

Innovation dynamics in tuberculosis control in India: the shift to new partnerships

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Innovation dynamics in Tuberculosis control in India: The shift to new partnerships

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Innovation dynamics in Tuberculosis control in India: The shift to new partnerships

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.

Recent developments in the literature emphasize that innovation is a complex endeavour that includes processes of negotiation, learning and alignment amongst researchers, health practitioners, firms and public authorities. The ground level realities for innovation in countries such as India where TB is a social as much as a clinical problem are complicated with challenges and constraints inherent to the health and wider social system that hamper learning, experimenting and thus innovation.

Based on preliminary results from qualitative fieldwork in India this paper will examine the innovation dynamics in one of the recent policy changes in TB control in India: the emergence of new partnerships between private medical providers, NGOs and the government. The paper traces where new ideas come from, how they make their way through the existing control structure and how the existing efforts to control TB respond to and cope with these new developments. The central argument is that the dynamics of innovation in a complex, conflicting and confusing setting like TB control can be understood as a continuous evolution of problems, promises and solutions.

Keywords: Innovation dynamics, public-private mix, Tuberculosis, India

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1. Introduction: Tuberculosis and the problem of innovation

Tuberculosis (TB) remains the first among the world's infectious killers, with more people dying from it than ever before; mainly due to its close links to social problems such as poverty, sanitation, population density, malnutrition, and stigma (Benatar, 2003; Farmer, 1997). India is the country with the highest number of TB patients 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 and the long term impact on patients lead to a severe economic burden and human suffering.

In recent years there has been increasing international attention to the threat of multi-drug resistant (MDR-TB) and extreme multi-drug resistant Tuberculosis (XDR-TB)¹ 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 the potential effect of MDR-TB on ongoing control efforts might be devastating, eliminating the successes achieved so far (Interview NGO consultant, activist, Pune, 29.1.2008). Next to increasing drug resistance the ongoing TB control efforts are challenged by increasing co-infection with HIV (Central TB Division, India, 2007), changing migration patterns and urbanization. At 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. 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 opportunities² (EASAC, 2006; Eurosurveillance, 2005; WHO, 2003b; Alan, 2003). Given these changes in the disease, its context and responses to it, one would expect the Indian TB control system to be receptive and open to whatever changes and new opportunities might appear and to foster innovation for TB in a variety of areas such as improved diagnostic tests, drugs, delivery mechanisms, service processes, institutions,

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 resistant to three or more of the six classes of second-line drugs (WHO, 2008).

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).

understandings and treatment regimes in order to be able to respond to the changing public health challenge. However, since TB is a social problem as much as a clinical problem as stated at the outset the ground level realities for innovation are far more complicated with challenges and constraints inherent to the health and wider social system that hamper learning, experimenting and thus innovation.

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). 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.

Against the background of this literature the research on which this paper is based tries to follow and understand innovations in TB control. Given the peculiarities of the context how do changes occur? What is the fate of envisioned improvements? Next to emerging responses to MDR-TB the Indian TB control has been shifting in recent years towards the formation of new partnerships between the government, the private medical sectors and the civil society. This paper focuses on the efforts to involve the private healthcare providers in India into the public health program which aim at strengthening the treatment efforts of the government. It examines the innovation

dynamics involved by looking at the processes of where new ideas come from and how they made their way through the existing control structure.

The different theories in the literature on innovation aim at explaining the evolution of innovations and new ideas and show how different solutions are evolving (Dosi, 1988; Nelson, 2001; Geels, 2002), how they are shaped, framed and guided by different understandings (Bijker, 1995; Latour, 1996) and promises involved (Borup et al, 2006; van Lente, 1993) and how selection and diffusion mechanisms are happening ultimately giving insights into the dynamics of change of a particular system, sector or technology (Jacobsson & Lauber 2006; Edquist, 1997; Carlsson, 1995; Malerba, 2004). Recent developments in the literature, emphasize that innovation in healthcare is a complex endeavour that includes processes of negotiation, learning and alignment amongst researchers, health practitioners, firms and public authorities (Morel et al., 2005; Mina et al, 2003; Ramlogan & Metcalfe, 2006; Consoli et al., 2006, Cunningham, 2005 ; Den Hertog, Groen & Weehuizen, 2005). Thus, the term ‘innovation dynamics’ will be used throughout this paper as struggles for improvement at various frontiers, involving ongoing, complex processes among a variety of stakeholders along a particular problem such as TB.

