identifying the current gaps in processes, coming to a technically sound and participatory consensus on how to close the gaps, documenting the processes and their improvements to meet the newly defined standard operating procedures, and capacity building to ensure that these new SOPs are understood and adhered to.

Pilots developed the concept in 16 hospitals and then have worked on tools and methodologies to scaling it up by expanding the programme to over 600 public health facilities. The next phase of expansion needs a policy directive at either national level and/or state levels.

In contrast to other innovation pathways, this is an institution led innovation. Potentially a pathway for all public health or management led innovations. NHSRC has led such innovations also in health informatics and district planning. The main features of this pathway is the identification of a problem that defies solution despite multiple efforts by a wide variety of implementers. Then searching the domain for the state of the art, and then drawing upon these examples building an innovative design, which is launched as a prototype and then incrementally improved upon with multi-stakeholder participation. After this to stay and add value to all links in the implementation chain- until evaluation and feedback for continual improvement and capacity building and ownership development for sustainability and scaling up.

Discussion:

Summing up, there are a number of pathways to innovation and each has its own logic of innovator, gatekeeper and terms for scaling up. The best practice that happens by *jugaad* requires to be recognised as an important source of innovations which needs support to scaling up. One also needs to recognise the role played by special institutions whether like SEARCH, JSS, or like CMC Vellore, SHRCs, NHSRC in developing and incubating innovations till the situation becomes ready for scaling up.

Scaling up depends on policy change, and this means both political contexts and on an idea attaining a critical mass of support – getting established in the discourse before it scales up. On the other hand innovations that come from the top (- development partners, corporate promoters, national programme innovations) arrive at scale, driven by policy priorities and need constant critical knowledge inputs for course corrections before they become efficient, effective and sustainable.

Knowledge organisations could also be the drivers for innovation – though these are the more often the exceptions than the rule. Nevertheless they play an important role in identifying, documenting, validating, disseminating, scaling up, championing and enabling the adaptation of innovations.

One interesting question that these case studies give rise to is the context why this period 2005 to 2010 has been so innovation rich. The space provided by the availability and flexibility of funding under NRHM is no doubt important but many of the innovations are not necessarily cost intensive. If anything they save expenses. Much more important is the perception of innovation as an important ingredient of change- and perhaps the role played by NRHM in designing, promoting and actively championing, health systems innovation and change. Once or twice a year there are meetings held of the states where such innovations are presented, discussed, disseminated and encouraged. The presence of NHSRC as an institution that actively contributes to innovation- either by tweaking programmes that were introduced on scale- through inputs provided by assessments and evaluation (Eg JSY and JSSK), or by just identifying a promoting best practices (home based newborn care), or by constantly pointing out to opportunities for innovation (retention of skilled workers in remote areas), or by itself leading innovation (development of quality management systems and in health informatics)- has all contributed to such innovation. One important difference with other agencies- is that by definition, many of them are tied down to doing the obvious-

monitoring for example or training. Indeed often this is the demand made of NHSRC and it takes some effort to go beyond the obvious.

The discussions over the common review mission findings are an example of the tension between the two. One mindset looks at the findings as essentially examples of government of India guidelines not being followed and its main recommendations- at least the only permissible recommendation- as – “please follow government of India guidelines”. Thus the findings are, for example: vacancies are not being filled, drug kits are not being refilled, trained persons are not posted where they ought to be, training is behind schedule, quality assurance committees are not functioning, ANMs are not staying at their place of work etc. The recommendations that would follow are: that vacancies are to be filled, drug kits must be refilled, trained persons are to be posted where they ought to be, training is to be on schedule, quality assurance committees must function properly etc. In contrast an innovation-friendly mindset could ask- why are these not happening, what are the barriers and is there some other way, we can get around the barriers and make it happen? Root cause analysis and counter-intuitive recommendations are critical. In such an approach, every problem and monitoring visit also becomes an opportunity for innovation. To the credit of the National Rural Health Mission, the latter approach however challenged, has managed to retain some space.

