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Drivers and Barriers of Innovation Dynamics in Healthcare

Towards a framework for analyzing innovation in Tuberculosis control in India

Abstract

Tuberculosis remains the biggest infectious killer in India and worldwide, and it has recently regained substantial international attention with its come-back in drug resistant forms. The environment, the disease and the societal response to it are changing and with it challenges and opportunities to control the disease. Innovation in a variety of areas such as improved diagnostic tests, drugs, delivery mechanisms, service processes, institutions and treatment regimes is needed in order to be able to respond to the changing public health challenge.

This paper reviews theoretical approaches to innovation of direct relevance to the case and examines what theoretical framework is useful to look at the problem of innovation in public health in India. Such an analysis can reveal drivers and barriers of change within the context of the Indian health system in a comprehensive, problem-oriented way and is thus able to add to existing research done on TB.

However, given that TB control is a public health challenge, concerned with problems of delivery and implementation, the concept of innovation has to go beyond technological innovation and the private sector. The case can therefore simultaneously contribute to innovation theory and improve our understanding of what change processes and innovation for concrete public health challenges in a country such as India mean.

After a short description of recent changes in TB control based on fieldwork in India the paper proceeds with an examination of existing frameworks on healthcare innovation upon their usefulness for such a case. The paper concludes with a proposal for a theoretical framework and areas for further empirical fieldwork.

1. Introduction

Tuberculosis (TB) is an infectious disease which can be transmitted through air and requires a very long and complicated treatment. Although there have been effective drugs around for 50 years there has not been enough serious effort to control the disease. Today, TB remains the first among the world's infectious killers, with more people dying from it than ever before. The TB crisis is worsening worldwide with increasing multi-drug resistant forms[1], so much so that experts are speaking of a timebomb that is about to explode and for which we are not prepared (Reichman & Hopkins, 2002).

There has been increasing international attention to the threat of multi-drug resistant (MDR-TB) and extreme multi-drug resistant Tuberculosis (XDR-TB) fuelled by the outbreak of XDR-TB in South Africa in 2006 which was widely published (Neel, Gandhi, et al., 2006). It is feared that in a country like India with the highest existing burden of TB in the world the potential effect of MDR-TB on ongoing control efforts might be devastating, eliminating the successes achieved so far (Interview with public health consultant, NGO, Pune, 29.1.2008). Next to increasing drug resistance the ongoing TB control efforts are characterized by new challenges such as co-infection with HIV, changing migration patterns, urbanization and weakening public health systems. In the same time new opportunities are emerging such as increased international political attention to TB, new financial resources, new international actors and advances in technologies and medicine.

The ecology of human diseases and the use of specialised knowledge to influence the former are today both subject to rapid changes. More and more actors are involved in the production, access and application of divers forms of health-related knowledge and thus there is a greater potential for rapid responses but also a risk of greater uncertainties with regard to the formulation of a coordinated response. It is thus central to reflect upon forms of institutions, governance and design of interventions to deal with dynamic health challenges (Bloom et al., 2007) such as Tuberculosis.

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[1] Multi-drug resistant Tuberculosis (MDR-TB) is defined as resistance to at least Rifampicin and Isoniazid, two of the most important standard anti-TB drugs. It develops due to infection with a resistant strain or due to poor treatment with inadequate drugs, insufficient drugs, selective, unstructured drug intake, poor drug quality or irregular drug supply (Central TB Division, India, 2007). XDR-TB, or Extensive Drug Resistant TB (also referred to as Extreme Drug Resistance) is MDR-TB that is also resistant to three or more of the six classes of second-line drugs (WHO, 2008).

In the international policy arena it has been argued that flexibility and innovation in public health systems are needed in order to react to this kind of changing challenges and opportunities[2] (EASAC, 2006; Eurosurveillance, 2005; WHO, 2003b; Alan, 2003). For the case of TB and MDR-TB in India innovation in a variety of areas such as improved diagnostic tests, drugs, delivery mechanisms, service processes, institutions, understandings and treatment regimes is needed in order to be able to respond to the changing public health challenge.

This paper will review theoretical approaches to innovation of direct relevance to the case of TB control[3] and examine what theoretical framework is useful to look at the problem of innovation in public health in India.

What has a perspective on innovation processes to offer beyond what is already known from the existing literature? The TB control efforts in India have been researched and analyzed from various disciplinary perspectives (see Porter & Grange, 1999 for an overview). Epidemiological studies estimate the changing burden of the disease, clinical and biomedical research is trying to improve drug regimens, products and processes for diagnosis and treatment. Research from an anthropological or sociological perspective analyzes among others the factors influencing adherence to treatment, different understandings of TB within communities, gender aspects, reasons for delays in diagnosis or quality of services, importance of poverty and social justice, thus trying to improve program performance (Narayanan et al., 2003; Porter & Grange, 1999; Murthy et al., 2001; Rangan, Ambe et al., 2003; Rangan, Gupte et al., 2003; Shina et al., 2004). This research is often subsumed under the expression operational research. In general, social sciences are suited to describe the range of diverse factors characterizing an infectious disease and a society's response towards it (Lienhardt, Ogden & Sow, 2003;

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[2] The flexibility in reaction that is needed is concerned with preparation of response and innovative capacity in a variety of areas such as rapid identification and surveillance, public health infrastructure, vaccines, diagnostics and therapeutics, training and manpower in clinical sciences and coordination of science agendas (Eurosurveillance, 2005). Besides large investment in different forms of R&D (EASAC, 2006) the challenges are to develop new public health solutions that are affordable, acceptable and applicable to local setting (WHO, 2003).

[3] Evidence has been collected during exploratory fieldwork in India in 2008 consisting of 45 semi-structured interviews (with public health experts, policymakers, scientists, scholars, physicians, medical staff, private practitioners, consultants and members of the civil society and international donor community), visits to research institutes, patients' homes and treatment sites. A first analysis of the data can be found in Engel (2008).

Walt, 1999). There is a complexity of structural factors strongly related to poverty that promote or retard the emergence or re-emergence of infectious disease for which Paul Farmer (1998) argued. Literature on the politics of TB control (Walt, 1999; Ogden, Walt & Lush, 2003; Porter & Kiehlmann, 2003) analyzes for example the design of TB programs, the translation of WHO policies into the national context of TB control pointing to the importance of power and processes of policymaking for TB policy design (Walt, 1999; Narayan, 1998; Porter & Ogden, 2001). Socio-historical analysis of TB programs (Bannerjee, 1993; Chakraborty, 2003; Narayanan et al., 2003; Kathir 2006) offer insights into the role of (indigenous) research for policy and program design and the impact of the national public health system on policy implementation and TB control efforts.

A perspective on innovation for TB control offers a more comprehensive reflection on change not only from a macro or policy perspective on the level of the TB program but at various levels (entrepreneurs, organizations, policy, program, system) and can take into account ongoing changes and improvements. With its central focus on both technological and social change it offers furthermore a reflection on progress in knowledge production and service delivery, on its drivers and barriers, on rigidities and flexibilities of the public health system in reacting to a changing or emerging public health challenge such as TB and the potential threat of MDR-TB. It can reveal how the system copes with uncertainty, how new opportunities are made use of (implementation, diffusion, discussion of appropriateness), whether there is a culture of innovation and how it looks like, whether and how social/technological change, improvements, new ideas are fostered, what barriers and drivers exist and what innovation and flexibility in a field level context mean. Thus, a framework for innovation in TB control should be the tool to provide answers to these questions.