The developments and debates around the initial pilot projects and innovators of the public-private Mix (PPM) activities provide insights into innovation dynamics in the TB control world. They show that change is not incentivized nor fostered, that innovative ideas need to be able to improve programme indicators, be sustainable and replicable, they need to overcome resistance in attitudes and mindsets at various levels of decision making and cope with implementation challenges, constraints of cost-effectiveness and operational feasibility. Controlling TB involves more than controlling germs by means of technology but has to take into account challenges in the health and wider social system. Thus, public health decision makers face a constant struggle between technical solutions and social contexts, between scientific knowledge, techno-managerial feasibility of public health programs and socio-cultural factors. In the same way innovation for TB is occurring at various frontiers of controlling the disease (coping with the germs, the health system and the wider social system) and has to take into account and is shaped by the different contexts in which the disease is taking place. This paper shows the struggles for improvement in TB control in India at the frontier of coping with the private medical sector. It will examine how in the practices of controlling the disease various definitions emerge from the problem at hand, the solutions sought for and the promises involved.

The strength of such an analysis is in getting a complete view of different understandings, interests and practices, how the problem is framed by various actors and then subsequently what solutions are sought for. It can provide insights into the political processes involved; examine how certain ideas are followed up and what imaginations and understandings are shaping these processes. This will ultimately make the TB world more aware of its own innovation dynamics mechanisms, where they are/are not working and why, and offers a reflection on direction of change and progress (Rycroft, 2003) in efforts controlling TB.

The paper is based on evidence that has been collected for a PhD project during two rounds of fieldwork in India in 2008 and 2009 consisting of 92 semi-structured interviews (with public health experts, policymakers, scientists, scholars, physicians, medical staff, private practitioners, consultants and members of the civil society, community volunteers, patients and international donor community), visits to hospitals, health centres, research institutes, community projects, patient homes and treatment sites. A network of informants across the country was built up using snowballing and following actors and actions. Interviews were generally of 1,5h length, and guided by a general topic list based on the main research interest, existing literature and insights gained during the fieldwork. Each interview was individually prepared and adjusted to the background and function of the interviewee. They were audio recorded with the permission of the informant and either verbatim transcribed or transformed to text in a draft manner (Gibbs, 2007). The software Atlas-ti was used to support the data analysis and help to break it down into manageable chunks (Gibbs, 2007; Rubin & Rubin, 2005). Analysis is based on writing thick descriptions, examining patterns and linkages between themes and codes, and aims at building middle level ground theory by coupling within-case analysis with cross-case patterns and pursuing an iterative between theory and data (Eisenhardt, 1989; Kelle & Kluge, 1999; Rubin & Rubin, 2005)

In what follows, a short overview on controlling TB in India will be provided (section 2) as a background against which the shift to new partnerships and the public-private mix (PPM) activities are occurring (section 3). The paper proceeds with a closer examination of the shift in problem understanding that led to PPM (section 4), the promises that PPM includes (section 5) and the different solutions that are now being implemented (section 6) and the challenges

therein. It concludes with a brief reflection on innovation dynamics with some recommendations for policy and further analysis (section 7).

2. Context: Controlling Tuberculosis in India

The TB control program of the Indian government, the Revised National Tuberculosis Program (RNTCP), which is being implemented since 1997, has at its core the DOTS strategy of the WHO³. Depending on the results of the diagnosis by sputum samples patients are put on a strongly standardized treatment of six to eight months 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, medical anthropologist - 2, Pune, 29.1.2008; Chakraborty, 2003; Udawadia & 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, medical officer RNTCP, Hyderabad, 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,

³ 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>).

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 and socio-political values reflected in program design for TB (Porter & Ogden, 1999)⁴.

Thus, controlling TB is not just about controlling TB germs by means of technology but needs to take into account challenges that originate from within the TB program (coping with the trade-off between a public health program and individual care)⁵, the public health system (deteriorating general public health services since the 1980s)⁶ and the wider social system (the close linkages of TB with economic development)⁷. As the activities in PPM will show 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 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 or might encounter resistance⁸. According to public health decision makers often a balance has to be found between different solutions. From the perspective of the government there is a clear trade-off between operational feasibility and

⁴ 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).

⁵ 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 it is argued 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.

⁶ 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; director research centre, Hyderabad, 10.3.2008; Bannerji, 1993).

⁷ 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)

⁸ 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 TB consultant, WHO, Delhi, 22.2.2008). Implementation of changes is not easy given constraints by the health system (high turn over in staff, lack of skills and infrastructure, motivation, stewardship) and the widely common political rivalry between state and centre government (Interview microbiologist, Mumbai, 2.2.2008)

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, TB consultant WHO - 2, Delhi, 22.2.2008).⁹

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 and opportunities and is important to keep in mind when looking at recent changes and debates in TB control in India.