Needs and Opportunities:

1. One major set of opportunities for innovation relate to recognising problems/constraints in existing efforts to strengthen health systems or barriers to achieving health programme objectives where the obvious solutions relating to increasing investment and better management on existing paths are not *sufficient* to solve the problem. For this we need to overcome the tendency to attribute the absence of solutions to a particular issue as a “flaw in implementation”, as is often the case with health systems related interventions rather than as a problem that really had no effective solutions in the first place. Rather it should be recognised as representing an urgent need for innovations. We give below a few broad health systems related areas where innovations are obviously required- but this is not exhaustive.
 - a. Service delivery – social enterprise models which deliver an assured package of services leading towards comprehensive health care, which are public sector organised with providing space for private participation, but not dependent on it. There is a special need to emphasise building models which are able to reach marginalised populations. There are innovations that appear to have been designed to benefit economically poor families, but none that look at other forms of marginalization.
 - b. Building outcome based programmes for preventive and promotive health care, where health care costs are shown to be reduced and health status improves because of measurable reduction in morbidity. For example there is still no proven effective model to address adolescent anemia on a state wide scale.
 - c. Human Resources- The central challenge is to find the right persons for the right place. A right person is a person with the right skills. But it is also more than that. The provider needs to have a bond with the community him or her serves- there is a relationship of

- trust and caring that needs to be established. And individual providers need to be part of a team.
- d. Quality of care- building systems where quality of care counts and where quality is a culture and there is a methodology for continual improvement of quality both in public sector providers and in private providers.
 - e. Improvements in regulation- on cost and quality of care, on ethical care provision, on rational drug use.
 - f. Building capacities and systems for increasingly decentralised planning and management, which increases the participation of communities in decision making.
2. Evidence based and participatory technology choice for public health programmes and for inclusion in health packages: for example to design a programme against the emergence of rickettsiosis in a specific state, or the emergence of chikungunya nationwide, a high incidence of suicides in a given area, or post disaster situation
 3. We also need innovations to address new and emerging problems that have not been addressed before or in new situations and specific contexts where they have not been addressed effectively before.

Ecosystem Requirements for Innovations in Health Systems:

1. *Institutional Reform for Innovation:* Change in the attitude of the “Gate Keepers” – the so called policy makers – higher bureaucracy and politicians. Involving all stakeholders in policy making. Having flexibility in policy to accommodate new ideas, and new ways of doing things.
2. *Institutions for Innovation:* Needs to be an ongoing process, and there must be a mechanism to continually update the list of innovations, assess, and share the findings with implementing agencies Searching proactively for innovations happening all around us and supporting them. Documenting and sharing good practices with practitioners in the field. Creating a public fund and registry to assess innovations and recommend their inclusion into large scale systems might be a good starting point.
3. *Decentralisation and Participation:* Empowerment of the field functionaries and communities.
4. *Innovation Incubators:* Incubating new ideas and mentoring innovators. Innovating financing of innovations.

1 Institutional Reform:

Institutions can be understood as the set of formal and informal rules that govern the functioning of health systems and programmes. These tend to be rigid, and people in charge see themselves as essentially custodians of these rules- in effect as gate-keepers. A change in attitude of gate-keepers is one of the important factors to develop a culture of problem solving and innovation in the organization. Bureaucracy is traditional and risk averse. It does not like to upset the apple cart. It therefore discourages innovations. Attitudinal change is however easier said than done. For innovation to be nurtured in a system the top must not only support new ideas and be willing to share in the responsibility for failure if any. We

must realize that even in failure there is a lesson learnt. In addition to this there must be the humility to learn from the experience of persons in the field. People at the top must “listen” to the person at the cutting edge. Good listening includes the ability of filtering out the noise. Many a times when a person in the field is making a complaint he is also suggesting a solution. If he is then he is an innovator. The policy maker must bear in mind that many of those ideas which seen farfetched in the beginning may actually work if given a trial in a proper environment. Positive attitude to new ideas at the top – sometimes called “Political Will” and “Administrative Will” - is an absolute pre-requisite for innovations to take root in the system. We may need a lot of advocacy and training at the top level to develop such an attitude.

Another aspect requiring institutional reform is the audit process. The rigidities of financing and accounting are a major impediment to innovation. Leave alone fault finding in case of failure. Even where success is obvious and acclaimed, innovations can be shut down due to audit objections. More often audit objections become grounds for bureaucratic resistance to change to manifest itself- rather than explain the audit para- succumb to it.

Yet another problem is the attribution of all programme failure to governance and administrative failure. The failure to imagine.