However, the case of TB in India also challenges existing literature on innovation which has mainly concentrated on the firm as the main actor, centered in recent years around innovation systems on a national, sectoral or technology level (Nelson, 2001; Edquist, 2001; Edquist, 1997; Malerba, 2004;, Carlsson, 1995; Jacobsson & Johnson, 2000) and has only started going beyond technological innovation, involving also change in services (Küpper, 2001; Tether & Metcalfe, 2004) and organizations (sources Teece, 1998;

Damanpour, 1991). The challenges and changes in TB control in India concern not exclusively new diagnostics, vaccines and therapeutics but also implementation, service delivery, access and adherence of patients, sustainability of the control efforts, and system related challenges. Although changes in technologies are clearly needed, they are strongly related to challenges and changes in service delivery. Thus, a perspective on innovation is needed that goes beyond technological innovation, including aspects of services, delivery, system organization and institutions.

In addition, TB is a public health challenge and thus mainly a public sector activity -although not exclusively: In India a vast, unregulated private medical sector caters to 70% of the population. Nonetheless, the state is the main actor responsible for TB control and therefore we are in need of concepts dealing with innovation in the public sector that are able to include activities in the private sector as well. An emerging strand of literature on healthcare innovation offers help (Cunningham, 2005; Consoli et al., 2006; Den Hertog, Groen & Weehuizen, 2005; Koch & Hauknes, 2005). These frameworks allow a broader understanding of innovation as change in knowledge production, service delivery, organizations, institutions and concepts and some of them have been developed particularly for the public sector.

This paper will proceed with a short overview of some of the recent changes in TB control in India and in a second step examine existing frameworks on healthcare innovation along with recent developments in the innovation system literature upon their usefulness for an analysis of those cases. The aim of the paper is to find an initial conceptual framework to handle innovation in healthcare for the case of infectious diseases in developing countries, and more specifically TB in India which will be approached in the conclusion.

2. Tuberculosis in India

India is the country with the highest TB burden in the world. It has been estimated that there are 1.8Mio. cases occurring annually. Every three seconds two Indians die of the in principle curable disease (Central TB Division, India, 2007). The huge death toll of the disease and the long-term impact on patients lead to a severe economic burden and

human suffering. The links between poverty and TB are long established (Benatar, 2003; Farmer, 1997). Potentially increasing numbers of co-infection with HIV and the increasing emergence of strains that are resistant to anti-TB drugs might worsen the situation (Central TB Division, India, 2007).

The Revised National Tuberculosis Program (RNTCP) is the TB control program of the Indian government and has at its core the DOTS strategy of the WHO[4]. Depending on the results of the diagnosis by sputum samples patients are distributed across four different categories[5] and put on a strongly standardized treatment with several antibiotics. The drugs for the complete treatment are put in a box which is deposited at a DOTS provider in the patient's vicinity (a local shop, pharmacy, post office or even a neighbour can be a designated DOTS provider). The patient has to swallow the drugs every alternate day under supervision of the DOTS provider. The government is in charge of the whole program from diagnosis centres to the delivery of drugs free of charge.

Results from fieldwork confirm previous research done on TB showing that opinions about the success or failure and appropriateness of the DOTS program in India differ (Porter & Ogden, 1999). Overall the RNTCP is judged by many as a success story particularly because of its internationally unprecedented rapid expansion in the recent years across the country. The RNTCP claims that it has achieved nearly full coverage across India (Central TB Division, 2007) but critical voices ask about the quality of that coverage since there is still a large number of patients who fail the treatment or who lack access to it (Interview with medical anthropologist, Pune, 29.1.2008; Chakraborty, 2003; Udwadia & Pinto, 2007).

Confronted with this critique the government tends to argue that the biggest challenge in TB control is ensuring compliance of the patient to the TB treatment (Interview with

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[4] The DOTS strategy is consisting of five elements: government commitment, case detection by sputum microscopy, standardised treatment regimens of 6-8 months with direct observation (DOT) for at least the initial two months, regular supply of anti-TB drugs, and a standardised recording and reporting system (WHO, http://www.who.int/tb/dots/en/ accessed on 20.7.2008).
[5] Depending on the results of three sputum samples the patient is put onto one of the three categories and subsequently on the standard DOTS treatment which takes 6 months
- Category I: new smear positive patients, seriously ill patients, co-infected HIV patients
- Category II: retreatment (defaulted and come back, failure and again started on treatment, relapsed cases (long ago, declared as cured, but again infected)
- Category III: new smear negative cases, not seriously ill, extra pulmonary TB
- Category IV: MDR, DOTS plus (not yet implemented)

medical officer, RNTCP, Government of Andhra Pradesh, 21.1.2008). The critics argue that the RNTCP is ignoring more social and cultural factors that could hinder a patient adhering to a treatment that comes practically to his/her doorstep (such as nutrition, transport, food security, other support mechanisms, gender or stigma). They argue that the RNTCP is purely based on the biomedical approach, on the battle against the germ, and that the human angle is missing (Interviews: health activist, Bangalore, 26.3.2008; medical anthropologist, Mumbai, 31.1.2008; professor in public health, Mumbai, 4.2.2008). These debates touch upon a classic public health dilemma between biomedical values and socio-political values reflected in program design for TB (Porter & Ogden, 1999)[6].

The challenges that TB control in India is facing today originate from within the TB program[7], the public health system[8] and the wider social system[9]. Results from fieldwork show that the few suggestions that have been put forward in order to make the RNTCP more responsible to local contexts and needs as a result of operational research, mostly carried out by medical anthropologists, are difficult to include in the program; Partly due to politics, but also because they often involve huge commitment and resources from the program, the medical staff and their skills (Interview medical anthropologist, Hyderabad, 16.1.2008) which might not be operationally feasible[10]. According to public health

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[6] Biomedical values characterize programs in standardized manner, assume that they are transferable between different contexts and evaluate programs in terms of cure and treatment rates. Socio-political values tend to see TB as a disease of poverty and demand from programs being flexible, accessible to patients' needs and living conditions, dealing with the side effects of treatment regimes and other structural and social factors such as gender or stigma (Porter & Ogden, 1999).

[7] There is a strong structure or protocol inherent in the treatment regime and one of the main points of critique from the private medical sector is that there is no room for care, for patient –practitioner interaction), flexibility in treatment, possibility to adapt to individual conditions or side effects, etc. (interview chest physician, Delhi, 21.2.2008). The focus is entirely on cure as defined by the guidelines and completion of treatment according to a protocol. Care is reduced to cure by a box full of drugs.

[8] The strong focus on population control and family planning during the 1980s and 90s and vertical infectious disease control programs have led to a slow deterioration of general public health services. Some of the most often cited challenges the public health system is facing today are poor surveillance and monitoring and therefore absence of reliable data, poor governance, corruption, lack of human resources and of stewardship, all of them strongly affecting TB control efforts (interviews: head national NGO, Hyderabad, 16.2.2008, health activist, Bangalore, 26.3.2008; Interview with director Blue Peter Research Centre, Hyderabad, 10.3.2008; Bannerji, 1993).

[9] Health is closely intertwined with economic development (Ramani & Mavalankar, 2005). Furthermore, it has been shown that issues such as nutrition, transport, food security, other support mechanisms, family or community support, gender or stigma influence access and adherence to treatment of TB patients (Rangan et al., 2003; Farmer, 2001; interviews: health activist, Bangalore, 26.3.2008; chest physician, Delhi, 21.2.2008)

decision makers often a balance has to be found between different solutions (Interview: former senior consultant World Bank, Delhi, 05.03.2008).