3. The shift to new partnerships

In the last years the Indian TB policy has been shifting under the heading of Public-Private Mix (PPM) towards more substantial inclusion of the private sector and NGOs into the program. Since India has a huge, unregulated and diversified private medical sector this is difficult to achieve. Providers range from highly qualified specialists to unqualified practitioners and local healers (who are operating mostly in rural areas or poorer neighbourhoods). Next to allopathic doctors, non-allopathic doctors are practicing different systems of medicine (Ayurveda, Yoga & Naturopathy, Unani, Siddha, Homeopathie). Due to the unregulated nature of the private sector there is hardly any data on prevalence of TB patients, surveillance and treatment practices available except for some anecdotal evidence based on small research studies (f.ex. Uplekar & Rangan, 1993; Uplekar, et al., 1998; Raman, Chadha, et al., 2000; Interview, TB consultant, WHO, Delhi, 22.2.2008). Further, poor prescribing practices in the private medical sector where

⁹ These trade-off arguments are criticized by the philosopher of technology, Andrew Feenberg (2002), as misleading. Ethical controversies often get caught up in the opposition of current standards, but this opposition is 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 don't 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.

inadequate, insufficient or non-standardized treatment regimes are common (Das, 2004) are creating failure cases and are breeding drug resistance. However, it has been estimated that more than half of the TB patients seek initial treatment in the private sector (Agarwal, Sehgal & Lal, 2005) due to convenience, hours of operation and issues of confidentiality (privacy is higher in the private sector and is important to some patient given potential stigma involved) and only access public health services at an advanced stage of the disease (often after they spent all their savings on treatment). Initially, the government was hesitant to include external partners which was regarded unnecessary (“patients will come to us if we run a good program”) and would potentially threaten quality and indicators given the unregulated nature of the private medical sector. By now, the RNTCP has officially recognized that in order to be able to treat more patients under a standardized treatment (important for cutting transmission and avoiding emergence of MDR-TB) the private medical sector needs to be included to strengthen existing control efforts (WHO India, 2009). However, implementation remains challenging as we will see further down.

The basic idea of the initial public-private mix (PPM) initiatives was that private practitioners (PPs) refer the TB patients to the RNTCP and can become their DOTS providers. In this way they keep their patients, can charge for consultations, but the patient receives the drugs free of charge and follows the standardized DOTS therapy by RNTCP but supervised by the PP. These ideas were tested in different pilot sites by independent actors since 1995, the early days of RNTCP. The first policy guidelines for involvement of NGOs (which could also become DOTS providers) and PPs were published in 2000 and 2001 respectively (Central Tb Division, 2005a & b). The initial idea has been broadened with the revision of the policy guidelines in 2008 when the separate guidelines were revised and merged into one comprehensive set, the revised schemes for PPs and NGOs (Central Tb Division, 2008a). The new schemes offer more possibilities for external partners to cooperate with RNTCP and mark a clear commitment by RNTCP for the value of working in partnerships: NGOs or PPs can still get registered as microscopy centres to diagnose TB or as DOTS providers. Further, NGOs can engage in TB advocacy, communication and social mobilization, in setting up transportation and collection of sputum samples in hard to reach areas, improve TB control in urban slums, take over management of a TB unit or engage in TB-HIV collaborative work. NGO or private laboratories

can provide MDR-TB testing and appoint a laboratory technician if there is none in the local testing centre (Central Tb Division, 2008a; Interview, RNTCP consultant - 2, Delhi, 15.1.2009).

4. PPM: A shift in problem understanding

The revision of the schemes happened after a three day consultation meeting held by the Central TB Division in January 2008 with 60-70 participants on the basis of which the new guidelines were formulated. The meeting was decisive and unique in that it brought together a wide range of stakeholders (RNTCP TB officers & staff, private practitioners' representatives, experts from outside the program, NGOs). Many of the activities developed and proposed by NGOs (such as transporting sputum, urban slum schemes) have been taken up (Interviews: RNTCP consultant - 2, Delhi, 15.1.2009; TB consultant WHO - 1, Delhi, 14.1.2009; Central TB Division, 2008a).