2. Decentralization and Participatory Processes.

Innovation will happen when people in the field stop looking to the top for solution of all their problems and start working towards solutions themselves. This needs both formal devolution of powers and a health systems design that gives them the space to innovate.

But it also needs a workforce which has self respect and self confidence. Both will come from an ability of analyzing problems and finding solutions. This does not happen overnight especially in a de-motivated work force with low morale. Empowerment of field functionaries is therefore essential to innovations in the system. The process of empowerment requires participatory proceses. It can begin with a simple brain storming about the problems faced in the field and its possible solutions. This should be accompanied with upgrading of knowledge and skills and demystification of difficult technical things. Field functionaries must realize that they are trusted and are an integral part of the team. They must have a sense of belonging to the organization and also a sense of ownership of the program. The two are of course interrelated. Good ideas coming from field functionaries should be tried out and even if they fail the effort should be praised. The credit of any successful innovation must be given to the person who initiated it. As a matter of fact the entire team should be credited with the success of the effort.

The community which is served should be involved in the process of policy making.

A formal and institutional mechanism of interaction of all stakeholders at regular intervals is necessary. This interaction should be in an atmosphere of goodwill and understanding. There should be an honest desire to learn from each other and support every stakeholder for the good of the organization. It must never be forgotten that community is the most important stakeholder. All our policies

programmes and services are for the benefit of the community. Unless the community derives the benefits intended for it all our efforts are a waste. It is therefore necessary to involve the community in the policy making exercise at all levels. There should be an institutional mechanism to consult with the community and also enlist community assistance in service delivery. The community will be able to suggest many useful interventions which may result in substantial savings in money and efforts. The success of all our programmes depends on the accessing of the services by the community. However it must be realized that in most cases the community is not homogenous. In many places it is fractured and sometimes even working at cross purposes. Our endeavor should be to ensure that the voice of the disadvantaged groups is heard. They are the ones who need our services most. Special methods may be needed to involve disadvantaged groups in the program. Some of these methods include meeting these groups separately, ensuring that members of these groups are nominated in all committees etc., and monitor the access of services by such groups separately.

Stakeholder consultations are important ingredients to health systems innovations. Other than the community and the workforce, there are other sections who are involved- technical persons, non government organisations, business concerns, other government authorities etc. Learning is always a two way process. Unless top decision makers listen to and consult with all the other stakeholders, their decisions are likely to be wrong. On the other hand unless people in the field interact with the top decision makers they do not know the limitations of funds, statutory requirements etc.

3. Institutions for Innovation:

Knowledge management institutions are important for innovation. The functions of such institutions would include the following:

- a. Searching proactively for innovations happening all around us and supporting them: Individuals and organizations People with limited resources keep innovating all the time to be able to perform their duties well. Innovations are happening all around us. There is a need to look for them proactively and document them, assess their potential and make replication and customization possible. . There should be more formal mechanisms of reporting documenting and assessing innovations in the system.
- b. Dissemination of best practices: This can happen through best practices sharing workshops, newsletters, web portals for sharing innovations, meetings and conferences etc.
- c. Validating innovations and learning for scaling up and adaptation: Innovators tend to be enthusiastic in their claims. Before being taken up for replication an objective evaluation is mandatory. This would also give learnings for scaling up, for one can understand the innovation in context. All innovations are not replicable in all areas. There can be innovations which are very specific to the needs of a community and specific to the socio-cultural ethos of the region where they take place. They should still be documented and assessed as they will surely lead to learning for people who

work in other areas as well though it may not be possible to adopt or adapt them for use.