From the perspective of the government there is a clear trade-off between operational feasibility and individual, flexible care and implementation (that would respond to socio-political values). But the trade-off also holds for certain biomedical solutions that aren't feasible to include because of financial or infrastructural constraints (f. ex. testing every patient for MDR-TB or adding two drugs instead of one in the relapse treatment regime) (Interview with TB consultant, WHO India office, Delhi, 22.2.2008).[11]

Thus, the fieldwork results show that even when the two positions in the debate of biomedical vs. socio-political values are acknowledged, the public health decision maker still has to undertake an almost impossible balancing act. There is a constant struggle between the social and the technical, between scientific knowledge, techno-managerial feasibility of the program and socio-cultural factors. The struggle for this balance also characterizes the reactions to changing challenges such as MDR-TB and is important to keep in mind when looking at recent changes and debates in TB control in India.

2.1 Recent changes and debates in TB control in India

The results from fieldwork show that there is a dominant understanding from the government side that flexibility in reacting to a public health challenge might not be operationally feasible given the constraints of the Indian public health context whereas experts outside the TB program push for more flexibility and criticize the barriers to

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[10] Furthermore, every change in the TB program involves a huge operational and resource intensive effort and it takes 3-5 years to roll it out in India given the size of the country (Interview with TB consultant, WHO India office, Delhi, 22.2.2008). Implementation of changes is not easy given constraints by the health system, lack of absorptive capacities, motivation, stewardship and the widely common political rivalry between state and centre government (Interview with microbiologist, research foundation, Mumbai, , 2.2.2008)

[11] These trade-off arguments that somehow hamper change are criticized by the philosopher of technology, Andrew Feenberg (2002, 1999), as misleading. Ethical controversies often get caught up in the opposition of current standards, but this opposition if factitious. Current technical standards and methods were once discussed and formulated as values, translated into technical codes and then taken for granted. The division between what appears as condition of technical efficiency and what as a value external to technical process is a process involving politics and biased by power. Farmer (2005) makes a similar argument related to the apparent trade-off between efficiency and equity in public health: an inegalitarian system can only be considered efficacious when unnecessary sickness and premature death dont matter. Regardless of these trade-off arguments being adequate or not, we found them to be prevalent in the thinking of decision makers in TB control in India.

change (Engel, 2008; interview with public health consultant, international NGO, Hyderabad, 24.3.2008; chest physician, private hospital, Hyderabad, 12.3.2008; head of international NGO India office, 10.3.2008).

Since implementation of the RNTCP started in 1997 several changes have been introduced to the TB program or are currently under discussion, some as a direct response to the threat of MDR-TB. In what follows, they are described in greater detail.

2.1.1 Introduction of Public Private Mix

In the last years the Indian TB policy has been shifting towards more substantial inclusion of the private sector and NGOs into the program in order to strengthen existing control efforts. The policy implies that NGOs can get registered as microscopy centres to diagnose TB or as DOTS providers. Furthermore, private physicians can refer TB patients to microscopy centres and become DOTS providers (Central Tb Division, 2005a & b; Central TB Division, 2008; Interview: medical officer, RNTCP, Government of Andhra Pradesh, Hyderabad, 21.1.2008). In this way they keep their patients, can charge for consultations, but the patient receives the drugs free of charge. The idea gained strength in a private hospital in Hyderabad, where a well-known and highly respected chest physician was running a pilot project on involvement of private practitioners since 1995 funded by DFID and the WHO. Initially the government of India opposed the involvement of private practitioners and giving out the drugs to them. After the pilot project in Hyderabad had attracted interest of the WHO and was followed by many more pilot sites across the globe and several operational research studies had shown its importance (among others the work of a group of medical anthropologists has been influential in India), WHO Geneva developed a policy in 2001 for involvement of private practitioners in DOTS and subsequently the government of India included it in its RNTCP (Interview chest physician, private Hospital, Hyderabad, 12.3.2008) and recently revised the guidelines again.

This is a good example of the initial resistance of the RNTCP against new ideas from the field and the strong influence of the WHO. In addition it shows the importance of individual entrepreneurs with personal relationships into higher bureaucratic levels.

2.1.2 Sputum Collection Centres & improved sputum transport

Another example of change in TB control comes from a NGO in Hyderabad which developed several so-called "TB models" to improve program implementation. They created the concept of sputum collection centres to overcome accessibility barriers (in rural areas these are geographical barriers in urban areas these are operational barriers as for example opening hours of microscopy centres) and improved the transportation of sputum samples by adding another chemical to make the sample transportable for a greater length of time (Interview with head of national NGO, Hyderabad, 16.2.2008). These innovations in implementation have been taken up by the government (again supported by personal relations) and are in the process of being implemented.

2.1.3 Reacting to MDR-TB: new diagnostic tests & DOTSplus

The improvement of diagnostic tests is seen by many researchers as one of the greatest challenges at the moment in TB control and in reaction to MDR-TB. The difficulty is to be able to distinguish between infection and active disease and to develop tests that are able to be utilized in the current health system and its levels of absorptive capacity. (In endemic settings like India almost the entire population is infected with the mycobacterium TB but only around 10% will develop the disease during their lifetime.) (Central TB Division, 2007; Interview with senior microbiologist, Tuberculosis Research Center (TRC), Chennai, 13.3.2008). As of now, there is absolutely no surveillance or diagnostic system for MDR-TB in the Indian public health system (Interview with microbiologist, research foundation, Mumbai, 2.2.2008). Diagnosing MDR-TB however, is not that simple. There are several techniques available or in development, but none of them standardized or evaluated for the TB program yet and all of them require higher laboratory capacity and bio-safety levels than currently in place (Interview with TB consultant, WHO India office, Delhi, 22.2.2008). Opinions differ about the appropriateness of different diagnostic techniques (solid culture, liquid culture, molecular tests) depending on turndown time, cost-effectiveness, feasibility, required laboratory and absorptive capacity of the public health system, etc. The strong focus on quality assurance for culture sensitive laboratories[12] by the government (pushed by the WHO as

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[12] For diagnosing MDR-TB laboratories are needed which are able to run culture sensitivity tests, e.g. testing the sensitivity of the TB bacteria to the most common anti-TB drugs.

many argue) is contested among public health experts and accused of slowing down the reaction unnecessarily since it is hampered by challenges inherent to the health system (mainly staffing) which might take a long time to change (Interviews: public health consultant, international NGO, Hyderabad, 24.3.2008; head of a national NGO, Hyderabad, 16.2.2008). These actors argue that fast reactions would be essential in dealing with the MDR threat and that it has to be seen how practical MDR diagnosis and treatment can be expanded and then simultaneously quality can be improved.

Various research initiatives by public, private or NGO laboratories are looking into better tests or adapting existing ones for the Indian context. Among them the ongoing adaptation of a low cost diagnostic test from Peru to the Indian context by PATH in Hyderabad (an international NGO with a specific focus on health technologies), the development of a rapid diagnostic test by NGO research institutes such as the Foundation for Medical Research in Mumbai, the Blue Peter Research Centre in Hyderabad or the private Hinduja Hospital in Mumbai, and the joint effort of the WHO India, Tuberculosis Research Centre Chennai and FIND (an international NGO) in setting up a network of research laboratories across the country to evaluate diagnostic tests are interesting examples of efforts in technological innovations.

In general, the treatment of MDR-TB is complicated, long, toxic, frustrating for the patient. Thus it cannot easily be standardized because it needs a lot of counselling and room for individual care which is difficult to include in a conform treatment scheme across India (Interview with chest physician, Delhi, 21.2.2008). The government is piloting treatment in accordance with the DOTSplus guidelines by WHO[13] in a hospital in Ahmedabad in order to standardize the treatment scheme for MDR-TB.