According to the private providers involved this meeting marked a shift in the attitude towards external partners in TB control in India which had been hesitating and to some extent resisting inclusion of other actors. Further evidence for a shift is provided in individual experiences of NGOs who are taking over greater responsibility for the program in certain areas and are gaining trust of RNTCP staff (Interview, international NGO field worker, Hyderabad, 24.2.2009). The formation of a national TB coalition among a consortium consisting of the largest Indian NGOs engaged in TB, the government and international agencies is another sign of an attempt to strengthen civil society response for TB in cooperation with the RNTCP.

According to a TB consultant at WHO (Interview, -3, Delhi, 14.1.2009) the shift to new partnerships was a natural step for the TB program after focusing on expanding coverage across the country first, then on improving quality control, on reaching global targets and now, in order to further improve and to be able to deal with challenges such as MDR-TB and HIV co-infection, the program is reaching out to new partnerships and social mobilization. This is also in line with trends in global TB policies and international attention applying pressure on India. Next to the WHO and the Stop TB partnership which have been changing their policy strategies in recent years towards inclusion of more social aspects in TB control (WHO, 2002; Stop TB Department, 2006) the Global Fund for Aids, TB & Malaria (GFATM) has been pushing for a response and contribution of the civil society in TB control in India. Furthermore, public private partnerships between the public and the private medical sector especially in low- and middle-income

countries have been in general strongly recommended in international policy contexts (WHO, 2000; World Bank, 1993).

According to a public health consultant of an international NGO the shift to new partnerships reflects an inherent desire of the RNTCP to really change after realizing they are unable to control TB on their own (Interview, international NGO programme manager -3, Hyderabad, 27.11.2008). Others are talking about a revolution in the mind set of the program officials particularly given the deep rooted tensions between private clinicians and public health experts (Interview, IMA consultant - 1, Delhi, 19.1.2009). According to the Central TB Division in Delhi it is simply the attempt to sustain successes achieved so far (Interview, central TB officer, Delhi, 15.1.2009). Thus, the formation of new partnerships is reflected by a shift at national policy level in problem understanding (from 'we can control TB on our own' to 'we need to partner with PPs and NGOs and mobilize communities') which resulted in including patients treated in the private medical sector and the communities where patients are living into the controlling efforts with the help of PPs and NGOs.

5. PPM: Including new promises

The experiences from initial PPM models developed within India provided important evidence of the value of including partners and paved the way for subsequent inclusion of the private medical sector in the TB control efforts. They further allow important insights into innovation dynamics in TB control.

5.1 Initial PPM models

The first person to do PPM in TB in India was a chest physician working at Mahaveer, a private, non-profit hospital in Hyderabad. The pilot project on involvement of private practitioners started in the early days of RNTCP in 1995. It was sponsored and supported by DFID and the WHO because initially the government of India opposed the involvement of private practitioners which involved giving out the drugs to them. The RNTCP was hesitant to involve PPs because studies had shown that there are many different treatment regimes among PPs (Uplekar et al., 1998) and they expected that PPs would want to keep responsibility for the patient. The government was also against involvement of non-allopathic PPs and non-qualified medical

practitioners in RNTCP who predominate in poorer areas and are in general seeing much more TB patients because they are more accessible to them (vicinity, flexible opening hours).

The team at Mahaveer gained new ideas from field experiences, talking to patients and PPs and experiences from Bangladesh in community DOTS and their own research projects. They developed processes of referrals, support material, patient education processes, and continuously refined and improved those always accompanied by research (Murthy et al., 2001; HUD, 2008). They argue for the importance of understanding the psyche of the patient, spending time with the patient and of respecting the decision of the PP to refer his patient (who is also his breadwinner and might potentially not return) to the RNTCP. These activities involve in general a lot of additional work beyond what is written in the guidelines (Interview, private physician -3, 27.2.2009). Mahaveer has been criticized for being dependent upon certain committed individuals and being impossible to replicate (Interview, medical anthropologist, Hyderabad, 28.11.2008). However, the team showed years later in their Urban DOTS project that based on the same principles processes can be adapted to a whole city. Mahaveer always lobbied for their ideas with statistical data on programme indicators, operational research studies and used personal influence of the innovator among policymakers who is a very well-known chest clinician and the connections to the WHO (Interview, private physician -2, Hyderabad, 24.11.2008).

After the pilot project in Hyderabad had gained the support of the WHO (Uplekar, 2003) and was followed by many more pilot sites in India as well as 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, f.ex. Uplekar & Rangan, 1993), the WHO developed a global policy in 2001 for involvement of private practitioners in DOTS and subsequently the government of India included it in its RNTCP (Interview, private physician -2, Hyderabad, 12.3.2008, Central TB Division, 2005a & b)¹⁰.