- d. Evaluation of Innovations and the Identification of Needs: Systematic evaluation of programmes and health systems are important to both identify needs for innovation, and to evaluate innovations that have been implemented to address specific health programme gaps or pose alternative models of service delivery. Randomised controlled trials would be appropriate in only a few situations, but where possible these could be used. The RCT is most effective when we have a single technical intervention which potentially works well in a wide variety of contexts. Where the innovation is itself complex being made up of many components, or the innovation is already in place and on scale, and where it is likely to be very sensitive to contexts or where there multiple subjective perceptions of the programme itself- then one needs innovation in evaluation design as well. Realistic Evaluation which studies how the same programme mechanisms play out in different contexts and which can incorporate multiple programme theories into its framework of analysis would also have much to offer. There are other evaluation tools- like comparative case studies, and participatory evaluation techniques that may be appropriate to specific questions.
- e. Leading on Innovation: Knowledge management institutions can also lead on innovation by subjecting a resistant problem to greater analytic scrutiny and by comparisons to similar problems and efforts to address these nationally and internationally. Also by supporting scaling up with value addition along the whole implementation chain- development of guidelines, adaptation to contexts, development of monitoring procedures, development of capacities- all of which are necessary ingredients of scaling up. In a sense all scaling up is a continuous process of innovation.
- f. Advocacy and Negotiation. Innovations which are small scale provoke little resistance. But when scaled up to large programme levels, various interest groups and stakeholders have concerns and even threat perceptions. Sustained advocacy and championing as well as negotiation are all necessary ingredients of successful scaling up and these seldom occur without institutional support.

4. Incubating Innovations:

Policies should be such that they actively promote or support innovation. This requires a lot of support including support at policy level, money, manpower, and effort to convert an idea into a working programme. We may learn from the idea of “Venture Capital” in business. There are many venture capitalists who invest in new ideas instead of the tried and tested ones. Of course the risk in such investment is greater but the returns far outweigh the risks. In social innovation also we need to develop methods where innovations can arise, flourish and grow. To enable such innovation friendly environment for health systems is a challenge. But here are a few suggestions:

Knowledge Institutions like the IIMs, IITs, some medical colleges with such a capacity, public health education faculties like NIHFW, NHSRC, PHFIs, IIMHRs etc

should be supported to create within themselves units which support and mentor new and promising ideas and “Incubate” them. Funds should be kept earmarked for this purpose. Of course many of these ideas will not succeed. However in the long run the benefits of such an approach will far outweigh any perceived loss. New ideas can be tried on a small scale as prototypes and then they could be incrementally and participatorily improved, and their scope can be gradually expanded once they have been proved to be successful. Similarly there can be a scheme of providing support to new and promising ideas by mentoring of relatively junior persons in the organization by seniors.

For innovations in community processes in community health- non government organisations with a track record of working in communities organised into a consortium with knowledge institutions and government departments could be a successful incubator. The department of science and society of DST has a programme, where in select institutions- some 15 across the nation are provided with core funds which they use to sustain a core team as well as carry out some innovation related activities- workshops, publications, studies etc. However their main activity is innovative projects each of which they have to separately projectise and get funds for. A successful organisation is expected to have about 70 or more percent of its turnover from such projects. Yet without the core support, institutional continuity, memory and stability needed for long term sustained work in this area is not gained. Reports like HLEG (High Level Expert Group on universal health care of the Planning Commission) propose expanded roles for ASHA and community processes but without incubation sites for developing these ideas, they would remain on paper. A modest number of such innovation sites exist- ARTH, Ekjut, Jamkhed, SEARCH etc- but all of these are dependent on international aid funding, and this brings about its own limitations. However currently no government funding in the health sector is visionary and innovative enough to support this. A proposal for the same (see annexure on CHILTS)is under consideration.

Another mechanism for central government to support states for innovation outside what the center’s list of mandatory activities is to fund promising new ideas through linking of such support to achievement of milestones related to institutional reform. Thus in the EU supported sector reforms programme States were asked to prepare an action plan where certain institutional reforms which required very little or no money were treated as milestones which earned money that could be used on other agreed activities. For example in Chhattisgarh, institutions reforms related to integration of different health societies as a mile stone which earned money which could be used for support to an activity that the State felt was a priority. This was the source of funds for the innovative and highly successful Community Health Programme of Mitans- which at that time had no other takers.

Annexure I

No.M.11020/01/2011-BOP
Ministry of Health & Family Welfare

Nirman Bhawan, New Delhi-110108
Dated: 13th May, 2011.

OFFICE MEMORANDUM

Subject: Setting up of Sectoral Innovation Council in the Department of Health & Family Welfare.

The Ministry has decided to set up a Sectoral Innovation Council with the following composition and terms of reference:-

Chairperson

Sh. P.K. Pradhan, S.S & MD (NRHM).