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[13] MDR treatment according to the DOTSplus guidelines takes 24 to 27 months and involves injection and drugs intake at six days a week (and on Sunday drugs only) in the intensive phase of which some is spent at a hospital. Later the patients move to ambulatory phase and tablets only (depending on the weight, above or less 45kg these are 10 or 13 drugs a day which are more toxic including worse side effects than the standard cocktail of antibiotics in the DOTS regimen.) The drug regimen DOTSplus is taken on a daily bases whereas in DOTS it is an intermittent regime. One can imagine that the existing problems of compliance are even bigger especially given the fact that most of the MDR patients already passed months or even years of unsuccessful TB treatment.

Debates revolve around how to best ensure adherence to MDR-TB treatment (Interview public health consultant, national NGO, Hyderabad, 16.2.2008)), and how to prevent spread of drug resistant strains[14].

The development of a new treatment regime can be characterized as a programmatic or healthcare delivery innovation. In accordance with these changes MDR-TB offers an opportunity to reintroduce flexibility into the control system.

2.1.4 Changes on international policy level: new actors & the New Stop TB Strategy

Further room for potential novelty is created by the existence of new funding opportunities (mainly the Global Fund to fight AIDS, Tuberculosis & Malaria). One of the most visible reactions to GFATM in India was the formation of a national TB consortium consisting of the largest Indian NGOs in the field of TB trying to become a primary recipient of the donor money[15]. Currently, there is room for change because of shared pressure from WHO and Stop TB partnership and regained international attention (Interview with microbiologist, medical research foundation, Mumbai 2.2.2008).

In 2002 the WHO published the expanded DOTS framework which emphasized a need for more flexibility in TB programmes in order to be better prepared for changing challenges:

> *"It is now necessary to widen the scope of the DOTS control strategy and make it a comprehensive support strategy – support to all providers, patients, and people to tackle the problem of TB. The expanded strategy lays equal emphasis on technical, managerial, social and political dimensions of DOTS. It acknowledges access to TB care as a human right and recognizes TB control as a social good with large benefits to society. It underscores the contribution TB control makes to poverty alleviation by reducing the great socio-economic burden that the disease inflicts on the poor." (WHO, 2002).*

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[14] A person who is put on DOTS treatment can transmit the disease as long as he/she is sputum positive. The MDR-TB patient put on a regular DOTS treatment will continue to be sputum positive, maybe less during some time. There will be a fall and rise phenomenon in the bacilli load. First maybe 20% of the bacilli will stay infectious, then these resistant ones rise to 40%. The initial improvement is then followed by worsening. Then the patient is sputum positive again and then she/he is transmitting only resistant organisms because the sensitive ones have died (Interview with chest physician, Delhi, 21.2.2008).

[15] But the mechanism of the GFATM is such that the government is controlling the country level mechanism (CCM) and thus India's application for support for TB control by the GFATM. This years' call is asking for support from the civil society but the government is not applying for any financial funds from the GFATM. This is judged by many NGOs in the national TB consortium as a very arrogant move (Interview with public health consultant, PATH India, Hyderabad, 24.3.2008). There seems to be a lot of political ego and rivalry involved

According to Porter and Kielmann (2003) this implies a perspective on TB that goes beyond the objective and rational view of biomedicine. Even more so does the new six-point Stop TB Strategy that was initiated in 2006 (Stop TB Department, 2006) which is trying to address the challenges of DOTS in providing access to TB treatment and care, including TB/HIV and MDR-TB patients. In addition, the new strategy seeks to strengthen health systems, engage all care providers, empower people with TB and communities, and promote operational and biomedical research[16]. International actors like the WHO and the World Bank had traditionally a very strong influence on TB policy in India (Walt 1999; Ogden et al., 2003). The adoption of these new global policy strategies is likely to trigger changes in more conceptual aspects of TB control. How far it actually impacts on national TB control efforts in India needs further examination.

The above mentioned changes in TB control can be summarized as follows:

> **Public Private Mix** – changing healthcare delivery & involving new actors
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> **Sputum Collection Centre** – changing healthcare delivery & access
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> **Sputum transport** – changing service technology
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> **New diagnostic tools** – developing & adapting a new technique or technology
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> **DOTS plus** – designing a new treatment scheme
>
> **International policy level** – changing international policy strategies and attention

These instances of change reflect an understanding of innovation for infectious diseases that goes beyond scientific and technological novelty involving service and delivery aspects, changes in system interaction and conceptual understandings. This corresponds to an emerging strand of literature on healthcare innovation (Cunningham, 2005; Consoli et al., 2006; Den Hertog, Groen & Weehuizen, 2005; Koch & Hauknes, 2005) which has

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[16] The new Stop TB Strategy is based on several approaches that have been explored by WHO globally since the introduction of DOTS: collaborative activities between HIV/AIDS and TB programs, effective ways of undertaking community care, and activities to engage all health care providers and strengthen primary respiratory care have been worked out; revised treatment guidelines and guidelines for treatment of MDR-TB (DOTS plus), international standards of TB care, and innovative mechanisms, such as the Global Drug Facility and the Green Light Committee, have been established to improve access to quality drugs, and TB care is now viewed as a basic human right (reinforced by the recently drafted Patients' Charter for Tuberculosis Care) Next to renewed international attention, new actors and alliances for development of new tools are beginning to produce results (Raviglione & Uplekar, 2006; Stop TB Department, 2006).

provided useful insights into the processes of innovation in healthcare albeit focused entirely on healthcare systems in Europe. It will be helpful to test and further develop these concepts for an Indian context.

The next section will thus review this literature on healthcare innovation along with some recent developments within the literature on innovation systems, examining the particularities of public sector innovation, a potential definition for healthcare innovation, and the understanding of policy innovation and innovation system in order to develop a suitable framework to analyze innovation for TB in India.

3. Towards a framework of healthcare innovation

How to define innovation for TB control? We have seen in the preceding sections that TB control involves a variety of challenges among which the development of new drugs and diagnostics is but one factor. Thus, it needs a rather broad understanding of innovation taking into account the service and public sector characteristics of diverse improvements in TB control.

The existing studies on healthcare innovation are related to innovation in the public sector and services. They are still very few and entirely based on a developed country context (Cunningham, 2005; Den Hertog, Groen & Weehuizen, 2005; Consoli et al., 2005). Nonetheless, they provide some important insights with regard to conceptualization and analysis of healthcare innovation. The following paragraphs will examine them along important elements that a framework to examine innovation for TB would need to cover, such as public sector and service aspects, definition and characterization of innovation processes, handling of policy and system aspects, and analytical feasibility. It will be examined how useful existing concepts are for an application to TB control in India. However, the aim is not to give an exhaustive review of the innovation system literature but to draw upon selected insights of direct relevance to the case. This will provide the basis for the development of a theoretical framework to analyze innovation for TB control in India which will be approached in the last section.

3.1 Healthcare Innovation – a Public Sector & Service Activity

Health sectors are very complex and next to technological and organizational innovation, innovation in the public sector and in services is important (Den Hertog, Groen and Weehuizen, 2005).

Since TB control is a public health challenge it is important to consider that innovation in the public sector is understood to be qualitatively different from innovation in the private sector (Cunningham, 2005; Koch & Hauknes, 2005, Bhatta, 2003). It has been argued that innovation in the public sector is more than simple adaptation of innovations (product or processes, technologies or management procedures for example) developed in the private sector. It is characterized by non-market and non-private activities, it can include development of new products but more often it is application of existing products or processes, changes in service delivery, policy or organizations. Thus, it is related to the attempt to define innovation in service activities and implies a broader perspective on innovation than technological products and processes.