Throughout the years, Mahaveer became a “famous pilgrim site for PPM” not at least after the US president (at that time Bill Clinton) visited Mahaveer hospital and not a government facility

¹⁰ It is with a bitter note of irony that one gets reminded that good, revolutionary ideas for TB control from India seem to need an international stamp before getting accepted within the country. Domiciliary treatment and the effect of direct observation was researched in Indian institutes in 1960s (Narayanan et al., 2003; Bannerjee, 1993) and intermittent regime in 1980s but was only introduced in India through DOTS via the WHO in 1997 (Interview, medical anthropologist -2, Pune, 29.1.2008). History seemed to repeat itself with the PPM initiatives.

on World TB day in 2000 when the theme was 'Forging new partnerships to stop TB'. The pictures of that day are still hanging in the main examination room above the DOTS boxes of the TB patients.

The early experiences of PPM at Mahaveer show an 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 highly committed individual entrepreneurs with personal relationships into higher bureaucratic levels and the generation of a critical mass of data impacting on program indicators. The last aspect might be difficult to provide for smaller players.

Two other PPM models followed in India which have been influential: Medecins sans Frontieres (MSF) and Inter aide (two international NGOs with national project offices) were running PPM pilot projects in Mumbai working as an intermediary between PPs and the RNTCP (transporting sputum, defaulter retrieval, patient support, PPs sensitization). The other model was developed in Kerala based on sensitization of PPs through the Indian Medical Association (IMA, the representation of the private allopaths).

Experiences and ideas developed in both of these models are strongly reflected in the new PP and NGO schemes. Similarly to the Mahaveer model both projects documented many ideas in research studies and used data and political influence (through WHO or the private medical lobby) to advocate for them (Copreaux & Dholakia, 2003; Rangan et al., 2003; Kumar et al., 2005). Both of them encountered resistance by RNTCP staff mainly at the district and state level (Interviews: IMA consultant -1, Delhi, 19.1.2009, NGO programme manager -1, Mumbai, 19.12.2008). Thus, the initial PPM models show similarities in the innovation dynamics involved. However, the next chapter shows that the three models differ in their suggestions as to how the PPM activities should best be run and up-scaled and their understanding of who would be the main actor responsible for it. Thus, they differ in defining the problem, the promises and the solutions for PPM activities and ultimately in their understanding of the disease and ideal control practices.

5.2 PPM models: problem understandings, promises and solutions

The team at Mahaveer is unhappy about how the initial ideas of PPM were taken up by the program and are now developing into a structure that was not intended to by the Mahaveer

model. According to the innovator PPM got institutionalized and implemented in a certain way: in a top down manner, involving the private practitioner association (IMA), missing out on the slum doctors and creating more bureaucratic barriers and ultimately again missing the psyche of the patient as the innovator argues. “So ideas may be good but then in the processes of implementation we fail. This will also fail again!” (Interview, private physician -2, Hyderabad, 24.11.2008). His plea is to create responsive and responsible public health institutions (which are existing but are uncoordinated and non-responsive), taking the patient’s perspective into account (the way he/she experiences the healthcare services), based on healthy partnerships with the PPs. The system can be made sustainable by coordinating and streamlining existing public health infrastructure. The role for NGOs in social mobilization and awareness creation is minimal since a person who is sick will knock on the door of the health provider and only search for alternatives if the institutions are not responsive (as for example referring for different tests) (Interview, Hyderabad, 9.3.2009).

The conclusion of the Mumbai model was that a NGO acting as an interface between RNTCP and PPs is needed because the system of PPM cannot sustain itself (lack of commitment by RNTCP staff) but has to be run from outside the program (Interview NGO programme manager - 1, Mumbai, 19.12.2008). Several NGOs argue for stronger involvement of NGOs based on trust and openness beyond extensions of service delivery and that the government has not yet been able to actually make use of the services of the NGOs available (Interview, international NGO field worker, Hyderabad, 24.2.2009). In the same line argues an NGO programme manager in Mumbai that a potential future role for NGOs should be, rather than supplementing activities which should be done by the RNTCP, taking over real responsibility by linking NGO activities with private medical sector. This could be done in a sort of private-private collaboration which is then linked to the public sector. The NGO sector could for example take responsibility for the patients who have difficulties in accessing the services (Interview NGO programme manager -1, Mumbai, 19.12.2008).