Members

- i) Shri Keshav Desuraju, AS (Health), MoHFW, New Delhi.
- ii) Dr. E.V. Ramana Reddy, Principal Secretary (H & FW), Karnataka.
- iii) Ms. Anu Garg, Commissioner cum Secretary (H & FW), Orissa.
- iv) Dr. Samit Sharma, Mission Director, (NRHM), Rajasthan.
- v) Dr. K. Srinath Reddy, PHFI, New Delhi.
- vi) Prof. Sujoy K. Guha, IIT Kharagpur.
- vii) Dr. Bishnu D. Pradhan, Mumbai.
- viii) Dr. Abhay K. Bang, SEARCh, Distt. Gadchiroli.
- ix) Dr. Alok Shukla, Election Commission, New Delhi- 110001.
- x) Shri Dinesh Abrol, NISTADS, New Delhi- 110012.
- xi) Prof. S.K. Mishra, SGPGIMS, Lucknow- 226014.
- xii) Dr. Narottam Puri, FICCI, New Delhi.
- xiii) Dr. Dileep Mavalankar, IIPH, Gandhinagar.
- xiv) Dr. P. Ashok Babu, DC Goalpara district, Assam.
- xv) Dr. T. Sundararaman, NHSRC, New Delhi- Member Secretary.

2. The Sectoral Innovation Council will have the following Terms of Reference:-

- (i) To map opportunities for innovation in the health sector.

- (ii) To explore possibilities of encouraging and rewarding young talents for innovative models in health sector.
- (iii) To prepare a roadmap (2010-2020) for decadal innovation in health sector.

3. The Sectoral Innovation council may co-opt experts as member and form sub-groups as required with approval of the Chairperson.

4. TA and DA for non-official members shall be paid as per the GOI rules.

5. This issues with approval of Secretary (H & FW).

Sd.

A.S. Sachdeva

Economic Adviser,

23061730

E-mail: asachdeva-pc@nic.in

Annexure II

List of Members of SIC Sub Groups

SIC SUB GROUP FOR PHARMACEUTICALS INCLUDING VACCINES AND IMMUNODIAGNOSTICS

1. Prof. Dinesh Abrol (Coordinator)
Chief Scientist,
National Institute of Science, Technology
And Development Studies
CSIR, New Delhi
2. Dr. Sarla Balachandran
Scientific Secretary,
Council for Scientific and Industrial Research
(GoI), New Delhi
Open Source Drug Development Initiative
3. Dr. Anil Gurtoo
Professor of Medicine
Lady Hardinge medical College,
New Delhi
4. Dr. Samir Brahmchari,
Director-General, CSIR &
Secretary, DSIR
Government of India
5. Mr. Bhavin Jain
Member Committee of Administration,
Pharmaceuticals Export Promotion Council;
Member, Consultative Board, NIPER
6. Mr. Lalit Kumar Jain
Federation of Small Scale Pharmaceutical
Manufacturers Association of India; N. Delhi
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ANNEXURE III

LIST OF PAPERS SUBMITTED FOR SIC BY SUB GROUP MEMBERS

A. PHARMACEUTICALS SUB GROUP

- I. WHO Global Strategy and plan of Action for Innovations (Dr. D Abrol)
- II. Status of Innovations in TB, Dengue and Diabetes in India (Dr. D Abrol)
- III. Mapping Needs and Opportunities for innovation in India's Pharma Sector (Dr. D Abrol)

B. MEDICAL DEVICES AND TECHNOLOGY SUB GROUP

- I. Directory of Indian Innovators in medical devices (IIT Delhi)
- II. Policy Issues for medical Devices Innovation (Dr. DS Nagesh)
- III.

C. ICT FOR HEALTH SUB GROUP

- I. JAANCH (submitted by PHFI)
- II. Best Practices In Telemedicine And Capacity Building (Manish Kumar)
- III. HMIS in India (Prof. Indrajit Bhattacharya)
- IV. Public Healthcare Informatics Management (Mr. KK Pal)
- V. Public Health IT Study (Dr. Pankaj Gupta)

D. HEALTH SYSTEMS AND PROGRAM DESIGN SUB GROUP

- I. Process of Health Systems Innovation (Dr. Alok Shukla, IAS)
- II. Field Implementer's View of Health Systems Innovation (Dr. P. Ashoke Babu, IAS)
- III. Directory of health systems Innovations in India (Dr. Rajani Ved, Mr. Abrar Khan)