However, according to Mulgan and Albury (2003) innovation in the public sector is often seen as an additional burden and not a core activity of vital importance as it is in the private sector. Thus, one needs to spend more time arguing why innovation in the public sector is actually important; an insight that is also reflected by the struggles of actors lobbying for innovation for TB control in the government of India (Interviews: public health consultant, international NGO, Hyderabad, 24.3.2008; chest physician, private hospital, Hyderabad, 12.3.2008; head of international NGO India office, 10.3.2008). But since public sectors touch interests of so many and take over socially relevant tasks, innovations can meet new needs and old needs more effectively and thus resulting values can be very high (Donahue, 2005). Thus, innovation in public sector is happening in a different context due to the legislative power of the state, due to the public good character and thus legitimacy and due to ethical dilemmas involved in the tensions between individual freedom, human rights and benefit of the masses.

In the last 20 years it was realized how important it is for the public sector to innovate in order to adequately respond to changing environment and societies and growing expectations by citizens and private sector. But incentives to innovate for government organizations and employers have still been low (Mulgan and Albury, 2003).

Among experts from the health sector innovation is mainly understood as a process leading to improved health system organization, improved quality or access, health management or security and surveillance or improved health care products. Often health policies treat science, technology and innovation as an exogenous variable[17]. Thus, in order to define innovative capacity for the healthcare sector an understanding is needed that goes beyond technological capacity including other elements such as social aspects of healthcare, new and effective means, managerial systems, processes of delivery, social and institutional mechanisms to encourage outreach, etc (Bhojwani, 2005)[18].

There is a strong need for insights into drivers and barriers of innovation, diffusion and implementation of new techniques, processes and systems in healthcare. The need for insights into these innovation processes is placed within the somewhat under-researched area of service innovation (Den Hertog, Groen and Weehuizen, 2005).

But the process of healthcare is not simply a delivery system. There is an important difference to industrial service development: Changes in the delivery constitute changes in the content of care. The way of implementing always affects the content of care

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[17] According to Ingeborg Meijer (Technopolis, NL, personal conversation 2007) health policymakers don't really aim at getting involved with the innovation cycle. They rather wait what new products and processes come out of research and see whether they can use them. This happens according to Meijer mainly because public health as a public sector is trying to keep health costs low. New products mean in most of the cases more expenses in health care that have to be reimbursed. So why improve on products that already work? This is also the reason why health policy is mainly concerned with innovation in implementation and not the knowledge creation part which is often regarded as exogenous or not that important. However, the recent advances in biotechnology are offering so many opportunities which are almost uncontrollable that according to Meijer (2007) the technology is pushing health related innovation policy. In the case of TB in a country like India new products might be non-existent or too costly or resource intensive and thus operationally not feasible. In the case of rapid diagnostic tests where new solutions to diagnose MDR-TB are urgently needed the push comes mainly from requirements of the field.

[18] The efforts of health sector reforms seem to be closely associated to these realizations. In general, health sector reforms are actions aiming at the improvement of the health system performance (Weil, 2000). It involves defining priorities, refining policies and reforming the institutions that implement the respective policies (Cassells, 1997). Very often it is reduced to processes of decentralization and introduction of user fees or privatization (Haddad et al., 2008). In developing countries, the influence of the World Bank with regard to health sector reforms has been essential and not without criticism (Rao & Nayar, 2006). It is important to consider the context of health sector reform strategies and their potential implications for changing TB control efforts. However, health sector reform is but one factor contributing to the dynamic environment in which every infectious disease control effort today has to work. The understanding of healthcare innovation goes beyond health sector reform which is mainly concerned with improvements on the health system level and a very specific set of strategies whereas healthcare innovation will be used here in a more problem-oriented and much more open way, involving various changes in healthcare not only the ones related to decentralization, privatization, etc. Concrete health sector reform strategies however might overlap with or get translated into specific forms of innovation for TB.

provided (Den Hertog, Groen and Weehuizen, 2005). The content of care changes for the patient for example if the TB treatment is provided by a designated DOTS provider in his/her vicinity and not by a physician at a TB hospital. This is why it is so essential to look at changes in delivery and services and implementation.

However, innovation in healthcare is not limited to innovation in implementation or delivery. There are strong linkages between the production of knowledge and access to and quality of health care. The content of care also changes with progress in knowledge and the context of care might influence production of knowledge. In India this can be exemplified by ongoing developments of liquid culture tests for diagnosing MDR-TB that require lower laboratory capacities than molecular tests despite the method is somewhat outdated.

It has been argued that product innovations like drugs, diagnostics and vaccines are needed but that the invention is built on the firm ground of scientific evidence and it is more a question of whether this evidence gets used and applied (Den Hertog, Groen and Weehuizen, 2005). From a social constructivist point of view this is too much in line with a technology-push perspective. Especially with regard to developing countries this implies a simple technology transfer model which is not adequate given the range of other factors influencing development and uptake of technology and also appropriateness of technological solutions or interventions. However, it reflects to some extent the current thinking by the WHO and the Central TB Division in India that TB is mainly an implementation challenge (Interview medical officer, RNTCP, Government of Andhra Pradesh, 21.1.2008). In addition, it is also inherent in the DOTS strategy itself: The narrow focus on implementation and patients having to swallow the drugs is one of the main points of critique on the RNTCP by public health experts outside the government (see chapter 2). It furthermore illustrates the strong dependence on biomedical knowledge and the scientific driven nature of healthcare solutions.

To conclude, changes in knowledge production and service delivery are interwoven and highly interrelated in healthcare. However, service innovation or operational innovation, innovation in institution, delivery and policy is important and rather complex in health care systems and there are important differences to industrial service delivery (Den

Hertog, Groen and Weehuizen, 2005). A conceptualization of innovation should thus incorporate these diverse forms of innovation and the emphasis on delivery and services.

3.2 Defining Innovation in Healthcare

The emerging work on public sector innovation understands innovation as a research heuristic, as an analytical tool not a descriptor of an objective reality (Koch & Hauknes, 2005). Based on the insights of the above discussion the following conceptualization for innovation in healthcare of Cunningham (2005) will be used as a working definition for innovation in TB control in India:

Innovation in healthcare is understood as "…doing something new i.e. introducing a new practice or process, creating a new product (good or service), or adopting a new pattern of intra- or inter-organisational relationships (including the delivery of goods and services)" (Cunningham, 2005). The emphasis is on novelty but not every change equals innovation only if there is new knowledge introduced as for example the recruitment of workers in order to import new knowledge or carry out novel tasks. According to Cunningham (2005) an innovation can contain some or all of the following elements of novelty/change:

- New characteristics or design of service products and production processes (Technological element)
- New or altered ways of delivering services or interacting with clients or solving tasks (Delivery element)
- New or altered ways in organising or administrating activities within supplier organisations (Organisational element)
- New or improved ways of interacting with other organisations and knowledge bases (System interaction element)
- New world views, rationalities and missions and strategies (Conceptual element)

The change that qualifies for an innovation can thus happen along some or all of these elements. This differentiation seems to be very useful to analyze different forms of innovation affecting TB control in India. All of these elements have been or are currently subject to change some of which have been discussed above. According to this understanding we can characterize the examples discussed in chapter 2 as follows:

> **Public Private Mix -** delivery & organizational & system interaction & conceptual element
>
> **Sputum Collection Centre** - delivery & organizational element
>
> **Sputum transport** - technological & delivery element
>
> **New diagnostic tools** - technological & system interaction & conceptual element
>
> **DOTS plus** - technological & delivery element
>
> **International policy level** - conceptual element

Furthermore, the innovation environment (the health sector, social system) is important where competing or facilitating developments happen and organizational capabilities and socio-technical constituencies influence the innovation (Cunningham, 2005).