An IMA official argues based on experiences from the Kerala model for an institution as an interface between the government and the private sector in order to deal with the deep rooted tensions, rivalry and suspicion and to overcome dependency on committed individuals (Interview, IMA consultant - 1, Delhi, 19.1.2009). IMA focuses on sensitization, motivation and training of PPs to join RNTCP and become DOTS provider. Then it is left to RNTCP and the PP

to make the partnership work. They have not gone yet into further challenges such as case holding, referral mechanisms and sustaining PPM activities which is exactly where other actors found that a facilitator is still needed, in sustaining the referral activities, provide continuous education, training, motivation, assurance and feedback. According to an IMA consultant NGOs do not have a big role to play in PPM activities. The main problem in TB is with private practitioners because they hold the bulk of the patients. Thus, IMA feels that PPs are neglected in the new PP and NGO schemes and heavily criticizes a stronger focus on NGOs (Interview, IMA consultant - 1, Delhi, 19.1.2009). The schemes however reflect the change of scope of the term Public-Private Mix from inclusion of only the private physicians to the whole private sector including private laboratories, NGOs and non-allopathic practitioners as an NGO programme manager argues (Interview NGO programme manager -1, Mumbai, 19.12.2008).

	Mahaveer Model	Mumbai Model	Kerala Model (IMA)
Problem	Psyche of patients & slum doctors important	PPM not sustainable inside RNTCP	Deep rooted tensions & dependency on individuals
Promises/ Ideals	Responsive public health institutions respecting patients & PPs	NGOs as facilitators, taking over real responsibilities	Institution as interface between government & private medical sector, empower the profession
Solutions	Coordinate & streamline existing infrastructure	NGOs collaborating with PPs	Sensitization, motivation & training through IMA

Table 1: Problem understanding of PPM, promises and solutions in three initial PPM models

These discussions provide insights in the ideals, visions, imaginations of the different models, what solutions can be offered and what promises can be made by the program. The initial PPM models show that the promises/ideals involved in the different PPM activities reflect the problem understandings of what the PPM model should solve and the solutions sought for. The three models involve different promises for the PPs (show more respect for referral decision, include them as equal partners, empower the profession), the patients (taking the patients psychology into account, spending time with the patient, assurance) and the NGOs (include them as partners with responsibility not mere service providers).

Furthermore, the data generated by the PPM models helped in convincing the RNTCP programme managers of the value of PPM by showing that if PPs are included and they have good case holding and success rates this will also improve the program's indicators (the case detection and cure rate) (Interview, RNTCP consultant -2, Delhi, 15.1.2009; Agarwal, Sehgal & Lal, 2005). Thus the PPM models contain and argue with promises for the RNTCP staff that external partners will contribute to programme indicators and can take over difficult areas or difficult to reach patients in order to help overcome acts of blaming and deep rooted tensions between the private and public health sector.

6. PPM: Implementing solutions

The Mumbai and the Mahaveer Model both got further developed and scaled up in what was called URBAN DOTS projects (2005 – 2008) with international donor funding (GFATM) covering an entire city and trying to provide additional information on the urban healthcare situation. Both of them ended without any immediate plans for replication or up-scaling. Some of the insights gained were used as inputs for the new PP and NGO schemes (Interviews: physician NGO – 1, 18.12.2008; private physician - 2, 9.3.2009; HUD, 2008).

However, the model that has been given the official responsibility to carry PPM forward by the government is the one by IMA (WHO India, 2009), based on the Kerala model, although the project they are running is also still funded by the Global Fund to Fight Aids, Tuberculosis & Malaria (GFATM). They provide trainings to states and district level physicians (Interview, physician NGO -1, Mumbai, 18.12.2009). NGOs and PPs can still run their own, local PPM activities but have to apply via the (more prescriptive) PP and NGO schemes at the district level where they still encounter resistance as discussed in the following chapter.

Several interviewees are sceptical about the impact of IMA's efforts which are concentrated on allopathic practitioners registered with them and do not reach the slum doctors and non-allopaths. Furthermore, the laborious processes of continuously motivating and assuring PPs, the referral processes, spending time with patients, etc. is not happening to the same extent through IMA as in the other models (Interview, private physician - 3, Hyderabad, 27.2.2009, NGO programme manager -1, Mumbai, 19.12.2008). However, that might have been among the reasons why it was taken up instead of the other models which include more work for RNTCP staff, thus encounter more resistance in implementation and are more difficult to replicate.

Furthermore, IMA has more political clout at the national level than the innovators from the Mahaveer or Mumbai model and they are able to immediately replicate the PPM through their local branches across the country. This shows that the decision of what counts as a valid solution is controlled by politics, operational feasibility and implementation constraints.