We have shown elsewhere (2008) that it is argued by the government of India that operational feasibility which is strongly related to the weak public health system and the size of the country is often a factor impeding change and innovation. There are strong links between poverty, the status of the health system (Hammer et al., 2007, Ramani & Mavalankar, 2005) and broader social system challenges (f.ex. migration, urbanization, privatization) and the persistence of TB and the emergence of MDR-TB (Farmer, 1997; Singh et al., 2002). TB is still a poverty related disease although the disease is showing up in wealthier parts of the society as well (Interview health activist, Bangalore, 26.3.2008).

It is discussed that the big paradox in health care innovation seems to be that the functioning of the health care system cannot keep up with progress in technological and professional competencies and is not able to profit from it (Hertog, Groen, Weehuizen, 2005). This contrast might be even bigger in a country like India, where the health system is facing additional structural problems and might be even less able to adapt and make use of existing knowledge or new technological opportunities.

It is thus important to examine how socio-political, socio-economic processes and cultural factors such as the current status of the health system, poverty, caste, education, stigma or gender impact on what forms of innovations are produced and thought over. As a health activist we interviewed argues: Any disease control effort should also aim at social innovation and sensitization of the health system (Interview Bangalore, 26.3.2008;

Narayan & Narayan, 1999) towards these social aspects. Currently there seem to be changes happening within the Indian health system (f.ex. stronger integrated primary health services, development of capacity and skills through Public Health Foundation) which might help to foster innovation and make the system more receptive to change. But these developments are only in their initial phases, are contested in their usefulness (Rao & Nayar, 2006), and it will take some time until they show any impact. The question is whether the current pace of change is sufficient to meet emerging requirements from the field such as growing MDR-TB and HIV co-infection.

Health systems are a complex set of rules, social norms, cultural values and policies, informal practices and tensions over professional boundaries and activities of actors and employers. Since most of these factors are institutionally rooted the respective improvements or solutions towards sustainability require systemic innovations or system transformations (Grin & Rotmans, 2005). Resistance to change has been observed widely and initiation of change is thus complicated (Callon, 1995; Elzen et al., 1996; Rip & Kemp, 1998). The literature on system transformation deals with these more systemic innovations (Grin & Rotmans, 2005) and offers instruments how to encourage or speed up such transformations (such as social experiments and strategic niche management) (Geels, 2002; Kemp, 2006).

There is definitely a need for a transition towards sustainability in the Indian health system and also in TB control for which several of our interviewees have argued (Interview health activist, Bangalore, 26.3.2008). There has been a change for example in vision and understanding in the way the WHO is dealing with TB. But whether this is reflected in more integrated and holistic actions in India needs further research.

However, one has to be aware that the discussion around future health system development is framed and conceived mainly based on experiences in a few advanced market economies with specific historical developments. This perspective might therefore not be optimal for low and middle income countries where it is very difficult to develop widely accepted health strategies and institutions given the dynamic context, the fragmented societies and multiple framings of sustainability (Bloom et al, 2007; Bloom & Standing, 2008).

The analysis should include these more systematic aspects of change and the embeddedness of the healthcare innovation within broader social systems and their impact on changing TB control efforts. In what follows, such integration is proposed.

3.3 The Need for a Problem-Orientation and Transient Systemic View

The literature on innovation has emphasized jointly the systemic character of innovation processes and teaches us the importance of connections and linkages among actors of the system in order to foster learning (Mugabe, 2005; Nelson 2001; Malerba, 2004; Edquist, 1997).

But how to make sense of the diversity of the different innovation processes that have been mentioned above? Most of the innovation literature focuses in case studies on a particular case of innovation or on an innovation system with national, sectoral or technological boundaries (f.ex. Nelson, 2001; Malerba, 2004; Jacobsson & Johnson, 2000)[19].

Our aim is to take a holistic view on progress in TB control that goes beyond a retrospective focus on single cases of innovation but examines barriers and drivers of changing and emerging practices along a particular public health challenge. We are interested in showing TB as a public health challenge in changing contexts and conditions with a variety of innovations that are fostered and implemented in response to those changes. Therefore a problem-oriented perspective on ongoing change processes is needed.

By putting the focus on an entire disease, thus embarking on a problem-oriented perspective on TB itself, we can examine different problem definitions and understandings, the development of the definition of the object of progress and changes in the dominant system of thought. Consoli et al. (2005) analyzed the history of medicine for a particular problem and were able to show that it is defined by struggles over

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[19] If the innovation system concept is applied to a developing country context the definition of innovation (which can be also imitative innovation, innovation as a learning process) and external pressures due to globalization on the national innovation system are important (Metcalfe & Ramlogan, 2006; Mytelka, 2000). If one focuses on innovation in the public sector in a developing country issues such as external pressures from international donor or NGO communities are becoming important as well. Systematic weaknesses of the innovation system related to weak political-policy processes and institutions (Mytelka & Oyeyinka, 2003) are additional problems in developing countries.

definition of what the problem is and therefore progress is also defined differently along with these different understandings.

In the same line Tether and Metcalfe (2004) argue that in order to be able to analyze the diversity involved in service innovation it helps to have a very transient and dynamic understanding of innovation systems where boundaries and actors are not fixed but evolve as the problem or the opportunity changes or is redefined[20]. This supports a perspective on change in practices along a particular problem such as TB control. When we understand innovation systems as evolving around problem sequences and opportunities, as constructed and equipped with a certain purpose (Ramlogan & Metcalfe, 2006; Mina et al., 2003), the innovation system concept loses its static boundaries (national or sectoral), allows analysis of frames of understanding and power and becomes more suitable to reflect on direction and guidance of innovation towards socially desirable goals or public goods such as public health.

Support for this argument comes from a recent development in innovation system literature which understands the concept of innovation systems more as a heuristic attempt to analyze actors, institutions and networks contributing to innovation (Hekkert et al., 2007). These authors argue that most of the innovation system analysis focus on the description of the structure of an innovation system on a macro level neglecting individual entrepreneurs and are thus too static and not able to provide insights into the actual dynamics within innovation systems. They argue for the need to understand how innovation systems function[21], for a systematical mapping of the activities that foster or hamper innovation (Hekkert et al., 2007).

Furthermore, the importance of the local level in addressing issues of innovation has been acknowledged in a recent workshop held on the contribution of innovation to reduce

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[20] According to Tether and Metcalfe (2004) the understanding of innovation in services within the innovation system literature does not reflect the actual diversity of innovation in services which is characterized by interrelationships between business models, organizational forms, technology and outputs which form important components and therefore knowledge other than R&D or technological knowledge such as market and procedural knowledge is important. The diversity of innovations in services and the multiple interactions between the system components and actors implies that there are several innovation systems forming and evolving along problem sequences.

[21] Hekkert et al. (2007) proposed functions of innovation systems as the processes that are highly important for well performing innovation systems.

poverty, hunger and disease. It was argued that cultural drivers and barriers to innovation have to be examined in-depth, and it has to be kept in mind that an aversion towards risk and resistance to innovation might not be per se 'irrational' (INNO GRIPS, 2007).

This corresponds with research in healthcare innovation processes and is precisely what our research on innovation dynamics around TB control is aiming to do, albeit not only focused on a technology as Hekkert et al. (2007) propose.