Despite the shift to new partnerships at national policy level, some of the interviewees are doubtful whether equal partnerships are built up or whether the government is more interested in outsourcing difficult work like responsibility for areas that are hard to reach or where indicators are low (Interview, international NGO field worker, Hyderabad, 24.2.2009). Furthermore, the current PPM activities continue to struggle with apprehensions at various levels of implementation. A lot has to do with the different understandings involved of controlling TB, of the role of PPs and NGOs and the meaning of community involvement.

6.1. Implementation challenges: Apprehensions & acts of blaming

The initial PPM activities had to face a wide range of apprehensions from both the public health and the private medical sector at various levels. This is partly based on the tensions between private practitioners and public health experts which are deep-rooted (Costa et al., 2008) and result in mutual acts of blaming. The quality of care in the public sector has a negative image among private physicians and the patients. The public sector worker on the other hand does not see the need to approach the private sector and blames the PPs for being unregulated and only interested in for-profit making (Interview, RNTCP consultant, Delhi, 15.1.2009) which is according to the PPs an insult of their profession. They want to be recognized as a profession with independent thinking and knowledge and don't want to be restricted in their freedom which for example regulating TB drugs according to them would be (Interview, IMA consultant - 1, Delhi, 19.1.2009). Furthermore, the Indian clinicians have felt neglected since the initiation of RNTCP when they weren't consulted and the government would rather turn to the WHO consultants who have as they argue less experiences with TB in India. With regard to PPM some of them feel that the RNTCP has now been trying to put them on board as service providers without a voice (Interview, physician NGO -1, Mumbai, 18.12.2009).

Part of the resistance and apprehensions on both sides could be overcome by the positive results from the initial PPM models and the general success of RNTCP. Initially, particularly the chest physicians were opposed to the RNTCP. They argued for example that intermittent regime would

not work since they were taught and experienced in daily treatment. Due to the evidence created by RNTCP they are easier convinced that DOTS can work, and gradually medical colleges, PPs, the corporate sector (employees state insurance; railways) and other ministries (defence, shipping, coal, mines, etc) are taking part in and supporting RNTCP (Interview, RNTCP consultant, Delhi, 15.1.2009). However, resistance in implementation by district and sub district level RNTCP and health staff could often not be overcome and continues to have a negative impact on implementation of PPM (NGO programme manager -1, Mumbai, 19.12.2008). Most likely because district TB officers can get away without doing PPM since there are still no clear demands, indicators and formalities established¹¹ which make PPM a laborious additional task that doesn't show any impact on the indicators, cannot be easily measured and thus has no immediate benefit for the health staff in charge (Interview, IMA consultant - 1, Delhi, 19.1.2009). This points to problems in implementing the solution due to challenges in the health system and has been criticized by the actors in all three PPM models. Next to these clashes between the public and the private medical sector, tensions between qualified and non-qualified practitioners, between policymakers and field level staff or NGO workers are resulting in acts of blaming impacting on innovation dynamics by hampering development and implementation of new ideas.

The new PPM guidelines offer more possibilities for NGOs to cooperate with the RNTCP. However, as the PPM models show there are different opinions on the role of NGOs for TB reflecting differences in understanding of community involvement and of controlling TB and the disease: For some community outreach means covering the remaining patients that aren't with PPs, medical colleges, public providers; for others it means reaching out to every patient (future or presently under treatment) in a different more engaging way, fostering treatment literacy and adherence. It is suspected by several public health experts (Interview NGO consultant, activist, Pune, 16.12.2008; international NGO programme manager -1, Delhi, 17.1.2009) that the current outreach efforts by the government are based on the former “...we are still led or directed by a generation of leadership for whom engaging the community means extension of service delivery mechanisms, not about participation in making the services work. Because it still comes from

¹¹ Thus, here actors argue for more standardization compared to the general critic of PPs on RNTCP for not offering enough flexibility, see chapter 2. Further analysis of actors' concepts on standardization and flexibility and how they are shaping innovation dynamics seems to be fruitful.

another command and control area where the doctor knew the best.” (Interview NGO consultant, activist, Pune, 16.12.2008). In order to change this approach one would have to understand the problem of TB differently and put the patient at the centre of the problem understanding and control efforts: “... *its not your technology, its not your program, it’s the patient which is at the centre! See, the TB program, what’s at the centre is the graphs.*” (Interview NGO consultant, activist, Delhi, 16.1.2009). This remark points to the science driven nature of the TB programme, a characterization used by critics of the programme who argue that the RNTCP tends to approach new ideas in a textbook manner, where everything has to be tested and proven beforehand rather than move in a more open, trial and error manner as in the HIV world for example. This is pointing to different dynamics around handling new ideas and innovations.

To conclude, the current PPM activities show that the change in problem understanding at the higher policy level is not necessarily happening at lower levels of implementation. Innovation dynamics are challenged by apprehensions between PPs and RNTCP staff, by acts of blaming, different understandings of community involvement, controlling and the disease which again are linked to the RNTCP, the health system and wider social structure.

Thus, the story of the initial PPM activities is one of shifts in problem understanding, inclusion of new promises and subsequent challenges and politics involved in implementing the solutions.

7. Discussion: Innovation Dynamics in TB control

The shift to new partnerships provides insights in how new ideas travel through the TB control world and the innovation dynamics involved. The developments and debates evolving around the initial pilot projects and innovators of PPM activities show that the development of new ideas or innovations for TB is not fostered or incentivized, needs a lot of commitment and resources for undertaking research and providing a critical mass of data which is difficult for smaller players to provide. Furthermore, individual innovative efforts are not coordinated. Proof of replicability and sustainability are necessary and further uptake into the policy agenda needs lobbying, good results on program indicators, political clout or individual relationships to highest decision making levels. In addition, innovative activity is often hampered in implementation challenges and resistance at various levels based on acts of blaming and challenges in the health system.

These processes of handling new ideas, lobbying efforts, encountering and overcoming apprehensions and resistance at various levels, dealing with implementation challenges, struggling with sustaining and replicating seem to be characteristic for innovation dynamics in TB control in India. Important in shaping these dynamics seem to be ideas and practices of controlling which are reflected in problem understandings, promises involved and ultimately in the solutions that are sought for. Innovation dynamics can thus be further understood by looking at the continuous evolution of the problems, promises and solutions. In the current case this can be examined both at the policy level of RNTCP and at a more micro-level of the initial PPM models.

The initial PPM models emphasize that it matters how the problem of TB is defined for what suggestions or ideals are drawn from that and the kind of solutions that are individually fostered or followed up. At the policy level the shift to new partnerships marks a change in attitude and problem understanding, and is asking for overcoming apprehensions and blaming among the public as well as private medical doctors by acknowledging that there is a mutual dependency on each other to control TB (shift in problem understanding). The PPM activities provide evidence for the promise of enhancing programme indicators and include new promises for PPs, patients and the NGO sector which have been previously not integrated or overlooked as some actors argue (inclusion of new promises). The way PPM activities are implemented and taken forward in the policy guidelines and activities of IMA shows that the decision of what counts as a valid solution is controlled by politics, operational feasibility and implementation constraints (controlling the solution).

In general, the Central TB Division, strongly influenced by the technical assistance of the WHO, decides upon national control practices. But local actors define controlling in their own area of activity for themselves as the initial PPM models in Mumbai and Mahaveer show. Thus, innovation dynamics in TB control is not only top-down driven decision-making but can be based on localized activities and on understanding and practices of control by NGOs or PPs. These can eventually be taken up into the policy agenda and lead to a global and national policy change as in the case of the initial PPM models. However, problems, promises and solutions will be further shaped by the implementing agency and might differ from the initial intentions.

Thus, the activities at the frontiers of controlling TB are shaped by ongoing struggles of controlling the problem, the promises and the solutions with varying success and impact. The

PPM activities and thus innovation dynamics are challenged by acts of blaming and apprehensions between PPs and RNTCP staff and different understandings of the role of NGOs, inclusion of community involvement, of disease and control which are linked to the RNTCP, the health system and wider social structure.

The insights gained into innovation dynamics in TB control in India suggest that a stronger exchange and clarification is needed among innovators in TB control on problem understandings and promises involved. This would be helpful in coping with acts of blaming and apprehensions between different actors which are hampering implementation of new solutions. Furthermore, the concepts of cost-effectiveness or operational feasibility which were found to be prevalent in the thinking of decision makers should be openly debated. 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 (Feenberg, 2002). These concepts are getting challenged by new promises and different problem understandings that some innovators argue for. The analysis of innovation dynamics reveals that established ideas like ‘trade-off’, ‘implementation’, ‘standardization’, ‘flexibility’ might be in need of a re-conceptualization in order to cope with changing diseases, contexts and solutions available. Further research along these lines is needed.

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