Several of our interviewees argued that the response to TB is always a reflection of the current status of the health system and wider social systems (Interviews: professor in public health, Delhi, 25.2.2008; medical anthropologist, Mumbai, 31.1.2008; health activist, Bangalore, 26.3.2008) and thus it is important to take these contexts into account. TB control in India has a long history both in terms of control efforts and policy development which often reflected socio-political conditions of that time (Bannerjee, 1993; Narayanan et al, 2003). According to a health activist (Interview Bangalore, 26.3.2008) the focus on technology and technological innovation, including program innovation is one way of addressing a problem like TB. The solution might look different if TB would be widely believed as a crippling problem, a humanitarian crisis. A similar argument has been made in the sociological history literature on social construction (Callon, 1999; Hughes, 1999). Thus, the definition of the problem constitutes the innovation system, it guides the kind of institution or policies that are set up, the search for solution and the effort put into it.

Existing public health debates show the tensions between biomedical and societal values (Porter & Ogden, 1999; Walt, 1999) and thus the importance of analyzing innovation for TB control in its context and with its politics.

A problem-oriented perspective allows examining the context and understandings which are leading to specific changes. In addition, it allows an analysis of innovation practices that are still ongoing or in initial phases such as the reactions to the emerging threat of MDR-TB.

Consoli et al. (2005) developed a scheme of progress in medical practice that applies such a problem-oriented perspective according to which the progress of medical practice can be characterized along four broad issues:

1. Epistemic: evolution of medical and scientific knowledge embodied in technology and procedures for diagnosis and therapy
2. Organizational: different ways the medical innovation system is resourced, constructed and organized
3. Institutional: informal and formal regulation of medical innovation and diffusion
4. Cultural: different understandings of the medical problem in different communities

Consoli et al. (2005) focused on the key scientific and technical advancements which characterized the history of medicine for a specific disease and highlighted the linkages between understanding, diagnosis and therapy, showing the dynamics between advancements in science and the techniques in place. However, the framework aims to explain production of knowledge not taking into account the service aspect of healthcare delivery. As has been argued above the aspect of delivery of care is essential for TB control in India.

The dimensions of the framework are very similar to Cunningham (2005) with a focus on organization, institutional/systemic and conceptual/cultural factors. However the framework of Cunningham is more suited to analyze change in services because it differentiates between change in technology and delivery elements. But it lacks the focus on how a problem is defined and understood by different actors, how this understanding develops over time and impacts on the innovation processes. For an analysis of TB control in India one could therefore use the framework of Cunningham (2005) and embody the idea of Consoli et al. (2005) to look at evolution of progress along the different elements or dimensions; thus allowing a more problem-oriented perspective.

3.4 Fostering Healthcare Innovation: Policy Learning

The main responsible actor in public health is the government. However, as results from fieldwork show the government is not necessarily the main actor fostering innovation and change. Cunningham (2005) found that innovation in public sector is complex, involving

a range of different, interlinked innovations and actors and with potentially diverse, far-reaching impact, thus the process fostering such innovations will also be complex.

Furthermore, Arentsen, Kemp and Luiten (2002) argue that although governments bear a special responsibility towards society in guiding future development, socio-technical change is a multi-actor process, characterized by immense complexity and fuelled by millions of decisions of different actors, where government can not manage or control such change processes top-down. Rather, socio-technical change is a governance challenge (referring to decisions and actions of public and private actors) than just a challenge for governments' policy (which is democratically legitimized collective decision-making and policy action). The government can thus develop policy strategies that are able to support, strengthen and redirect governance of many actors involved in socio-technical change processes in socially responsible directions (Arentsen, Kemp & Luiten, 2002).

TB control in India is not a system that has at its core the aim to create innovations, new solutions and ideas, but the core aim is to implement an existing solution, to deliver a service and in this way cope with a problem (Engel, 2008). The government will very unlikely be the main trigger of innovative efforts or practices. Rather they are imposed from outside, either by requirements from the field (emergence of new challenges), individual entrepreneurs or international actors such as the WHO. According to actors pushing for change in TB control in India it is essential to convince the government of taking up the innovation and integrate it into the RNTCP in order to have a meaningful impact (Interviews: public health consultant, international NGO, Hyderabad, 24.3.2008; chest physician, private hospital, Hyderabad, 12.3.2008).

Thus, there is no formal innovation policy for TB in India in a narrow sense but there has been policy innovation or policy learning affecting TB control[22].

This confirms the argument that has been made that policy learning or policy innovation is an important element of innovation in public sectors such as health and that innovation should be based upon and accompanied by policy learning (Kemp and Weehuizen, 2006;

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[22] Innovation policy is understood as policy explicitly aimed at fostering innovation, whereas policy innovation is understood as change in policy or policy learning. Policy learning can be broadly defined as a change in the way of thinking (Kemp & Weehuizen, 2006) or as Koch & Hauknes (2005) put it the ability of the policymaker to learn what is needed in order to change behaviour.

Cunningham, 2005). According to Kemp and Weehuizen (2006) policy learning is a conscious and structured change in thinking about a specific policy issue and innovation is a change in doing. A change in practices can precede or be followed by a change in thinking. "Policy learning is often (and possibly always) a *precursor* of innovation in the public sector, and it is a possible (and desirable) *consequence* of innovations that have been adopted, and thus again a possible precursor for new innovation, in a cause-effect chain." (Kemp & Weehuizen, 2006).

Most of the innovations for TB mentioned in the previous paragraphs have been accompanied by policy learning or shift in policy. Given the high dependency on different forms of expert knowledge in the case of infectious disease policy it is believed to be useful in assessing policy learning and the knowledge based on which it is happening.

Cunningham (2005) includes policy learning in his analysis of innovation drivers and barriers. The separation of an analysis of service delivery and policy issues within the cases was found to be artificial because processes of policy learning and innovation in healthcare are overlapping and interlinked, involving different innovation environments. In TB the policy and service level are strongly related as well since the government is not only responsible for policy formulation but also service delivery of the program although the latter is done by the state governments who are rarely involved in policy formulation. Cunningham decided to combine policy and service delivery issues and focus on policy learning throughout the innovation analysis. The policy change is integrated into the assessment of the innovation process. It is recognized that policymakers play an important part as facilitators and drivers and their actions, reports and decisions thus receive due attention. But the policy learning is not explicitly analyzed in the same way as the literature on policy change suggests (by identifying actor coalitions, discourses etc) although elements of such an analysis can be noticed. It remains a bit unclear how exactly such an analysis can be undertaken.

In general, the literature on public sector innovation acknowledges the importance of policy beliefs for framing problems and directing change (Kemp & Weehuizen, 2006).

This points again to the importance of applying a problem-oriented view and understanding innovation and accompanying policy learning as evolving around the problem sequences or set of opportunities that are defined by the constituencies involved (Metcalfe and Ramlogan (2006), Mina et al, 2003; Consoli.et al., 2005).

There is a vast literature in political science examining interests, institutions and discourses in shaping policymaking (Sabatier, 1991; Rein & Schön, 1993; Hall, 1993; Hajer, 1993; Grindle, 1999; Kingdon, 2002). Kemp and Weehuizen (2006) argue that the literature on policy learning is very much concerned with the effects of learning and not so much with a detailed analysis of how people learn (for example through experience, observation, systematic study, interaction). They propose to simplify the analysis and link it more to innovation in public sector by looking at different types of policy learning (technical, conceptual and social learning, which would work with the framework of Cunningham, 2005 & Consoli et al., 2005), at what has been learned, how it has been learned and what role this learning played for the policy change by conducting interviews and undertake document analysis.

A recent overview of health policy analysis in low and middle income countries clearly shows how important it is to integrate politics, process, and power into such studies. The literature on policy change in low and middle income countries is still very fragmented, diverse and mainly descriptive (Gilson & Raphaely, 2008). For India only a handful of studies have examined the Indian health policymaking process (Mooij, 2003; Mooij, 2007; Jeffery, 1988; Porter & Kielmann, 2003, HEPVIC, 2006).

Thus, it is felt to be equally important to analyze discourse coalitions trying to influence policy making, thus incorporating more political aspects. However, such an analysis also depends on access and depth of material and data available. These complex processes are requiring long-term and in-depth analysis which might be only possible from an ex-post perspective. Some of the changes in TB control in India mentioned above are ongoing. A decision on how policy learning can best be integrated theoretically will have to be based on insights from further empirical research.

To conclude, policy learning is a central element in healthcare innovation but the main driver for healthcare innovation is not necessarily the state. It is thus useful to analyze

drivers and barriers of healthcare innovation where the state plays an important part in shaping or encouraging multi-actor governance processes of change. The next chapter looks at how such an analysis can actually be undertaken.

3.5 Analyzing Healthcare Innovation

Studies on public sector innovation in the UK look at drivers and barriers for the initiation of a particular innovation and the factors influencing development, diffusion and acceptance of that innovation. They place this analysis within the wider context of institutions, services and national public health sector. "Thus, the characteristics of the individual innovations could be examined within their wider service and policy reference frames and specific policy lessons identified." (Koch & Hauknes, 2005). The innovation process is understood as an iterative, complex process. However, the authors argue that for an analysis it makes sense to use a life story, and thus rather linear, model of an innovation and map developments along it (Cunningham, 2005; Koch & Hauknes, 2005). It has been argued that there is still a common temptation in debates on medical innovation, particular innovative health technologies, to fall back on a linear model of innovation by emphasizing policies to facilitate the translation of basic research into clinically useful technologies and practice. But as Consoli et al. (2005) show this understanding is inadequate, the progress in medical know-how is much more based on multiple and multiple-directional relationships. "..there is a two way street between bedside and bench." (Consoli et al., 2005). A qualitative, detailed analysis of drivers and barriers of the different innovation processes presented above would provide insights into actual innovation dynamics and be able to show the different multi-directional relationships in these processes.

Cunningham (2005) examined in exploratory case studies drivers and barriers of different healthcare innovation cases in Europe (using an embedded case study approach, Yin, 1989) and focused on policy learning throughout the innovation analysis. The origins of the innovation in question and the critical events in its development were tracked. The context of the innovation was examined by mapping the national health system and the

immediate innovation environment. Key actors, structure, processes and critical events for the actual innovation case were analyzed. They found that dialogue and openness to change among key groups are required and often missing. Furthermore openness to think outside the box, teamwork, independent thinking and seizing of opportunities and innovation champions are crucial. Other important drivers can be a new challenge from the field, political push, change in culture, competitive drivers (such as targets although they can also hinder innovation) and technological factors. Barriers can exist in the form of size and complexity of the health system, heritage, legacy, routines, professional resistance, risk aversion, political profile and accountability, complexity of public health decisions and potential impact, large range of stakeholders that need to be consulted, pace and scale of earlier change within the system, lack of capacity for organizational learning, lack of resources and technical barriers.

The preliminary insights from field work found all of these barriers being prevalent in the TB environment in India. They have been cited by public health experts as important problems hindering the success of TB control and implementation of the TB control program and they have been characterized by critics of the program as rigidities inherent in the system hampering innovative responses to new challenges such as MDR-TB. Some of the drivers that have been identified so far are innovation champions, influence of international actors and requirements from the field (Engel, 2008).

However, as we have argued above the focus on individual innovation cases should be replaced for this analysis by a problem-oriented view and thorough integration of different system levels.

Den Hertog, Groen & Weehuizen (2005) are mapping patterns of innovation through the healthcare system. They emphasize interaction and cooperation between different functions and disciplines within the healthcare process and between different system levels of actors like policymakers, practitioners and managers. In order to enhance interaction and therefore innovation the potential walls and ceilings have to be broken through. They argue for the importance of innovation coalitions and the multilevel character of healthcare innovations.

In India we found tensions between political staff trained in administrative skills and technical staff, between private and public practitioners where professional autonomy is a source of resistance to change. In the same time innovators from bottom-up were found to be frustrated because they are unable to scale up and lack support and political commitment (interviews: public health consultant, international NGO, Hyderabad, 24.3.2008; chest physician, private hospital, Hyderabad, 12.3.2008).

However, despite these hints it remains unclear how exactly successful improvements made their way through the Indian healthcare system, which innovation coalitions have been involved and what walls and ceilings had to be broken down. It seems useful to examine the above mentioned instances of change in TB control in more detail, analyzing drivers and barriers in order to test and further develop these concepts for a developing country context and the infectious disease area.

4. Summing up: a conceptual framework for innovation in TB control

After this short review of results form the field and corresponding theory we can conclude that the recent developments in innovation system literature such as embracing activities in services and public sectors, trying to understand micro-level innovation dynamics and linking it to system level transformations towards sustainability is helpful in providing insights for a framework to analyze change and innovation dynamics around public health challenges such as TB in India.

As the initial insights into changes in TB control have shown there is a need for a broader understanding of innovation including aspects of delivery, services, organizations and systems while taking into account the particularities of healthcare as a public good and public sector and the importance of the wider social system. A useful working definition has been presented in chapter 3.2 that takes these considerations into account.

We have seen how important policy learning is for healthcare innovation which is also confirmed by results from the field of TB control pointing to the political nature of the

case. However, the existing concepts on healthcare innovation are a bit unclear as to how exactly an analysis of policy learning can be included. Here seems to be room for theoretical contribution and further research.

Furthermore, the link to existing innovation system concepts has been explored and it has been argued for an understanding of innovation systems as constructed, with a purpose, highly transient and dynamic and evolving around problem sequences (Mina et al, 2003; Ramlogan & Metcalfe, 2006). A fundamental question to an innovation system is according to Ramlogan and Metcalfe (2006) the openness of the current structure towards innovative challenges, an aspect which would be an important outcome of an analysis of innovation for TB control in India; particularly in the light of international policy calls for flexible reactions to emerging infectious diseases.

The recent changes in TB control that have been introduced since the implementation of DOTS in India in 1997 and which have been characterized above as consisting of different elements of healthcare innovation need to be analyzed in greater detail. Such an analysis will map drivers and barriers along changes in technological, delivery, organizational, system interaction and conceptual elements, examine interaction and cooperation between different functions, disciplines and system levels within TB control. Given that the conditions are not necessarily fostering change, it will further be interesting to look at failed innovation attempts and local changes that weren't taken up (yet) and introduced into the TB program. Thus, the analysis goes beyond an ex-post examination of introduced changes involving ongoing change efforts as well. The understanding of governance of innovation for TB control as a multi-actor process that can be influenced by the central and state governments, by health staff, researchers, patients or the disease itself will be helpful in this regard.

Such an analysis can reveal how a public health control structure copes with uncertainty created by changing challenges, how new opportunities are made use of, whether there is a culture of innovation and how it looks like, whether and how social/technological change, improvements, new ideas are fostered and what barriers and drivers are impacting these developments. The analysis is however not judgemental or evaluative although different opinions and positions are represented. Rather, it aims at showing the

development of change and improvements within public health policy and control practices along a specific public health challenge.

A further analysis of the above mentioned instances of innovation in TB control will explore the meaning, the possibilities and the usefulness for the Indian public health system to innovate and react flexibly to emerging and changing challenges such as TB. Such insights can eventually help to enhance and foster response capacity of a public health system and simultaneously contribute to theoretical literature on innovation in healthcare.

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